UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services, et al. Defendants.	Case No. 3:23-CV-14221-ZNQ-DEA

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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March 6, 2024

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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 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 Plaintiff Novartis Pharmaceuticals Corporation that the operative terms used in a government contract it must sign to participate in a voluntary Medicare program should be considered compelled "speech" subject to heightened First Amendment scrutiny. This is an extraordinarily troubling claim because a price-setting contract is a regulation of conduct, not speech, and the contract at issue here requires no mandated pledge or affirmation of drug manufacturers. It memorializes the obligations assumed by the contracting parties utilizing statutory terms as defined by Congress, and it does so without mandating or limiting to any extent the speech of drug manufacturers.

Plaintiff seeks to stretch the compelled speech doctrine far beyond the types of government-imposed obligations it precludes. This Court should reject plaintiff's 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 plaintiff 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 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

[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; Fiona Scott Morton and Lysle T. Boller, *Enabling Competition in Pharmaceutical Markets* 1 (Brookings Hutchins Ctr. Paper No. 30, 2017), https://www.brookings.edu/articles/enabling-competition-in-pharmaceutical-markets/; *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.'").

determined by statutory price ceilings and who are authorized to negotiate below those 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 address this problem. 42 U.S.C. §§ 1320f–1320f-7. The IRA establishes a formal process (the "Negotiation Program"), under which the Secretary of Health and Human Services ("Secretary") is now allowed to engage in negotiations with drug manufacturers over an appropriate price for certain drugs, taking into account factors Congress deemed relevant to setting a price Medicare will pay. *Id.* § 1320f-3. Following a back-and-forth negotiation, the Secretary is authorized to establish a maximum price that Medicare Part D will pay consistent with the criteria set by Congress. *Id.*

B. The 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 designed by Congress to ensure consideration of certain factors it deemed relevant to setting a fair price and to allow drug manufacturers meaningful input into the price-setting process:

1. The Secretary's selection of covered drugs. 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 must agree to engage in a negotiation process with the Secretary if they wish to sell the drug to Medicare recipients. *Id.* § 1320f-2.

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[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.

3. The negotiation process to set a maximum price. To participate in the negotiation process, the drug manufacturer must provide the Secretary with information Congress deemed relevant to setting a price. This information includes details about the research and development costs incurred by the manufacturer, unit production costs for the drug, federal financial support received in developing the drug, pending or approved patent applications, and revenue and sales data for the drug. *Id.* §§ 1320f-2, 1320f-3(e). The Secretary then submits an initial offer of a price Medicare will pay for the drug based upon his analysis of manufacturer-provided data along with available market evidence on alternative treatments. *Id.* § 1320f-3(e)(1)–(2). The manufacturer can accept this offer or propose a counteroffer justified by the same factors Congress specified in the IRA. *Id.* § 1320f-3(b)(2)(C). This provides the manufacturer an opportunity to ensure factual accuracy of the information considered by the Secretary and to draw attention to any special circumstances that might bear on the price. After responding to any counteroffer, the Secretary sets the maximum price Medicare will agree to pay. The law defines this as the "maximum fair price," and the Secretary may set it no higher than a statutory "ceiling price" separately defined in the IRA. *Id.* § 1320f-3.

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

5. Enforcement of the maximum price. Manufacturers who do not want to sell to Medicare recipients at the price set by the Secretary can decline to do so, either by withdrawing from the Medicare program altogether or by selling their interest in the particular drug to a third-party who will sell at the established price. Sanctions may be imposed on a manufacturer who

agrees to participate in the program but then charges more than the "maximum fair price" set by the Secretary. *Id.* §§ 1320f-5, 1320f-6.

Manufacturers of drugs selected for the Negotiation Program who wish to sell to Medicare recipients must sign a Manufacturer Agreement. As relevant to the First Amendment claim advanced here, the Manufacturer Agreement commits plaintiff to do two things: 1) participate in the back-and-forth price negotiation with the Secretary over the proper application of statutory factors to the specific circumstances of their drug, and 2) sell the drug to Medicare recipients at no more than the "maximum fair price" set by the Secretary at the end of the negotiation process.[5] It is the need to sign this Agreement for which plaintiffs are seeking declaratory and injunctive relief. Compl. ¶¶ 200-208.

