24-2092

In the United States Court of Appeals for the Second Circuit

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,

Plaintiff-Appellant,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, IN HIS OFFICIAL CAPACITY AS SECRETARY OF HEALTH AND HUMAN SERVICES; CENTERS FOR MEDICARE AND MEDICAID SERVICES; AND CHIQUITA BROOKS-LASURE, IN HER OFFICIAL CAPACITY AS ADMINISTRATOR OF CENTERS FOR MEDICARE AND MEDICAID SERVICES,

Defendants-Appellees.

On Appeal from the United States District Court for the District of Connecticut
No. 23-cv-01103, Hon. Michael P. Shea

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

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, *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 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 Boehringer Ingelheim Pharmaceuticals, Inc. ("Plaintiff" or "Boehringer") 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.

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

[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.

established, conduct-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-selling drugs alone cost Medicare $46 billion in 2022, more than double the cost from just four years prior.[5] Runaway costs imposed a heavy financial burden

[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).

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

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

[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).

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. JA252-53. 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 publish an explanation justifying his calculation of the "maximum fair price." *Id.* § 1320f-4. Manufacturers may also publish their own account of the negotiations. JA220.

[8] JA225-28. 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. 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 Program as having limited impact on their businesses.[12]

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[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] Bristol Myers Squibb's CEO told shareholders, "[N]ow that we've seen the final price, we're increasingly confident in our ability to navigate the impact of IRA on Eliquis." Transcript, *Bristol Myers Squibb Q2 2024 Earnings Call* (July 26, 2024, 6:00 AM EST), https://www.fool.com/earnings/call-transcripts/2024/07/26/bristol-myers-squibb-bmy-q2-2024-earnings-call-tra. Doug Langa, the executive in charge of Novo Nordisk's North America operations, similarly assured investors that IRA negotiations involve only "a minor part of our business" and that the company "expect[s] limited impact there." Motley Fool Transcribing, *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/.

ARGUMENT

Boehringer asserts that participation in the Negotiation Program "forc[es] [it] to endorse the Government's preferred messages." Appellant's Br. 34. Plaintiff contends that 1) participation in the Program is not voluntary, *id*. at 47-57, and 2) having to sign a contract with terminology it disapproves compels it to speak in violation of the First Amendment. *Id.* at 34-46. Neither contention is correct. Participation in the Program is neither compelled nor involves expressive conduct, and signing the Manufacturer Agreement does not compel participants to express any view. The terms used in the Manufacturer Agreement simply define the parties' obligations using the same 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, "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 College 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. This Court and other courts of appeals have repeatedly rejected similar challenges to Medicare requirements specifically because "participation in Medicare is voluntary." *See, e.g.*, *Garelick v. Sullivan*, 987 F.2d 913, 917 (2d Cir. 1993). Unable to identify any actual compulsion to participate in the Negotiation Program, Boehringer points to economic pressure to participate that it purportedly faces. Appellant's Br. 47-50. The district court distinguished Boehringer's inapposite authority and correctly rejected its attempt to equate marketplace incentives with government compulsion.

To rise to the level of 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 also, 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).[13] No such compulsion exists here.

[13] Boehringer's other authority holds the same. *See Axson-Flynn v. Johnson*, 356 F.3d 1277, 1290 (10th Cir. 2004) (cited in Appellant's Br. 54-55) (finding actual

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 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. The Supreme Court made clear in *Grove City College* that no compelled speech claim exists where such options are available. 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.

So also here. Indeed, this Court has already rejected a similar challenge to a Medicare requirement premised on Plaintiff's theory of coercion. In *Garelick v. Sullivan*, anesthesiologists challenged statutory caps on the amount they could charge Medicare Part B beneficiaries. 987 F.2d 913 (2d Cir. 1993). This Court rejected the challenge because the anesthesiologists "voluntarily chose to provide

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compulsion where school "made it abundantly clear" student could not remain in program without speaking).

services in the price-regulated Part B program," and "retain the right to provide medical services to non-Medicare patients free of price regulations." *Id.* at 916.

Other courts of appeals have likewise held that participation in Medicare is voluntary. *See, e.g.*, *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) (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) ("Despite the strong financial inducement to participate in Medicaid, a nursing home's decision to do so is nonetheless voluntary.").[14]

[14] Every district court to rule on compelled-speech challenges to the Negotiation Program has rejected the challenge because, in part, participation in the Program is 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").

