UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BRISTOL MYERS SQUIBB CO., Plaintiff, v. XAVIER BECERRA, U.S. Secretary of Health and Human Services, *et al.*, Defendants.	Civil Action No. 23-cv-03335-ZNQ
JANSSEN PHARMACEUTICALS, INC., Plaintiff, v. XAVIER BECERRA, U.S. Secretary of Health and Human Services, *et al.*, Defendants.	Civil Action No. 23-cv-03818-ZNQ

REPLY BRIEF IN SUPPORT OF DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Plaintiffs caricature the Drug Price Negotiation Program established in the Inflation Reduction Act (IRA), 42 U.S.C. §§ 1320f *et seq.*, as "unilateral[]" "government price-setting." *Janssen Pharms., Inc. v. Becerra*, Case No. 3:23-cv-3818, Pl.'s Combined Resp. & Reply Br., ECF No. 71 at 1 (Janssen Resp.). Even if Congress *had* enacted such a law, it would have trampled no constitutional principle. After all, prescription drugs have "long been the source of public concern and the subject of government regulation." *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1007 (1984). And the Supreme Court has made clear that Congress can impose various "condition[s]" on manufacturers of such "dangerous chemicals," who have no inherent right to sell those drugs at all. *Horne v. Dep't of Agric.*, 576 U.S. 350, 365-66 (2015) (discussing *Monsanto Co.*, 467 U.S. at 1007). But the Court ultimately need not wade into that thicket.

In enacting the Negotiation Program, Congress did nothing more than set terms on which Medicare will do business with willing participants. Congress has long set similar terms for other federal health care programs administered by the Department of Defense and the Department of Veterans Affairs. *See, e.g.*, 38 U.S.C. § 8126(a)-(h). And it has clear authority to do so.

As another district court correctly recognized, Congress's authorization for the Secretary to negotiate how much Medicare pays for drugs "cannot be considered a constitutional violation" because drug manufacturers "are not legally compelled to participate in the [Negotiation] Program—or in Medicare generally." *Dayton Area Chamber of Com. v. Becerra*, No. 3:23-cv-156, --- F. Supp. 3d ---, 2023 WL 6378423, at *11 (S.D. Ohio Sept. 29, 2023) (*Chamber*). "[P]harmaceutical manufacturers who do not wish to"

make their drugs available at negotiated prices can "opt out" by, for example, withdrawing from the Medicare and Medicaid programs or divesting their interests in the drugs subject to negotiation before 2026, when the negotiated prices would first take effect. *Id.* This basic fact, as Defendants explained in their opening brief, disposes of Plaintiffs' constitutional challenges. *See Bristol Myers Squibb Co. v. Becerra*, Case No. 3:23-cv-3335, Defs.' Mot. Sum. J. Br., ECF No. 38-1 at 11-15 (Defs.' MSJ Br.). While Plaintiffs may be dissatisfied with the conditions that Congress attached to future Medicare spending, acceptance of those conditions and "participation in Medicare, no matter how vital it may be to a business model, is a completely voluntary choice." *Chamber*, 2023 WL 6378423, at *11.

Seeking to dispute this result, Plaintiffs argue that the Negotiation Program should not be seen as a proper condition because it impermissibly forces them to choose between either negotiating the price of selected drugs or forgoing all Medicare and Medicaid funding—which Plaintiffs claim they cannot afford to lose. *Bristol Myers Squibb Co. v. Becerra*, Case No. 3:23-cv-3335, Pl.'s Combined Resp. & Reply Br., ECF No. 80 at 12-13 (BMS Resp.); Janssen Resp. at 7-10. But Plaintiffs' argument is premised on cases analyzing government demands for property in the context of *regulatory* regimes. By contrast, entities "that wish to participate in Medicare and Medicaid have always been obligated to satisfy a host of conditions" that are packaged together as part of one offer, without being able to pick and choose individual conditions they wish to accept or reject. *Biden v. Missouri*, 595 U.S. 87, 94 (2022). Contrary to Plaintiffs' suggestion, presenting such offers is well within Congress's prerogative to ensure that federal funds are spent according to its view of the "general Welfare." U.S. Const., art. I,

§ 8, cl. 1. And Plaintiffs' attempts to evade this established framework not only misread the underlying legal authorities but also would—by Plaintiffs' own admission—rewrite decades of established law about Congress's spending powers. Plaintiffs do not come close to justifying this extraordinary result. Drug manufacturers may choose whether they wish to participate in Medicare—but they do not have a constitutional right to unilaterally dictate how much the government spends on their drugs.

Plaintiffs' constitutional arguments fail in other respects, too. As Defendants explained in their opening brief, Plaintiffs' primary legal theory—that the Negotiation Program effects a physical taking of their property—is irreconcilable with the text and structure of the IRA. *See* Defs.' MSJ Br. at 25-30. Notwithstanding Plaintiffs' efforts to read between the lines of the statute in search of hidden meanings, Congress did not require manufacturers to relinquish any drugs they do not wish to sell. Absent such a requirement, Plaintiffs' physical-taking theory—the only taking theory they posit—has no foothold.

Similar errors infect Plaintiffs' First Amendment challenge. Plaintiffs continue to insist that the Negotiation Program will force them to sign agreements with the Centers for Medicare & Medicaid Services (CMS) in which they must adopt the government's message. BMS Resp. at 34; Janssen Resp. at 28-29. But that assertion is belied by the plain language and purpose of the actual agreements, which Plaintiffs have now signed. Even a cursory review of those agreements reveals that they are purely commercial instruments, which pertain solely to the manufacturers' conduct and do not require them to express or adopt any viewpoint at all. Plaintiffs are free to believe—and to say—whatever they want about these arrangements and about the Negotiation

Program generally. But Plaintiffs' unsupported views that the agreements are expressive does not give rise to a First Amendment claim.

In enacting the IRA, Congress followed decades of precedent establishing the kinds of conditions that can be attached to the government's Spending Clause programs. Rather than rewrite this precedent for Plaintiffs' benefit, this Court should follow the *Chamber* decision and recognize that Plaintiffs' constitutional claims fail "as a matter of law." 2023 WL 6378423, at *11.

