

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

BRISTOL MYERS SQUIBB COMPANY,

Plaintiff,

v.

XAVIER BECERRA, in his official capacity
as Secretary of the Department of Health and
Human Services, et al.,

Defendants.

Case No. 3:23-cv-3335-ZNQ-JBD

JANSSEN PHARMACEUTICALS, INC.,

Plaintiff,

v.

XAVIER BECERRA, in his official capacity
as Secretary of the Department of Health and
Human Services, et al.,

Defendants.

Case No. 3:23-cv-3818-ZNQ-JBD

**[PROPOSED] BRIEF OF AMICUS CURIAE ABRAMS INSTITUTE FOR
FREEDOM OF EXPRESSION IN SUPPORT OF DEFENDANTS' OPPOSITION TO
PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT AND CROSS-MOTION**

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TABLE OF CONTENTS

TABLE OF CONTENTS i

TABLE OF AUTHORITIES ii

INTEREST OF THE AMICUS 1

BACKGROUND 2

 A. Congress Created the Medicare Drug Negotiation Program to Address Exorbitant
 Drug Prices Being Charged Uniquely to Medicare Recipients 2

 B. The Drug Negotiation Program Determines the Maximum Medicare Price for
 Certain Drugs Based on Factors Congress Deemed Relevant and Fair 3

ARGUMENT 5

THE MEDICARE DRUG NEGOTIATION PROGRAM DOES NOT COMPEL SPEECH
IN VIOLATION OF THE FIRST AMENDMENT 5

 A. Participating in the Drug Negotiation Program Is Voluntary, Not Compelled 6

 B. The Manufacturer Agreement Regulates Conduct, Not Speech 7

 C. Signing the Manufacturer Agreement Is Not Expressive Conduct and Does Not
 Limit Plaintiffs’ Protected Expression to Any Extent 12

CONCLUSION 16

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Arkansas Times LP v. Waldrip as Tr. of Univ. of Ark. Bd. of Trustees</i> , 37 F.4th 1386 (8th Cir. 2022)	11, 16
<i>Arkansas Times LP v. Waldrip</i> , 143 S. Ct. 774, 215 L. Ed. 2d 46 (2023).....	12
<i>C.N. v. Ridgewood Bd. of Educ.</i> , 430 F.3d 159 (3d Cir. 2005).....	6
<i>California Motor Transp. Co. v. Trucking Unlimited</i> , 404 U.S. 508 (1972)	9
<i>City of Austin v. Reagan Nat’l Advert. of Austin, LLC</i> , 596 U.S. 61 (2022)	11
<i>City of Dallas v. Stanglin</i> , 490 U.S. 19 (1989)	10
<i>Dayton Area Chamber of Com. v. Becerra</i> , 2023 WL 6378423 (S.D. Ohio Sept. 29, 2023)	2, 6
<i>Expressions Hair Design v. Schneiderman</i> , 581 U.S. 37 (2017)	8
<i>Gallo Cattle Co. v. California Milk Advisory Bd.</i> , 185 F.3d 969 (9th Cir. 1999).....	6
<i>Garelick v. Sullivan</i> , 987 F.2d 913 (2d Cir. 1993).....	6
<i>Giboney v. Empire Storage & Ice Co.</i> , 336 U.S. 490 (1949)	9
<i>Glickman v. Wileman Bros. & Elliott</i> , 521 U.S. 457 (1997)	9
<i>Grove City College v. Bell</i> , 465 U.S. 555 (1984)	7
<i>Hurley v. Irish-Am. Gay, Lesbian & Bisexual Grp. of Bos.</i> , 515 U.S. 557 (1995)	16

Meese v. Keene,
481 U.S. 465 (1987) 13, 14, 15

Miami Herald Pub. Co. v. Tornillo,
418 U.S. 241 (1974) 16

Nevada Comm’n on Ethics v. Carrigan,
564 U.S. 117 (2011)..... 10

Nicopure Labs, LLC v. Food & Drug Admin.,
944 F.3d 267 (D.C. Cir. 2019) 8, 15

Ohralik v. Ohio State Bar Ass’n,
436 U.S. 447 (1978) 10

Pac. Gas & Elec. Co. v. Pub. Utilities Comm’n of California,
475 U.S. 1 (1986) 15

