

UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

CASE NOS. 24-1820 & 24-1821

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.

**MOTION OF MANHATTAN INSTITUTE FOR LEAVE TO FILE AN *AMICUS CURIAE*
BRIEF IN SUPPORT OF APPELLANTS AND REVERSAL**

Prospective *amicus curiae*, Manhattan Institute, respectfully requests leave to file an amicus brief in this case. The Manhattan Institute is a nonprofit public policy research foundation whose mission is to develop and disseminate new ideas that foster greater economic choice and individual responsibility. It has historically

sponsored scholarship and filed briefs opposing regulations that interfere with constitutionally protected liberties, including the property rights and speech rights at issue in this case. A copy of the Amicus Brief is attached to this filing. The brief is desirable because it focuses on points not made in the appellants' brief that are relevant to this Court's disposition of the case, specifically an analysis of case law addressing unconstitutional conditions, coercive government practices, and the law of consensual agreements. Further, the Manhattan Institute has an interest in the case because of its mission to foster greater economic choice and individual responsibility, which are threatened by the Drug Price Negotiation Program.

Motions for leave to file a brief as amicus curiae should be granted when the "criteria set out in Rule 29(b) are met," which simply requires "that the amici have a sufficient 'interest' in the case and that their brief is 'desirable' and discusses matters that are 'relevant to the disposition of the case,'" *Neonatology Assocs., P.A. v. C.I.R.*, 293 F.3d 128, 129 (3d Cir. 2002) (Alito, J.); accord *Lefebure v. D'Aquila*, 15 F.4th 670, 673 (5th Cir. 2021); 16AA Charles A. Wright & Arthur R. Miller, *Federal Practice & Procedure* § 3975 (5th ed. 2023 update).

Because prospective amicus curiae Manhattan Institute has satisfied the requirements of Rule 29(b), it respectfully requests that this Court grant its motion.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. Rule 32(g), I hereby certify that the foregoing motion complies with the length limitations set forth in Fed. R. App. P. 27(d)(2)(A) because it contains 275 words as counted by Microsoft Word, excepting those portions excluded by Fed. R. App. P. 27(a)(2)(B). I further certify that the foregoing complies with the type-space and type-style requirements of Rules 32(a)(5), and 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word for Office 365 in Size 14 Times New Roman font.

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CERTIFICATE OF SERVICE

I hereby certify that on July 19, 2024, this brief was electronically filed with the Clerk of Court using the appellate CM/ECFV system.

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EXHIBIT A

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OF APPELLANTS AND REVERSAL**

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CORPORATE DISCLOSURE STATEMENT

Pursuant to rule 26.1 of the federal rules of appellate procedure, *amicus curiae* states it is a non-profit 501(c)(3) organization. Amicus curiae has no corporate parent and is not owned in whole or in part by any publicly held corporation.

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STATEMENT OF INTEREST OF AMICI

The Manhattan Institute is a nonprofit public policy research foundation whose mission is to develop and disseminate new ideas that foster greater economic choice and individual responsibility. It has historically sponsored scholarship and filed briefs opposing regulations that interfere with constitutionally protected liberties, including the property rights and speech rights at issue in this case.

INTRODUCTION

“Selling produce in interstate commerce, although certainly subject to reasonable government regulation, is . . . not a special governmental benefit that the Government may hold hostage, to be ransomed by the waiver of constitutional protection.” *Horne v. Dep’t of Agric.*, 576 U.S. 350, 366 (2015). What’s true for produce is true for prescription drugs. Although subject to reasonable government regulation, selling prescription drugs may not be held hostage by the federal government. But that is precisely what the government has done in passing the misnamed Medicare Drug Price Negotiation Program (the “Program”), part of the Inflation Reduction Act (“IRA”), effectively commandeering a portion of the most widely prescribed prescription drugs for government use without just compensation, while simultaneously compelling untrue speech about such

commandeering (i.e., requiring that pharmaceutical companies describe that commandeering as “negotiations” for “fair prices”).

To obtain positive optics with the public the government compels pharmaceutical companies to affirm that they have “engaged in negotiation” with the government to determine the “maximum fair price” of selected prescription drugs, and they “agree” to provide access to these drugs at less than fair market value. In short, the government pretends through these forced declarations that the Program’s requirements are instead a voluntary arms-length negotiation. Pharmaceutical companies are also required to state, falsely, that they are engaging in such negotiations. Such compelled speech is a First Amendment violation and has zero legitimate public interest and is indeed contrary to public interest, as it is false.

The district court rejected appellants’ Fifth Amendment takings and First Amendment free speech claims on the grounds that appellants’ overall participation in Medicare and Medicaid is voluntary. In so doing, the district court substituted fiction for fact, and theory for reality. Having first created government programs in which the government becomes the purchaser for nearly 50% of the prescription drug market and encourages pharmaceutical companies to sell their important life-saving drugs for use by over a hundred million Americans, the government necessarily created for itself great market power. Pharmaceutical

companies became willing participants in Medicare and Medicaid based on settled expectation interests that the government would be an arms-length good faith purchaser. However, once having achieved its market position, rather than using its market power to in fact attempt to negotiate for lower prices respecting particular drugs, the government passed the IRA and the Program, which is unconstitutional as applied, as explained herein.