This Court in *Garelick* found that participation in Medicare Part B was voluntary even though participation resulted in significant economic hardship. Although New York law compelled anesthesiologists practicing in hospitals to provide services to Medicare beneficiaries, this Court explained that anesthesiologists could avoid the requirement by practicing on an outpatient basis. Plaintiff's claim that practicing on an outpatient basis was not economically viable did not suffice because "economic hardship" is not sufficient to establish compulsion. *Garelick*, 987 F.2d. at 917. Other courts of appeal have repeatedly held that economic pressure to participate in Medicare does not make participation involuntary. *See, e.g.*, *Whitney v. Heckler*, 780 F.2d 963, 972 (11th Cir. 1986) ("[T]he fact that Medicare patients comprise a substantial percentage of [plaintiffs'] practices does not render their participation 'involuntary.'"); *Minnesota Ass'n*, 742 F.2d at 446; *St. Francis Hosp. Ctr.*, 714 F.2d at 875.

Boehringer attempts to distinguish *Garelick* because those plaintiffs alleged only that they would face "economic hardship" from not participating in Medicare, while Boehringer claims that their "power of choice [is] illusory." Appellant's Br. at 51 (citation omitted). That is a distinction without a difference. Boehringer has simply made a business decision that participating in the Negotiation Program is more profitable than divesting its interest in Jardiance or refusing to sell products to Medicare at all.

Boehringer equally misses the mark in claiming that *Garelick* conflicts with the Supreme Court's *Horne* decisions. *See id.* at 52 (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 that could be avoided only by exiting the industry entirely. *Horne II*, 576 U.S. at 365. CMS does not require Boehringer, or any other drug manufacturer, to exit the pharmaceutical industry if they don't want to sell to Medicare. *See also* Appellees' Br. 41-43.

Any financial drawbacks a manufacturer faces from choosing not to participate in the Program are 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). Boehringer contends that CMS is not *truly* a market participant, but a regulator because the IRA allows it to implement the drug price negotiation program. Appellant's Br. at 56. This simply ignores precedent confirming that government can act as a market participant even when its "regulations are trained on the specific market in which it participates." *Brooks v. Vassar*, 462 F.3d 341, 358 (4th Cir. 2006); *see also* Appellees' Br. 38.

Boehringer's attempts to counter the uniform rejection of its compulsion claim by relying on inapposite authority. It cites *United States v. Butler*, 297 U.S. 1 (1936) and *Carter v. Carter Coal Co.*, 298 U.S. 238 (1936) for the proposition that economic incentive is tantamount to coercion. Appellant's Br. at 47-48. But these *Lochner*-era cases involved regulations that presented a choice of being subjected to the government's regulation or not selling in the private market at all. *See* Appellees' Br. 39. The Negotiation Program is not similarly restrictive.

Boehringer fares no better in pointing to *National Federation of Independent Businesses v. Sebelius*, 597 U.S. 519 (2012) (*NFIB*). That inapposite case dealt with questions about the federalism-based limits on Congressional authority to place conditions on funds it makes available to states. An issue not present here. *See* Appellees' Br. 35-39. Plaintiff identifies one case that gestures at an interpretation of *NFIB* that would find coercion when Medicare threatens to withdraw funding from a private party. Appellant's Br. at 50 (citing *Am. Health Care Ass'n v. Burwell*, 217 F. Supp. 3d 921, 929 (N.D. Miss. 2016)). But that district court decision involved a preliminary injunction motion and found other factors dispositive for its conclusion. *Am. Health Care Ass'n*, 217 F. Supp. 3d at 946; *see also Ca. Ass'n of Private Postsecondary Schs. v. DeVos*, 436 F. Supp. 3d 333, 348 n.1 (D.D.C. 2020) (noting that *Am. Health Care Ass'n* turned on the failure of CMS to justify sufficiently a proposed rule).

In short, Boehringer fails to identify any authority supporting its oft-rejected theory of government compulsion. The Negotiation Program is another instance of the government functioning as a market actor and participation in the Program is not compelled.

II. PROGRAM PARTICIPANTS ARE NOT COMPELLED TO SPEAK

Boehringer'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.

