

**IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT**

Novo Nordisk Inc.;
Novo Nordisk Pharma, Inc.,

Plaintiffs-Appellants,

v.

Secretary, United States Department of Health and Human Services; United
States Department of Health and Human Services; Administrator, Centers for
Medicare & Medicaid Services; Centers for Medicare & Medicaid Services,

Defendants-Appellees.

On Appeal from the United States District Court for the District of New Jersey,
No. 3:23-cv-20814 (Hon. Zahid N. Quraishi)

**BRIEF OF *AMICUS CURIAE* ABRAMS INSTITUTE FOR FREEDOM OF
EXPRESSION IN SUPPORT OF APPELLEES AND AFFIRMANCE**

David A. Schulz
MEDIA FREEDOM & INFORMATION
ACCESS CLINIC
YALE LAW SCHOOL
1675 Broadway, 19th Floor
New York, NY 10019
(212) 663-6162
schulzd@ballardspahr.com

Flavio L. Komuves
WEISSMAN & MINTZ
220 Davidson Ave., Suite 410
Somerset, NJ 08873
(732) 563-4565
fkomuves@weissmanmintz.com

*Counsel for Amicus Curiae Abrams
Institute for Freedom of Expression*

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure and Rule 26.1 of the Third Circuit Local Appellate Rules, *amicus curiae* states that it has no corporate parent and is not owned in whole or in part by any publicly held corporation.

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INTEREST OF THE AMICUS¹

The Abrams Institute for Freedom of Expression at Yale Law School promotes the freedoms of speech and press, access to information, and government transparency. The Abrams Institute regularly litigates First Amendment claims in support of its mission to promote the clear, consistent, and robust constitutional protections for speech and press that are essential for democracy to flourish.

The Abrams Institute respectfully submits this amicus brief to address the claim by Plaintiffs-Appellants Novo Nordisk, Inc. and Novo Nordisk Pharma, Inc. (collectively, “Plaintiffs”) that the operative terms used in a standardized government contract required to participate in a voluntary Medicare program become the “compelled speech” of anyone who signs the contract. The district court properly rejected the argument because the price-setting contract at issue does not compel anyone to speak—it defines the parameters of a financial transaction. As the court found, signing the contract neither mandates nor limits the speech of participating drug manufacturers to any extent.

Plaintiffs seek to stretch the compelled speech doctrine far beyond any reasoned limit. Their broad definition of compelled “speech” would require courts

¹ *Amicus* files this brief with the parties’ consent pursuant to Fed. R. App. P. 29(a)(2). No party or party’s counsel authored this brief in whole or in part, and no person other than *amicus curiae* and its counsel made a monetary contribution to fund the preparation or submission of this brief.

to apply strict scrutiny to the language used in vast swaths of well-established, conduct-regulating law, from contracts and antitrust to health and safety regulations. Plaintiffs’ novel view of the First Amendment’s reach contradicts its history, purpose, and past application. It should be flatly rejected.

FACTUAL BACKGROUND

Medicare Part D provides prescription drug coverage to approximately 55.5 million seniors each year.² In 2021, the cost of Part D to taxpayers was almost \$216 billion and threatened to double over the next decade.³ The prices of drugs covered by Part D ballooned out of control⁴ because Congress had prohibited the Centers for Medicare and Medicaid Services (“CMS”), unlike every other market actor, from negotiating over the prices demanded by drug manufacturers. *See* 42 U.S.C. § 1395w-111(i)(1). The ten top-selling drugs alone cost Medicare \$46 billion in

² Kenneth Finegold et al., Dep’t of Health & Human Servs., *Medicare Part D Enrollees Reaching the Out-of-Pocket Limit by June 2024*, at 3 (Oct. 22, 2024), <https://aspe.hhs.gov/sites/default/files/documents/757a8acd9b7c4f44a4a4bbfa41d5831c/oop-cap-ib.pdf>.

³ Ass’t Sec’y for Planning & Evaluation, Dep’t of Health & Human Servs., *Medicare Drug Price Negotiation Program: Understanding Development and Trends in Utilization and Spending for the Selected Drugs*, at 3 (Dec. 14, 2023), <https://aspe.hhs.gov/sites/default/files/documents/4bf549a55308c3aadc74b34abcb7a1d1/ira-drug-negotiation-report.pdf>.

⁴ H.R. Comm. on Oversight & Reform, 117th Cong., *Drug Pricing Investigation* 57 (Dec. 2021).