The Program *mandates* that Medicare recipients be given access to prescription drugs at below market prices, with the only alternative being that the pharmaceutical companies withdraw entirely from both Medicaid and Medicare programs¹, but *also* simultaneously the government requires that the pharmaceutical companies state, in writing, that the below market prices are not actually mandates, but instead the product of fictional negotiation. Further, by compelling speech that no drug company would willingly make absent the government's arm twisting, the Program violates the First Amendment.

This case raises important questions about consent, coercion, and the limits the Constitution imposes on government conditions. According to the government, there are no constitutional problems with the Program because participation in the Program is voluntary and drug companies consent to its terms. But the

¹ This supposed withdrawal ability is neither practical nor lawful under the terms of the IRA for the reasons set forth by Appellants, and because CMS has no power to alter the meaning of the statutory termination provisions by way of regulation.

government's argument is belied by the reality of the Program, which compels participation through the threat of excise taxes, civil penalties, and preclusion from approximately 50% of the prescription drug market. Because participation in the Program is not in reality voluntary, because the Program compels false speech, and because the so-called agreements that knit the Program together are a product of undue influence and are against public policy, the district court's order granting the government's motion for summary judgment should be reversed.

ARGUMENT

I. Participation In The Program Is Not Voluntary.

A. How the Program Works.

In August 2022, Congress passed, and the President signed into law the Inflation Reduction Act, 42 U.S.C. §§ 1320(f), et seq. The IRA created the Medicare Drug Price Negotiation Program, which requires the Secretary of Health and Human Services ("Secretary"), through the Centers for Medicare and Medicaid Services (CMS) to negotiate with drug manufacturers the price of certain medications covered under Medicare. 42 U.S.C. § 1320(f).

The Program required the Secretary to select and publish a list of the 10 drugs with the highest total gross covered prescription drug costs under Medicare Part D by September 1, 2023, which would then be subject to price negotiation. 42 U.S.C. § 1320f(d)(1).

The manufacturer of each selected drug was required to then either: a) enter into an agreement with the Secretary on October 1, 2023, to take part in the price negotiation process, 42 U.S.C. § 1320f(d)(2)(A); or pay a daily excise tax on all U.S. sales of that drug (not just Medicare sales), *unless* it withdraws *all of its drugs* from federal healthcare programs. 26 U.S.C. §§ 5000D(b)(1), 5000D(c). The agreements themselves are not subject to negotiation but take the form of boilerplate contracts—complete with signature lines for the manufacturer and CMS—titled “Medicare Drug Price Negotiation Program Agreement.”² Not surprisingly, every manufacturer signed the “agreement” to “negotiate.”³

Each manufacturer of a selected drug was then required to submit information to the Secretary regarding research and development costs, unit production costs, patent applications, and market data. 42 U.S.C. §§ 1320f(d)(5)(A), 1320f-3(e) 1320f-2(a)(4). If a manufacturer agrees to participate in the Program but fails to provide the requested information, it is subject to a \$1 million civil penalty for every day of the violation. 42 U.S.C. § 1320f-6(c).

² The template agreement is available at <https://www.cms.gov/files/document/inflation-reduction-act-manufacturer-agreement-template.pdf>.

³ See Medicare Drug Price Negotiation Program: Manufacturer Agreements for Selected Drugs for Initial Price Applicability Year 2026, available at <https://www.cms.gov/files/document/fact-sheet-manufacturer-agreements-selected-drugs-ipay-2026.pdf>.

After this information is provided, the Secretary and manufacturers “shall . . . negotiate a maximum fair price” for each drug. 42 U.S.C. § 1320f-3(a)(1). This process begins when the Secretary issues an initial price offer to the manufacturer based upon several measurements. 42 U.S.C. §§ 1320f-3(b)(2)(B), 1320f-3(e)(1)-(2). The manufacturer must either accept the offer or propose a counteroffer to the Secretary. 42 U.S.C. § 1320f-3(b)(2)(C). After the manufacturer accepts the offer or the Secretary responds to the counteroffer, the Secretary then must set the maximum fair price for the drug by August 1, 2024. 42 U.S.C. § 1320f(d)(5). The “agreement” to the “maximum fair price” must be memorialized in Addendum 1 to the parties’ Medicare Drug Price Negotiation Program Agreement, titled “Negotiated Maximum Fair Price.” Like the initial negotiation agreement, the maximum-fair-price agreement must be signed by the manufacturer and CMS.