According to Boehringer, the IRA "dictates the content of [its] speech," Appellant's Br. 42-43, and violates the First Amendment by requiring it to "attest" in the Manufacturer Agreement "that [it] 'negotiate[d]' the prices set through the Program" and "agrees" that the price set is the "maximum fair price," *id.* at 2. Boehringer contends that this forces it to pronounce that the "market rates . . . charged in the past" and charged outside of Medicare "are *unfair*." *Id.* at 2. The IRA does no such thing. The Manufacturer Agreement defines the non-expressive conduct Boehringer must undertake to participate in the Negotiation Program and does not require Boehringer to speak, publish, or endorse any message. *See* 42 U.S.C. § 1320f-3; JA299 (Manufacturer Agreement, Section IV(f)).

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.

1. Participation in the Negotiation Program is conduct.

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 Boehringer'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 Boehringer 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 Boehringer'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 Boehringer 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. Boehringer's reliance upon *Agency for International Development v. Alliance for Open Society International, Inc.* ("*USAID*") is thus entirely misdirected. *See* Appellant's Br. 38. 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 of belief. It does not require Boehringer to adopt or endorse any message.[15] To the contrary, it expressly disclaims that Plaintiff makes any representation beyond complying with the terms of the Agreement. JA299. The Manufacturer Agreement does not limit what Boehringer can say about the Program, or the prices it produces.

For this same reason, the Manufacturer Agreement does not implicate speech as do laws compelling information to be provided to prison officials, *see Burns v. Martuscello*, 890 F.3d 77, 84 (2d Cir. 2018) (cited in Appellant's Br. 35, 38), 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., Council 31*, 585 U.S. 878, 884-85 (2018) (cited in Appellant's Br. 34-35).

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[15] *USAID* would not support an unconstitutional conditions argument even if the Agreement did compel Boehringer 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" Plaintiff's 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.

Boehringer'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).

Boehringer implicitly concedes that the government could require it "to sign a document merely agreeing to comply with a price set by CMS" without implicating the First Amendment. *See* Appellant's Br. 43. The Negotiation Program is the statutory mechanism Congress enacted to do just that. It is a form of price regulation, like the approach long used by DOD, the VA, and the Coast Guard.[16] Congress imposed a statutory ceiling on the price Medicare can pay for a drug, 42 U.S.C. § 1320f-3(c), and directed the Secretary to gather information and negotiate price reductions below that ceiling, 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,

[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).

292 (D.C. Cir. 2019) (explaining that a regulation "bearing only on product price" regulates conduct).

Seeking to evade this distinction, Boehringer contends that, under *Expressions Hair*, the Negotiation Program should face First Amendment scrutiny because it allegedly has more than an incidental impact on speech. *See* Appellant's Br. 42-43. However, *Expressions Hair* concerned a law that directly controlled what merchants could *say* to their 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 its consumers, government officials, or anyone at all. *See infra* Part II.B.2.

The district court correctly determined that signing and abiding by the terms of the Manufacturer Agreement involves conduct, not speech. SPA31-32.

2. The conduct required to participate in the Program is non-expressive.

Straining to find some First Amendment hook, Boehringer alternatively contends that signing the Manufacturer Agreement and participating in the Program involve "expressive conduct." Appellant's Br. 44 (citing *Texas v. Johnson*, 491 U.S. 397, 404-05 (1989)). Even if viewed through that lens, a regulation of expressive conduct triggers First Amendment scrutiny only if an intent to convey a particularized message is present and the likelihood is great that the message would be understood by those who viewed it. *See Johnson*, 491 U.S.

at 404 (citing *Spence v. Washington*, 418 U.S. 405, 410-11 (1974)); *Young v. New York City Transit Auth.*, 903 F.2d 146, 152-53 (2d Cir. 1990); *Church of Am. Knights of the Ku Klux Klan v. Kerik*, 356 F.3d 197, 205 (2d Cir. 2004); *see also Cressman v. Thompson*, 798 F.3d 938, 961 (10th Cir. 2015) (holding that, in context of a compelled-speech claim, "a court will only find symbolic speech where a plaintiff can identify a message that a reasonable onlooker would perceive"). Neither prerequisite exists here.

