Nos. 24-1820 & 24-1821

IN THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

Bristol Myers Squibb Co,
Plaintiff-Appellant,
v.
Xavier Becerra, *et al.*,
Defendants-Appellees.

Janssen Pharmaceuticals, Inc.,
Plaintiff-Appellant,
v.
Xavier Becerra, *et al.*,
Defendants-Appellees.

On Appeal from the United States District Court for the District of New Jersey, Nos. 23-cv-3335 & 23-cv-3818 (Hon. Zahid N. Quraishi)

BRIEF OF *AMICUS CURIAE* 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 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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42 U.S.C. § 1395w-111(i) 2

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Other Authorities

Agreement, Black's Law Dictionary (12th ed. 2024) 24

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

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 ..... 5, 6

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Negotiate, *Black's Law Dictionary* (12th ed. 2024) 24

Richard G. Frank & Richard J. Zeckhauser, *Excess Prices for Drugs in Medicare: Diagnosis and Prescription* 7 (Harv. Kennedy Sch. Working Paper, Paper No. RWP18-005, 2018), https://ssrn.com/abstract=3116330 2

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INTEREST OF THE AMICUS[1]

The Abrams Institute for Freedom of Expression at Yale Law School promotes freedom of speech, freedom of the press, access to information, and government transparency. The Abrams Institute regularly litigates First Amendment claims and has a keen interest in promoting a clear and consistent understanding of the robust constitutional protections for the freedoms of speech and press, whose proper definition and application serve as critical safeguards of our democratic system.

The Abrams Institute respectfully submits this amicus brief to address the claim by Plaintiffs-Appellants Bristol Myers Squibb Company and Janssen Pharmaceuticals, Inc. (hereafter collectively "Plaintiffs") that the operative terms used in a government contract they must sign if they elect to participate in a voluntary Medicare program should be considered compelled "speech." This is a troubling First Amendment argument that was properly rejected by the district court because a price-setting contract is a regulation of conduct, not speech, and signing the contract at issue conveys no mandated message that drug manufacturers must

[1] *Amicus curiae* files this brief with the consent of all parties 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. *See* Fed. R. App. P. 29(a)(4)(E).

embrace. It rather memorializes the contracting parties' obligations and does so without mandating or limiting the speech of drug manufacturers to any extent.

Plaintiffs seek to stretch the compelled speech doctrine far beyond the types of government obligation it precludes. This Court should reject Plaintiffs' strained First Amendment claim. If taken to its logical conclusion, the broad view of "speech" advanced by Plaintiffs would threaten to subject to heightened First Amendment scrutiny vast swaths of well-established law—from contracts and antitrust to health and safety regulations. It is contrary to First Amendment purpose and precedent and should be rejected.

BACKGROUND

A. The Medicare Drug Price Setting Process

At its inception, Medicare's prescription drug program generously subsidized much-needed prescriptions for seniors, but it left all negotiating power in the hands of private insurers. *See* 42 U.S.C. § 1395w-101 *et seq*.; 42 U.S.C. § 1395w-111(i). The government's subsidies were so comprehensive that insurers had little incentive to press drugmakers for lower prices, and Medicare's prescription drug expenses spiraled out of control.[2] In 2021, Congress resolved to fix this problem by bringing

[2] Richard G. Frank & Richard J. Zeckhauser, *Excess Prices for Drugs in Medicare: Diagnosis and Prescription* 7 (Harv. Kennedy Sch. Working Paper, Paper No. RWP18-005, 2018), https://ssrn.com/abstract=3116330; *see* S. Rep. No. 116-120, at 4 (2019).

Medicare in line with long-successful programs at the Department of Defense ("DOD") and Veterans Affairs ("VA") by allowing it to negotiate directly with prescription drugmakers.[3] This initiative culminated in the Inflation Reduction Act ("IRA"). 42 U.S.C. §§ 1320f–1320f-7.

Through the IRA, Congress identified factors it considered relevant to setting prices for Medicare drug payments, required drug manufacturers wishing to sell to Medicare to provide information needed to weigh these factors, and required the Secretary of Health and Human Services ("Secretary") to participate in a negotiation process with the manufacturers to ensure their information was properly understood and properly weighed before the Secretary set a maximum price Medicare would pay. *Id.* § 1320f-3. There are five key components to the process mandated by Congress (the "Negotiation Program" or "Program"):

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

2. The manufacturer's decision to participate. Manufacturers of selected drugs may agree to engage in a negotiation process and, if they do, must provide the Secretary with the information Congress deemed relevant to setting a price,

[3] *See* 38 U.S.C. § 8126(a)-(h) (limits on drug prices paid by DOD 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.

including research and development costs, unit production costs, federal financial support for the drug's development, patent application status, and revenue and sales data. *Id.* §§ 1320f-2, 1320f-3(e).