2022, more than double the cost from four years prior.⁵ Runaway costs imposed a heavy financial burden on both the Medicare program and the seniors who used Medicare coverage to access essential medications.⁶

Congress addressed this untenable situation in 2022 through the Inflation Reduction Act (“IRA”), which granted the Secretary of Health and Human Services (“HHS” or the “Secretary”) the authority to negotiate drug prices paid by Medicare based on a model used by the Departments of Defense and Veterans Affairs.⁷ The Medicare drug price negotiation program (the “Negotiation Program” or “Program”) has five key components:

1. Drug selection. The Secretary selects negotiation-eligible drugs using criteria set by Congress. *Id.* § 1320f-1.

2. Decision to participate. Manufacturers of selected drugs choose whether to participate in the Negotiation Program. Choosing to participate requires a drug manufacturer to sign a Manufacturers Agreement and provide the Secretary with data Congress deemed relevant to setting the drug’s price. *Id.* §§ 1320f-2, 1320f-

⁵ *Medicare Drug Price Negotiation Program*, *supra* note 3, at 15.

⁶ See Eli Y. Adashi et al., *The Inflation Reduction Act: Recasting the Medicare Prescription Drug Plans*, 64 Am. J. Prev. Med. 936, 937 (2023).

⁷ See 38 U.S.C. § 8126(a)-(h) (limits on drug prices paid by Department of Veterans’ Affairs and other federal agencies); *see also* Cong. Budget Off., *A Comparison of Brand-Name Drug Prices Among Selected Federal Programs* 14-17 (Feb. 2021), <https://www.cbo.gov/system/files/2021-02/56978-Drug-Prices.pdf>.

3(e). If a manufacturer chooses not to participate, Medicare will no longer pay for any of that manufacturer's drugs, but if the manufacturer divests its interests in the selected drug, Medicare will continue to pay for its other products.⁸

3. Negotiation. The process then involves a typical negotiation over proper application of Congressionally determined factors. *Id.* § 1320f-3. The Secretary submits an initial offer based upon the manufacturer-provided data and market evidence on alternative treatments. *Id.* §§ 1320f-3(b)(2)(B), 1320f-3(e)(1)-(2). The manufacturer can accept the offered price or make a counteroffer, informed by the same factors specified in the IRA. *Id.* § 1320f-3(b)(2)(C). The Secretary must consider any counteroffer and its rationale. If the Secretary rejects the counteroffer, the manufacturer will be offered at least one (and up to three) negotiating meetings to discuss the proper application of the IRA's pricing factors. *CMS Revised Guidance, supra* note 88, at 156-57. Afterward, the Secretary sets the maximum price Medicare will pay—a price Congress in the IRA termed the “maximum fair price.” *Id.* § 1320f-3(b)(1).

⁸ See Ctrs. for Medicare & Medicaid Servs., *Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026*, at 129-32 (June 30, 2023), <https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf> (Hereinafter “*CMS Revised Guidance*”). Under certain circumstances a manufacturer may withdraw from the program after opting in, subject to the payment of an excise tax. *Id.*

4. Public explanation. The Secretary must publish an explanation justifying his calculation of the “maximum fair price.” *Id.* § 1320f-4. Manufacturers may also publish their own account of the negotiations. *CMS Revised Guidance*, *supra* note 88, at 124.

5. Enforcement. If a manufacturer chooses to participate in the Program but then charges Medicare recipients more than the price set through the negotiation process, an excise tax is imposed on that particular drug. 42 U.S.C. §§ 1320f-5, 1320f-6.

The Negotiation Program has operated as intended. By August 1, 2024, CMS secured agreements for all ten negotiation-eligible drugs.⁹ In each case, CMS raised its initial offer; in four cases CMS accepted the manufacturer’s revised counteroffer.¹⁰ If the agreements reached on these ten drugs had been in place in 2023, Medicare would have saved \$6 billion.¹¹ For their part, manufacturers have generally described the outcome as having limited impact on their businesses.¹²

⁹ Ctrs. for Medicare & Medicaid Servs., *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026* (Aug. 14, 2024), <https://www.cms.gov/newsroom/fact-sheets/medicare-drug-price-negotiation-program-negotiated-prices-initial-price-applicability-year-2026>.

¹⁰ *Id.*

¹¹ *Id.*

¹² *See, e.g.*, Transcript, *Novo Nordisk (NVO) Q2 2024 Earnings Call* Transcript (Aug. 7, 2024), <https://www.fool.com/earnings/call-transcripts/2024/08/07/novo-nordisk-nvo-q2-2024-earnings-call-transcript/> (Doug Langa, Executive Vice President for

ARGUMENT

Plaintiffs assert that participation in the Negotiation Program “requires manufacturers to say in writing that they ‘agree’ the price imposed by CMS is the ‘maximum fair’ price.” Appellants’ Br. 65. They contend that 1) participation in the Program is not voluntary and 2) having to sign a contract that uses terminology they disapprove compels them to speak in violation of the First Amendment. Neither contention is correct. Participation in the Program is not compelled and, even if it were, participants are not compelled to express any view. The terms used in the Manufacturer Agreement simply define the parties’ obligations using the terms Congress used in the IRA and such contractual terms are not a form of expression subject to judicial scrutiny under the First Amendment.