ARGUMENT

I. THE NEGOTIATION PROGRAM IS NOT A TAKING BECAUSE PARTICIPATION IS VOLUNTARY

As much as the drafters of the IRA may have wanted pharmaceutical manufacturers to negotiate discounts for their high-price drugs, the statute does "not legally compel[]" them to do so. *Chamber*, 2023 WL 6378423, at *11. Both the IRA's text and CMS's implementing guidance give manufacturers multiple options "to opt out" of the Negotiation Program—before, during, or after negotiations. *Id.*; *see also* CMS, Medicare Drug Price Negotiation Program: Revised Guidance at 34 (June 30, 2023), https://perma.cc/K6QB-C3MM (Revised Guidance). That should be the end of Plaintiffs' takings challenge. *See, e.g.*, *Franklin Mem'l Hosp. v. Harvey*, 575 F.3d 121, 129 (1st Cir. 2009) ("Of course, where a property owner voluntarily participates in a regulated program, there can be no unconstitutional taking."). Because "there is no constitutional right (or requirement) to engage in business with the government," Congress took no property when it made the Negotiation Program a condition of manufacturers' "voluntary" participation in Medicare and Medicaid. *Chamber*, 2023 WL 6378423, at *11.

Attempting to resist this result, Plaintiffs press a series of old and new objections to the choices Congress put before them. But their request to rewrite Congress's bargain profoundly misunderstands the underlying authorities. And, as Plaintiffs themselves essentially acknowledge, their legal theory is inconsistent with decades of well-settled precedent about how the government can structure its funding programs. Accepting Plaintiffs' theory would require the Court to undertake an unjustified and radical rewriting of Spending Clause law.

A. The Negotiation Program is a Proper Condition on Voluntary Participation in Federal Healthcare Programs

1. Plaintiffs Incorrectly Analyze the Negotiation Program as If It Were a Regulatory Condition

As a starting point, Plaintiffs seek to undermine the voluntariness of the Negotiation Program by analogizing to cases analyzing government demands for property in the context of *regulatory* regimes. BMS Resp. at 9-12; Janssen Resp. at 7-10. Plaintiffs interpret these cases to suggest that participation in the Negotiation Program could only be voluntary if it came "in exchange" for an appropriate "benefit"—something Plaintiffs insist is absent here because the benefit (Medicare coverage) is something they already enjoy. Janssen Resp. at 9-10; *see also* BMS Resp. at 12-13. But Plaintiffs fail to grasp the difference between regulatory and *spending* programs, and fail to appreciate that conditions Congress attaches to the latter are subject to a fundamentally different form of constitutional review.

The defining feature of all the cases on which Plaintiffs rely is that they analyzed conditions that the government imposed as part of an obligatory legal framework—which parties could not readily avoid or exit. *See generally* BMS Resp. at 9-12; Janssen

Resp. at 7-10. Thus, in *Monsanto*, manufacturers had no choice but to surrender their proprietary data if they wished to sell their pesticides to private customers under an environmental regulatory regime. *Monsanto*, 467 U.S. at 1007. The Court saw the surrender of property not as a taking but rather as a voluntary exchange for a license to sell chemicals, because that license was not something the government was otherwise required to provide. *See id.* (requirement that "submitter give up its property interest in [proprietary] data" is not "an unconstitutional condition on" the license "to market pesticides"). In *Horne*, growers of raisins had to physically surrender a portion of their crop to the government as part of an agricultural regulatory program if they wished to grow and sell raisins on open markets—but the Court concluded that this requirement was a taking rather than an exchange for a governmental benefit because sales of raisins were not otherwise barred. *Horne*, 576 U.S. at 366 (explaining that "[s]elling produce in interstate commerce, although certainly subject to reasonable government regulation, is [] not a special governmental benefit," in part because "[r]aisins are not dangerous pesticides"). In both circumstances, the question of whether the demand for property was part of an exchange for a non-illusory benefit (and therefore not a taking) only arose because the regulated parties could not avoid the government's property demand without "ceasing to" sell their product to *anyone*—which, as the Court observed, "proves too much" because doing so would deprive the owners of all economic use of products in which they had a "property right[]." *Id.* at 365 (citation omitted).

Similar reasoning animated the D.C. Circuit's recent decision in *Valancourt Books, LLC v. Garland*, 82 F.4th 1222, 1232 (D.C. Cir. 2023)—on which BMS heavily relies. *See* BMS Resp. at 12-14; *see also* Janssen Resp. at 10. In that case, the D.C. Circuit

confronted a takings challenge to a provision of the Copyright Act requiring "the owner of the copyright in a work [to] deposit two copies of the work with the Library of Congress" or pay a fine. *Valancourt*, 82 F.4th at 1226. The panel concluded that, under the "particular circumstances" before the court, that requirement was mandatory and inescapable because it arose automatically upon publication of the work. Within that framework, the court considered whether the condition could be justified as part of a "voluntary exchange for a governmental benefit," but concluded that it could not because "the purported 'benefit' [was] illusory." *Id.* at 1232. As the panel explained, "copyright owners receive[d] no additional benefit for the works they forfeit[ed]" because the "[m]andatory deposit is not required to secure the benefits of copyright." *Id.* And, absent at least some benefit, the demand constituted a physical taking of plaintiffs' books. *Id.* at 1235.[1]

This reasoning does not apply, however, when Congress acts pursuant to its *spending* powers to set terms on which the government will buy products. Under those circumstances, the government is neither restricting entities from engaging in interstate commerce nor burdening their ability to sell goods to private buyers. Rather, the conditions are inherently "voluntary"—and thus cannot compel entities to surrender property—because there is no "right (or requirement)" to conduct business with the

[1] The same was true in the much older cases on which Janssen relies, *Thompson v. Deal*, 92 F.2d 478 (D.C. Cir. 1937) and *Union Pac. Railroad Co. v. Pub. Serv. Comm'n*, 248 U.S. 67, 70 (1918). Like *Monsanto* and *Horne*, those cases also involved regimes that parties could not readily exit—meaning the parties were involuntarily subject to the government's property demands. *See Thompson*, 92 F.2d at 480 (statute fixed the quota of cotton production); *Union Pac.*, 248 U.S. at 67 (plaintiff subject to statutory prohibitions against issue of a bond unless the prohibition was waived by a state commission).