As a threshold matter, the Manufacturer Agreement itself disavows any intent to convey a specific message about the price set through participation in the Program. It provides that "the term 'maximum fair price' . . . reflects the parties' intention that such terms be given the meaning specified in the statute and does not reflect any party's views regarding the colloquial meaning of those terms." JA299. The Manufacturer Agreement also states that signing it does not signify any endorsement of the views of the government by the drug manufacturers. *Id.*[17]

More fundamentally, Boehringer's expressive conduct theory fails because Boehringer never clarifies what particularized message is conveyed by actions

[17] *Pacific Gas & Elec. Co. v. Pub. Utils. Comm'n*, 475 U.S. 1 (1986) ("*PG&E*"), does not support Boehringer's contention that "disclaimers cannot negate a compelled-speech injury." Appellant's Br. 46. In *Pacific Gas*, the Court explained that the disclaimer there served "to avoid giving readers the mistaken impression that [the third party's] words are really those of [plaintiff]." *See PG&E*, 475 U.S. at 15 n.11.

taken to participate in the Program, such as "making a counteroffer" (which Boehringer is not required to do even if it elects to participate in the Program, *see* 42 U.S.C. § 1320f-3(b)(2)(C)). Boehringer variously defines the message its conduct supposedly conveys as being that "the Program involves genuine negotiation," Appellant's Br. 44; Boehringer "agrees with and bears partial responsibility" for the price, *id.* at 45; CMS has brought manufacturers "to the negotiating table," *id.*; or whatever various politicians have said about the program, *id.* These vague and variable "messages" allegedly conveyed by participation in the Program are nothing like the specific expression compelled by requiring Jehovah's Witnesses to display the motto "Live Free or Die" on their license plates, *Wooley*, 430 U.S. at 715, or requiring students to salute the flag every day, *Barnette*, 319 U.S. at 627-29.

Boehringer's expressive conduct argument fails for lack of a particularized message alone.[18] Without a "particularized" message, there can be no likelihood that the public will interpret Boehringer's participation in the Negotiation Program as conveying a certain message. There are any number of reasons a drug manufacturer might decide to participate in the Negotiation Program that have

[18] Boehringer's reliance on *John Doe No. 1 v. Reed*, is entirely off-point: that case addressed the expression conveyed by signing a referendum petition, which the Court recognized necessarily expressed a political view given the role of the petition in the electoral process. 561 U.S. 186, 194-95 (2010).

nothing to do with its views on the fairness of the resulting price. *Cf. 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 mall's owner). The transparency of the statutory process and the Manufacturer Agreement's express disclaimer about the meaning of "maximum fair price" further dispel any likelihood the public will understand participation in the Program to express any view about the fairness of the price.

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 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.

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

Boehringer 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 "advance the Government's preferred messages regarding the Program." Appellant's Br. 36. 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 Boehringer'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)). 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 and reliance, respectively.").

Boehringer's First Amendment objection to the term "agree" exemplifies the untenable nature of its contract-as-compelled speech argument. Appellant's Br. 36-37. 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."). Boehringer's attempt to transmute "agree" from a performative utterance necessary for contract formation into an implicit adoption of another's viewpoint is baseless.

Similarly, "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 Boehringer suggests, connote that each side has equal bargaining power. *See* Appellant's Br. 37. Though Boehringer 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 that "the market prices [Boehringer] has charged in the past . . . [were] unfair."[19] *See* Appellant's Br. 35. Rather, it is a 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. The Agreement makes this meaning explicit, stating that "maximum fair price" is the term defined by Congress in the authorizing statute. JA299.

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

[19] Even assuming "agree" and "maximum fair price" expressed a view on pricing, signing the Agreement is unlikely to be understood as Plaintiff endorsing that view. Accordingly, Plaintiff's claim fails the second prong of the *Johnson* test, described *supra* at 19. *See Johnson*, 491 U.S. at 404; *cf. FAIR*, 547 U.S. at 62 (finding that law schools do not adopt the views of military recruiters by announcing their presence).

the meaning urged by Boehringer because it is "axiomatic that the statutory definition of the term excludes unstated meanings of that term." *Id.* at 484.

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 Boehringer 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) (holding 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, 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 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 Boehringer's theory of protected speech is upheld.

Boehringer'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 Boehringer'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.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rules of Appellate Procedure 29 and 32, undersigned counsel certifies that the foregoing brief:

1. Complies with the type-volume limitation of Local Rules 29.1(c) and 32.1(a)(4)(A) because, excluding the parts of the document exempted by Fed. R. App. P. 32(f), this document contains 6,494 words.

2. This document complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because this document has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Times New Roman font.

Dated: January 22, 2025

By: /s/ *David A. Schulz*
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