PruneYard Shopping Ctr. v. Robins,
447 U.S. 74 (1980) 14, 15

Reed v. Town of Gilbert,
576 U.S. 155 (2015) 11

Rumsfeld v. F. for Acad. & Institutional Rts., Inc. (“FAIR”),
547 U.S. 47 (2006) *passim*

Sorrell v. IMS Health Inc.,
564 U.S. 552 (2011)..... 9, 10

Texas v. Johnson,
491 U.S. 397 (1989) 13

Twin City Fire Ins. Co. v. Country Mut. Ins. Co.,
23 F.3d 1175 (7th Cir. 1994)..... 9

United States v. United Foods Inc.,
533 U.S. 405 (2001) 15

W. Union Tel. Co. v. Lenroot,
323 U.S. 490 (1945) 14

West Virginia State Bd. of Ed. v. Barnette,
319 U.S. 624 (1943) 13

Wooley v. Maynard,
430 U.S. 705 (1977) 13

Statutes

15 U.S.C. § 781..... 11

21 U.S.C. § 353(b)(4)(A)..... 11

26 U.S.C. § 6039F..... 11

28 U.S.C. § 1746 10

38 U.S.C. § 8126(a)-(h) 3, 8

42 U.S.C. § 1320f..... 13

42 U.S.C. § 1320f-1 3

42 U.S.C. § 1320f-2 8

42 U.S.C. § 1320f-3 7, 4, 5, 14

42 U.S.C. § 1320f-4 4

42 U.S.C. § 1320f-5 4

42 U.S.C. § 1320f-6 4

42 U.S.C. § 1395w-101..... 2

42 U.S.C. § 1395w-111(i)..... 2

Other Authorities

A Comparison of Brand-Name Drug Prices Among Selected Federal Programs, Cong. Budget Office 14 (Feb. 2021), <https://www.cbo.gov/system/files/2021-02/56978-Drug-Prices.pdf> 3

Ian Ayres, *Regulating Opt-Out: An Economic Theory of Altering Rules*, 121 Yale L.J. 2032, 2037 (2012)..... 10

Jun Li and Di Wu, *The Price Effect of Drug Price Ceilings: Intended and Unintended Consequences*, 68 Management Science 5758, 5775 (2021) 4

Medicare Drug Price Negotiation Template Agreement, Ctrs. for Medicare & Medicaid Servs., <https://www.cms.gov/files/document/inflation-reduction-act-manufacturer-agreement-template.pdf>..... 5

Retail Gasoline Price Ceilings and Regulatory Capture: Evidence from Canada, 13 Am L. & Econ. R. 532, 534-36 (2011) 4

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

S. Rep. No. 116-120 (2019) 2

Uniform Commercial Code § 2-316(2)..... 10

INTEREST OF THE AMICUS¹

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 defending robust constitutional protections for the freedoms of speech and press as critical safeguards of our democratic system.

The Abrams Institute respectfully submits this amicus brief to address the claim by plaintiffs Bristol Myers Squibb Company and Janssen Pharmaceuticals, Inc. that the operative terms used in a government contract they must sign to participate in a voluntary Medicare program should be considered compelled “speech” protected by the First Amendment. This is an extraordinarily troubling claim because a price-setting contract is a regulation of conduct, not speech, and the contract at issue here contains no mandated pledge or affirmation that drug manufacturers must embrace. It memorializes the obligations being assumed by the contracting parties utilizing statutory terms as defined by Congress, and it 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 obligations it precludes. This Court should reject plaintiffs’ extraordinary effort to use the First Amendment as a constraint on the terminology the government may use in stating contractual obligations. 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, to antitrust, to health and safety regulations.

¹ No counsel for a party 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.

BACKGROUND

A. Congress Created the Medicare Drug Negotiation Program to Address Exorbitant Drug Prices Being Charged Uniquely to Medicare Recipients

In 2003, Congress created Medicare Part D, which subsidizes the cost paid by private insurance plans for prescription drugs administered outside of hospital or outpatient settings. 42 U.S.C. § 1395w-101 *et seq.* As enacted, the federal government was prohibited from participating in negotiations between drug manufacturers and private insurance plans over the price of prescription drugs under Part D. 42 U.S.C. § 1395w-111(i). Because the subsidies private prescription drug plans received from Medicare largely insulated the plans from the prices drug manufacturers chose to charge Medicare recipients, there was little incentive for the plans to fight for lower drug prices.²