Notably, the term "maximum fair price" used in the Agreement is the statutory term used by Congress to denote the maximum price the Secretary is authorized to set after taking into account the various factors Congress deemed relevant. *See* 42 U.S.C. § 1320f-3(e). To confirm that this 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 participation in the Negotiation Program does not signify any endorsement of government's pricing views. *See* Medicare Drug Price Negotiation Template Agreement, at 4.

The statutory term "maximum fair price" reflects Congress' determination that the price paid by Medicare should consider factors unique to each drug. The IRA separately imposes a

[5] The Center for Medicare and Medicaid Services has released a template for the negotiation agreements (hereinafter, "Medicare Drug Price Negotiation Template Agreement"). *See* 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.

price ceiling for covered drugs tied to specific pricing data for the subject drugs and calculated using the lesser of one of two methods. 42 U.S.C. § 1320f-3(c). One method sets the ceiling at the average of what Medicare Part D and Medicare Advantage plans pay for the drug. The other method sets the ceiling by multiplying the "average non-Federal manufacturer price" by a certain percentage depending on the drug at issue. *Id.* § 1320f-3. Yet, imposing such a calculated price ceiling often has the effect of anchoring prices at the ceiling level even when market forces would dictate a lower price.[6] The IRA avoids this by authorizing the Secretary to determine a price below the ceiling, which Congress labeled the "maximum fair price." 42 U.S.C. §§ 1320f-3(b)(1).

ARGUMENT

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

Plaintiff's compelled speech claims are premised on two fundamentally flawed assertions, 1) that it is forced to sign the Manufacturer Agreement, and 2) signing compels it to falsely affirm that the price-setting process is a meaningful "negotiation" that produces a "fair" price that is the "maximum fair price."[7] Neither assertion withstands scrutiny. Plaintiff's First Amendment claim fails because its participation in the Negotiation Program is voluntary, and the Manufacturer Agreement neither compels nor limits plaintiffs' protected speech to any extent.

[6] *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).

[7] Pl's Mem. of Law in Supp. of Summ. J. Mot. at 2, ECF No. 18 (hereinafter, "Novartis Br.").

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." *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). Participation in the Negotiation Program is no exception.

Contrary to its protestations, plaintiff is not "forced to enter into a sham 'negotiation' process . . . ." Compl. ¶ 1. If plaintiff does not wish to participate in the Negotiation Program, it can either transfer its interest in the drug selected for the program, Entresto, to another entity and continue selling its other drugs to Medicare recipients or withdraw from the Medicare and Medicaid programs. *See* Medicare Drug Price Negotiation Program: Revised Guidance (June 30, 2023), https://perma.cc/K6QB-C3MM (Revised Guidance) at 33-34, 120-21, 129-32; *see also* Pub. L. No. 117-169, § 11003 (enacting 26 U.S.C. § 5000D(c)(1)). If plaintiff does participate, it can also choose to sell Entresto to Medicare recipients at a price above the price set by the Secretary but must then pay an excise tax on those sales. *See* 26 U.S.C. § 5000D.

Plaintiff objects that it must forgo benefits it receives from participation in Medicare if it chooses not to enroll in the Program, Novartis Br. at 18, but imposing requirements on those who chose to participate does not render participation 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). Given the available alternatives, participation in the Program remains voluntary, even if plaintiff deems the alternatives less desirable.

Indeed, the Southern District of Ohio has already held that participation in the Program is voluntary. 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, the court found 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 explained, "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.*

The Supreme Court made clear in *Grove City College v. Bell* that no viable First Amendment compelled speech claim can exist where participation in a government program is voluntary. 465 U.S. 555 (1984). Plaintiffs in that case contended that the First Amendment rights of Grove City College and its students were infringed by a law conditioning federal assistance on the school's compliance with Title IX, but the Court refused to take up the claim because Grove City was able to "terminate its participation in the [] Program and thus avoids [its] requirements." *Id.* at 575. So also here. This Court need not address plaintiff's First Amendment claim because the "actual compulsion" required for a compelled speech claim does not exist.