3. Pricing and negotiation. The process proceeds as a typical negotiation. The Secretary submits an initial offer based upon the manufacturer-provided data and market evidence on alternative treatments. *Id.* § 1320f-3(e)(1)-(2). The manufacturer can accept this initial offer or make a counteroffer, informed by the same factors specified in the IRA. *Id.* § 1320f-3(b)(2)(C). The Secretary must consider the manufacturer's counteroffer and its rationale. If the Secretary accepts the manufacturer's counteroffer it becomes the agreed price; if the Secretary rejects it, the Secretary will hold up to three in-person negotiating sessions with the manufacturer, where representatives of each party discuss the proper application of the IRA's pricing factors. JA633-34. After these negotiation sessions, the Secretary sets the maximum price that Medicare will pay for the drug, which Congress defined in the IRA as the "maximum fair price." This price must be no higher than a statutory "ceiling price" separately defined in the IRA.[4] 42 U.S.C. §§ 1320f-3(b)(1).

4. Public explanation. The law requires the Secretary to publish the maximum price Medicare will pay along with an explanation of how the statutory factors were

[4] The statutory price ceiling for a drug must be either what Medicare Part D and Medicare Advantage plans pay after rebates, or a percentage of the price that wholesalers pay, whichever is lower. 42 U.S.C. §§ 1320f-3(c).

applied to determine this price. *Id*. § 1320f-4. A manufacturer is also free to develop a written record of price offers and negotiation sessions and may publicly disclose this information "at its discretion." JA635.

5. Enforcement. Sanctions may be imposed if a manufacturer who signed an agreement to participate in the Program charges Medicare participants more than the "maximum fair price" set by the Secretary. 42 U.S.C. §§ 1320f-5, 1320f-6.

During the pendency of this litigation, the Negotiation Program has been operating as intended. On February 1, 2024, the Centers for Medicare & Medicaid Services ("CMS") transmitted its initial offers to drug manufacturers, after which the parties began six months of data analysis and negotiation.[5] The first round of negotiations concluded on August 1, 2024. *Id.* CMS successfully reached agreements for all ten drugs eligible for the program. During the negotiations, CMS increased its offer for every drug. *Id.* For four drugs, CMS accepted the manufacturer's revised counteroffer after negotiation meetings. *Id.* The negotiated prices, if effective in 2023, would reportedly have saved Medicare $6 billion across

[5] *See* 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.

the ten selected drugs. *Id.* For their part, manufacturers have expressed relief at the results of the negotiation program.[6]

B. The Drug Manufacturers' First Amendment Objection

Last June, Plaintiffs Bristol Myers Squibb Company ("BMS") and Janssen Pharmaceuticals, Inc. ("Janssen") separately filed suit to enjoin the Program. JA80, 470. Their lawsuits, in part, objected to a provision of the Negotiation Program that requires participating drug manufacturers to sign an agreement (the "Manufacturer Agreement" or "Agreement"), claiming this compels them to speak in violation of the First Amendment. JA79-80; JA460-61. As relevant to this claim, the Manufacturer Agreement commits a drug manufacturer to do two things: (a) participate in a back-and-forth price negotiation with the Secretary over the proper application of the statutory factors to their drug based upon data they provide to the Secretary, and (b) sell the drug to Medicare participants at no more than the

[6] Bristol Myers Squibb CEO Chris Boerner 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. AstraZeneca CEO Paul Soriot similarly called Medicare's price offer "relatively encouraging," and Executive Vice President Ruud Dobber described the process as an "active negotiation." Drew Armstrong, *AstraZeneca CEO Calls Opening IRA Drug Price Offer 'Relatively Encouraging' in First Characterization of Talks*, Endpoint News (Feb. 8, 2024, 11:04 AM EST), https://endpts.com/astrazeneca-ceo-calls-opening-ira-drug-price-offer-relatively-encouraging-in-first-characterization-of-talks/.

"maximum fair price" set by the Secretary at the end of the negotiation process.[7] Notably, the "maximum fair price" referenced in the Agreement is the statutory term used by Congress in the IRA to denote the price determined by the Secretary after considering the manufacturer-provided data and market evidence of alternative treatments. *See* 42 U.S.C. § 1320f-3(e). The Manufacturer Agreement makes this clear by stating expressly that "maximum fair price" as used in the Agreement "does not reflect any party's views regarding the colloquial meaning of those terms" and participation in the Negotiation Program does not signify any endorsement of the government's pricing views. JA302.