The predictable result was excessively high drug prices charged to Medicare. *See* S. Rep. No. 116-120, at 4 (2019). By 2021, Medicare Part D was paying the highest net prices by far for brand-name prescription drugs when compared to the prices paid by direct federal purchasers such as the Department of Defense (“DOD”) and Veterans Affairs (“VA”), whose prices are determined by statutory price ceilings and are authorized to negotiate further below those

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 also* *Dayton Area Chamber of Com. v. Becerra*, No. 3:23-CV-156, 2023 WL 6378423, at *3 (S.D. Ohio Sept. 29, 2023) (“Although this lack of authority to negotiate drug prices was at first ‘relatively economical, it has led to rapidly rising costs to Medicare in recent years. . . . The result has been a shift of financial burden to the Medicare program, which undermines the program’s premise of leveraging market competition to reduce prices to beneficiaries and taxpayers.’”).

ceilings.³ One Congressional Budget Office study, for example, found in 2021 that the average net price for a sample of high-priced drugs in Medicare Part D was forty-six percent higher than the average net price at DoD’s retail pharmacy network, TRICARE.⁴

Congress enacted the Inflation Reduction Act of 2022 (“IRA”) to remedy this problem. 42 U.S.C. §§ 1320f–1320f-7. The IRA establishes a negotiation process (the “Negotiation Program”), which authorizes the Secretary of Health and Human Services (“Secretary”) to directly determine the prices Medicare Part D pays for certain covered drugs. *Id.* § 1320f-3.

B. The Drug Negotiation Program Determines the Maximum Medicare Price for Certain Drugs Based on Factors Congress Deemed Relevant and Fair

There are five key components to the Negotiation Program enacted by Congress:

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

2. The manufacturer’s agreement to participate. Manufacturers of selected drugs may agree to engage in a negotiation process and, if so, must provide the Secretary with information Congress deemed relevant to setting a price, including research and development costs incurred, unit production costs, federal financial support for the drug, pending or approved patent applications, and revenue and sales data. *Id.* §§ 1320f-2, 1320f-3(e).

3. Price setting. The Secretary submits an initial offer based upon this manufacturer-provided data along with market evidence on alternative treatments. *Id.* § 1320f-3(e)(1)-(2). The manufacturer can accept this initial offer or propose a counteroffer justified by the same factors specified in the IRA. *Id.* § 1320f-3(b)(2)(C). After responding to any counteroffer, the Secretary

³ *A Comparison of Brand-Name Drug Prices Among Selected Federal Programs*, Cong. Budget Office 14 (Feb. 2021), <https://www.cbo.gov/system/files/2021-02/56978-Drug-Prices.pdf>; 38 U.S.C. § 8126(a)-(h) (limits on drug prices paid by DOD and other federal agencies).

⁴ *Id.* at 17.

sets what the law defines as the “maximum fair price” to be paid by Medicare, which must be no higher than a statutory “ceiling price” separately defined in the IRA.⁵ *Id.* § 1320f-3.

4. Public explanation of price set by the Secretary. The law then requires the Secretary to publish the maximum price Medicare will pay for the drug and must publicly explain how the statutory factors were applied to determine this price. *Id.* § 1320f-4.

5. Enforcement. Sanctions may be imposed on a manufacturer who signed an agreement to participate in the program but charges more than the “maximum fair price” set by the Secretary. *Id.* §§ 1320f-5, 1320f-6.

Drug manufacturers wishing to participate in the Negotiation Program must sign a Manufacturer Agreement, which is the only specific provision of the Negotiation Program plaintiffs challenge. BMS Compl. ¶¶ 104, 107; Janssen Compl. ¶¶ 105–06. As relevant to their First Amendment claims, the Manufacturer Agreement commits plaintiffs to do two things: 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 then sell the drug to Medicare at no more than the “maximum fair price” set by the Secretary at the end of the negotiation process.⁶ Notably, the “maximum fair price” is the statutory term used by Congress

⁵ The IRA imposes a price ceiling that “must be the lesser of (1) what Medicare Part D and Medicare Advantage plans pay for the drug (net of all rebates) or (2) a percentage of the price wholesalers pay for the drug.” Janssen Br. at 14. Price ceilings often have the effect of anchoring prices at the ceiling level even when market forces would dictate a lower price. *See* Anindya Sen et al., *Retail Gasoline Price Ceilings and Regulatory Capture: Evidence from Canada*, 13 Am L. & Econ. R. 532, 534-36 (2011) (explaining risk of regulatory capture with price ceilings); Jun Li and Di Wu, *The Price Effect of Drug Price Ceilings: Intended and Unintended Consequences*, 68 Management Science 5758, 5775 (2021) (finding drugs had artificially high prices when price ceilings were in effect). The IRA avoids this by authorizing the Secretary to pursue a price lower than the ceiling, referred to as the “maximum fair price.” 42 U.S.C. §§ 1320f-3(b)(1).