government in the first instance. 2023 WL 6378423, at *11; *see, e.g.*, *Shah v. Azar*, 920 F.3d 987, 998 (5th Cir. 2019) ("[P]articipation in the federal Medicare reimbursement program is not a property interest."). Unlike the raisins in *Horne*, federal Medicare funds are property that "belong[s] to the State" and manufacturers have no right in that property "other than such as the state may permit [them] to acquire." *Horne*, 576 U.S. at 366-67 (discussing *Leonard & Leonard v. Earle,* 279 U.S. 392, 396 (1929) (quotes omitted)). "[N]o one has a 'right' to sell to the government that which the government does not wish to buy." *Coyne-Delany Co. v. Cap. Dev. Bd.*, 616 F.2d 341, 342 (7th Cir. 1980); *see also Perkins v. Lukens Steel Co.*, 310 U.S. 113, 127 (1940) (government has authority to "determine those with whom it will deal"); *J.H. Rutter Rex Mfg. Co. v. United States*, 706 F.2d 702, 712 (5th Cir. 1983) (rejecting contractor's claim for "Fifth Amendment property entitlement to participate in the awarding of government contracts").

Given this distinction between demands for property as part of a regulatory regime and conditions that Congress sets for participation in federal spending programs, it is not surprising that courts have not employed Plaintiffs' proposed framework to evaluate takings challenges to Medicare or Medicaid conditions. *See, e.g.*, *Baker Cnty. Med. Servs., Inc. v. U.S. Att'y Gen.*, 763 F.3d 1274, 1279-80 (11th Cir. 2014) (rejecting hospital's "challenge [to] its rate of compensation in a regulated industry for an obligation it voluntarily undertook . . . when it opted into Medicare"); *Franklin Mem'l Hosp.*, 575 F.3d at 129-30; *Garelick v. Sullivan*, 987 F.2d 913, 916-19 (2d Cir. 1993); *Burditt v. U.S. Dep't Health & Hum. Servs.*, 934 F.2d 1362, 1376 (5th Cir. 1991); *Whitney v. Heckler*, 780 F.2d 963, 972 (11th Cir. 1986) ("[A]ppellants are not required to treat Medicare patients, and the temporary freeze is therefore not a taking within the meaning of the

Fifth Amendment."). Rather, courts have rejected such challenges on the threshold ground that "participation in the Medicare program is a voluntary undertaking"—and have not further analyzed the propriety of the condition. *Livingston Care Ctr., Inc. v. United States*, 934 F.2d 719, 720 (6th Cir. 1991); *see Baptist Hosp. E. v. Sec'y of Health & Hum. Servs.*, 802 F.2d 860, 869-70 (6th Cir. 1986) (same); *see also Baker Cnty.*, 763 F.3d at 1279-80 (surveying cases); *Garelick*, 987 F.2d at 917 (same); *see generally Chamber*, 2023 WL 6378423, at *11 (discussing this precedent).

This approach makes sense. "Unlike ordinary legislation, which imposes congressional policy on regulated parties involuntarily, Spending Clause legislation operates based on consent: in return for federal funds, the [recipients] agree to comply with federally imposed conditions." *Cummings v. Premier Rehab Keller, PLLC*, 596 U.S. 212, 219 (2022) (internal quotes and citation omitted). "[I]f a party objects to a condition on the receipt of federal funding, its recourse is to decline the funds." *Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.*, 570 U.S. 205, 214 (2013). Accordingly, there is no need to consider whether a party obtained a separate benefit to determine that the government's conditions are part of a voluntary exchange. *Contra* Janssen Resp. at 9-10; BMS Resp. at 12-13.

The Negotiation Program, of course, *is* voluntary in the way that all Medicare and Medicaid conditions are—and in a way that the conditions in regulatory programs like *Horne* and the other cases Plaintiffs cite were not. Unlike the plaintiffs in *Horne*—who were required to turn over a portion of their raisin crop to the government or forgo all raisin sales to anyone—drug manufacturers' ability to make commercial sales is not conditioned on them complying with the Negotiation Program. To the contrary,

manufacturers who are unwilling to participate in the Negotiation Program can continue selling their drugs to everyone *but* the government, and be free of the Negotiation Program's terms. *See Chamber*, 2023 WL 6378423, at *11; *contra* Janssen Resp. at 21-23 (incorrectly arguing that the government is acting as regulator because it imposes legal requirements on those who participate in the Negotiation Program). Structuring conditions in this way raises no Fifth Amendment takings concerns because Plaintiffs "do not have a property interest in a particular reimbursement rate" from Medicare. *Managed Pharmacy Care v. Sebelius*, 716 F.3d 1235, 1252 (9th Cir. 2013); *Painter v. Shalala*, 97 F.3d 1351, 1358 (10th Cir. 1996) (holding that a physician has no property interest in "having his [Medicare] reimbursement payments calculated in a specific manner"); *contra* Janssen Resp. at 11 (arguing that manufacturers have a "reliance" interest). Congress was thus free to create the Negotiation Program as a condition of future Medicare participation.

2. The Negotiation Program Withstands Scrutiny Even Under Plaintiffs' Erroneous Framing

Setting aside these analytical distinctions, the Negotiation Program would still survive scrutiny under Plaintiffs' proposed framing—even if it were incorrectly analyzed as part of a "regulatory regime." Janssen Resp. at 10-11; BMS Resp. at 13-14.

1. As the D.C. Circuit observed in *Valancourt*, "any forfeiture of property might arguably be voluntary" where there is "a simple, seamless, and transparent way to opt out of" the regulatory regime in which the demand for property is made. 82 F.4th at 1235. The problem in *Valancourt* was that no exit option was "cognizable to copyright owners:" "no statute, regulation, or guidance" indicated that plaintiff could

relinquish its copyright in lieu of depositing books. *Id.* at 1235-36. The agency "did not suggest at any point that Valancourt could avoid the deposit requirement by simply disavowing its copyrights, much less explain how Valancourt could exercise that option," and instead "implied that Valancourt was obligated to deposit regardless of any voluntary action it took." *Id.* at 1236.