The Program sets what the government will pay for selected drugs. In other words, the “maximum fair price” isn’t the product of true free-market negotiation. Instead, the ceiling price is either 75%, 65%, or 40% of a benchmark market-based price. 42 U.S.C. § 1320f-3(b)(2)(F), (c)(1)(C). The “maximum fair price” price is to be published by September 1, 2024. 42 U.S.C. §§ 1320f(a)(3), 1320f(d)(6). These prices then go into effect on January 1, 2026. 42 U.S.C. § 1320f(d)(5).

After signing the “agreement,” the manufacturer must provide “access to such price to” Medicare beneficiaries beginning in 2026. 42 U.S.C. § 1320f-2(a)(1).

Violations of the access provision are punished by a monetary penalty of 10 times the difference between the price the manufacturer charges and the “maximum fair price,” for each unit sold, *id.* § 1320f-6(a), *plus* a \$1 million daily penalty for violating the “agreement,” *id.* § 1320f-6(c).

B. The Government’s and District Court’s Reasoning.

Each of the three district courts to address the constitutionality of the Program thus far focused its analysis on the alleged voluntariness of the Program. Because participation in Medicare is completely voluntary, these courts concluded, the Program does not violate the Constitution: *Bristol Myers Squibb Co. v. Becerra*, No. CV 23-3335, 2024 WL 1855054, at *8 (D.N.J. Apr. 29, 2024); *Dayton Area Chamber of Com. v. Becerra*, No. 3:23-CV-156, 2023 WL 6378423, at *11 (S.D. Ohio Sept. 29, 2023); *AstraZeneca Pharms. LP v. Becerra*, No. CV 23-931-CFC, 2024 WL 895036, at *15–16 (D. Del. Mar. 1, 2024).

There are fundamental flaws with this reasoning. First, even if participation in Medicare may initially and *generally* be voluntary, it does not follow that participation in a *specific* Medicare program is voluntary. By way of example, one may enter another’s home voluntarily, but then be coerced to stay because of the homeowner’s threats. A manufacturer’s decision to participate in Medicare prior to the enactment of the Program should not be used to declare the Program

constitutional by voluntary consent. Instead, this Court must analyze whether participation in this *specific Program* is voluntary.

This leads to a second problem: participation in the Program is *not* voluntary under any legal or colloquial understanding of the term. Consider how the Program works. *First*, CMS alone decides which initial 10 drugs are selected for the Program, and which drugs are selected in each applicable period thereafter. *Second*, manufacturers must enter into agreements with CMS to negotiate “maximum fair prices.” By the terms of the Program, the “negotiation” is a one-way discussion. The price of a selected drug cannot go up; instead, the price is capped at between 40% and 75% of market benchmarks. *Third*, manufacturers must disclose confidential information to CMS for purposes of helping CMS “achieve the lowest maximum fair price for each selected drug.” 42 U.S.C.A. § 1320f-3(b)(1)-(2)(A). *Fourth*, manufacturers must negotiate with CMS on an expedited and mandated schedule, with the Secretary unilaterally setting the maximum fair price for the drug by August 1, 2024. 42 U.S.C. § 1320f(d)(5). *Fifth*, manufacturers must “provide access to a price that is equal to or less than the maximum fair price for such drug” to Medicare recipients and to pharmacies, hospitals, physicians, and others who dispense the drug to Medicare recipients. 42 U.S. Code §§ 1320f-2(a)(1)(A)-(B), 1320f-6(a).

None of these five steps are voluntary. They are all statutorily mandated provisions. And notably, these provisions do not apply based on a *manufacturer's participation* in Medicare, or to any other action by a manufacturer. Instead, they apply based on the *government's* expenditures in the applicable time frame.

According to the government, a manufacturer has not one, but four choices: 1) it can pay an excise tax, 26 U.S.C. §§ 5000D(b)(1); 2) pay civil penalties, 42 U.S.C. § 1320f-6(a), (c); 3) divest itself completely of its most profitable prescription drugs, Revised Guidance at 131-32; or 4) withdraw *all of its drugs* from federal healthcare programs, 26 U.S.C. §§ 5000D(c).

These “choices” are not voluntary. To be voluntary, a choice must be “[d]one by design or intention,” and [u]nconstrained by interference [or] impelled by outside influence.” Black’s Law Dictionary (11th ed. 2019). In contrast, an involuntary choice is one “[n]ot resulting from a free and unrestrained choice.” Black’s Law Dictionary (11th ed. 2019).

Frost & Frost Trucking Co. v. Railroad Comm’n of Cal. is instructive. 271 U.S. 583 (1926). There, the Court considered whether a State could condition a private carrier’s use of public highways on the requirement that it submit to all the conditions of being a common carrier. The Court held that this regulation was unconstitutional, reasoning “[i]t would be a palpable incongruity to strike down an act of state legislation which, by words of express divestment, seeks to strip the

citizen of rights guaranteed by the federal Constitution, but to uphold an act by which the same result is accomplished under the guise of a surrender of a right in exchange for a valuable privilege which the state threatens otherwise to withhold.” *Id.* at 593–94. Like here, the government argued that there was no constitutional violation, because private carriers had a choice. The Court rejected the illusory choice, reasoning that although with “regard to form alone, the act here is an offer to the private carrier of a privilege, which the state may grant or deny, upon a condition which the carrier is free to accept or reject,” but “[i]n reality, the carrier is given no choice, except a choice between the rock and the whirlpool—an option to forego a privilege which may be vital to his livelihood or submit to a requirement which may constitute an intolerable burden.” *Id.* at 593.