⁶ The Center for Medicare and Medicaid Services has released a template for the negotiation agreements (hereinafter, “Medicare Drug Price Negotiation Template Agreement”). *See*

to denote the price determined pursuant to the procedures mandated in the IRA—*i.e.*, the price determined based on the data provided by manufacturers and evidence of alternative treatments. *See* 42 U.S.C. § 1320f-3(e). To confirm that the term is being used as defined in the statute, the Manufacturer Agreement expressly provides that “maximum fair price” “does not reflect any party’s views regarding the colloquial meaning of those terms” and that participation in the Negotiation Program does not signify any endorsement of government’s pricing views. Medicare Drug Price Negotiation Template Agreement, at 4.

ARGUMENT

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

Plaintiffs’ compelled speech claims are premised on two fundamentally flawed assertions, that they are (1) forced to sign the Manufacturer Agreement and (2) signing compels them to affirm that the price-setting process is a “negotiation” and the resulting price is “fair.”⁷ Neither assertion withstands scrutiny and plaintiffs have no First Amendment claim because their participation in the Negotiation Program is voluntary, and the Manufacturer Agreement neither limits nor compels speech to any extent.

Medicare Drug Price Negotiation Template Agreement, Ctrs. for Medicare & Medicaid Servs., at 2–4, <https://www.cms.gov/files/document/inflation-reduction-act-manufacturer-agreement-template.pdf>.

⁷ Compl. ¶¶ 2-3, 71, 75, *Bristol Myers Squibb Co. v. Becerra*, No. 23-cv-03335 (D.N.J. June 16, 2023), ECF No. 1 (hereinafter, “BMS Compl.”); Pl’s Mem. of Law in Supp. of Mot. for Summ. J. at 23-26, *Bristol Myers Squibb Co. v. Becerra*, No. 23-cv-03335 (D.N.J. June 16, 2023), ECF No. 36-3 (hereinafter, “BMS Br.”); Compl. ¶¶ 14, 106-109, *Janssen Pharms. v. Becerra*, No. 23-cv-03818 (D.N.J. July 18, 2023), ECF No. 1 (hereinafter, “Janssen Compl.”); Pl’s Mem. of Law in Supp. of Mot. for Summ. J. at 29-31, *Janssen Pharms. v. Becerra*, No. 23-cv-03818 (D.N.J. July 18, 2023), ECF No. 30-1 (hereinafter, “Janssen Br.”).

A. Participating in the Drug 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.” *C.N. v. Ridgewood Bd. of Educ.*, 430 F.3d 159, 189 (3d Cir. 2005). There can be no compelled speech claim where participation in a government program is voluntary, and “participation in Medicare is voluntary.” *Garelick v. Sullivan*, 987 F.2d 913, 917 (2d Cir. 1993) (affirming dismissal of unconstitutional takings challenge to Medicare Part B regulations because participation was voluntary and there was no compulsion to provide the service).

In a case brought by various local affiliates of the United States Chamber of Commerce advancing similar challenges to the constitutionality of the Negotiation Program, Judge Newman of the Southern District of Ohio recently explained that because “there is no constitutional right (or requirement) to engage in business with the government, the consequences of that participation cannot be considered a constitutional violation.” *Dayton Area Chamber of Com.*, 2023 WL 6378423, at *11 (denying plaintiffs’ motion for preliminary injunction). As the court observed, “participation in Medicare, no matter how vital it may be to a business model, is a completely voluntary choice,” and as a result the ““maximum fair price”” determined through the Negotiation Program “cannot be considered confiscatory because pharmaceutical manufacturers who do not wish to participate in the Program have the ability—practical or not—to opt out of Medicare entirely.” *Id.*