As explained below, the district court correctly concluded that a drug manufacturer's voluntary participation in this price-setting program does not compel it to engage in expression protected by the First Amendment.

ARGUMENT

THE MEDICARE DRUG NEGOTIATION PROGRAM DOES NOT COMPEL SPEECH IN VIOLATION OF THE FIRST AMENDMENT

Plaintiffs' compelled speech claim is premised on two fundamentally flawed assertions: (1) they are forced to sign the Manufacturer Agreement, and (2) signing compels them to affirm through constitutionally protected speech that the price-

[7] The Center for Medicare and Medicaid Services has released a template for the negotiation agreements. JA298; JA676.

setting process is a "negotiation" that produces a price they "agree" to be the "maximum fair price."[8] The district court properly rejected these arguments.

First, the district court properly found that Plaintiffs' participation in both Medicare and the Negotiation Program is voluntary. This conclusion is supported by decisions from other courts of appeals and every district court to have ruled on a drug manufacturer's challenge to the Negotiation Program, *see* JA13-15, and Plaintiffs have no authority to the contrary, *see* JA16-18. Because "a violation of the First Amendment right against compelled speech occurs only in the context of actual compulsion," the voluntary act of participating in the Negotiation Program raises no compelled speech concern. JA19 (quoting *C.N. v. Ridgewood Bd. of Educ.*, 430 F.3d 159, 189 (3d Cir. 2005)).

Second, the district court properly found that the Negotiation Program regulates commercial conduct, not the communication of information. *See* JA20-22. As the district court explained, "the primary purpose of the Program is to determine the price manufacturers may charge for those specific drugs they choose to sell to Medicare," and the "agreements and negotiations are incidental mechanisms the Government uses to set those prices." JA22.

Third, the district court properly found that neither participation in the Negotiation Program nor signing the implementing Agreement constitutes First

[8] *See* BMS Br. 11, 27-37; Janssen Br. 4, 39-46.

Amendment-protected expressive conduct. *See* JA22-24. Executing commercial contracts with the government is not expressive conduct subject to First Amendment prohibitions. JA23.

This Court should affirm.

A. Participating in the Negotiation Program Is Voluntary, Not Compelled

As a threshold matter, "a violation of the First Amendment right against compelled speech occurs only in the context of actual compulsion." *Ridgewood*, 430 F.3d at 189. There can be no compelled speech claim where participation in a government program is voluntary, and for decades other circuits have consistently found participation in Medicare to be voluntary. *See, e.g.*, *Garelick v. Sullivan*, 987 F.2d 913, 917 (2d Cir. 1993) ("All court decisions of which we are aware that have considered takings challenges by physicians to Medicare price regulations have rejected them in the recognition that participation in Medicare is voluntary."); *Baptist Hosp. East v. Sec'y of HHS*, 802 F.2d 860, 869 (6th Cir. 1986) ("[P]articipation in the Medicare program is wholly voluntary.").

The Negotiation Program is no more compulsory than other aspects of Medicare. It offers an "if-then" relationship: if a manufacturer chooses to sell its drugs to Medicare, then the manufacturer must abide by the terms of the Negotiation Program. JA11. Drug manufacturers are not "legally compelled to participate in the Program." *Dayton Area Chamber of Com. v. Becerra*, 696 F. Supp. 3d 440, 457 (S.D.

Ohio 2023); *see also Ridgewood*, 430 F.3d at 189 (finding that compelled speech requires "government action that is 'regulatory, proscriptive, or compulsory in nature'") (citation omitted).

The district court was thus entirely correct in holding that "the Program is voluntary and that Plaintiffs are not being compelled or forced to participate in the Program." JA20. Every court to consider the Negotiation Program has ruled the same way.[9]

The alternatives to participating in the Negotiation Program confirm its voluntary nature. *See* Gov't Br. 38-40. A manufacturer can elect not to sell its drugs to Medicare and Medicaid recipients and operate entirely in private markets, *see* 26