I. DRUG MANUFACTURERS ARE NOT COMPELLED TO PARTICIPATE IN THE NEGOTIATION PROGRAM

As a threshold matter, Plaintiffs’ participation in the Negotiation Program cannot give rise to a compelled-speech claim because their participation is voluntary. Though Plaintiffs might have a strong financial incentive to participate in the Program, they are not compelled to do so. Through the Negotiation Program, CMS

Novo Nordisk’s North America operations, assures investors that the drugs for which Novo Nordisk has completed negotiations with Medicare involve only “a minor part of our business” and that the company “expect[s] limited impact there.”).

acts as a market participant, not as a regulator, and CMS is free to set the terms on which it is willing to do business.

The Supreme Court has long recognized the First Amendment concerns presented when a party is required to “speak as the State demands or face sanctions.” *303 Creative LLC v. Elenis*, 600 U.S. 570, 589 (2023) (striking down a Colorado law that required a graphic designer to create websites expressing messages counter to her religious beliefs). But “a violation of the First Amendment right against compelled speech occurs only in the context of actual compulsion.” *C.N. v. Ridgewood Bd. of Educ.*, 430 F.3d 159, 189 (3d Cir. 2005). To rise to the level of such compulsion, “the governmental measure must punish, or threaten to punish, protected speech by governmental action that is ‘regulatory, proscriptive, or compulsory in nature.’” *Id.* (first quoting *Phelan v. Laramie Cnty. Cmty. Coll. Bd. of Trs.*, 235 F.3d 1243, 1247 (10th Cir. 2000); then quoting *Laird v. Tatum*, 408 U.S. 1, 11 (1972)); *see, e.g., Wooley v. Maynard*, 430 U.S. 705, 715 (1977) (speech compelled by criminal sanctions imposed for obscuring state motto on license plate); *W. Va. State Bd. of Educ. v. Barnette*, 319 U.S. 624, 634 (1943) (speech compelled by regulation requiring schoolchildren to salute the flag). No such compulsion exists here.

Selected manufacturers that choose not to participate in the Negotiation Program face no legal sanction and can continue to sell their products to anyone in

the market. Medicare, however, will no longer pay for them. Alternatively, a manufacturer may choose to divest its interest in the selected drug, in which case Medicare will continue to pay for the manufacturer's other products. Like any other market actor, the government has the ability "to determine those with whom it will deal, and to fix the terms and conditions upon which it will make needed purchases." *See Perkins v. Lukens Steel Co.*, 310 U.S. 113, 127 (1940).

Any financial consequences a manufacturer faces from choosing not to participate are a product of the government's market power, not its regulatory power. Recognizing this distinction, federal courts of appeals have consistently found participation in Medicare by providers of services and products to be voluntary, even where there are strong financial inducements to participate. As the Seventh Circuit explained, the fact that "practicalities may in some cases dictate participation [in Medicare] does not make participation involuntary." *St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875 (7th Cir. 1983); *see also, e.g., Garelick v. Sullivan*, 987 F.2d 913, 916-17 (2d Cir. 1993) (Medicare participation is voluntary where providers can "provide medical services to non-Medicare patients free of price regulations"); *Baker Cnty. Med. Servs., Inc. v. U.S. Atty. Gen.*, 763 F.3d 1274, 1279-80 (11th Cir. 2014) (participation in Medicare is voluntary); *Baptist Hosp. E. v. Sec'y of Health & Hum. Servs.*, 802 F.2d 860, 869 (6th Cir. 1986) (same); *cf. Franklin Mem'l Hosp. v. Harvey*, 575 F.3d 121, 130 (1st Cir. 2009) (provider participation in

Medicaid is voluntary); *Minn. Ass’n of Health Care Facilities, Inc. v. Minn. Dep’t of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984) (same).