The opposite is true here. *See Chamber*, 2023 WL 6378423, at *11. As the *Chamber* court recognized, manufacturers can avoid the Negotiation Program's requirements by, among other things, divesting their interest in the selected drug or withdrawing from Medicare and Medicaid by terminating their participation agreements. *See id.*; *see also* Defs.' MSJ Br. at 16-18 (detailing the exit options). Doing so is straightforward. A manufacturer need only notify CMS of its intent to withdraw from the relevant agreements "30 days in advance of the date that excise tax liability otherwise may begin to accrue." Revised Guidance at 33-34.[2] This course is clearly described in CMS's Revised Guidance, which relies on the statutory authority in the Social Security Act (SSA). *See id.* at 130 (explaining how CMS intends to exercise its authority); *see generally* 42 U.S.C. §§ 1395w-114a(b)(4)(B)(i), 1395w-114c(b)(4)(B)(i) (providing for "good cause" termination). So, unlike the plaintiff in *Valancourt*, manufacturers have a "cognizable" notice of the withdrawal options from a formal "guidance." 82 F.4th at 1235-36. There is no dispute that plaintiffs are well aware of these options. Accordingly, the Negotiation Program is voluntary "because pharmaceutical manufacturers who do not wish to

[2] Alternatively, as Defendants previously noted, a manufacturer can transfer ownership of the drug. *See* Revised Guidance at 131-32.

participate in the Program have the ability—practical or not—to opt out of Medicare entirely." *Chamber*, 2023 WL 6378423, at *11.

Notably, Plaintiffs still do not contend that they actually wish to exercise any of the withdrawal options. Instead, they make a passing objection that those options, as specified in the Revised Guidance, were developed "only in the course of litigation" and are in tension with the provisions of the SSA. BMS Resp. at 14 (quoting *Valancourt*, 82 F.4th at 1237). But the rush of *some* pharmaceutical manufacturers to challenge the IRA even before CMS had finalized its guidance—guidance which those manufacturers knew was forthcoming—can hardly be laid at the feet of the agency. *See id.* And the Revised Guidance, which governs how the agency will conduct the program's first round of negotiations, is worlds different from the situation in *Valancourt*, where "the *only* affirmative indication of a costless abandonment option [was] in the government's statements in th[e] litigation." *Valancourt*, 82 F.4th at 1237 (emphasis added).

Further, contrary to the Plaintiffs' claims, the options for withdrawal CMS outlined are fully in line with the agency's statutory authority. *See* BMS Resp. at 14-15; Janssen Resp. at 12. Simply put, it is hard to see how the 30-day exit window that CMS provided in the Revised Guidance is inconsistent with the statutory "good cause" standard, particularly when Plaintiffs themselves claim that the absence of a speedy exit option would raise serious constitutional questions. *See, e.g.*, *United States ex rel. Polansky v. Exec. Health Res., Inc.*, 599 U.S. 419, 429 n.2 (2023) ("good cause" is "a uniquely flexible and capacious concept, meaning simply a legally sufficient reason" (citation omitted)). Plaintiffs notably fail to provide *any* response on this point, despite Defendants

previously articulating it in their opening papers. *See* BMS Resp. at 14-15; Janssen Resp. at 12; *see generally* Defs.' MSJ Br. at 17.

Likewise, Plaintiffs fail to rebut (or even acknowledge) that—even under the extended withdrawal timeline that Plaintiffs concede exists absent CMS's guidance—manufacturers can *still* notice their withdrawal from Medicare and Medicaid and have that withdrawal take effect before any negotiated prices become operative. *See* Defs.' MSJ Br. at 16-18. This option fully resolves Plaintiffs' stated concerns because it is only the sale of drugs at negotiated prices—not any other aspect of participation in the Negotiation Program—that Plaintiffs characterize as a taking. Janssen's categorical objection to *any* delay in withdrawal is thus inconsistent with its own legal theory. Janssen Resp. at 13. And, as Defendants previously noted, it is also inconsistent with Supreme Court precedent. *Yee v. City of Escondido*, 503 U.S. 519, 527-28 (1992) (finding no taking where a property owner could choose to leave a price-capped market with "6 or 12 months notice").

2. BMS separately argues that withdrawing is not "costless" within the meaning of *Valancourt* because doing so would imperil the profits they make on *other* sales to Medicare. BMS Resp. at 13-14. But nothing in *Valancourt* suggests that the D.C. Circuit would consider lost earnings either from the selected drug or other drugs a "cost" of withdrawing. *See Valancourt*, 82 F.4th at 1236-37. The holder of the copyright in *Valancourt* would clearly be giving up such future earnings by surrendering the copyright (if it could): the entire premise of the copyright system is that there is tremendous value in obtaining a copyright. *See id.* at 1233 (noting that "copyright is not a natural right" but rather "a uniquely governmental benefit"). Yet the D.C. Circuit did not discuss the

potential loss of such benefits as a "cost" to consider. Rather, the impermissible "cost" that the D.C. Circuit identified was the "fee" to "record a notice of abandonment." *Id.* at 1237. There would have been no need for the court to consider this "fee" if the loss of the copyright benefits were itself a relevant "cost" to the challenger. And Plaintiffs do not—and cannot—allege that any similar fee exists here.

Indeed, positing as Plaintiffs do that any withdrawal option must be free of *any* consequence is an untenable reading. Plaintiffs cite no case for the proposition that the absence of any financial burden is necessary to make Medicare conditions voluntary for purposes of the Fifth Amendment. *See* BMS Resp. at 13-15. To the contrary, as the *Chamber* court explained, precedent all points the other way. *Chamber*, 2023 WL 6378423, at *11 ("[P]articipation in Medicare, no matter how vital it may be to a business model, is a completely voluntary choice." (discussing cases)); *see also Baker Cnty.*, 763 F.3d at 1280 (argument that "opting out of Medicare would amount to a grave financial setback" is insufficient for a takings analysis (citing *Garelick*, 987 F.2d at 917); *St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875 (7th Cir. 1983) ("[T]he fact that practicalities may in some cases dictate participation does not make participation involuntary."). And this is true regardless of whether the condition is new to the program in which Plaintiffs previously participated. *See* 42 U.S.C. § 1304 (noting that Congress reserves the right to change Medicare terms); *contra* Janssen Resp. at 10. Where, as here, an exit option is available, Plaintiffs' decision not to pursue it—for whatever reason—is itself an indication that, going forward, Plaintiffs consent to the condition imposed.

