No. 24-2968

IN THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

Novartis Pharmaceuticals Corporation,

Plaintiff-Appellant,

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-14221 (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.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Regulations

Other Authorities

INTEREST OF AMICUS[1]

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 Plaintiff-Appellant Novartis Pharmaceuticals Corporation ("Plaintiff" or "Novartis") that the operative terms used in a 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 any speech—it defines the parameters of a financial transaction. As the court found, signing the contract does not mandate any protected speech by a participating drug manufacturer because both the agreement and negotiations are incidental to the price-setting program.

Plaintiff seeks to stretch the compelled speech doctrine far beyond any reasoned limit. Its broad definition of compelled "speech" would require courts to apply strict scrutiny to the language used in vast swaths of well-established, conduct-

[1] No party or its counsel had any role in authoring this brief. No person or entity—other than *amicus curiae* and its counsel—contributed money that was intended to fund preparing or submitting this brief.

regulating law, from contracts and antitrust to health and safety regulations. Plaintiff's novel view of the First Amendment's reach contradicts its history, purpose, and past application. It should be flatly rejected.

Pursuant to Federal Rule of Appellate Procedure 29(a)(2), *amicus* has authority to file this brief because all parties have consented to the filing.

FACTUAL BACKGROUND

Medicare Part D provides prescription drug coverage to approximately 55.5 million seniors each year.[2] But the program comes at a price. In 2021, the cost of Part D to taxpayers was nearly $216 billion and growing, threatening to double over the next ten years.[3] The prices of drugs covered by Part D ballooned out of control[4] 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-

[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).

selling drugs alone cost Medicare $46 billion in 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 rely on it 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 Department of Defense ("DOD") and Veterans Affairs ("VA").[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 Manufacturer Agreement and provide the Secretary with data Congress deemed relevant to setting the drug's price. *Id.* §§ 1320f-2, 1320f-3(e). If a manufacturer chooses not to participate, Medicare will no longer pay for any of

---

[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).

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. JA419-20. Afterward, the Secretary sets the maximum price Medicare will pay—a price Congress in the IRA termed the "maximum fair price." 42 U.S.C. § 1320f-3(b)(1). The "maximum fair price" may not be set higher than a statutory "ceiling price" separately defined in the IRA. *Id.* § 1320f-3(c).

4. Public explanation. The Secretary must publicly explain and justify his calculation of the "maximum fair price." *Id*. § 1320f-4. Manufacturers may also publish their own account of the negotiations. JA421.

[8] JA392-95. Under certain circumstances, a manufacturer may withdraw from the program after opting in, subject to the payment of an excise tax. *Id.*

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. Plaintiff Novartis's ENTRESTO® was selected, among nine other products, by CMS for price-negotiation,[9] and by August 1, 2024, CMS had secured agreements with various manufacturers for all ten negotiation-eligible drugs.[10] In each case, CMS raised its initial offer; in four cases CMS accepted the manufacturer's revised counteroffer.[11] If the agreements reached on these ten drugs had been in place in 2023, Medicare would have saved $6 billion.[12]

---

[9] Press Release, Novartis, *Novartis Statement about Entresto® (sacubitril/valsartan) selection for Medicare Drug Price Negotiation Program* (Aug. 9, 2023), https://www.novartis.com/news/novartis-statement-about-entresto-sacubitrilvalsartan-selection-medicare-drug-price-negotiation-program.

[10] 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.

[11] *Id.*

[12] *Id.*

ARGUMENT

Novartis contends that (1) participation in the Program is not voluntary, and (2) the contract it must sign to participate compels Novartis to "denounce" its prices and falsely claim to be participating "in a genuine 'negotiation,'" in violation of the First Amendment. Appellant's Br. at 46-47. Neither contention is correct. Participation in the Program is not compelled, and signing the Manufacturer Agreement involves no First Amendment-protected expression. The terms in the Manufacturer Agreement define the parties' obligations using the same language used by Congress in the IRA and such contract provisions terms are not a form of expression subject to judicial scrutiny under the First Amendment. The Manufacturer Agreement neither compels nor limits Novartis's speech to any extent.

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

As a threshold matter, "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). There is no viable First Amendment compelled speech claim where participation in the challenged government program is voluntary. *See Grove City Coll. v. Bell*, 465 U.S. 555, 575-76 (1984).