B. The Manufacturer Agreement Regulates Conduct, Not Speech

Plaintiff's First Amendment claim fails for the further reason that the Manufacturer Agreement regulates conduct, not speech. The Manufacturer Agreement simply requires plaintiff to negotiate with the Secretary and to sell its drugs to Medicare recipients at no more than the "maximum fair price" set by the Secretary at the end of the negotiation process. The Agreement defines what plaintiff must *do*, not what it must say. *See Rumsfeld v. F. for Acad. & Institutional Rts., Inc.*, ("*FAIR*"), 547 U.S. 47, 60 (2006). Specifically, the statute implemented by the Manufacturer Agreement requires the following of a drug manufacturers who elects to participate in the Program:

> [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 . . . .
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> [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.

Plaintiff attempts to recast these obligations as requirements to speak, not requirements to act. It alleges that the IRA "compels speech by forcing Novartis—like other pharmaceutical manufacturers—to convey the message that the rates set by CMS are the product of 'negotiation,' to represent falsely that it has 'agreed' on a price when that price is actually dictated by CMS, and to endorse the view that CMS's selected price is the 'maximum fair price' for its drug." Compl. ¶ 115. According to plaintiff, the term "maximum fair price" implies that "the market-based prices the manufacturer currently charges are unfair," and signing the

agreement compels it to affirm this view in violation of its First Amendment rights. Novartis Br. at 2. The Manufacturer Agreement does no such thing.

The Supreme Court rejected plaintiffs' compelled speech theory in *FAIR*. The Solomon Amendment at issue in that case required universities to afford military recruiters the same access to campus and students as other recruiters if they wanted to receive federal funding. *FAIR*, 547 U.S. at 56-57. Like plaintiff here, the *FAIR* plaintiffs challenged the Amendment on the grounds it compelled them to express something with which they disagreed, support for the then-effective "Don't Ask, Don't Tell" military policy. *Id*. at 52. The Supreme Court rejected the 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). The Manufacturer Agreement in the very same way affects drug manufacturers' conduct, not their speech. It requires them to provide relevant information to the Secretary, to negotiate over a "maximum fair price," and to sell their drugs at the resulting price set by the Secretary.

Notably, neither the Negotiation Program nor the Manufacturer Agreement requires plaintiff to create any speech of its 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. Unlike in *FAIR*, no First Amendment scrutiny whatsoever is required because plaintiff need independently express nothing—not even incidentally—to participate in the Negotiation Program. *See also Arkansas Times LP v. Waldrip as Tr. of Univ. of Ark. Bd. of Trustees*. 37 F.4th 1386 (8th Cir. 2022), *cert. denied sub nom. Arkansas Times LP v. Waldrip*, 143 S. Ct. 774 (2023) (rejecting First Amendment challenge to certification prohibiting certain conduct by government contractors that

did not require them to "publicly endorse or disseminate a message"). The only "speech" at issue is the terminology of the Agreement itself.

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). It has thus 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 non-expressive 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 situation or declare a fact, speech acts perform action themselves. Austin, at 1. Many regulations of such performative speech exist that are exempt from heightened First Amendment scrutiny,[8] some even require the use of specific words and phrases.[9] Terms in the

[8] *Ohralik v. Ohio State Bar Ass'n* provides numerous examples of regulations of commercial activity where speech is a component of the activity—from "corporate proxy statements" to "the exchange of information about securities"—that do not offend the First Amendment. 436 U.S. 447, 456 (1978). In *Sorrell v. IMS Health Inc.*, Justice Breyer gave still further examples of laws involving speech that did not run afoul of the First Amendment. 564 U.S. 552, 589 (2011) (Breyer, J., dissenting).

[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

Manufacturer Agreement defined in the IRA are no different. They do no more than actuate non-expressive conduct—namely negotiating for, and selling drugs at a set price. 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 plaintiff's theory that words used to define its contractual obligations constitute its 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 a variety of government regulations that should not trigger First Amendment scrutiny, such as a regulation requiring specific content to appear on product labels, namely a business's operating costs and information about the range of operating costs for other products that the regulation covers, *see* 42 U.S.C. § 6294; a requirement that taxpayers describe foreign gifts received in excess of $10,000, mandating that the gifts are described in the manner dictated by the Secretary, *see* 26 U.S.C. § 6039F; and a requirement mandating that prescription drugs, at a minimum, 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 could all be subjected to constitutional challenge. Requiring First Amendment scrutiny of such performative speech

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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).

would "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).