[9] *See Dayton Area Chamber of Com.*, 696 F. Supp. 3d at 456-57 (finding that "participation in Medicare, no matter how vital it may be to a business model, is a completely voluntary choice," and that "pharmaceutical manufacturers who do not wish to participate in the Program have the ability—practical or not—to opt out of Medicare entirely") (citation omitted); *Novo Nordisk Inc. v. Becerra*, No. 23-cv-20814, 2024 WL 3594413 at *6 (D.N.J. July 31, 2024) ("Plaintiffs cannot conflate any financial or practical compulsion that participation in Medicare might exact with legal compulsion that obligates participation in either Medicare or the Program."), *appeal docketed*, No. 24-02510 (3d Cir. Aug. 19, 2024); *AstraZeneca Pharms. LP v. Becerra*, No. 23-cv-931, 2024 WL 895036, at *16 (D. Del. Mar. 1, 2024) (holding that the Program's financial incentive "is not, as AstraZeneca contends, 'a gun to the head.' It is a potential economic opportunity that AstraZeneca is free to accept or reject") (citations omitted), *appeal docketed*, No. 24-1819 (3d Cir. May 2, 2024); *Boehringer Ingelheim Pharms., Inc. v. U.S. Dep't of Health & Human Servs.*, No. 23-cv-01103, 2024 WL 3292657, at *15 (D. Conn. July 3, 2024) (finding that a drugmaker's "participation in Medicare and Medicaid is voluntary, even if [it] has a considerable economic incentive to participate"), *appeal docketed*, No. 24-2092 (2d Cir. Aug. 8, 2024).

U.S.C. § 5000D(c)(1); JA597-98, it can divest its interest in a drug selected for negotiations and continue to sell other drugs to Medicare and Medicaid recipients, JA608-09, and it can sell the selected drug to Medicare recipients at any price they choose and incur an excise tax, *see* 26 U.S.C. § 5000D(a)-(h). These alternatives do not impede Plaintiffs' ability to sell their products on the private market.

Unable to deny the available alternatives, Plaintiffs argue that legal compulsion to participate in the Negotiation Program is not required for their compelled speech claim—forgoing profits from their Medicare and Medicaid sales, they say, should be enough. Janssen Br. 33-35; BMS Br. 39. But the fact that the alternatives may not be as profitable as selling to Medicare at a price of Plaintiffs' choosing does not render the Negotiation Program involuntary. *Cf. 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."); *Livingston Care Ctr., Ind. v. United States*, 934 F.2d 719, 721 (2d Cir. 1991) ("Just as those who choose to serve individuals not covered by Medicare assume the risks of the private market, those who opt to participate in Medicare are not assured of revenues."). Simply put, there is no obligation (or right) to contract with the government.

Nor does Janssen's strained reading of *Ridgewood* support a contrary conclusion. *See* Janssen Br. 49-50. That case confirms that a compelled speech claim

requires "actual compulsion," even when it does not take the form of a direct threat. *Ridgewood*, 430 F.3d at 189. Janssen's other authority holds the same. *See* Janssen Br. 50 (citing *Axson-Flynn v. Johnson*, 356 F.3d 1277, 1290 (10th Cir. 2004) (finding actual compulsion despite absence of an explicit threat where school "made it abundantly clear" student could not remain in program without speaking)). Whatever disadvantages may exist for failing to participate, the Negotiation Program imposes no obligation on drug manufacturers to participate. Plaintiffs' claim of compulsion also elides longstanding precedent holding that "[l]ike private individuals and businesses, the Government enjoys the unrestricted power . . . to determine those with which it will deal, and to fix the terms and conditions upon which it will make needed purchases." *Boehringer*, 2024 WL 3292657, at *19 (quoting *Perkins v. Lukens Steel Co.*, 310 U.S. 113, 127 (1940)).

This Court need not further address Plaintiffs' compelled speech claims because Plaintiffs "are not obligated" to participate in the Drug Negotiation program. *See Grove City College v. Bell*, 465 U.S. 555, 575-76 (1984) (rejecting college's claim that conditioning federal funds on compliance with Title IX violated First Amendment because college could decline federal funds).

B. The Manufacturer Agreement Regulates Conduct, Not Speech

Plaintiffs' First Amendment claim fails for the further reason that the Manufacturer Agreement regulates conduct, not speech. By signing the

Manufacturer Agreement a drug manufacturer agrees to provide information to the Secretary, participate in negotiation sessions over the proper application of statutory pricing considerations to their specific drugs, and sell its drug to Medicare recipients at no more than the price set by the Secretary at the conclusion of this process, which the enabling law and the Agreement call the "maximum fair price." *Supra* 2-5; *see* 42 U.S.C. § 1320f-2(a). The Agreement defines what Plaintiffs must *do*, not what they must say. *See Rumsfeld v. F. for Acad. & Institutional Rts., Inc.* ("*FAIR*"), 547 U.S. 47, 60 (2006).