Here, the Negotiation Program cannot give rise to a compelled-speech claim because Plaintiff's participation in the Program, and Medicare more generally, is

voluntary. To constitute the "actual compulsion" needed for a compelled-speech claim, "the governmental measure must punish, or threaten to punish, protected speech by governmental action that is 'regulatory, proscriptive, or compulsory in nature.'" *Ridgewood Bd. of Educ.*, 430 F.3d at 189 (citations omitted); *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.

As Novartis rightly recognizes, 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. *See* Appellant's Br. at 36. Medicare, however, will no longer pay for them. Alternatively, a manufacturer that does not wish to participate can choose to divest its interest in the selected drug, and Medicare will continue to pay for the manufacturer's other products. *Id.* at 35-37. Despite this recognition, Novartis contends that this lack of compulsion is not "legally relevant" to a Fifth Amendment claim, *id.* at 36, but as far as the First Amendment is concerned, this lack of compulsion is fatal.[13]

[13] Although Novartis contends that it could not withdraw from the Program before the deadline to agree to negotiate, *see* Appellant's Br. 53-54, this ignores the statute's provided 30-day exit period. *See* Appellee's Br. 55-56.

As the Supreme Court made clear in *Grove City College*, no compelled speech claim exists where such options are available. 465 U.S. at 575-76. Plaintiffs in that case contended that the First Amendment rights of Grove City College and its students were infringed by a law that conditioned federal assistance on the school's compliance with Title IX. The Court refused to take up the claim because the college was able to "terminate its participation in the [] Program and thus avoids [its] requirements." 465 U.S. at 575.

This case is no different. Courts of appeals have consistently held that "participation in Medicare is voluntary." *See, e.g.*, *Garelick v. Sullivan*, 987 F.2d 913, 917 (2d Cir. 1993); *St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875 (7th Cir. 1983) (explaining that the fact that "practicalities may in some cases dictate participation [in Medicare] does not make participation involuntary"); *Baker Cnty. Med. Servs., Inc. v. U.S. Atty. Gen*., 763 F.3d 1274, 1279-80 (11th Cir. 2014); *Baptist Hosp. E. v. Sec'y of Health & Hum. Servs*., 802 F.2d 860, 869 (6th Cir. 1986); *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) ("Despite the strong financial inducement to participate in Medicaid, a nursing home's decision to do so is nonetheless voluntary.").

Indeed, every district court to rule on compelled-speech challenges to the Negotiation Program at issue here has found participation in the Program to be voluntary. *See, e.g.*, *Dayton Area Chamber of Com. v. Becerra*, 696 F. Supp. 3d 440, 456 (S.D. Ohio 2023) (noting that "participation in Medicare, no matter how vital it may be to a business model, is a completely voluntary choice"); *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"). As the district court rightly recognized, JA5, Novartis is not compelled to sell to Medicare patients. It has simply made a business decision that participating in the Negotiation Program is more profitable than divesting its interest in ENTRESTO® or refusing to sell products to Medicare at all.

Attempting to counter this uniform weight of authority, Novartis cites to inapposite rulings in the *Horne* cases. *See* Appellant's Br. at 34-36, 37-43 (citing *Horne v. Dep't of Agriculture*, 569 U.S. 513 (2013) (*Horne I*); *Horne v. Dep't of Agriculture*, 576 U.S. 350 (2015) (*Horne II*)). The *Horne* duo is easily distinguished because they involved direct regulation imposed on raisin growers, who could avoid them only by leaving the industry entirely. *Horne II*, 576 U.S. at 365. CMS does

not require Novartis to exit the pharmaceutical industry if they choose not to sell to Medicare. It does not even stop them from selling the specific drug at issue. *See supra* at 4 n.8.

Novartis mistakenly compares the *Horne* plaintiffs—grape growers who wanted to sell raisins on the open market—to a producer of pharmaceuticals seeking access to certain customers. Appellant's Br. at 39-40. The comparison fails. First, Novartis is seeking access to reimbursement processes for particular *customers*, not the ability to sell them a certain product. Second, the *Horne* producers faced an unavoidable choice—abide by agricultural regulations, or sell no raisins to anyone at all. *See Horne II*, 576 U.S. at 354 ("Under the [regulation], a percentage of a grower's crop *must* be set aside for . . . the Government, free of charge) (emphasis added). Novartis, by contrast, has a plethora of options: it may choose to negotiate with the government and use its program to access Medicare recipients; it may choose to divest from the drug; it may choose to decline the government's offer and sell to any other buyer it wishes. *See supra* at 4-8.