A similar reality is present here. The government claims “no constitutional violation, because manufacturer’s have a choice.” But the choice is not voluntary—it’s the rock or the whirlpool—and thus no choice at all.

C. The Program Must Be Evaluated Under the Law Concerning Consensual Agreements.

The government is right to identify choice as vital to the question before this Court. But it narrowly focuses on the alleged choice of manufacturers, without considering the actions of the government. If, as the district court concluded, the agreements are ordinary commercial contracts, then these agreements and the Program must be evaluated under the law concerning consensual agreements.

When looked at from this angle, the constitutional infirmity of the Program is clear.

It is true that the government is not obligated to contract with a specific individual or entity. The government can choose to enter or leave a market or form a contract with one entity but not another. But when it does enter a market and form contracts, it is not identical to other, solely private entities. Instead, it is constrained by the Constitution in ways that private entities are not.

For example, federalism principles dictate that the federal government cannot coerce “a State to adopt a federal regulatory system as its own.” *Nat’l Fed’n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 577–78 (2012) (“*NFIB*”). This is a structural limitation on the power of the federal government mandated by the Constitution.

Likewise, under the First Amendment no-compelled-speech doctrine, the government cannot compel a “grant recipient to adopt a particular belief as a condition of funding.” *Agency for Int’l Dev. v. All. for Open Soc’y Int’l, Inc.*, 570 U.S. 205, 218 (2013) (hereinafter “*AID*”). If the federal government cannot compel speech in exchange for grant funding, then it logically follows that it cannot compel speech in exchange for a government contract.

The key here is that simply calling a condition a contractual term or part of an ordinary agreement between two free entities—manufacturers on the one hand, and the government on the other—does not solve the constitutional problem. Columbia

Law School professor Philip Hamburger rightly rejects the argument that “what government does in its private capacity (notably, purchasing) is not confined by the constitutional limits on what it does in its public or governmental capacity (such as regulation),” because “the Constitution’s provisions for legislative and judicial powers and its guarantees of rights do not come with an exception for whatever the government can characterize as done in its contractual or otherwise private capacity.” Philip Hamburger, *Purchasing Submission: Conditions, Power, and Freedom* 63 (2021). Instead, “the Constitution limits government generally, without any such exception.” *Id.*

In other words, just as the government cannot, by *regulation*, require a person or entity to give up a constitutional right in exchange for a discretionary benefit, *see Dolan v. City of Tigard*, 512 U.S. 374, 385 (1994), neither can it evade constitutional limitations through supposed contractual consent. Simply put, the “government may not do indirectly what it may not do directly,” Kathleen M. Sullivan, *Unconstitutional Conditions*, 102 Harv. L. Rev. 1413, 1415 (1989), whether through regulatory or contractual conditions.

At the very least, “[w]hen the government employs private consensual arrangements to evade the Constitution’s limits on public power, the government should . . . be subject to the law regarding consensual arrangements.” Burger,

supra at 217. As relevant here, consensual agreements may be found void or voidable by undue influence or because they are against public policy.

1. The Agreements Are Voidable Because of Undue Influence.

Apart from the constitutional question, a contract or other consensual agreement may be void on account of undue influence. Hamburger, *supra* at 213. This is basic black letter law. *See, e.g., Taylor v. Bemiss*, 110 U.S. 42, 45 (1884); Black’s Law Dictionary (11th ed. 2019) (“Consent either to conduct or to a contract, transaction, or relationship is voidable if the consent is obtained through undue influence.”); 17A C.J.S. Contracts § 260 (“Undue influence invalidates contracts obtained thereby, although such contracts are subject to subsequent ratification.”).

Although “undue influence is notoriously difficult to reduce to a simple rule,” it is “apt to be found where one party is overbearing in relation to another[.]” Hamburger, *supra* at 213. *Black’s Law Dictionary* defines “undue influence” as the “improper use of power or trust in a way that *deprives a person of free will and substitutes another’s objective*; the exercise of enough control over another person that a questioned act by this person *would not have otherwise been performed*, the person’s free agency having been overmastered.” (emphasis added). This Court has noted that although the concept is not “susceptible of unitary definition,” nonetheless the “essence of the idea is the subversion of another person’s free will in order to obtain assent to an agreement.” *Francois v. Francois*, 599 F.2d 1286,

1292 (3d Cir. 1979). “The proper inquiry is not just whether persuasion induced the transaction but whether the result was produced by the domination of the will of the victim by the person exerting undue influence.” *Id.*