So also here. Plaintiffs have three avenues to bypass the negotiation process altogether, *see* Defs.’ Opposition Mem. at 6 (ECF Nos. 33-1 (Janssen), 38-1 (BMS)), and the prospect of foregoing the benefits of participation in Medicare does not render the Negotiation Program involuntary. *See Gallo Cattle Co. v. California Milk Advisory Bd.*, 185 F.3d 969, 975 & n.7 (9th Cir. 1999) (holding that regulation imposing requirements on cheesemakers to enjoy benefits of

an advertising program did not compel speech because cheesemaker could choose not to participate and forego the benefits of the program). As in *Rumsfeld v. F. for Acad. & Institutional Rts., Inc.*, (“FAIR”), this Court need not address plaintiffs’ First Amendment concerns because they “are not obligated” to participate in the Drug Negotiation program. 547 U.S. 47, 59 (2006) (citing *Grove City College v. Bell*, 465 U.S. 555, 575-76 (1984)).

B. The Manufacturer Agreement Regulates Conduct, Not Speech

Plaintiffs have no First Amendment claim for the further reason that the Manufacturer Agreement they object to signing regulates conduct, not speech. It requires them to provide information to the Secretary, to negotiate over the proper application of statutory considerations to their specific drugs, and to sell their drugs at the prices set by the Secretary at the conclusion of this process. The Agreement defines what plaintiffs must *do*, not what they must say. See *FAIR*, 547 U.S. at 60.

Plaintiffs acknowledge the government is permitted to determine the maximum price that Medicare Part D will pay for covered drugs. BMS Compl. ¶¶ 71, 82 (stating that Congress could have “unilaterally impose[d] price caps that Medicare would pay for covered medicines”); BMS Br. at 21 (stating that Congress could have “simply set[] a maximum price the Government would pay”); BMS Br. at 25; see also Janssen Br. at 35. The Negotiation Program is the process by which the government does just that. 42 U.S.C. § 1320f-3(c). The statutory price ceiling and provisions requiring negotiation over the potential for further reduced prices underscore that the Negotiation Program is a price regulation akin to what the DOD and VA⁸ have long been authorized to do. See *Expressions Hair Design v. Schneiderman*, 581 U.S. 37, 47 (2017) (finding

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

standard price regulations do not implicate First Amendment); *Nicopure Labs, LLC v. Food & Drug Admin.*, 944 F.3d 267, 292 (D.C. Cir. 2019) (explaining a regulation’s “bearing only on product price” demonstrates its character as regulation of conduct). The Negotiation Program operates as a price setting mechanism that regulates conduct, not speech.

The Manufacturer Agreement similarly dictates what manufacturers participating in the Negotiation Program must do, not their expression. The agreements are required by the IRA, which provides:

[T]he Secretary shall enter into agreements with manufacturers of selected drugs . . . under which . . . the Secretary and the manufacturer . . . negotiate to determine . . . a maximum fair price for such selected drug of the manufacturer in order for the manufacturer to provide access to such price to maximum fair price eligible individuals

* * * *

[A]ccess to the maximum fair price . . . with respect to such selected drug, shall be provided by the manufacturer to maximum fair price eligible individuals

42 U.S.C. § 1320f-2.

Plaintiffs attempt to unmoor the statutory term “maximum fair price” from its statutory context to make their claim that signing the Manufacturer Agreement is an affirmation of agreement that the price set by the Secretary is “fair” in some normative sense. But the Supreme Court has stressed the importance of statutory context in differentiating an economic regulation from a restriction on speech. *See FAIR*, 547 U.S. at 58 (noting that the fact legislation was subject to First Amendment constraints “does not mean that we ignore the purpose of this legislation when determining its constitutionality”); *Glickman v. Wileman Bros. & Elliott*, 521 U.S. 457, 469 (1997) (finding generic advertising assessments did not compel speech given their ancillary nature to a more comprehensive economic regulation).

The Manufacturer Agreement does not require manufactures to express any view on the fairness of the resulting price; it simply lays out their obligations to the government if they participate in the Negotiation Program. As the Supreme Court instructed in *Sorrell v. IMS Health Inc.*, “restrictions on economic activity” are distinct from “restrictions on protected expression.” 564 U.S. 552, 567 (2011). 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); *see also 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 subject to First Amendment protection).