Simply put, the Negotiation Program operates as a price setting mechanism that regulates conduct, not speech. Plaintiff openly acknowledges that the government may regulate the price that Medicare Part D will pay for covered drugs. Compl. ¶ 86 (stating that "the government may have an interest in minimizing what it pays for prescription drugs, which it could in theory have furthered through straightforward price setting"); Novartis Br. at 29 (acknowledging "the government's unfettered power to unilaterally set the price"). 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 the 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 VA have long been authorized to do.[10] *See Expressions Hair Design v. Schneiderman*, 581 U.S. 37, 47 (2017) (finding 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).

C. The Agreement's Terms Simply Confirm Statutory Compliance

Plaintiff unmoors the Manufacturer Agreement's use of the term "maximum fair price" from its statutory context to argue that signing the Agreement requires it to convey that "the market-based prices the manufacturer currently charges are unfair." Novartis Br. at 2. But the IRA defines the term "maximum fair price" and its use in the Agreement must be accorded its

[10] 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).

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 phrase in neutral, non-defamatory terms). Indeed, 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 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 requiring plaintiff to negotiate over the proper application of statutory factors and then sell at the "maximum fair price" determined by the Secretary uses the statute's language to confirm

compliance with the dictates of the statute. Signing the Agreement simply commits plaintiff to adhere to the statutory provisions.

D. Signing the Manufacturer Agreement Does Not Limit or Compel Plaintiff's Protected Expression to Any Extent

Plaintiff urges that the act of signing a Manufacturer Agreement amounts to forcing Novartis "to convey that the current market prices charged by manufacturers, including those agreed to in genuine negotiations with private insurers, are *unfair*." Novartis Br. at 30 (emphasis in original). It does no such thing. Signing the Manufacturer Agreement does not require plaintiff to express any message, nor does it limit its freedom of expression in any way. 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.

The Manufacturer Agreement itself expressly disavows that the drug manufacturer signing the Agreement 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 plaintiff's customers are likely to conclude that its participation in the Negotiation Program means plaintiff agrees the resulting price is "fair." 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). Here, there is no likelihood that the general public will interpret the signing of the Manufacturer Agreement as conveying a certain message. *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 a 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.

The compelled speech doctrine prohibits the government from forcing anyone to speak a message that is not their own. *FAIR*, 547 U.S. at 63. The doctrine prohibits the government from requiring Jehovah's Witnesses to display the motto "Live Free or Die" on their license plates, *Wooley v. Maynard*, 430 U.S. 705, 714 (1977), or requiring students to salute the flag every day, *West Virginia State Board of Education v. Barnette*, 319 U.S. 624, 642 (1943). The

Manufacturer Agreement requires no such express oath or affirmation by the drug manufacturer; it mandates no public statement by plaintiff at all. Agreeing to negotiate over a statutorily defined "maximum fair price" and then sell at that price is nothing like requiring schoolchildren to salute the flag daily or forcing a Jehovah's Witness to display an evocative motto on their license plate. Plaintiff's attempt to equate the two "trivializes the freedom protected in *Barnette* and *Wooley*." *FAIR*, 547 U.S. at 48.[11]

Plaintiff's First Amendment objections to the Negotiation Program are entirely off-base for the further reason that nothing limits to any extent its right to express its views about the price imposed by the Secretary, the process by which the price was determined, or any other topic. As in *PruneYard*, plaintiff "[is] free to publicly dissociate [itself] 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").

CONCLUSION

Plaintiff's motion for summary judgment should be denied, and Defendants' cross-motion for summary judgment should be granted.

Dated: March 6, 2024

Respectfully submitted,

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[11] Neither does this negotiation agreement implicate speech as do laws requiring crisis pregnancy centers to disseminate information about abortion services, *Nat'l Inst. of Fam. & Life Advocs. v. Becerra*, 138 S. Ct. 2361, 2365 (2018).

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