If, as the district court concluded, “the Program’s agreements are ordinary commercial contracts,” 2024 WL 1855054, at *11, they are void under the doctrine of undue influence. Consider the following relevant facts:

- The legislature enacted Medicare, which is now the largest federal drug benefit program, covering “nearly 60 million aged or disabled Americans.” *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1808 (2019);
- The federal government “dominates” the U.S. 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);⁴
- When it enacted Medicare Part D (and until it enacted the Program) Congress expressly prohibited the Government from “interfere[ing] with the negotiations between drug manufacturers and pharmacies and [private plan sponsors].” 42 U.S.C. § 1395w-111(i);
- Manufacturers reasonably rely on patents and receiving fair market prices to recoup the investment costs of bringing a new drug to market, which on average is more than \$2 billion;⁵

⁴ Notably, “[t]he maximum fair prices set by CMS will have effects far beyond Medicare. State Medicaid programs follow a ‘best price’ that sets Medicaid prices at the lowest available to any U.S. entity, including Medicare. Many private insurers provide prescription drug coverage to Medicare Part D beneficiaries and will also look to the maximum fair prices for their non-Medicare subscribers.” Daniel E. Orr, *Congress Must Fix the Inflation Reduction Act Before Millions Lose Treatment for Rare Diseases*, 42 Yale L. & Pol’y Rev. inter Alia 1, 6 (2023).

⁵ Stephen Ezell, *Ensuring U.S. Biopharmaceutical Competitiveness*, Info. Tech. & Innovation Found. 30 (July 2020), <https://www2.itif.org>. One economic analysis

- A manufacturer can either sign the agreement to negotiate and agree to a “maximum fair price” below the fair market value, or a) pay substantial excise taxes, b) divest itself of the selected drug, c) withdraw *all of its drugs* from federal healthcare programs, or d) pay extensive civil penalties.

These facts establish that the aim of the Program is “subversion of another person’s free will in order to obtain assent to an agreement.” *Francois*, 599 F.2d at 1292. Without the inherent—and intentional—coerciveness of the Program, manufacturers would never sign the Program’s agreements. *See Kentucky v. Biden*, 23 F.4th 585, 595–96 (6th Cir. 2022) (“The federal government of course knows that these reliance interests exist, which is why it seeks to purchase states’ submission by leveraging those interests to force their acquiescence to the contractor mandate.”) (citing *Hamburger*, *supra* at 18).

NFIB is instructive. The Court emphasized that it has “repeatedly characterized . . . Spending Clause legislation as ‘much in the nature of a contract.’” *NFIB*, 567 U.S. at 576–77 (quoting *Barnes v. Gorman*, 536 U.S. 181, 186 (2002) and *Pennhurst State School and Hospital v. Halderman*, 451 U.S. 1, 17 (1981)). “The legitimacy of Congress’s exercise of the spending power thus rests on whether the State voluntarily and knowingly accepts the terms of the ‘contract.’” *Id.* at 577 (quotation omitted). Treating Spending Clause legislation as akin to a contract has

“predicts that because of IRA price controls, 40% fewer new drugs will come to market by 2035.” *Orr*, *supra* at 8.

led the Court “to scrutinize Spending Clause legislation to ensure that Congress is not using financial inducements to exert a ‘power akin to undue influence.’” *Id.* (quoting *Steward Machine Co. v. Davis*, 301 U.S. 548, 590 (1937)). Although “Congress may use its spending power to create incentives for States to act in accordance with federal policies,” if “pressure turns into compulsion . . . the legislation runs contrary to our system of federalism.” *Id.* (quotation omitted).

Admittedly, *NFIB* concerned Spending Clause legislation that coerced State participation in Medicare, whereas here the Spending Clause legislation involves the coercion of private entities. The federalism principles at play in *NFIB* are thus not relevant here. Nonetheless, the case and the principles enunciated there are analogous. Both concern the Spending Clause, government health insurance programs, and alleged undue influence. If threatening a mere ten percent of states’ budgets constitutes undue influence—or, as the Supreme Court quipped, “a gun to the head,” *NFIB*, 567 U.S. at 581—then surely a threat to ban a manufacturer from fifty percent of the prescription drug market passes the point “at which pressure turns into compulsion.” *Id.* (quotation omitted).

The agreements vital to the Program are voidable as obtained by undue influence. Because the constitutionality of the Program rests on the alleged voluntariness of the agreements, but the agreements themselves are unenforceable, this Court should strike down the law.