Any financial drawback a manufacturer faces from choosing not to participate in the Program is a product of the government's market power, not its regulatory power. 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).

Novartis contends that CMS is acting as a regulator—not a market participant—because the IRA empowers it to manage drug price negotiations. Appellant's Br. at 41-42. This contention simply disregards longstanding precedent confirming that the government may participate as a market actor even while regulating it. *See, e.g.*, *Wyoming v. Oklahoma*, 502 U.S. 437, 459 (1992) (finding the Commerce Clause "does not restrict the State's action as a free market participant," while also legitimately imposing purchasing restrictions on state-owned utility companies); *Brooks v. Vassar*, 462 F.3d 341, 358 (4th Cir. 2006) (recognizing government may act as a as market participant even when its "regulations are trained on the specific market in which it participates"). Instead, Novartis again cites inapposite authority, this time involving a *criminal* penalty of up to six months in prison. Appellant's Br. at 41-42 (citing *Am. Trucking Ass'ns, Inc. v. City of Los Angeles*, 569 U.S. 641, 652 (2013)). That punishment is miles removed from any allegation Novartis has made about CMS's "compulsion."

In short, Novartis fails to identify any authority supporting its oft-rejected theory of government compulsion. The Negotiation Program is another routine example of the government acting as a market participant. Novartis's participation—or lack thereof—is not compelled.

II. PROGRAM PARTICIPANTS ARE NOT COMPELLED TO SPEAK

Novartis's First Amendment claim fails for a second reason: no First Amendment-protected speech is compelled by the act of signing a contract specifying the terms of participation in the Program. The Manufacturer Agreement defines the non-expressive conduct Novartis must undertake to participate in the Negotiation Program. It does not require Novartis to speak, publish, or endorse any message. *See* 42 U.S.C. § 1320f-3; JA261 (Manufacturer Agreement, Section IV(f)).

In grasping for some First Amendment hook, Novartis misstates the Agreement's terms. Citing no distinct provision, Novartis cobbles together quotes from the Agreement for its claim that the Program "commits the manufacturer to publicly 'agreeing' that the price CMS eventually chooses—no matter how low—is the 'maximum fair price' for the drug." Appellant's Br. 9. Novartis contends that this forces it to "denounce its current pricing as unfair," *id*. at 46, but the Agreement itself negates this claim. It provides expressly that "[i]n signing this Agreement, the Manufacturer does not make any statement regarding or endorsement of CMS' views," and makes clear that the term "maximum fair price" is used in the Agreement as a "statutory term[]" and "does not reflect any party's views" regarding its colloquial meaning. JA261. Novartis's First Amendment claim is entirely misdirected.

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

The Manufacturer Agreement is a routine 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 and requires no expressive conduct. The Supreme Court has squarely held that a statement obliging the performance of non-expressive action, as in the Manufacturer Agreement, does not implicate—much less violate—the First Amendment.

In *Rumsfeld v. Forum for Academic & Institutional Rights, 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 to that of other recruiters. 547 U.S. 47, 55 (2006). Like Novartis's 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 52-53. The Supreme Court rejected that argument and upheld the law because it "regulate[d] conduct, not speech. It affect[ed] what law schools must *do*—afford equal access to military recruiters—not what they may or may not *say*." *Id.* at 60.

Likewise, the Manufacturer Agreement requires Novartis to act—to provide relevant information to the Secretary, negotiate over the "maximum fair price" as defined by statute, and sell its drugs to Medicare recipients at no more than the price ultimately set by the Secretary. It defines Novartis's required conduct, not its

required speech. The Court in *FAIR* rejected the 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; *see also Arkansas Times LP v. Waldrip*, 37 F.4th 1386, 1394 (8th Cir. 2022) (rejecting First Amendment challenge to certification prohibiting certain conduct by government contractors because signing certification was "incidental to the regulation of conduct"), *cert. denied*, 143 S. Ct. 774 (2023). Participation in the Program does not require Novartis to produce *any* protected speech, even incidentally.