Finally, Plaintiffs' claims to the contrary notwithstanding, it is also worth noting that manufacturers *do* receive "additional benefits" in exchange for their agreement to

a negotiated price for their selected drugs. *Valancourt*, 82 F.4th at 1233. The IRA guarantees that a selected drug will be included in the formulary of all Medicare Part D plans if the manufacturer reaches an agreement with CMS as to the maximum fair price for that drug. 42 U.S.C. § 1395w-104(b)(3)(I)(i). Plaintiffs may choose to accept this benefit, or they may choose to depart from the Medicare and Medicaid programs. In either instance, the choice is theirs, and the voluntary nature of that choice defeats Plaintiffs' takings claim.

3. Plaintiffs' Alternative Unconstitutional Conditions Arguments Fail

All of these same reasons likewise defeat Plaintiffs' related attempts to undermine the Negotiation Program by invoking the test articulated by the Supreme Court in *Nollan* and *Dolan*, which asks whether an exaction sought by the government is "rough[ly] proportiona[l]" to the benefit being sought by a property owner. BMS Resp. at 21-22;[3] *see Dolan v. City of Tigard*, 512 U.S. 374, 391 (1994); *Nollan v. Cal. Coastal Comm'n*, 483 U.S. 825, 834-37 (1987); *see also 2910 Georgia Ave. LLC v. D.C.*, 234 F. Supp. 3d 281, 305 (D.D.C. 2017). Contrary to Plaintiffs' suggestion, these cases do not set forth a general unconstitutional-conditions framework. Rather, the Supreme Court has made clear that the *Nollan* and *Dolan* test is reserved for the "'special application' of . . . land-use permits." *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013) (discussing the doctrine); *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 538 (2005) (noting

[3] Although Janssen does not make this argument as explicitly as BMS, it also cites *Dolan* in support of its argument that the Negotiation Program improperly "requires Janssen to surrender its First and Fifth Amendment rights 'in exchange for a discretionary benefit conferred by the government.'" Janssen Resp. at 36 (citing *Dolan*, 512 U.S. at 385). Though less explicit, the argument is the same.

the "special context of land-use exactions"). That is for good reason. The "realities of the permitting process" render applicants "especially vulnerable" to the government's demands "because the government often has broad discretion to deny a permit that is worth far more than property it would like to take." *Koontz*, 570 U.S. at 604-05. Evaluating whether a land-use exaction is "proportional[]" to the governmental benefit thus ensures that the condition is part of a voluntary exchange. *Id.*; *see also Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2079 (2021) (explaining this framework).[4]

By contrast, no such proxy tests are necessary or appropriate when Congress merely sets the terms on which the government will do business—business to which the party has no free-standing entitlement and which it can freely decline. Courts do not, for example, superintend government contracts to ensure that they are voluntary and provide contractors sufficient compensation or benefit to avoid a Fifth Amendment taking. *See, e.g.*, *St. Christopher Assocs., L.P. v. United States*, 511 F.3d 1376, 1385 (Fed. Cir. 2008) ("In general, takings claims do not arise under a government contract because . . . the government is acting in its proprietary rather than its sovereign capacity" and any right to compensation has "been voluntarily created" (citations omitted)). Plaintiffs may be unhappy that Congress created the Negotiation Program as a condition of future Medicare and Medicaid participation. *See* Janssen Resp. at 10, 37. But their dissatisfaction does not mean the condition is improper in a constitutional sense.

[4] Plaintiffs cite *Cedar Point*, 141 S. Ct. 2063, for the proposition that the *Nollan* and *Dolan* test is not restricted to "zoning." BMS Resp. at 21-22. But *Cedar Point* likewise concerned the physical appropriation of *land*. *See* 141 S. Ct. at 2069. Defendants remain unaware of any precedent extending that framework beyond the context of restrictions on the use of real property. And Plaintiffs do not contend that the Negotiation Program burdens the use of land.

Congress has made clear that the terms of Medicare and Medicaid can change over time and that new conditions may be added. *See, e.g.*, 42 U.S.C. § 1304 (Congress reserves the right to change Medicare terms). Manufacturers cannot claim that having to decide whether to continue participating in light of that new condition renders the program legally involuntary. *Contra* Janssen Resp. at 10.

B. The Negotiation Program is Not "Coercive"

Plaintiffs fare no better with their attempts to argue that, even in the absence of legal compulsion, requiring participation in the Negotiation Program as a condition of receiving reimbursement from Medicare and Medicaid is impermissibly "coercive." BMS Resp. at 15-20; *see also* Janssen Resp. at 17. Plaintiffs base this argument on the Supreme Court's decision in *National Federation of Independent Business v. Sebelius*, 567 U.S. 519 (2012) (*NFIB*).[5] But Plaintiffs' arguments on this ground fail to correct the legal errors Defendants previously identified—and place *NFIB* so far outside its context that it would radically rework federal spending law.

1. In an effort to show that *NFIB* applies, Plaintiffs first contend that the decision provides a general framework for analyzing *any* Spending Clause condition, not just conditions that the government attaches on grants it offers to states. BMS Resp. at 17-18. But that is demonstrably wrong. Federalism was the animating concern of the *NFIB* "coercion" inquiry. *NFIB*, 567 U.S. at 577 (plurality opinion) (explaining the

[5] Janssen also claims that older cases "applied the same [] principle." Janssen Resp. at 17-18 (citing *Union Pacific*, 248 U.S. at 70 and *Thompson*, 92 F.2d at 478). As noted above, those cases are inapplicable because they dealt with coercion in the context of a regulatory—rather than a spending—regime. *See supra* n.1. But to the extent Janssen relies on those cases as supporting its *NFIB*-style "coercion" argument, that argument fails for all the reasons discussed in this section.

need to protect "the status of the States as independent sovereigns in our federal system"). That inquiry is derived exclusively from cases addressing how principles of federalism limit Congress's authority to attach funding conditions on grants to states. *See id.* at 579-81 (discussing, *inter alia*, *South Dakota v. Dole*, 483 U.S. 203 (1987)). In discussing the "coercion" inquiry, the lead opinion did not cite to or discuss *any* other type of unconstitutional conditions case. *See generally id.* This absence is particularly noteworthy because—as Plaintiffs recognize—the unconstitutional conditions doctrine has been established for over a century. *See* BMS Resp. at 18 & n.5; Janssen Resp. at 17.