Plaintiffs attempt to recast these obligations as requirements to speak, not requirements to act, by arguing that the Negotiation Program compels them to "endorse the Government's message that the Program involves "negotiate[d] 'agreement[s]' on a 'maximum fair price.'" Janssen Br. 4; *accord* BMS Br. 11. According to Plaintiffs, the Manufacturer Agreement forces them to endorse a message that "prices would be 'unfair' but for the IRA." BMS Br. 30. The Manufacturer Agreement does no such thing.

The Supreme Court in *FAIR* rejected Plaintiffs' theory of compelled speech through an endorsement implied by required conduct, and its reasoning applies fully here. *See* 547 U.S. at 60. *FAIR* involved a challenge to the so-called Solomon Amendment, a law that required universities to afford military recruiters the same access to campus and students as other recruiters if they wanted to receive federal

funding. *Id.* at 51. Like Plaintiffs here, the *FAIR* plaintiffs challenged the law on the grounds that allowing recruiters on campus compelled them to express something with which they disagreed—support for the then-in-effect homophobic "Don't Ask, Don't Tell" military policy. *Id*. at 52. The Supreme Court rejected the First Amendment challenge, explaining that the Solomon Amendment "regulates conduct, not speech. It affects what the law schools must *do*—afford equal access to military recruiters—not what they may or may not *say*." *Id.* at 60 (emphasis in original).

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 at no more than the price ultimately set by the Secretary. It regulates Plaintiffs' conduct, not their speech. *See id.*

Notably, neither the Negotiation Program nor the Manufacturer Agreement requires Plaintiffs to create any speech of their own, in contrast to *FAIR* where the law schools were required to produce incidental speech of their own to facilitate the military's recruitment efforts (*e.g*., post bulletin board notices or send scheduling emails). *Id*. at 62. Here, Plaintiffs need not affirmatively express anything—even incidentally—to participate in the Negotiation Program. *See Arkansas Times LP v. Waldrip as Tr. of Univ. of Ark. Bd. of Trustees*. F.4th 1386 (8th Cir. 2022) (rejecting First Amendment challenge to certification prohibiting certain conduct by

government contractors that did not require them to "publicly endorse or disseminate a message"), *cert. denied sub nom. Arkansas Times LP v. Waldrip*, 143 S. Ct. 774 (2023).

The district court's conclusion that signing and implementing the Agreement involves conduct, not speech, is entirely consistent with courts' repeated recognition that rate or price setting is conduct that may be regulated. Plaintiffs acknowledge that the First Amendment does not prohibit the government from determining the maximum price that Medicare will pay for covered drugs. *See* BMS Br. 25; Janssen Br. 55. The Negotiation Program is the process by which Congress has enacted to do just that. *See* 42 U.S.C. § 1320f-3(b)(2)(F). The statutory price ceiling imposed by Congress and Congress' requirement that the Secretary gather information and negotiate for a further reduced price underscore that the Negotiation Program is a price regulation akin to what the DOD and VA have long had in place.[10] As the Supreme Court instructed in *Sorrell v. IMS Health Inc.*, such "restrictions on economic activity," for First Amendment purposes, are distinct from "restrictions on protected expression." 564 U.S. 552, 567 (2011). The former do not implicate the First Amendment. *See Expressions Hair Design v. Schneiderman*, 581 U.S. 37, 47

[10] 38 U.S.C. § 8126(a)-(h) (requiring drug manufacturers wishing to participate in Medicaid to enter into agreements giving the VA, DOD, Coast Guard, and any Public Health Service agency an option to purchase drugs at negotiated prices below statutory ceilings).

(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).

Plaintiffs rely on *Expressions Hair* to argue that the Negotiation Program is nonetheless subject to First Amendment scrutiny because its regulation of conduct has more than an incidental impact on speech. Janssen Br. 45-46; BMS Br. 33. But the law at issue in that case directly controlled what merchants could *say* to their customers about their pricing structure, and not *how* their prices could be set. *Expressions Hair*, 581 U.S. at 47-48. The IRA does no such thing. It does not specify what a drug manufacturer can say to its consumers, the general public, 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 is a regulation of conduct, not speech.