Just as facilitating the presence of military recruiters on campus did not require law schools to express the recruiters' views in *FAIR*, agreeing to sell at a statutorily defined "maximum fair price" does not require manufacturers to take a stance on the value of the negotiation process or the fairness of the resulting price. Novartis's reliance upon *Agency for International Development v. Alliance for Open Society International, Inc.* ("*USAID*") is thus entirely misdirected. *See* Appellant's Br. 52-53. In *USAID*, federal agencies required grant recipients expressly 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. 205, 210 (2013). The Supreme Court held this funding

condition unconstitutional because it required award recipients to adopt and state as their own the government's view about the harms of prostitution. *Id.* at 218.

The facts here are nothing like those in *USAID*. The Manufacturer Agreement requires no affirmation or public statement of belief. It does not require Novartis to adopt or endorse any message.[14] To the contrary, it expressly disclaims that Plaintiff makes any representation beyond complying with the terms of the Agreement.[15] JA261. The Manufacturer Agreement does not limit what Novartis can say about the Program, or the prices it produces.

---

[14] Even if the Agreement did compel Novartis to speak, *USAID* would not support an unconstitutional conditions argument. There, the Supreme Court 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 Novartis claims to be compelled is not beyond "the contours of the program itself." Rather, it specifies the drug prices that Congress is willing to reimburse.

[15] Novartis elides the Supreme Court's discussion of its unconstitutional conditions cases in *Rust v. Sullivan*, 500 U.S. 173, 197 (1991). *See* Appellant's Br. 53. There, the Court explained that its unconstitutional conditions cases "involve situations in which the government has placed a condition on the *recipient* of the subsidy rather than on a particular program or service, *thus effectively prohibiting the recipient from engaging in the protected conduct outside the scope of the federally funded program*." *Id*. (second emphasis added). Novartis is not prohibited from engaging in any expressive conduct, *see Bristol Myers Squibb Co. v. Becerra,* Civ. No. 23-3335 and *Janssen Pharm. Inc. v. Becerra*, Civ. No. 23-3818, 2024 WL 1855054, *12 (D.N.J. Apr. 29, 2024) and "nothing in the statute prevents [manufacturers] from publicly criticizing the Program or the final drug prices," *id.*

For this same reason, the Manufacturer Agreement does not implicate speech as do laws imposing criminal penalties for failing to display the state motto, "Live Free or Die," on all cars licensed in New Hampshire, *see Wooley v. Maynard*, 430 U.S. 705, 707 (1977) (cited in Appellant's Br. 47), nor is it akin to the unavoidable obligation of a public employee to subsidize a union's political speech, *see Janus v. Am. Fed'n of State, Cnty., & Mun. Emps.*, 585 U.S. 878, 884-85 (2018) (same). The Manufacturer Agreement requires no similar public affirmation of any type. Novartis's reliance on such inapposite cases merely highlights its failure to "demonstrate that the First Amendment even applies." *Clark v. Cmty. for Creative Non-Violence*, 468 U.S. 288, 293 n.5 (1984).

Novartis concedes that the government could "establish[] a price regulation system" without implicating the First Amendment. *See* Appellant's Br. 50. That Congress chose to exercise the government's market power to control the drug prices paid by Medicare does not render the Program unconstitutional. The Program adopts a mechanism to reduce the price paid by Medicare, like the approach long used by DOD, the VA, and the Coast Guard.[16] Congress set a statutory ceiling on the price Medicare can pay for a drug, 42 U.S.C. § 1320f-3(c), then directed the Secretary to

[16] *See* 38 U.S.C. § 8126(a)-(h) (requiring drug manufacturers participating in Medicaid to enter into agreements giving the VA, DOD, Coast Guard, and other federal agencies an option to purchase drugs at negotiated prices below statutory price ceilings).

gather information and negotiate price reductions below that ceiling based on specific factors Congress deemed relevant, 42 U.S.C. § 1320f-3(b)(2)(F). Such "restrictions on economic activity" do not implicate the First Amendment and are distinct from "restrictions on protected expression." *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 567 (2011); *see also Expressions Hair Design v. Schneiderman*, 581 U.S. 37, 46-47 (2017) (explaining that price regulations are not subject to First Amendment scrutiny); *Nicopure Labs, LLC v. Food & Drug Admin.*, 944 F.3d 267, 292 (D.C. Cir. 2019) (explaining that a regulation "bearing only on product price" regulates conduct, not speech).

