UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

DAYTON AREA CHAMBER OF COMMERCE, *et al.*,

Plaintiffs,

v.

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

Defendants.

Case No. 3:23-cv-00156-MJN-PBS

CONSENT MOTION FOR LEAVE TO FILE BRIEF OF AMICUS CURIAE ABRAMS INSTITUTE FOR FREEDOM OF EXPRESSION IN SUPPORT OF DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND MOTION TO DISMISS OR, IN THE ALTERNATIVE, CROSS-MOTION FOR SUMMARY JUDGMENT

The Abrams Institute for Freedom of Expression at Yale Law School respectfully seeks leave to file the accompanying brief (**Exhibit A**) as *amicus curiae* in support of Defendants' motion to dismiss or, in the alternative cross-motion for summary judgment and in opposition to Plaintiffs' motion for summary judgment.

Movants will rely upon the attached memorandum of law in support, the proposed amicus brief, and the proposed Order. Plaintiffs and Defendants consent to this motion.

Respectfully submitted,

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[1] The views expressed herein do not purport to represent the institutional views of Yale Law School, if any.

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CORPORATE DISCLOSURE STATEMENT OF THE ABRAMS INSTITUTE FOR FREEDOM OF EXPRESSION

Pursuant to Rule 7.1 of the Federal Rules of Civil Procedure, proposed *amicus curiae* Abrams Institute for Freedom of Expression states that it is an unincorporated association organized within Yale Law School, that it does not have a parent corporation, and that no publicly held corporation owns 10% or more of its stock. Pursuant to Local Civil Rule 7.1.1, proposed *amicus curiae* Abrams Institute for Freedom of Expression states it is not aware of any publicly held corporations or their affiliates that have a substantial financial interest in the outcome of the litigation by reason of insurance, a franchise agreement, or an indemnity agreement.

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was served upon the following counsel of record electronically through the Court's ECF system on this 21st day of December, 2023:

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Exhibit A

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

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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 Plaintiffs Dayton Area Chamber of Commerce ("Dayton Area Chamber"), Ohio Chamber of Commerce ("Ohio Chamber"), Michigan Chamber of Commerce ("Michigan Chamber"), and Chamber of Commerce of the United States of America ("U.S. Chamber") that the operative terms used in a government contract one of plaintiffs' drug manufacturer members[2] must sign to participate in a voluntary Medicare program should be considered compelled "speech" subject to 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 the drug manufacturers. It memorializes the specific 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.

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[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.

[2] Plaintiffs' Amended Complaint names two of their members with interests that are allegedly affected by this litigation, Pharmacyclics and AbbVie. However, only Pharmacyclics is a manufacturer of a drug selected for the Medicare negotiation program. AbbVie is the controlling shareholder of Pharmacyclics, but is not the primary manufacturer of any such drug. *See* Am. Compl. ¶¶ 37, 42, ECF No. 57; *see also* Defs.' Mem. of Law in Opp'n to Pls.' Mot. for Summ. J. and in Supp. of Defs.' Mot. to Dismiss or, in the Alternative, Cross Mot. for Summ. J., at 10, ECF No. 71.

Even if plaintiffs had standing to assert the First Amendment rights of drug manufacturers, their complaint seeks to stretch the compelled speech doctrine far beyond the types of government-imposed 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 protected "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.

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.[3]

[3] 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* Order Denying Defs.' Mot. to Dismiss and Pls.' Mot. for Prelim. Inj. (Sept. 29, 2023), ECF No. 55 (hereinafter, the "Sept. 29, 2023 Order") ("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

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 who are authorized to negotiate below those ceilings.[4] 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.[5]

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 a fair price. *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.*

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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.'").

[4] *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).

[5] *Id.* at 17.

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.

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 the 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 intertest 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 claims advanced here, the Manufacturer Agreement commits a drug manufacturer 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.[6] It is the need to sign this Agreement for which plaintiffs are seeking declaratory and injunctive relief. *See* Am. Compl. ¶¶ 1, 2, 49, 252.

[6] 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.

Notably, the term "maximum fair price" used in the Agreement is the statutory term used by Congress to denote the maximum price the Secretary was 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 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.[7] 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).

[7] *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).

ARGUMENT

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

Plaintiffs' compelled speech claims are premised on two fundamentally flawed assertions, 1) that drug manufacturers are forced to sign the Manufacturer Agreement, and 2) signing compels manufacturers to falsely affirm that the price-setting process is a meaningful negotiation that produces a price they "agree" to be the "maximum fair price." Am. Compl. ¶¶ 147, 252. Neither assertion withstands scrutiny. Plaintiffs' First Amendment claim fails because participation in the Negotiation Program is voluntary, and the Manufacturer Agreement neither compels nor limits to any extent the protected speech of drug manufacturers.

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 plaintiffs' protestations, manufacturers are not forced to enter into a "sham 'negotiation' process. . . ." Am. Compl. ¶ 13. If a manufacturer does not wish to participate in the Negotiation Program, it can either transfer its interest in the covered drug to another entity and continue selling 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 a manufacturer does participate, it can also choose to sell the drug to Medicare recipients at a price above the price set by the Secretary but must then pay an excise tax on those sales. *See* 16 U.S.C. §5000D.

Plaintiffs object that drug manufacturers must forgo benefits they receive from participation in Medicare if they choose not to enroll in the Program, Am. Compl. ¶ 16, 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 drug manufacturers deem the alternatives less desirable.