Indeed, it has long been recognized that offers, acceptances, and agreements are speech acts, the terms of which are subject to regulation without First Amendment scrutiny. *See Twin City Fire Ins. Co. v. Country Mut. Ins. Co.*, 23 F.3d 1175, 1182 (7th Cir. 1994) (describing nonexpressive conduct that takes the form of speech as “performative utterance”); *see also* J.L. Austin, *How to Do Things with Words*, at 4-11 (2d ed. 1975). While some utterances describe a state of affairs or declare a fact, other utterances, so-called “speech acts,” perform an action themselves. Austin, at 1. The regulation of such speech acts may even require the use of specific words and phrases.⁹ Many regulations of performative speech exist that have never been

⁹ 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).

subjected to heightened First Amendment scrutiny.¹⁰ The obligation in the Manufacturer Agreement here to sell at the “maximum fair price” as defined in the IRA is no different. It does no more than actuate nonexpressive commercial conduct, and the First Amendment “has no application when what is restricted is not protected speech.” *Nevada Comm’n on Ethics v. Carrigan*, 564 U.S. 117, 121 (2011).

Accepting plaintiffs’ claim that the words used to define their 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 the 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 a variety of government regulations that should not trigger First Amendment scrutiny, such as a securities regulation requiring specific content in a registration statement, *see* 15 U.S.C. § 78l, a requirement that taxpayers describe foreign gifts received in excess of \$10,000, *see* 26 U.S.C. § 6039F, and a requirement that mandates prescription drugs bear the label “Rx only,” *see* 21 U.S.C. § 353(b)(4)(A). 576 U.S. 155, 177 (2015) (Breyer, J. concurring). Under plaintiffs’ conception of the First Amendment, such regulatory requirements could all be subjected to constitutional challenge. Requiring First Amendment scrutiny of such performative speech would threaten our federalist system by

¹⁰ *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).

allowing courts to “substitut[e] judicial for democratic decision-making” and would 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).

The Supreme Court’s analysis in *FAIR* applies directly here. 547 U.S. at 60. The *FAIR* plaintiffs challenged a law prohibiting schools receiving federal funding from denying military recruiters the same access to their campuses and students provided other recruiters. *Id.* at 51-52. They asserted that this law infringed their First Amendment right against compelled speech by forcing schools to permit military recruiters on campus to express a homophobic policy (“Don’t Ask, Don’t Tell”) at odds with their values. *Id.* at 52. The Supreme Court rejected the challenge, holding that the law “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*.”¹¹ *Id.* at 60; *see also Arkansas Times LP v. Waldrip as Tr. of Univ. of Ark. Bd. of Trustees*, 37 F.4th 1386, 1394 (8th Cir. 2022) (“Although [the anti-boycott certification] requires contractors to agree to a contract provision they would otherwise not include, it does not require them to publicly endorse or disseminate a message. Instead, the certification targets the noncommunicative aspect of the contractors’ conduct—unexpressive commercial choices.”), *cert. denied sub nom. Arkansas Times LP v. Waldrip*, 143 S. Ct. 774, 215 L. Ed. 2d 46 (2023).

As in *FAIR*, the Manufacturer Agreement challenged here dictates only what drug manufacturers must do to participate in the Negotiation Program. Plaintiffs are not engaged in compelled speech when they agree to disclose information to the Secretary, respond to the

¹¹ While the law in *FAIR* did require law schools to produce speech to facilitate the military’s recruitment efforts (e.g., post bulletin board notices or send scheduling emails), such speech was plainly incidental to the law’s regulation of conduct. *Id.* at 62. Here, neither the Negotiation Program nor Manufacturer Agreements require plaintiffs to create any of their own speech.

Secretary's application of statutory considerations to their drugs, and sell their drugs at the prices set by the Secretary. There is simply no compelled speech at issue.

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

Plaintiffs urge 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. This, they object, is "a belief with which [they] disagree and would never otherwise express," Janssen Br. at 28-29 (cleaned up), and "an ideological message inimical to their own views." BMS Compl. ¶ 75. But signing the Manufacturer Agreement conveys no such expression. It 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 convey any "overwhelmingly apparent" particularized message. *Id.* Signing the Manufacturer Agreement conveys no such expression. Just as facilitating the presence of military recruiters on campus did not require law schools to take a stance on the content of the recruiters' messages in *FAIR*, agreeing to negotiate towards a statutorily defined "maximum fair price" that falls below a required price ceiling for a drug does not require manufacturers to take a stance on the value of the negotiation process or the fairness of the resulting price.