Seeking to evade this distinction, Novartis contends that the Negotiation Program should face First Amendment scrutiny under *Expressions Hair* because it allegedly has more than an incidental impact on speech. *See* Appellant's Br. 49-50. However, *Expressions Hair* concerned a law that directly controlled what merchants could *say* to customers about their pricing structure, and not *how* their prices could be set. 581 U.S. at 47-48. The IRA does nothing similar. It does not specify what a drug manufacturer can say to consumers, government officials, or anyone at all.

As in *FAIR*, the Manufacturer Agreement dictates only what a drug manufacturer must do to participate in the Negotiation Program. It regulates conduct, not speech. Concluding to the contrary that participation in the Negotiation Program itself conveys a compelled message would threaten improperly to "extend

First Amendment protection to every commercial transaction on the ground that it 'communicates' to the customer 'information' about a product or service." *Nicopure Labs*, 944 F.3d at 291.

Accordingly, the district court correctly determined that signing and abiding by the terms of the Manufacturer Agreement involves conduct, not speech. JA6.

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

Novartis is equally off-base in contending that the terms "agree," "negotiate," and "maximum fair price" used in the Manufacturer Agreement are subject to First Amendment scrutiny because they "promote the government's narrative and mislead the public about the Program's true nature." Appellant's Br. 46. The Agreement is a legal instrument that memorializes the elements of each side's participation in the Program using terminology that confirms compliance with the drug-price requirements imposed by Congress. Endorsing Novartis's attempts to expand First Amendment protection to the choice of terms used to state these obligations would "trivialize[] the freedom protected" by the compelled-speech doctrine. *See FAIR*, 547 U.S. at 62.

It has long been recognized that offers, acceptances, and agreements are "verbal acts," the terms of which are subject to government regulation without First Amendment scrutiny. *See Lowe v. SEC*, 472 U.S. 181, 232 (1985) (White, J., concurring) (explaining that "offer and acceptance are communications incidental to

the regulable transaction called a contract," and are therefore not subject to First Amendment scrutiny). 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.* (citing U.C.C. § 2–316 (Unif. L. Comm'n 2022)). Yet 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 and reliance, respectively.").

Novartis's First Amendment objection to the term "agree" exemplifies the untenable nature of its contract-as-compelled speech argument. Appellant's Br. 48. 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.").

Novartis's attempt to transmute "agree" from a performative utterance necessary for contract formation into an implicit adoption of another's viewpoint is baseless.

The term "negotiation," as commonly understood, describes the process by which the drug prices are set through the Program. *See Negotiate*, *Black's Law Dictionary* (12th ed. 2024) ("To communicate with another party for the purpose of reaching an understanding."). Negotiation does not, as Novartis suggests, denote that each side has equal bargaining power. *See* Appellant's Br. 47-48. Though Novartis may not prefer the outcome of the negotiation, this does not demonstrate that a "negotiation" did not take place. The Agreement's means of articulating the process each side is committing to undertake is "performative" speech and not subject to First Amendment scrutiny.

The term "maximum fair price" is also performative in the contract. Agreeing to participate in the Negotiation Program and to sell at the "maximum fair price" ultimately set by the process is not a forced expression "denounce[ing] its current pricing as *unfair*."[17] *See* Appellant's Br. 46 (emphasis added). Rather, it is a

[17] 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 high likelihood that message would be understood by others. *Texas v. Johnson*, 491 U.S. 397, 404 (1989). Even assuming "agree," "negotiation," or "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*

confirmation that the price was set in the Program pursuant to the procedures in 42 U.S.C. § 1320f-3, the source of the contract term.[18] The Agreement makes this meaning explicit, frequently reiterating that "maximum fair price" is the term defined by Congress in the authorizing statute. JA259, 261.

As the Supreme Court has instructed, 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 the statute's definition). The statutory definition of "maximum fair price" forecloses the meaning injected by Novartis because it is "axiomatic that the statutory definition of the term excludes unstated meanings of that term." *Id.* at 484.