Conversely, the Supreme Court has also not relied on *NFIB*'s "coercion" test when dealing with the broader doctrine of unconstitutional conditions in suits by private parties. The very next term after deciding *NFIB*, for instance, the Court decided *Koontz*, explaining that the unconstitutional conditions doctrine "vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up." 570 U.S. at 604. It also decided *Agency for International Development*, which likewise analyzed unconstitutional conditions in the context of the government seeking "to leverage funding to regulate speech outside the contours of the program" at issue. 570 U.S. at 214-15. In neither of those decisions involving funding to private parties did the Court so much as cite *NFIB*, much less employ its analysis. *See Koontz*, 570 U.S. at 604; *Agency for Int'l Dev.*, 570 U.S. at 214. Similarly, the decision from last term in *Cummings*—which, as BMS notes, discussed the "voluntar[iness]" of Spending Clause legislation in the context of identifying remedies available to private parties—also did not cite *NFIB*. 596 U.S. at 219.

Plainly, the Supreme Court has not treated *NFIB* as establishing a generally applicable unconstitutional-conditions standard. *Contra* BMS Resp. at 18; Janssen Resp. at 17. Plaintiffs' argument to the contrary thus comes down to the observation that—like other unconstitutional conditions cases that *NFIB* did not reference—*NFIB* uses the term "coercion." *See id.* But Plaintiffs fail to cite any authority to support their assertion that this "overlap" in terminology makes different constitutional tests and standards interchangeable. *See id.* Using similar words does not make analytically disparate cases the same. *See, e.g.*, *Turkiye Halk Bankasi A.S. v. United States*, 598 U.S. 264, 278 (2023) ("This Court has often admonished that 'general language in judicial opinions' should be read 'as referring in context to circumstances similar to the circumstances then before the Court and not referring to quite different circumstances that the Court was not then considering.'" (quoting *Illinois v. Lidster*, 540 U.S. 419, 424 (2004))). And Plaintiffs do not even acknowledge the authority Defendants cited recognizing that *NFIB* is limited to the unique context of federalism. *See, e.g.*, *Northport Health Servs. of Ark., LLC v. HHS*, 14 F.4th 856, 869 n.5 (8th Cir. 2021) (explaining that *NFIB* "coercion" inquiry "describe[s] the federal government's limited constitutional authority under the Spending Clause to regulate the states, not a federal agency's ability to regulate [private] facilities' use of federal funding"), *cert. denied*, 143 S. Ct. 294 (2022); *see also Northport Health Servs. of Ark., LLC v. HHS*, 438 F. Supp. 3d 956, 970-71 (W.D. Ark. 2020) ("No part of the Court's decision in *NFIB* touched on the government's power to place conditions on private entities.").[6]

[6] Plaintiffs have, however, dropped reliance on the Third Circuit decision in *Doe v. University of Sciences*, 961 F.3d 203, 213 (3d Cir. 2020), which they invoked in their

2. Similarly, Plaintiffs' suggestion that *NFIB*'s "coercion" inquiry can reach the federal government's purchases of goods or services is a radical concept that does not track *NFIB*'s language or logic and is unsupported by other precedent.

The animating principle of *NFIB*—which Plaintiffs disregard in their response—was that the government should not be able to use its Spending Clause powers to end-run restrictions on its ability to *regulate*. 567 U.S. at 580-81. But the Supreme Court has "long held the view that there is a crucial difference, with respect to constitutional analysis, between the government exercising 'the power to regulate or license, as lawmaker,' and the government acting 'as proprietor.'" *Engquist v. Oregon Dep't of Agric.*, 553 U.S. 591, 598 (2008) (quoting *Cafeteria & Restaurant Workers v. McElroy,* 367 U.S. 886, 896 (1961)). When the government acts in the latter capacity, constitutional review "'must rest on different principles than review of . . . restraints imposed by the government as sovereign.'" *Id.* at 599 (quoting *Waters v. Churchill*, 511 U.S. 661, at 674 (1994)); *see also Waters*, 511 U.S. at 671 ("[T]he government as employer . . . has far broader powers than does the government as sovereign."). For this reason, courts do not superintend government contracting decisions to ensure that the compensation contractors agree to accept reflects "fair market value" for their products. As the Supreme Court has confirmed across a range of different constitutional contexts, "[w]here the government is acting as a proprietor, managing its internal operations, rather than acting as lawmaker with the power to regulate or license, its action will *not* be subjected to the heightened review to which its actions as a lawmaker may be subject." *Int'l Soc'y for Krishna*

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opening brief. As Defendants explained, that decision does not bear the weight that Plaintiffs sought to put on it.

Consciousness, Inc. v. Lee, 505 U.S. 672, 678 (1992) (emphasis added); *see also Waters*, 511 U.S. at 675 (the "government's interest in achieving its goals as effectively and efficiently as possible is elevated from a relatively subordinate interest when it acts as sovereign to a significant one when it acts as employer"); *Ridley v. Mass. Bay Transp. Auth.*, 390 F.3d 65, 79 (1st Cir. 2004) ("[A] lower level of scrutiny usually applies when the government acts as proprietor."). Of course, "the Government unquestionably is the proprietor of its own funds, [so] when it acts to ensure the most effective use of those funds, it is acting in a proprietary capacity." *Bldg. & Const. Trades Dep't, AFL-CIO v. Allbaugh*, 295 F.3d 28, 35 (D.C. Cir. 2002).

The same principle animates cases Defendants cited in their opening brief dealing with the difference between states acting as regulators as opposed to purchasers. *See Chamber of Com. of U.S. v. Brown*, 554 U.S. 60, 70-71 (2008) (distinguishing between government acting "as a regulator rather than a market participant"); *see also Bldg. & Const. Trades Council of Metro. Dist. v. Associated Builders & Contractors of Mass./R.I., Inc.*, 507 U.S. 218, 229 (1993) (discussing the "conceptual distinction between regulator and purchaser"); *Associated Builders & Contractors Inc. N.J. Chapter v. City of Jersey City*, 836 F.3d 412, 417-18 (3d Cir. 2016). In seeking to distinguish those decisions, BMS Resp. at 19, Plaintiffs miss the underlying point that governments, be they state or federal, are subject to different constitutional constraints when they act as market participants. *See, e.g.*, *Allbaugh,* 295 F.3d at 36 ("[C]ondition that the Government imposes in awarding a contract or in funding a project is regulatory only when . . . it 'addresse[s] employer conduct unrelated to the employer's performance of contractual obligations to the [Government].'" (quoting *Bldg. & Const. Trades Council*, 507 U.S. at 228-29)).