2. The Agreements Are Void As Against Public Policy.

In addition to undue influence, a contract or agreement against public policy is void and unenforceable. Hamburger, *supra* at 214; *see also Oubre v. Entergy Operations, Inc.*, 522 U.S. 422, 431–32 (1998) (Breyer, J. concurring) (stating that a contract against “law or public policy” is void); *Evans v. Jeff D.*, 475 U.S. 717, 759 (1986) (Brennan, J., dissenting) (discussing the “well-established principle that an agreement which is contrary to public policy is void and unenforceable” (citing cases)). This doctrine is “firmly rooted in precedents accumulated over centuries.” 2 E. Allan Farnsworth, *Farnsworth on Contracts* 9-10 n. 4 (3d ed. 2004). The Constitution trumps any other claimed “public policy” asserted by the government, such as the policy to lower prescription drug costs or provide affordable health insurance to seniors. As Professor Hamburger notes, “the Constitution is a public policy that rises above mere conditions, whether stipulated by Congress or agencies.” Hamburger, *supra* at 216. In other words, a contract that impairs constitutional rights is against public policy and void: “the Constitution protects rights such as the freedom of speech, and it is against the Constitution’s public policy for the government to use conditions to impose restrictions that abridge the freedom of speech or other constitutional rights.” *Id.* at 216-17.

This seemingly obvious premise—that the government cannot evade the Constitution through contract or agreement because such agreements are void (not

simply voidable) as against public policy—nonetheless is often ignored by the government:

This application of a doctrine drawn from the law on consensual arrangements is all the more compelling because the government systematically uses such arrangements to evade the Constitution's pathways for power, its federalism, and its guarantees of rights. On the theory that conditions are merely consensual arrangements, the government has gone far in unraveling much of the Constitution's structures and its protections for freedom, including its rights. This is a profound danger, and it is therefore essential to recognize that the law itself addresses this threat from consensual transactions.

Hamburger, *supra* at 217.

What Professor Hamburger highlights in this passage is precisely what the government tries to do here. The government makes the claim that participation in Medicare is voluntary, and therefore there is no constitutional problem with the Program. But the voluntariness of an agreement against public policy is irrelevant. *Id.* at 216. If a condition to an agreement is unconstitutional, the agreement is void.

The government wants to have its cake and eat it too. On the one hand, it treats the Program's agreements as ordinary and voluntary commercial contracts. But on the other hand, it does not apply the basic rules of the law controlling consensual transactions, including the doctrines invalidating agreements formed by undue influence or those against public policy.

As the Supreme Court has repeatedly said, “[e]ven though government is under no obligation to provide a person, or the public, a particular benefit, it does not

follow that conferral of the benefit may be conditioned on the surrender of a constitutional right.” *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 513 (1996). This applies if the particular benefit at issue is an agreement or contract with the government. The government is under no obligation to contract with a person or a particular company, but it does not follow that the conferral of a contract may be conditioned on the surrender of a constitutional right.

Consider the consequences if it could be. The government could establish a caste society, one in which the government could purchase the surrender of an individual’s or corporation’s constitutional rights, with devastating consequences. *See Philip Hamburger, Unconstitutional Conditions: The Irrelevance of Consent*, 98 Va. L. Rev. 479, 490 (2012) (“government by contract tends to create an unofficial caste system, which offers the formalities of equal freedom, but which actually deprives the financially weak of their liberty, thus reinforcing financial vulnerabilities with legal inequalities”).

A world in which the government could evade the structure and limits of the Constitution through coercive agreements is not one imagined by the Founders. Indeed, resistance to government coercion was at the center of the founding. *See Thomas C. Grey, Origins of the Unwritten Constitution: Fundamental Law in American Revolutionary Thought*, 30 Stan. L. Rev. 843, 885 (1978) (arguing that Britain’s Coercive Acts of 1774 “led to the calling of the First Continental

Congress in 1774, to the arming of the backcountry men of Massachusetts, and thence to Lexington and Concord, Bunker Hill, and war”).

That the government “has broad powers,” cannot seriously be disputed. *Horne v. Dep’t of Agric.*, 576 U.S. 350, 362 (2015). Nonetheless, “the means it uses to achieve its ends must be ‘consist[ent] with the letter and spirit of the constitution.’” *Id.* (quoting *McCulloch v. Maryland*, 4 Wheat. 316, 421, 4 L.Ed. 579 (1819)). This Court should reject the government’s argument that it can evade constitutional norms through the means of alleged voluntary agreements.

II. The Program Violates Both The Fifth And First Amendments.

A. The Program Constitutes A Fifth Amendment Takings.

“Government action that physically appropriates property is no less a physical taking because it arises from a regulation.” *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 149 (2021); *Horne v. Dep’t of Agric.*, 576 U.S. 350, 361 (2015) (same). The question in a *per se* taking case is “whether the government has physically taken property for itself or someone else—by whatever means—or has instead restricted a property owner’s ability to use his own property.” *Id.*

Under *Horne*, the government cannot require a raisin grower to set aside a certain percentage of its crop for government use without just compensation. 576 U.S. at 354. Under *Cedar Point Nursery*, the government cannot require an employer to grant a labor organization the “right to take access” to the employer’s

property to solicit support for unionization. 594 U.S. at 143. The Program here combines the constitutional flaws in *Horne* and *Cedar Point Nursery*. First, it requires drug manufacturers to set aside a portion of selected drugs to later be dispensed and administered to Medicare recipients at below fair market value (i.e., without just compensation). As in *Horne*, the prescription drug companies will receive some compensation, but at below fair market value. Thus, a Fifth Amendment takings has occurred.