Indeed, this Court has already held that participation in the Program is voluntary. 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." Sept. 29, 2023 Order, at 23(denying plaintiffs' motion for preliminary injunction). As this 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.*

As the Supreme Court made clear in *Grove City College v. Bell*, 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 plaintiffs' First Amendment claim because the "actual compulsion" required for a compelled speech claim does not exist.

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. The Manufacturer Agreement simply requires drug manufacturers to negotiate with the Secretary and to sell their 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 a drug manufacturer must *do*, not what it must say. *See Rumsfeld v. F. for Acad. & Institutional Rts., Inc.*, ("*FAIR*") 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 . . . .
>
> * * * *
>
> [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 recast these obligations as requirements to speak, not requirements to act. They allege that the IRA "authorizes the Secretary of HHS to pick a price as low as he or she chooses and compels manufacturers to 'agree' that whatever price the Secretary dictates is the 'maximum fair price.'" Am. Compl. ¶ 10. According to plaintiffs, the term "maximum fair price" implies that "no price higher than the Secretary's price could also be fair," and signing the agreement compels a drug manufacturer to affirm this view in violation of its First Amendment rights. Am. Compl. ¶ 252. 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. 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 drug manufacturers 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. Unlike in *FAIR*, no First

Amendment scrutiny whatsoever is required because drug manufacturers 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*. 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 Manufacturer Agreement defined in the IRA are no different. They do no more than actuate non-expressive conduct--namely negotiating for and selling drug 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 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).

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[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. at 552, 589 (2011) (Breyer, J., dissenting). *See also Campbell v. Robb*, 162 F. App'x 460, 468 (6th Cir. 2006) (acknowledging "the general principle that government retains its full power to regulate commercial transactions directly, despite elements of speech and association inherent in such transactions").

[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).

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 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 "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. Plaintiffs openly acknowledge that the government may regulate the price that Medicare Part D will pay for covered drugs. Am. Compl. ¶ 252 (stating that "[i]t is one thing for the government to cap prices for a private company's goods or services"). 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.*

[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).

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

Plaintiffs unmoor the Manufacturer Agreement's use of the term "maximum fair price" from its statutory context to argue that signing the Agreement requires drug manufacturers to represent that "no price higher than the Secretary's price could also be fair" Am. Compl. ¶ 252. But the IRA defines the term "maximum fair price" and its use 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 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 drug manufacturers 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 drug manufacturers to adhere to the statutory provisions.

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

Plaintiffs urge that the act of signing a Manufacturer Agreement requires a drug manufacturer to "parrot the government's viewpoint or pay a crippling fine." Am. Compl. ¶ 146. It does no such thing. Signing the Manufacturer Agreement does not require drug manufacturers to express any message and does not limit their 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 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' citation to *Janus v. Am. Fed'n of State, Cnty., & Mun. Emps*, is entirely off-point as that case addressed a law requiring non-union members to pay a percentage of union dues, which the Court held to constitute the "compelled subsidization of private speech." 138 S. Ct. 2448, 2464 (2018).

The Manufacturer Agreement itself expressly disavows that a 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 consumers of a covered drug are likely to conclude that the manufacturer's participation in the Negotiation Program means it 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 Manufacturers 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 a manufacturer 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. Plaintiffs' attempt to equate the two "trivializes the freedom protected in *Barnette* and *Wooley.*" *FAIR*, 547 U.S. at 48.[11]

Plaintiffs' First Amendment objections to the Negotiation Program are entirely off-base for the further reason that nothing limits to any extent the right of a drug manufacturer to express its views about the price imposed by the Secretary, the process by which the price was

[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); laws requiring financial disclosures to potential donors by charitable fundraisers, *Riley v. Nat'l Fed'n of the Blind of N. Carolina, Inc.*, 487 U.S. 781 (1988); or a law requiring public employees to accept a union as their exclusive bargaining representative, *Thompson v. Marietta Educ. Ass'n*, 972 F.3d 809, 813 (6th Cir. 2020).

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").

CONCLUSION

Plaintiffs' motion for summary judgment should be denied, and Defendants' motion to dismiss or, in the alternative, cross-motion for summary judgment should be granted.

Respectfully submitted,

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[1] Law Students Elisa Kong, Aaron Mak, and Rachel Troy were integral to the research, drafting, and editing of this brief. The views expressed herein do not purport to represent the institutional views of Yale Law School, if any.

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

DAYTON AREA CHAMBER OF COMMERCE, *et al.*,

Plaintiffs,

v.

UNITED STATES DEPARTMENT of HEALTH and HUMAN SERVICES *et al.*,

Defendants.

Case No. 3:23-cv-00156-MJN-PBS

District Judge Michael J. Newman

Magistrate Judge Peter B. Silvain, Jr.

Having considered the consent motion of the Abrams Institute for Freedom of Expression to appear and file a brief as *amicus curiae* in support of Defendants' motion to dismiss or, in the alternative cross-motion for summary judgment and in opposition to Plaintiffs' motion for summary judgment; and all parties, by and through their counsel, having received due notice of the motion and having the opportunity to be heard; and for good cause shown,

IT IS on this _____ day of _____, 2023, **ORDERED**.

1. The Abrams Institute for Freedom of Expression's motion for leave to appear and file a brief as *amicus curiae* is hereby granted;
2. The proposed *amicus curiae* brief is hereby deemed filed.

_____
Hon. Michael J. Newman, U.S.D.J.

or

_____
Hon. Peter B. Silvain, Jr., U.S.M.J.