Because *Meese* settles the matter, *see Bristol Myers Squibb Co. v. Becerra*, Civ. No. 23-3335 and *Janssen Pharm, Inc. v. Becerra*, Civ. No. 23-3818, 2024 WL 1855054, *11 (D.N.J. Apr. 29, 2024) , Novartis cannot meaningfully distinguish it. First, Novartis asserts that, unlike the *Meese* plaintiffs, it does not challenge

---

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).

[18] The term "fair" is common throughout government contracting. *See* 2 Karen L. Manos, *Government Contract Costs & Pricing* § 84:19 (2024) ("The Government's stated pricing policy is to award contracts at fair and reasonable prices.").

Congress's use of the term "maximum fair price" in the IRA, *see* Appellant's Br. 51, ignoring its own argument challenging just that, *see id*. at 50 ("Congress could have used more neutral, purely descriptive terms like 'maximum allowable price' or even the 'ceiling price[.]'"). Next, Novartis relies on an off-point, out-of-circuit case regarding compelled disclosures. *See id*. at 51 (citing *Nat'l Ass'n of Mfrs. v. SEC*, 800 F.3d 518, 530 (D.C. Cir. 2015)). That case involved a regulation requiring companies to post publicly on their website that their products were not "conflict-free." *Nat'l Ass'n of Mfrs v. SEC*, 748 F.3d 359, 371 (D.C. Cir. 2014). Indeed, the D.C. Circuit emphasized that the issue was not the statute's use of "conflict-free" but rather the requirement that companies must publicly disclose information. *Nat'l Ass'n of Mfrs.*, 800 F.3d at 528-30. The plaintiff there was indisputably required to speak, *id.* at 523; nothing similar exists here. Novartis is neither compelled to speak nor restricted from doing so to any extent.

Simply put, the contract terms define a specific course of conduct; they do not compel an expression of any view and do not warrant First Amendment scrutiny. *See Ark. Times LP*, 37 F.4th at 1394 (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"). As discussed below, to hold otherwise would render many public transactions subject to judicial First Amendment scrutiny, an outcome that would

clog the courts, hamstring the government's ability to contract with private actors, and kneecap many forms of routine regulation.

III. ACCEPTING PLAINTIFF'S 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 Novartis asks of this Court, would threaten to expose large swaths of government contract law and regulation to First Amendment challenge. *See Perkins*, 310 U.S. at 127-28 ("Judicial restraint of those who administer the Government's purchasing would constitute a break with settled judicial practice and a departure into fields hitherto wisely and happily apportioned by the genius of our polity to the administration of another branch of Government."). Thinly veiled contract disputes blown up to constitutional proportion would inevitably follow.

Entire sectors of private industry are dominated—sometimes completely—by contracting with government, 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) (finding unconstitutional retaliation against government contractors for protected speech), but no court has adopted the rule Plaintiff now asserts: requiring First Amendment review of contract terminology. *See* Frederick Schauer, *Out of Range: On Patently Uncovered Speech*, 128 Harv. L. Rev. 346, 352

(2015) (noting that "there 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 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. *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). Plaintiff's 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 Plaintiff's 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 to 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 Novartis's theory of protected speech is upheld.

Novartis's 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"). Plaintiff's Lochnerian 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 Plaintiff's 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 Novartis's 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 Plaintiff's First Amendment compelled speech claim.

Dated: February 26, 2025

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 SCHOOL[19]
1675 Broadway, 19th Floor
New York, NY 10019

[19] The views expressed herein do not purport to represent the institutional views of Yale Law School, if any. Law students Anthony Cosentino, Nicholas Jones, and Raymond Perez, and Clinical Fellow Tobin Raju were integral to the research, drafting, and editing of this brief.

(212) 663-6162
schulzd@ballardspahr.com

Counsel for Amicus Curiae Abrams Institute for Freedom of Expression

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 5,308 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: February 26, 2025

/s/ Flavio L. Komuves
Flavio L. Komuves

CERTIFICATE OF SERVICE

I hereby certify that on February 26, 2025, 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: February 26, 2025

/s/ Flavio L. Komuves
Flavio L. Komuves