Second, the Program requires drug manufacturers to “provide access to a price that is equal to or less than the maximum fair price for such drug” to Medicare recipients and to pharmacies, hospitals, physicians, and others who dispense the drug to Medicare recipients. 42 U.S. Code §§ 1320f–2(a)(1)(A)-(B), 1320f-6(a). Providing “access to a price” is no different than being required to provide access to a prescription drug (or access to raisins or space in a barn). The product comes with the price. There can be no price without a product. By requiring “access to a price” that is below fair market value, the government is requiring drug companies to sell selected drugs without just compensation.

Notably, the Program’s access provision has nearly identical language to the regulation in *Cedar Point Nursery*, which appropriated “a right to physically invade the growers’ property—to literally ‘take access.’” 594 U.S. at 152 (quoting

the California regulation). Under *Cedar Point Nursery*, there can be no dispute that providing “access” to a prescription drug implicates the Fifth Amendment.

Means are important. “The Constitution . . . is concerned with means as well as ends.” *Id.* at 152 (quoting *Horne*). When the government physically takes property for itself or someone else “*by whatever means*,” it violates the Fifth Amendment. *Id.* at 149 (emphasis added). The means the government employs here are no more constitutional than the means employed in *Horne* and *Cedar Point Nursery*.

And again, the alleged voluntariness of the Program does not save it. The Supreme Court held as much in *Horne*. In response to the government’s contention that farmers could avoid the regulation by growing another crop (or selling their land), the Court noted that “[t]he taking here cannot reasonably be characterized as part of a . . . voluntary exchange.” *Horne*, 576 U.S. at 366. This Court should apply the same reasoning to the Program and hold that it violates the Fifth Amendment.

B. The Program Violates The No-Compelled-Speech Doctrine.

1. The Compelled Speech is Not Incidental to Regulated Conduct.

The Program here compels speech, and not just commercial conduct. The district court concluded that “the Program regulates conduct, not speech,” reasoning that the “primary purpose of the Program is to determine the price manufacturers may charge for those specific drugs they choose to sell to Medicare,” and the “agreements and negotiations are incidental mechanisms the

government is using to set those prices.” 2024 WL 1855054, at *10-11. The court appears to have been relying on *Rumsfeld v. F. for Acad. & Institutional Rts., Inc.* for its holding. 547 U.S. 47 (2006). But this case is nothing like *Rumsfeld*.

In response to law schools restricting the access of military recruiters to law students because of disagreement with the Government’s policy on homosexuals in the military, Congress enacted the Solomon Amendment, which denied federal funding to institutions of higher education that denied military recruiters access equal to that provided other recruiters. *Id.* at 51. An association of law schools and faculty sued, arguing that the law violated their First Amendment free speech rights. The Court disagreed, reasoning that “the Solomon Amendment regulates conduct, not speech,” and “affects what law schools must do—afford equal access to military recruiters—not what they may or may not say.” *Id.* at 60. Further, the amendment “neither limits what law schools may say *nor requires them to say anything.*” *Id.* at 60 (emphasis added). Although it recognized that “recruiting assistance provided by the schools often includes elements of speech,”—e.g., sending emails or posting notices on bulletin boards—the Court concluded this sort of recruiting assistance “is *plainly incidental* to the Solomon Amendment’s regulation of conduct.” *Id.* at 61–62 (emphasis added).

The Program at issue here is distinguishable from the Amendment at issue in *Rumsfeld*. Unlike the Amendment, the Program *does* mandate speech. Drug

manufacturers *must* affirm that the price at which they *must* sell their product is the “maximum fair price.” The government knows the American public does not support stunting research and development of new, lifesaving medications by capping the sale of patented drugs. The government therefore developed a scheme whereby it could effectively cap its spending by compelling drug manufacturers to “negotiate,” agree, and affirm that they are selling their valuable products at the “maximum fair price”—which is not constitutionally permissible. If the Program simply required manufacturers to negotiate with the government in good faith under the same terms and conditions it negotiates with private insurers, that would be different.

Rather than *Rumsfeld*, the more fitting case is *Expressions Hair Design v. Schneiderman*, 581 U.S. 37 (2017). There, the Supreme Court considered whether a New York law that forbade merchants from imposing a surcharge for the use of a credit card regulates speech, or only commercial conduct. *Id.* at 39. The Court held that the law did regulate speech, reasoning that it was different than typical price regulation, which simply regulates the amount that a store can collect and that only “*indirectly dictate* the content of that speech.” *Id.* at 47 (emphasis added). By contrast, New York’s law regulated “how sellers may communicate their prices.” *Id.*

The Program does both here, regulating not only the price of certain prescription drugs, but also directly regulating how manufacturers may communicate about their prices. Specifically, manufacturers must affirm that the price for their prescription drugs are the result of negotiations and an agreement between the manufacturer and the government for the maximum fair price. *Expressions Hair Design* not *Rumsfeld* should guide this Court’s analysis.