C. The Terms Used in the Manufacturer Agreement Are Not Themselves Subject to First Amendment Scrutiny

A regulation of conduct is not subject to First Amendment scrutiny "merely because the conduct was in part initiated, evidenced, or carried out by means of language, either spoken, written, or printed." *Giboney v. Empire Storage & Ice Co.*, 336 U.S. 490, 502 (1949) (citations omitted); *cf. California Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 514 (1972) (holding that speech used as an

"integral part" of prohibited conduct is not protected by the First Amendment). It has long been recognized that offers, acceptances, and agreements are speech acts, the terms of which may be regulated by the government without First Amendment scrutiny. As the Seventh Circuit has explained, "performative utterances" encompass a range of conduct that takes the form of speech. *Twin City Fire Ins. Co. v. Country Mut. Ins. Co.*, 23 F.3d 1175, 1182 (7th Cir. 1994). While some performative utterances describe a state of affairs or declare a fact, others perform an action themselves, the so-called "speech acts." *See* J.L. Austin, *How to Do Things with Words* 4-11 (2d ed. 1975).

Many regulations of performative utterances exist that are exempt from heightened First Amendment scrutiny. *Ohralik v. Ohio State Bar Ass'n* provides numerous examples of speech exempt from First Amendment scrutiny, from "corporate proxy statements" to "the exchange of information about securities." 436 U.S. 447, 456 (1978). In *Sorrell*, Justice Breyer gave still further examples of laws involving speech that did not run afoul of the First Amendment. 564 U.S. at 589 (Breyer, J., dissenting). Some performative utterances even require the use of specific words and phrases. The Uniform Commercial Code (UCC), for example, requires contracting parties to use very specific expressions to alter certain default rules. *See* Ian Ayres, *Regulating Opt-Out: An Economic Theory of Altering Rules*, 121 Yale L.J. 2032, 2037 (2012). To "exclude or modify the implied warranty of

merchantability" in a contract for the sale of goods, the contract must either use the word "merchantability" or expressly state words to the effect that "[t]here are no warranties which extend beyond the description [of the good] on the face hereof." UCC § 2-316(2) (Unif. L. Comm'n 1977). Other legal instruments similarly require the use of specific language or roughly similar statements. *See* 28 U.S.C. § 1746 (1976) (setting forth exact phrasing necessary to effectuate oaths aside from those to appointed offices).

Terms used in the Manufacturer Agreement are no different. They do no more than describe or actuate non-expressive conduct—namely the process for negotiating the price Medicare will pay for a drug. The First Amendment "has no application" because the speech used to form the Manufacturer Agreement "is not protected speech." *See Nevada Comm'n on Ethics v. Carrigan*, 564 U.S. 117, 121 (2011) (rejecting First Amendment challenge to a Nevada law prohibiting legislators who have conflicts of interest with a legislative proposal from voting on or advocating for it).

Accepting Plaintiffs' theory that words used to define contractual obligations constitute First Amendment protected speech would have serious implications. Given that "[i]t is possible to find some kernel of expression in almost every activity a person undertakes," classifying an agreement to negotiate a "maximum fair price" as protected expression would call into question even the most benign, standard

agreements with government agencies. *See City of Dallas v. Stanglin*, 490 U.S. 19, 25 (1989) (explaining "walking down the street or meeting one's friends at a shopping mall" is insufficiently expressive to implicate the First Amendment).

In *Reed v. Town of Gilbert*, Justice Breyer identified many government regulations that should not trigger First Amendment scrutiny, such as requiring manufacturers to include specific information on product labels, *see* 42 U.S.C. § 6294, taxpayers to describe foreign gifts in a manner dictated by the Treasury Secretary, *see* 26 U.S.C. § 6039F, or prescription drugs to bear the label "Rx only," *see* 21 U.S.C. § 353(b)(4)(A). 576 U.S. 155, 177 (2015) (Breyer, J. concurring). Under Plaintiff's conception of the First Amendment, such regulatory requirements would all be subject to constitutional challenge. Requiring First Amendment scrutiny of such performative speech would improperly "substitut[e] judicial for democratic decision-making" and dilute the First Amendment's essential protections. *City of Austin v. Reagan Nat'l Advert. of Austin, LLC*, 596 U.S. 61, 80 (2022) (Breyer, J. concurring) (citation omitted).

D. Signing the Manufacturer Agreement Is Not Expressive Conduct and Does Not Limit Plaintiffs' Protected Expression to Any Extent

Plaintiffs First Amendment claim rests upon yet another faulty premise. They contend that the simple act of signing a Manufacturer Agreement that uses the term "maximum fair price" compels them to affirm that the price set by the Secretary is a "fair" price. Janssen Br. 41-42; BMS Br. 27-28. Plaintiff Janssen argues these are

"value-laden assertions," Janssen Br. 40. Plaintiff BMS contends that it is forced to "parrot messages inimical to its own[.]" BMS Br. 29. Each Plaintiff cites *John Doe No. I v. Reed* to support this dubious proposition, Janssen Br. 41; BMS Br. 28, but *John Doe* addressed the communicative impact of signing a *political petition*, not a technical contract defining the process for setting the price to be paid for a pharmaceutical. 561 U.S. 186, 192.