Multiple district courts have rejected compelled-speech challenges to the Negotiation Program at issue here for the same reason, holding that “participation in Medicare, no matter how vital it may be to a business model, is a completely voluntary choice.” *Dayton Area Chamber of Com. v. Becerra*, 696 F. Supp. 3d 440, 456 (S.D. Ohio 2023); *see also Boehringer Ingelheim Pharms., Inc. v. U.S. Dep’t of Health & Hum. Servs.*, No. 23-cv-01103, 2024 WL 3292657, at *12-15 (D. Conn. July 3, 2024) (rejecting a compelled-speech claim because participation in Medicare is voluntary); *Bristol Myers Squibb Co. v. Becerra*, No. 23-3335, 2024 WL 1855054, at *9 (D.N.J. Apr. 29, 2024) (finding that while “[s]elling to Medicare may be less profitable than it was before,” that does not make the “decision to participate any less voluntary”); *AstraZeneca Pharms. LP v. Becerra*, 719 F. Supp. 3d 377, 395-96 (D. Del. 2024) (finding that the IRA does not “require[] AstraZeneca to sell its drugs to Medicare beneficiaries”).

Plaintiffs attempt to counter this uniform rejection of their compulsion claim by pointing to entirely inapposite authority. They cite *Wooley* for the basic proposition that “[f]orcing manufacturers to express the government’s preferred viewpoint is unconstitutional” and *Janus v. Am. Fed’n of State, Cnty., & Mun. Emps., Council 31*, 585 U.S. 878, 893 (2018), for its holding that “[a]n ‘involuntary

affirmation of objected-to beliefs’ is a textbook example of unconstitutionally compelled speech.” Appellants’ Br. 66. But no such forced expression or involuntary affirmation exists here. The voluntary decision to participate in the Negotiation Program requires no public display of imposed speech like the mandate in *Wooley* that imposed criminal penalties for failing to display the state motto, “Live Free or Die,” on all cars licensed in New Hampshire. 430 U.S. at 707. Nor is a manufacturer’s voluntary participation in the Negotiation Program akin to the unavoidable obligation of a public employee to subsidize a union’s political speech at issue in *Janus*. 585 U.S. at 884-85. While Plaintiffs may consider their available choices in the marketplace to be suboptimal, they are not subject to any compulsion to participate in the Program that is remotely similar in kind or degree to the compulsion presented in *Wooley* and *Janus*.

Plaintiffs inaccurately portray the Fifth Circuit as recently finding the Negotiation Program not to be voluntary. Appellants’ Br. 62. It did no such thing. In *National Infusion Center Association v. Becerra*, the Fifth Circuit reversed the dismissal of a claim by an association of health care providers who contended that their revenues would drop if drug manufacturers participated in the Program. 116 F.4th 488, 509 (5th Cir. 2024). The plaintiffs were not themselves subject to the Program and the Fifth Circuit did not address whether participation is voluntary. *See id.* at 498-99; *see also id.* at 509-10 (Ramirez, J., concurring in part and dissenting

in part) (emphasizing that the Negotiation Program itself is “voluntary” for drugmakers, and dissenting on other grounds). Rather, the Fifth Circuit concluded that the plaintiffs had alleged a sufficient likelihood of harm to establish their standing because manufacturers of the drugs they prescribe are “all but certain” to negotiate with HHS and “reach[] an agreement” on drug prices since the manufacturers are “guided by basic economic rationality.” *Id.* at 500. The Fifth Circuit’s decision is not the least bit contrary to the uniform district court holdings finding that the manufacturers’ participation in the Program is voluntary.

Other authority invoked by Plaintiffs is similarly misstated or inapposite. For instance, *Horne v. Department of Agriculture*, 576 U.S. 350 (2015) (cited at Appellants’ Br. 59), is easily distinguished because it involved direct regulation of grape growers backed by civil fines that could be avoided only by exiting the industry entirely. Other inapposite cases cited by Plaintiffs involved restrictions imposed to receive government benefits, *see Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595 (2013) (Appellants’ Br. 60); questions about the federalism limits on federal authority, *see Nat’l Fed’n of Indep. Bus. v. Sebelius*, 567 U.S. 519 (2012) (Appellants’ Br. 61-62); and the scope of the Dormant Commerce Clause, *see S.-Cent. Timber Dev., Inc. v. Wunnicke*, 467 U.S. 82 (1984) (Appellants’ Br. 63); *Cardinal Towing & Auto Repair, Inc. v. City of Bedford*, 180 F.3d 686, 691 (5th Cir. 1999) (Appellants’ Br. 63). None of these cases address whether the use of market

incentives can be deemed the type of “compulsion” that renders participation involuntary. Plaintiffs even cite one case that contradicts their argument by recognizing that certain restrictions on government do not apply when the government acts “as a market participant.” *Keystone Chapter, Associated Builders & Contractors, Inc. v. Foley*, 37 F.3d 945, 955 n.15 (3d Cir. 1994) (quoting *Bldg. & Constr. Trades Council v. Associated Builders & Contractors*, 507 U.S. 218, 229 (1993)) (Appellants’ Br. 63).