Contrary to Plaintiffs' suggestion, these distinctions do not vanish merely because the government can also regulate the relevant market (in often-unrelated ways). Janssen Resp. at 21-23; BMS Resp. at 20. As the authority Defendants previously identified makes clear—and as Plaintiffs fail to acknowledge—"the Supreme Court has approved applying the market participant exception even when a State's regulations are trained on the specific market in which it participates." *Brooks v. Vassar*, 462 F.3d 341, 358 (4th Cir. 2006); *see Hughes v. Alexandria Scrap Corp.,* 426 U.S. 794, 797 (1976) (the State of Maryland not only participated in the automobile scrap market but also regulated it); *see also Chance Mgmt., Inc. v. South Dakota,* 97 F.3d 1107, 1113 (8th Cir. 1996) (finding that, despite South Dakota's heavy regulation of the state lottery and all other forms of gambling, the State's pervasive involvement in running the lottery was not "regulation of 'the market,'" but rather was no more than "administering its own business"). The state can impose taxes or restrictions to "regulate[] the [] market," and that "is not sufficient to preclude its status as a market participant." *Brooks*, 462 F.3d at 358 (state can regulate liquor market and be a participant).

So too here. As Defendants detailed in their opening brief, Congress designed the Negotiation Program to achieve "[e]fficient and equitable procurement" of high-cost prescription drugs. Defs.' MSJ Br. at 21-22. These steps to limit government outlay on selected drugs constitute a valid exercise of Congress's power to control federal spending—and reflect Congress's view that the "general Welfare" is best served by reducing expenditure on certain high-cost pharmaceuticals. U.S. Const., art. I, § 8, cl. 1; *cf. Sabri v. United States*, 541 U.S. 600, 608 (2004) ("The power to keep a watchful eye on expenditures . . . is bound up with congressional authority to spend in the first

place."). And the mere fact that antitrust laws may restrict private entities from enacting similar pricing controls does not mean that the imposition of such controls is *regulation* in a constitutional sense. *Contra* BMS Resp. at 20; Janssen Resp. at 23.

Simply put, *NFIB*'s "coercion" test has no place in the procurement (rather than regulatory) context of the Negotiation Program—and Plaintiffs offer no reasoned basis to apply it here.

3. A sure sign of a problem with Plaintiffs' "coercion" theory is its logical implications. According to Plaintiffs, the Negotiation Program is "coercive" because the most straightforward way to avoid it is to forgo Medicare and Medicaid participation generally—which, Plaintiffs claim, "ransoms those separate funds." BMS Resp. at 21. But the same argument could be said about numerous Medicare and Medicaid conditions that have long been understood as permissible.

For example, Congress has long required drug manufacturers wishing to participate in Medicaid to enter into agreements with the Secretary of Veterans Affairs, which make their covered drugs available for procurement by the Department of Veterans Affairs and other agencies at or below statutory ceiling prices. *See* 38 U.S.C. § 8126(a)-(h). Similarly, Congress routinely requires that parties accepting Medicare and Medicaid funding observe conditions that reach beyond the specific products or services that Medicare reimburses. *See, e.g.*, *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113-16 (2011) (describing requirements under 42 U.S.C. § 1396r-8(a)(1), which conditions participation in the Medicaid Drug Rebate Program on participation in the 340B program, through which participating drug manufacturers must give discounts to various categories of private purchasers); *see also Baker Cnty.*, 763 F.3d at 1277-78 (noting that, "[a]s a

condition of participating in and receiving payments from Medicare, a hospital must also opt into EMTALA," which generally "requires participating hospitals to provide care to anyone who visits an emergency room"). Plaintiffs' argument would, perforce, declare all of those programs coercive—something no court has previously found. *See, e.g.*, *Sanofi-Aventis U.S., LLC v. HHS*, 570 F. Supp. 3d 129, 209-10 (D.N.J. 2021), *rev'd in part on other grounds*, 58 F.4th 696 (3d Cir. 2023).

And that's not all. Even more fundamentally, hospitals, nursing homes, and other entities are not eligible for Medicare reimbursement for any one service unless they sign a participation agreement acknowledging their acceptance of the prescribed rates for all of their services that are reimbursable by Medicare. 42 U.S.C. § 1395cc; *see also id.* § 1395a(b). These participation agreements require the provider to comply with a series of conditions of participation. *See, e.g.*, 42 U.S.C. §§ 1395cc(b)(2)(B), 1395x(e)(9); 42 C.F.R. §§ 482.1-482.104 (part 482, providing "[c]onditions of [p]artici-pation for [h]ospitals"). These include numerous requirements concerning hospital "[a]dministration" and operation, 42 C.F.R. §§ 482.11-482.15; basic hospital functions, such as staffing and various types of diagnostic and care procedures, *id.* §§ 482.22-482.23, 482.26; and various aspects of "pharmaceutical services," *id.* § 482.25. Many of these conditions are not limited to providers' interaction with Medicare beneficiaries, but instead apply to the providers generally. *See, e.g.*, *id.* § 482.12 (requiring hospitals have "effective governing body"); *id.* § 482.21 (requiring hospitals to "maintain an ef-fective, ongoing, hospital-wide, data-driven quality assessment and performance im-provement program"); *see generally id.* § 482.22-482.45 (requiring numerous hospital functions); *see also Cummings*, 596 U.S. at 217-18 (noting that Congress prohibits

"discriminat[ion] . . . on certain protected grounds" "by healthcare entities" receiving federal funds). And the consequence of declining to accept *any* condition—including any new condition that CMS determines is necessary—is potential loss of reimbursement for all services, even unrelated ones.