The district court properly rejected Plaintiffs' argument, finding that "manufacturers' signatures on the agreements [do not] evidence any expressive conduct." JA23. The Agreement does not require a drug manufacturer to adopt or endorse any message, nor does it limit a manufacturer's freedom of expression in any way. And signing the agreement does not convey any particularized message. Just as facilitating the presence of military recruiters on campus did not require law schools to express the recruiters' views in *FAIR*, agreeing to 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.

Plaintiffs unmoor the statutory term "maximum fair price" in the Agreement from its statutory context in arguing that signing the Manufacturer Agreement requires them to affirm that the price set by the Secretary is "fair" in some normative sense. The "maximum fair price" is a statutorily defined term and as used in the Agreement must be accorded its statutory meaning. *See Meese v. Keene*, 481 U.S.

465, 485 (1987) (rejecting First Amendment challenge that law requiring certain films to be labelled "political propaganda" conveyed a defamatory meaning where statute defined the term in neutral, non-defamatory terms). The statutory meaning of "maximum fair price" is not the colloquial meaning, but rather is defined as "the price negotiated pursuant to section 1320f-3 of this title," the section detailing the offer and counter-offer process for setting a maximum Medicare price. 42 U.S.C. §§ 1320f(c)(3), 1320f-3. The IRA requires the "maximum fair price" resulting from this negotiation process to be based upon specific enumerated factors, 42 U.S.C. § 1320f-3(e), and not to exceed a statutory ceiling price, 42 U.S.C. § 1320f-3(c).

As the district court recognized, JA24, Congress has the power to "define the terms that it uses in legislation," and courts have a duty to "construe legislation as it is written, not as it might be read by a layman, or as it might be understood by someone who has not even read it." *Meese*, 481 U.S. at 484-85; *see also W. Union Tel. Co. v. Lenroot*, 323 U.S. 490, 502 (1945) (explaining statutory definitions "prevail over colloquial meanings"). The Supreme Court thus rejected in *Meese* the notion that a statutory term maintains its expressive value when used in the context intended by Congress. *Meese*, 481 U.S. at 485.

Plaintiff BMS seems to recognize that it cannot "challeng[e] Congress' use of the term 'maximum fair price,'" so it claims instead to be challenging a perceived "speech mandate" to use that term. BMS Br. 36. This is simply a shell game, and

one that *Meese* rejects. The Manufacturer Agreement uses the term "maximum fair price" to confirm compliance with the dictates of the statute. The Agreement does not mandate speech, but rather commits a manufacturer to provide its drug at the price required under the IRA.

To avoid any doubt, the Manufacturer Agreement itself expressly disavows that the drug manufacturer is adopting any meaning other than the statutory meaning. It states that "the term 'maximum fair price' reflects the parties' intentions 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." JA302. The Agreement also states that participation in the Negotiation Program does not signify any endorsement of the views of the government by the drug manufacturers. *Id.* Given these express statements and because the contractual term "maximum fair price" must in any event be "construed consistently with the neutral definition contained in the text of the statute itself, the constitutional concerns . . . completely disappear." *Meese*, 481 U.S. at 485.

Nor is there any basis to believe that Plaintiffs' customers are likely to conclude that their participation in the Negotiation Program means Plaintiffs agree the resulting price is "fair." *See FAIR*, 547 U.S. at 65 (finding little risk that the public would believe the schools endorsed military recruiters' messages); *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); *see also Carrigan*, 564 U.S. at 127 ("[T]he fact that a nonsymbolic act is the product of deeply held personal belief—even if the actor would like it to *convey* his deeply held personal belief—does not transform action into First Amendment speech."); *Falcone v. Dickstein*, 92 F.4th 193, 213 (3d Cir. 2024) ("Amid valid government-mandated health and safety measures, refusing to wear a face mask is not expressive conduct protected by the First Amendment."), *cert. denied sub nom. Murray-Nolan v. Rubin*, 144 S. Ct. 2560 (2024).[11] There are any number of reasons a drug manufacturer may decide to participate in or forego the Negotiation Program having nothing to do with its views on the fairness of the resulting price. Moreover, the transparency of the statutory process belies any claim that the public is likely to believe that signing the Manufacturer Agreement expresses a view about the fairness of the price.