The compelled-speech doctrine prohibits the government from forcing anyone from speaking a message that is not their own. *FAIR*, 547 U.S. at 63; *see also Wooley v. Maynard*, 430 U.S. 705, 714 (1977) (state cannot compel a Jehovah's Witness to display the motto "Live Free or Die" on their license plate); *West Virginia State Board of Education v. Barnette*, 319 U.S. 624, 642 (1943) (state cannot require students to salute the flag every day). But signing a contract is not inherently expressive conduct. The Manufacturer Agreement requires no express oath or affirmation by the drug manufacturer attesting that the price set by the Secretary is subjectively

“fair.” Simply agreeing to negotiate to determine and sell at a statutorily defined “maximum fair price” is nothing like requiring schoolchildren to salute the flag, nor does it bear any resemblance to forcing a Jehovah’s Witness to display a motto on his license plate. Plaintiffs’ attempt to equate the two “trivializes the freedom protected in *Barnette* and *Wooley*.” *FAIR*, 547 U.S. at 48.

Moreover, even if expression could arguably be conveyed simply by entering into the Agreement, it is not the expression to which plaintiffs object.¹² The term “maximum fair price” used in the Agreement is a statutorily defined term and 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 IRA defines “maximum fair price” not in a colloquial sense, but as “the price negotiated pursuant to section 1320f-3 of this title,” the section that articulates the offer and counter-offer process Congress devised for the Program. 42 U.S.C. §§ 1320f(c)(3), 1320f-3. The Act requires the “maximum fair price” resulting from this negotiation process to be based upon factors enumerated in the statute, 42 U.S.C. § 1320f-3(e), and not exceed a statutory ceiling price, 42 U.S.C. § 1320f-3(c).

It is within Congress’s 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 term “maximum fair price” is no exception. The contract

¹² 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).

provisions requiring plaintiffs to negotiate over, and then sell at, the “maximum fair price” use the statute’s language to confirm compliance with the dictates of the statute.

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.” Medicare Drug Price Negotiation Template Agreement, at 4. 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 about the meaning of “maximum fair price,” and because the contractual term “maximum fair price” is in any event to 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 schools endorsed the 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). There are any number of reasons a drug manufacturer may decide to participate in or forego the Negotiation Program that have 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 drug manufacturers signing the Manufacturer Agreement are expressing any view about the fairness of the price. Concluding otherwise could “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.

Plaintiffs’ First Amendment objections to the Negotiation Program are entirely off-base for the further reason that nothing limits to any extent their right to express their views about 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 the views of the speakers or handbillers.” 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”).

Plaintiffs’ authorities compel no other conclusion. *Pac. Gas & Elec. Co. v. Pub. Utilities Comm’n of California*, 475 U.S. 1, 17-18 (1986), is inapt because it addressed speech compelled by requiring a public utility to include a third-party newsletter in the bills it sent to all of its customers, whereas participating drug manufacturers are not required to deliver a message or viewpoint to anyone. Similarly off-point are *United States v. United Foods Inc.*, 533 U.S. 405, 410-11 (2001), where mushroom producers were required to fund an advertising campaign that promoted a message the plaintiff disavowed; *Hurley v. Irish-American Gay, Lesbian & Bisexual Group of Boston*, 515 U.S. 557, 581 (1995), involving a forced public message to everyone attending a parade; and *Miami Herald Publication Company v. Tornillo*, 418 U.S. 241, 258 (1974), concerning a law compelling communication to all readers of a daily newspaper. In contrast to each of these precedents, participating in the Negotiation Program does not require a drug manufacturer to disseminate any message at all. *Accord Arkansas Times*, 37 F.4th at 1394

(rejecting First Amendment claim where challenged contract provision did not require plaintiffs “to publicly endorse or disseminate a message”).

CONCLUSION

Plaintiffs’ motions for summary judgment should be denied, and Defendants’ cross-motion for summary judgment should be granted.

Dated: October 30, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing Brief of Amicus Curiae Abrams Institute for Freedom of Expression in Support of Defendants' Opposition to Plaintiffs' Motion to Summary Judgment and Cross-Motion has been served upon all counsel of record via ECF.

Dated: October 30, 2023

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