2. The Program Unconstitutionally Compels Viewpoint-Based Speech.

“Speech compulsions, the Court has often held, are as constitutionally suspect as are speech restrictions.” Eugene Volokh, *The Law of Compelled Speech*, 97 Tex. L. Rev. 355 (2018). Although there are various categories of compelled-speech cases, the most egregious violation of the no-compelled-speech doctrine is when the government compels viewpoint-based speech; indeed, “[t]he Supreme Court has never upheld a viewpoint compulsion of speech.” Richard F. Duncan, *Viewpoint Compulsions*, 61 Washburn L.J. 251, 272–73 (2022). As shown by Professor Volokh, “Government coercion is presumptively unconstitutional . . . when it compels people to speak things they do not want to speak.” Volokh, *supra* at 368–70; *see, e.g., Nat’l Inst. of Fam. & Life Advocs. v. Becerra*, 585 U.S. 755, 766 (2018) (holding that a compelled-notice provision “is a content-based regulation of speech” because “[b]y compelling individuals to speak a particular message, such notices alter the content of their speech”) (cleaned up).

The three most relevant compelled-speech cases for this Court’s consideration are *W. Virginia State Bd. of Educ. v. Barnette*, 319 U.S. 624 (1943), *Wooley v. Maynard*, 430 U.S. 705 (1977), and *Agency for Int’l Dev. v. All. for Open Soc’y Int’l, Inc.*, 570 U.S. 205 (2013) (hereinafter, “*AID*”). These cases prohibit the government from compelling speech as a condition of a government privilege. In *Barnette*, the Court held that schoolchildren could not be required to pledge allegiance to the flag because “compulsion . . . to declare a belief” unconstitutionally compelled “affirmation of a belief and an attitude of mind.” *Id.* at 631–33. In *Wooley*, the Court concluded that New Hampshire could not compel drivers to display the state motto—“Live Free or Die”—on their vehicle license plates. 430 U.S. at 717. The Court reasoned that the Constitution forbade making this display “a condition to driving an automobile,” which is “a virtual necessity for most Americans.” *Id.* at 715. Finally, in *AID*, the Court struck a federal law requiring the recipient of federal HIV/AIDS funding to affirm that it “is opposed to ‘prostitution and sex trafficking because of the psychological and physical risks they pose for women, men, and children.’” 570 U.S. at 210. The Court stated that the case was “not about the Government’s ability to enlist the assistance of those with whom it already agrees,” but “about compelling a grant recipient to adopt a particular belief as a condition of funding.” 570 U.S. at 218.

These cases reveal that the government cannot compel speech—which is viewpoint discrimination—by making the speech a *condition* on receipt of a benefit. But that’s exactly what the Program requires pharmaceutical companies to do here. To obtain the benefit of selling to Medicare recipients, drug companies are compelled to make statements that they don’t agree with, including that the “maximum fair price” of their drug is less than its fair market value—implying that the price the company sold its drugs at prior to the Program was *not fair*.

It is hard to see how this case differs from *AID* in any material respect. *AID* concerned billions of dollars in government aid; the Program concerns billions of dollars in government spending on Medicare. The regulation in *AID* required that the recipient of any funding under the Act agree in the funding agreement—which could be a “contract,” 45 C.F.R. § 89.1, subd. a—that it is opposed to prostitution and sex trafficking. The agreement giving pharmaceutical companies access to the government-sponsored health insurance market requires them to affirm that a drug is being sold at its “maximum fair price.” And notably, both *AID* and this case involve political optics. In *AID*, the government wanted funding recipients “*to adopt a similar stance*” to the government’s purpose of eradicating prostitution and sex trafficking. 570 U.S. at 218. “By demanding that funding recipients adopt—as their own—the Government’s view on an issue of public concern,” the program by its very nature affected “protected conduct outside the scope of the federally

funded program.” *Id.* (quotation omitted). So too here. The government didn’t simply set prices in a take it or leave it manner. Instead, it aimed to commandeer the companies’ mouthpieces in order to spread the government’s view on Medicare drug pricing, a matter of clear public concern.

As in *AID*, were the agreements “enacted as a direct regulation of speech,” they “would plainly violate the First Amendment.” *Id.* at 213. And as in *AID*, the Government may not evade the Constitution by imposing that requirement as a condition on the receipt of federal funds.

CONCLUSION

The Medicare Drug Price Negotiation Program is unprecedented. And even if its ends have merit—trying to curtail healthcare spending—the means it uses are unconstitutional. This Court should affirm longstanding constitutional principles and hold that the Program violates the First and Fifth Amendments.

Respectfully submitted,

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Dated: July 19, 2024

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 6499 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 (Times New Roman) 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 19, 2024

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CERTIFICATE OF SERVICE

I hereby certify that on July 19, 2024, this brief was electronically filed with the Clerk of Court using the appellate CM/ECFV system.

July 19, 2024

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