Plaintiffs' objections to variations of the terms "agreement" and "negotiate" used in the Manufacturer Agreement are equally misdirected. BMS Br. 37; Janssen Br. 43-44. Plaintiffs argue that the Agreement contains provisions to which they do not "agree" and that the process called a negotiation affords them no power to

[11] Whether conduct possesses sufficient communicative elements to bring it within the First Amendment's purview depends on (1) whether an intent to convey a particular message is present and (2) whether there is a high likelihood that message would be understood by others. *Texas v. Johnson*, 491 U.S. 397, 404 (1989).

"negotiate." All apart from the fact that these terms are used in their ordinary meanings,[12] signing a contract is a "speech act," a form of conduct carried out by words that is not subject to First Amendment scrutiny. *See supra* 16-19. Again, including these terms in the Manufacturer Agreement does not compel speech of a government message but actuates the obligations of the parties to the contract.

Plaintiff's citation to *Agency for International Development v. Alliance for Open Society International, Inc.* ("*USAID"*), 570 U.S. 205 (2013), is misdirected for similar reasons. *See* Janssen Br. 43, 55; BMS Br. 29, 38. Like other unconstitutional conditions cases, *USAID* concerned a government program that compelled organizations to adopt a particular policy position (opposition to prostitution) unrelated to that government program in order to receive federal funding. *USAID*, 570 U.S. at 218. The Negotiation Program, however, imposes no such obligation to affirm "a belief that by its nature cannot be confined within the scope of the Government program." *Id.* at 221. Indeed, as demonstrated, it imposes no obligation to affirm the government's views about anything, and to the contrary expressly disavows even an implied acceptance of the government's views. *See supra* 22.

[12] The contract is an "agreement," meaning "a mutual assent to do a thing." *Agreement, Black's Law Dictionary* (12th ed. 2024). And "negotiation" properly describes the process by which the drug prices are set. To negotiate means "to communicate with another party for the purpose of reaching an understanding." *Negotiate*, *Black's Law Dictionary* (12th ed. 2024). Though Plaintiffs may not prefer the outcome of the negotiation, it does not mean that the parties did not negotiate.

Further still, the Manufacturer Agreement imposes no limit on Plaintiffs' right to express their own views about anything—the price imposed by the Secretary, the process by which the price was determined, or any other topic. As in *PruneYard*, Plaintiffs "are free to publicly dissociate themselves" from views they do not accept. 447 U.S. at 88; *see also FAIR*, 547 U.S. at 64-65 (noting that nothing in the law restricted what schools could say about the military's policies); *Meese*, 481 U.S. at 480 (noting that law requiring "political propaganda" label did not "prohibit, edit, or restrain" the dissemination of any material "to protect the public from conversion, confusion, or deceit").

The compelled-speech doctrine prohibits the government from forcing anyone to speak the government's message. *FAIR*, 547 U.S. at 63. It prevents the government from requiring a Jehovah's Witness to display the motto "Live Free or Die" on their license plate, *Wooley v. Maynard*, 430 U.S. 705, 705-06 (1977), or requiring students to salute and pledge allegiance to the flag, *W. Va. State Bd. of Educ. v. Barnette*, 319 U.S. 624, 642 (1943). But signing a contract is not inherently expressive conduct protected by the First Amendment, nor is agreeing to sell a drug at a price the IRA defines as the "maximum fair price" First Amendment-protected expression. The requirements of the Negotiation Program and Manufacture Agreement bear no resemblance to forcing a Jehovah's Witness to display a motto on his license plate

that he considers morally repugnant. Any attempt to equate the two "trivializes the freedom protected" by the First Amendment. *See FAIR*, 547 U.S. at 48.

As the trial court recognized, a "manufacturer's signature does not convey any message beyond its agreement with Defendants to the terms of the contract." JA23. This Court should affirm.

CONCLUSION

Plaintiffs' participation in the Medicare Drug Negotiation Program is voluntary and signing the Manufacturer Agreement required to participate does not compel speech in violation of the First Amendment.

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Respectfully submitted,

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[13] The views expressed herein do not purport to represent the institutional views of Yale Law School, if any. Law students Peter Camardo, Anthony Cosentino, Andrea DenHoed, Raymond Perez, Federico Roitman, and Clinical Fellows Stacy Livingston and Tobin Raju were integral to the research, drafting, and editing of this brief.

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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 6,097 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: September 16, 2024

/s/ Flavio L. Komuves
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CERTIFICATE OF SERVICE

I hereby certify that on September 16, 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: September 16, 2024

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