Plaintiffs fail to establish that the Negotiation Program is anything other than an instance of the government functioning as a market actor and fail to show that participation in the Program is compelled.

II. PROGRAM PARTICIPANTS ARE NOT COMPELLED TO SPEAK

Plaintiffs’ First Amendment claim fails for a second reason: there is no First Amendment-protected speech at issue here. Plaintiffs mischaracterize the Negotiation Program as requiring manufacturers to express the view “that they ‘agree’ that the price imposed by CMS is the ‘maximum fair’ price,” Appellants’ Br. 65, but the Program does no such thing. The Manufacturer Agreement defines Plaintiffs’ commitments in dealing with Medicare recipients without requiring Plaintiffs to speak or to endorse any message. *See* 42 U.S.C. § 1320f-3; JA178.

A. The Manufacturer Agreement Requires Plaintiffs to Act, Not to Speak

The Manufacturer Agreement is a run-of-the-mill contract that does no more than memorialize a promise between two parties to perform certain actions. *See* 42 U.S.C. § 1320f-2(a). It requires no affirmation or pledge to support any view. The Supreme Court has squarely held that such a statement of obligation to perform a non-expressive action does not implicate—much less violate—the First Amendment.

In *Rumsfeld v. F. for Acad. & Institutional Rts., Inc.* (“*FAIR*”), a group of law schools challenged a law that made federal university funding contingent on schools allowing military recruiters access to their campuses equal with other recruiters. 547 U.S. 47, 55 (2006). Like Plaintiffs’ theory here, the law schools argued that this requirement compelled them to express support for the military’s then-in-effect policy of barring openly gay individuals from service. *Id.* at 52. The Court rejected that argument and upheld the law because it “regulate[d] conduct, not speech. It affect[ed] what the law schools must do—afford equal access to military recruiters—not what they may or may not *say*.” *Id.* at 60.

So also here, the Manufacturer Agreement requires Plaintiffs to act—to provide relevant information to the Secretary, negotiate over the “maximum fair price” as defined by law, and sell their drugs to Medicare recipients at no more than the price ultimately set by the Secretary. It defines Plaintiffs’ required conduct, not their speech. The Court in *FAIR* rejected plaintiffs First Amendment argument even

though the universities were required to produce “incidental” speech to facilitate the military’s recruitment efforts, such as posting notices or sending scheduling e-mails. 547 U.S. at 62. Participation in the Program here does not require Plaintiffs to produce *any* expressive speech, even incidentally.

Plaintiffs again miss the mark in relying on prototypical compelled-speech cases like *Wooley* and *Janus*. See Appellants’ Br. 66-67. Just as this case does not involve any compulsion of the type presented in *Wooley* and *Janus*, it does not involve any protected speech like that presented in *Wooley* and *Janus*. The statutes in *Wooley* and *Janus* compelled plaintiffs to express or support a clear message; the Agreement here compels Plaintiffs to convey no message at all. See *Wooley*, 430 U.S. at 706-7 (requiring Jehovah’s Witness to display state motto “Live Free or Die”); *Janus*, 585 U.S. at 888 (requiring public employees to subsidize union’s policy positions with which they disagreed).

Plaintiffs are similarly off base in claiming *Agency for International Development v. Alliance for Open Society International, Inc.* (“*USAID*”), 570 U.S. 205 (2013) supports their compelled speech claim. See Appellants’ Br. 65-66. To the contrary, it further underscores how *Wooley* and *Janus* are entirely inapposite.

In *USAID*, the Supreme Court held unconstitutional a funding condition imposed by multiple federal agencies that required grant recipients to “agree in the award document that [they are] 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. Like the license plate in *Wooley* and the union speech in *Janus*, *USAID* involved a government requirement to adopt and endorse as their own a view with which the plaintiffs disagreed—the government’s beliefs about the harms of prostitution. *Id.* at 218. In sharp contrast to the acknowledgment required of grant recipients in *USAID*, the Manufacturer Agreement here does not require Plaintiffs to adopt or endorse any message. Quite to the contrary, it expressly affirms Plaintiffs’ right to state any views they wish about the Negotiation Program and the Medicare drug prices it produces.¹³ JA178.

Through the Negotiation Program, the Secretary engages in negotiations with drug manufacturers to set the price CMS will pay for selected drugs. The Manufacturer Agreement is the legal instrument that memorializes each side’s participation in the process and obligation to use the price it produces. Endorsing Plaintiffs’ attempts to expand First Amendment protection to the choice of terms

¹³ Nor would *USAID* support an unconstitutional conditions argument even if the Agreement did compel Plaintiffs to speak. The Supreme Court in *USAID* distinguished between permissible conditions “that define the limits of the government spending program—those that specify the activities Congress wants to subsidize,” and impermissible conditions “that seek to leverage funding to regulate speech outside the contours of the program itself.” 570 U.S. at 214–15. The “speech” Plaintiffs claim to be compelled is not beyond “the contours of the program itself,” but rather specifies the drug prices that Congress is willing to reimburse.

used to state these commitments would “trivialize[] the freedom protected” by the compelled speech doctrine. *See FAIR*, 547 U.S. at 62.

B. Terms Used in the Agreement to Establish the Parties’ Obligations Are Not Subject to First Amendment Scrutiny

Plaintiffs are equally off-base in contending that the terms “agree” and “maximum fair price” in the Manufacturer Agreement “express the government’s preferred viewpoint.” Appellants’ Br. 65-66. The Agreement simply defines the parties’ conduct using terminology that confirms compliance with the drug price requirements imposed by Congress. As the Seventh Circuit explained in a criminal-law context, a term used to establish an agreement is a performative utterance “commit[ting] the speaker to a course of action,” and not speech that conveys information. *United States v. Montana*, 199 F.3d 947, 950 (7th Cir. 1999) (finding terms used to establish an agreement not subject to hearsay rule “because they do not make any truth claims”).

Indeed, the law can and does require “particular magic words” to be used to form or amend certain contracts. *See* Ian Ayres, *Regulating Opt-Out: An Economic Theory of Altering Rules*, 121 Yale L.J. 2032, 2037 (2012). For example, the Uniform Commercial Code requires that certain contracts use specific words, like “merchantability.” *Id.*; *see also* U.C.C. § 2-316 (Unif. L. Comm’n 2022). But these contract terms are not subject to First Amendment scrutiny “because such speech is leagues away from the outer boundaries of plausible First Amendment coverage.”

Frederick Schauer, *Out of Range: On Patently Uncovered Speech*, 128 Harv. L. Rev. F. 346, 352 (2015); *see also* Amanda Shanor, *First Amendment Coverage*, 93 N.Y.U. L. Rev. 318, 357 (2018) (“In the realm of contracts and fraud, the lack of First Amendment coverage reflects respect for the basic social relationships of promise.”).

Plaintiffs’ First Amendment objection to the term “agree” in the Manufacturer Agreement exemplifies the untenable nature of their contract-as-compelled speech argument. The term “agree” is foundational to the creation of any binding contract; it effectuates the contract, affirming the parties’ assent to *perform* the contract’s terms. *See Agreement, Black’s Law Dictionary* (12th ed. 2024) (“A mutual understanding between two or more persons about their relative rights and duties regarding past or future performances; a manifestation of mutual assent by two or more persons”). The attempt by Plaintiffs to transmute “agree” from its performative role in contract formation into an implicit adoption of another’s viewpoint is baseless.

The term “maximum fair price” is similarly performative in the contract. Agreeing to participate in the Negotiation Program and to sell at the “maximum fair price” ultimately set by the Secretary is not a forced expression of a view on the fairness of the final price.¹⁴ It is a confirmation that the price was set pursuant to the

¹⁴ In any event, regulations of conduct can trigger First Amendment scrutiny only if (1) the “speaker” has an intent to convey a particularized message, and (2) there is a

procedures in 42 U.S.C. § 1320f-3, the source of the contract term. The Agreement makes this meaning explicit, stating that “maximum fair price” is the term defined by Congress in the authorizing statute. JA178.

As the Supreme Court has explained, such statutory terms must be interpreted “as . . . written, not as [they] might be read by a layman, or as [they] might be understood by someone who has not even read [the statute].” *Meese v. Keene*, 481 U.S. 465, 484-85 (1987) (rejecting claim that a mandatory “political propaganda” movie label conveyed a pejorative meaning different from than the statute’s definition). The statutory definition of “maximum fair price” thus forecloses the meaning urged by Plaintiffs because it is “axiomatic that the statutory definition of the term excludes unstated meanings of that term.” *Id.* at 484; *see also* JA13 (adopting the equivalent holding of *Bristol Myers Squibb Co. v. Becerra*, No. CV 23-3335 (ZNQ) (JBD), 2024 WL 1855054, at *11 (D.N.J. Apr. 29, 2024)).

Simply put, the contract terms define a specific course of conduct; they do not compel an expression of any view. As such, Plaintiffs’ First Amendment claim is

high likelihood that message would be understood by others. *Texas v. Johnson*, 491 U.S. 397, 404 (1989). Even assuming “agree” and “maximum fair price” expressed a view on pricing, signing the Agreement would fail the second prong of the *Johnson* test. *Cf. FAIR*, 547 U.S. at 62 (finding law schools do not adopt the views of military recruiters by announcing their presence); *PruneYard Shopping Ctr. v. Robins*, 447 U.S. 74, 87 (1980) (finding it unlikely that the views of those handing out leaflets in a shopping mall would be imputed to the mall’s owner).

entirely misdirected. *See Ark. Times LP v. Waldrip*, 37 F.4th 1386, 1394 (8th Cir. 2022) (rejecting a First Amendment challenge to a government contracting requirement that prohibited contractors from engaging in anti-Israel boycotts but did not require them to “publicly endorse or disseminate a message”), *cert. denied*, 143 S.Ct. 774 (2023). As discussed in Section III below, to hold otherwise would render many public transactions subject to judicial First Amendment scrutiny, an outcome that would clog the courts, hamstringing the government’s ability to contract with private actors, and kneecap many forms of routine regulation.

C. Plaintiffs’ Requested Remedy Is Not Practicable, In Any Event

Plaintiffs appear to contend that the First Amendment renders the entire contract unenforceable, *see* JA97, 99, but this is not a workable remedy. While a specific contractual provision that violates the First Amendment may be deemed unenforceable, courts are hesitant to invalidate entire contracts without compelling justification. *See, e.g., USAID*, 570 U.S. at 205 (affirming injunction that enjoined only enforcement of unconstitutional condition in contract at issue).

As this Court recently noted during argument in an appeal by different drug manufacturers challenging the same Negotiation Program, contract reformation could simply adjust the language to reference the statute’s required price without using terms to which Plaintiffs object (e.g., replacing “maximum fair price” with “the price listed in § 1420-e”). Oral Argument at 46:01, *AstraZeneca Pharms. LP v.*

Becerra, (3d Cir. 2024) (No. 24-1819) (https://www2.ca3.uscourts.gov/oralargument/audio/24-1819-1820-1821_Astazeneca-BristolMyers-Janssensv.SecretaryUSDeptHHS.mp3). But as the Supreme Court has instructed, “courts should hesitate, and then hesitate some more, before modifying a contract.” *Kansas v. Nebraska*, 574 U.S. 445, 470 (2015). Contract reformation would be particularly inappropriate here because it would change no rights, obligations, or liabilities between the parties. *See* Restatement (Second) of Contracts § 166 (Am. L. Inst. 1981).

III. ACCEPTING PLAINTIFFS’ NOVEL FIRST AMENDMENT CLAIM WOULD HAVE FAR-REACHING, ADVERSE CONSEQUENCES

Rejecting the bedrock principle that contract terms are not subject to First Amendment scrutiny, as Plaintiffs request, would threaten to subject large swaths of government contract law and regulation to First Amendment litigation. Thinly veiled contract disputes blown up to constitutional proportion would inevitably follow.

Entire sectors of private industry are dominated—sometimes completely—by contracting with governments at all levels, from streetcars to streetlights to armor-piercing rounds. Defense, infrastructure, energy, sanitation, public transit, corrections, and space exploration are just the beginning of a very long list. The First Amendment does have a legitimate role to play in this realm, *see, e.g., Bd. of Cnty. Comm’rs v. Umbehr*, 518 U.S. 668, 673 (1996) (holding unconstitutional

retaliation against government contractors for protected speech), but no court has adopted the rule Plaintiffs now assert, requiring First Amendment review of contract terminology. *See* Frederick Schauer, *Out of Range: On Patently Uncovered Speech*, 128 Harv. L. Rev. 346, 353 (2015) (noting that “[t]here has never been a Supreme Court or lower federal court or state court case even dealing with why the speech that makes a contract or will is not covered by the First Amendment”).

Were this Court to become the first to apply First Amendment scrutiny to the terms of a government contract, the consequences would be far-reaching. The federal government alone commits three-quarters of a trillion dollars across millions of new individual contracts each year. *See A Snapshot of Government-Wide Contracting for FY 2023*, Gov’t Accountability Off. (June 25, 2024) (<https://www.gao.gov/blog/snapshot-government-wide-contracting-fy-2023-interactive-dashboard>). If government contracts—federal, state and local—could be subjected to First Amendment challenge for viewpoints purportedly implicit in their operative terms, lawsuits like this would proliferate. *See, e.g.*, Federal Acquisition Regulation, Definitions, 48 C.F.R. § 2.101 (outlining the extraordinary range of contracting terms routinely used in federal procurement contracts).

Plaintiffs’ compelled speech theory could even subject long-standing government regulation to judicial scrutiny because of the terminology used. For example, three landmark federal statutes long ago established “fair” labor standards

for federal contractors that could become subject to First Amendment challenge under Plaintiffs’ strained theory of compelled speech. *See Federal Contract Labor Standards Statutes*, Cong. Rsch. Serv. 1-17 (Dec. 4, 2007), <https://crsreports.congress.gov/product/pdf/RL/RL32086/7>) (discussing the Davis-Bacon Act of 1931, 40 U.S.C. §§ 3141-3148, the Walsh-Healy Public Contracts Act of 1936, 41 U.S.C. §§ 6501-6511, and the Service Contract Act of 1965, 41 U.S.C. §§ 6701-6707). Under these laws the Department of Labor requires federal contractors to agree (and to inform their employees of their agreement) to pay, at a minimum, the wages “established by the Fair Labor Standards Act.” *See* 41 U.S.C. § 6703 (requiring public contractors agree to and notify employees of compliance with Fair Labor Standards Act); 48 C.F.R. § 52.222-41(c), (g) (mandating employers communicate compliance by displaying Department of Labor poster, Dep’t of Lab. Pub. No. WH-1313 (Apr. 2009) (<https://www.dol.gov/agencies/whd/posters/government-contracts/sca>)). A federal contractor could object that this contract term compels it to agree that lower wages would *not* be “fair,” if Plaintiffs’ theory of protected speech is upheld.

Plaintiffs’ theory would authorize a flood of litigation that would muddy the scope of First Amendment protections and hamstring government’s ability to contract with private actors. *See* Robert Post & Amanda Shanor, *Adam Smith’s First Amendment*, 128 Harv. L. Rev. F. 165, 166-67 (2015) (critically examining the

increasing use of the First Amendment as “engine of constitutional deregulation”). Plaintiffs’ *Lochner*ian approach to public contracting also misconstrues judicial power. *See* Amanda Shanor, *The New Lochner*, 2016 Wis. L. Rev. 133, 177–82 (2015). Recognizing the dangers presented by the type of judicial overreach inherent in Plaintiffs’ request for First Amendment judicial review here, the Supreme Court long ago rejected as impermissible a similar reliance on the Due Process Clause to second-guess Congress’s economic powers. *See West Coast Hotel Co. v. Parrish*, 300 U.S. 379, 392 (1937) (abrogating *Lochner v. New York*, 198 U.S. 45 (1905)).

This Court should flatly reject Plaintiffs’ effort to pursue their transcendent deregulatory agenda through a novel application of the First Amendment.

CONCLUSION

For the foregoing reasons, this Court should affirm the district court’s dismissal of Plaintiffs’ First Amendment compelled speech claim.

Dated: December 23, 2024

Respectfully submitted,

/s/ Flavio L. Komuves
Flavio L. Komuves (018891997)
WEISSMAN & MINTZ
220 Davidson Ave., Suite 410
Somerset, NJ 08873
(732) 563-4565
fkomuves@weissmanmintz.com

David A. Schulz
MEDIA FREEDOM & INFORMATION
ACCESS CLINIC
YALE LAW SCHOOL¹⁵
1675 Broadway, 19th Floor
New York, NY 10019
(212) 663-6162
schulzd@ballardspahr.com

*Counsel for Amicus Curiae Abrams
Institute for Freedom of Expression*

¹⁵ The views expressed herein do not purport to represent the institutional views of Yale Law School, if any. Law students Anthony Cosentino, Andrea DenHoed, Raymond Perez, Federico Roitman, and Clinical Fellow Tobin Raju were integral to the research, drafting, and editing of this brief.

CERTIFICATE OF COMPLIANCE

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

1. Pursuant to Third Circuit Local Appellate Rules 28.3(d) and 46.1(e), 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 5,279 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. Pursuant Third Circuit Local Appellate Rule 31.1(c), the text of the electronic brief is identical to the text in the paper copies and that CrowdStrike Falcon Sensor has been run on the file and no virus was detected.

Dated: December 23, 2024

/s/ Flavio L. Komuves
Flavio L. Komuves

CERTIFICATE OF SERVICE

I hereby certify that on December 23, 2024, I electronically filed the foregoing brief with the Clerk of this Court using the CM/ECF system, and counsel for all parties will be served by the CM/ECF system.

I further certify that seven paper copies of the foregoing brief were sent to the Clerk's Office via UPS.

Dated: December 23, 2024

/s/ Flavio L. Komuves
Flavio L. Komuves