Under Plaintiffs' theory, an array of run-of-the-mill conditions could therefore be said to "ransom [] separate funds to coerce a distinct transaction involving [] different" populations or services. BMS Resp. at 21; *see also id.* (arguing that conditions can be coercive if they do not "'place[] a direct restriction on how a [recipient] uses [the] federal funds'" (quoting *Gruver v. La. Bd. of Supervisors*, 959 F.3d 178, 183 (5th Cir. 2020)). Thus, a hospital could complain that its failure to satisfy conditions related to pharmacy services should not deprive it of Medicare reimbursement for surgery or radiology services, because the "condition . . . has nothing to do with the funds being held hostage." BMS Resp. at 20. Other examples abound. In Plaintiffs' world, Medicare and Medicaid would turn into a veritable grab-bag of conditions from which providers could pick and choose as their business interests required. That would amount to a fundamental restructuring of how federal health care programs work.

Nor would the problems stop there. As the Supreme Court has noted, "[p]ursuant to its authority to 'fix the terms on which it shall disburse federal money,' . . . Congress has enacted four statutes prohibiting recipients of federal financial assistance from discriminating based on certain protected grounds." *Cummings*, 596 U.S. at 217-18 (citation omitted).[7] Congress has separately authorized the President to prescribe

[7] These include (1) Title VI of the Civil Rights Act of 1964, which forbids race, color, and national origin discrimination in federally funded programs or activities, 42

policies that he deems necessary to promote economy or efficiency in federal procurement. 40 U.S.C. §§ 101 *et seq*. In Plaintiffs' construction, these conditions are all potentially constitutionally vulnerable under the *NFIB* "coercion" framework—and entities ranging from educational institutions to defense contractors can claim a constitutional right to take government money while refusing to comply with the accompanying obligations.

Fortunately, the Supreme Court has recently made clear that it does not share Plaintiffs' maximalist reading of *NFIB*. As Defendants observed in their opening brief, the Court granted a stay of an injunction against a COVID-19 vaccine mandate that CMS had imposed for workers at federally funded healthcare facilities. *Missouri*, 595 U.S. at 94. In doing so, the Court observed "the longstanding practice" of Congress and CMS, under which "healthcare facilities that wish to participate in Medicare and Medicaid have always been obligated to satisfy a host of conditions that address the safe and effective provision of healthcare"—conditions which function as a single package. *Id.* Notably, the Court did this even in the face of the challengers raising an *NFIB* "coercion" argument similar to the one Plaintiffs present here, in which they asserted that the condition improperly sought to leverage other federal funds. *See Becerra v. Louisiana*, Nos. 21A240, 21A241, Resp. to Stay App. at 27, 2021 WL 8939385 (Dec. 30, 2021) (arguing that the vaccination "condition was impermissibly coercive because the

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U.S.C. § 2000d; (2) Title IX of the Education Amendments of 1972, which prohibits sex-based discrimination, 20 U.S.C. § 1681; (3) the Rehabilitation Act, which bars funding recipients from discriminating because of disability, 29 U.S.C. § 794; and (4) the Affordable Care Act, which outlaws discrimination on any of the preceding grounds, in addition to age, by healthcare entities receiving federal funds, 42 U.S.C. § 18116. *See Cummings*, 596 U.S. at 218 (describing these restrictions).

consequence of opting out would be the loss of *all* Medicare and Medicaid funds" (emphasis in original) (citing *NFIB*, 567 U.S. at 580-81)); *Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination*, 86 Fed. Reg. 61,555, 61,574 (Nov. 5, 2021) (noting that "providers and suppliers that are cited for noncompliance may be subject to . . . termination of the Medicare/Medicaid provider agreement").

BMS misses this failed invocation of the *NFIB* "coercion" argument in *Missouri*. BMS Resp. at 19 (mistakenly denying that "anyone argue[d] that the condition failed" on *NFIB* grounds). But that is itself revealing. The theory was so misguided that not even the dissents acknowledged it, nor questioned Congress's authority to condition federal funds on an entity satisfying *all* applicable rules. *See generally Missouri*, 595 U.S. at 98-104 (Thomas, J., dissenting); *id.* at 105-06 (Alito, J., dissenting).

In short, there is no indication that, in deciding *NFIB*, the Supreme Court was transforming a federalism-specific "coercion" limitation into an omnibus framework governing how the federal government spends funds to purchase goods or services from the private sector. No court, to Defendants' knowledge, has embraced such a reading. The Court in *Chamber* rejected it. *See Dayton Area Chamber of Com. v. Becerra*, No. 3:23-cv-156, Reply in Supp. of Mot. for Prelim. Inj., ECF No. 49 at 12-14 (S.D. Ohio Aug. 25, 2023) (arguing that the Negotiation Program was "coercive" in violation of *NFIB*). Plaintiffs offer no reason for this Court to chart a new course.

C. Plaintiffs Provide No Basis to Depart From Decades of Precedent Finding Medicare Conditions Voluntary

Rejecting Plaintiffs' reliance on *NFIB* and similarly inapposite regulatory-conditions cases leads to the conclusion the *Chamber* court correctly adopted: because the

Negotiation Program is merely a condition on voluntary Medicare and Medicaid participation, and can be freely avoided, it creates no constitutional violation. *Chamber,* 2023 WL 6378423, at *11. Although Plaintiffs attempt to minimize that decision as dealing only with the due process claim at issue in that case, *see, e.g.*, BMS at 26, they miss that the *reason* the court rejected that claim was because it applied the correct legal framework to conclude that the Program was "completely voluntary." *Chamber,* 2023 WL 6378423, at *11. Indeed, as the *Chamber* court recognized, this conclusion necessarily follows from the decades of "clear" precedent rejecting analogous Takings Clause challenges to Medicare reimbursement rates. *Id.*

Recognizing that those precedents stand in their way, Plaintiffs invite the Court to simply disregard all of it as limited or outdated. *See* BMS Resp. at 23-26; *see also* Janssen Resp. at 8. But, as explained above, Plaintiffs' preferred constitutional tests do not reach the types of arrangements these cases address—indeed, the Supreme Court's recent decision in *Missouri* refutes Plaintiffs' claims that *NFIB*'s state-coercion inquiry applies in the Medicare context. Further, as Defendants observed in their opening brief, some of these cases postdate *NFIB* and *Horne*—and correctly find them inapplicable. *See, e.g.*, *Northport Health*, 14 F.4th at 869 n.5; *see also Se. Ark. Hospice, Inc. v. Burwell*, 815 F.3d 448, 450 (8th Cir. 2016) (discussing "voluntariness" of the "Medicare hospice program" and citing *Horne*, 576 U.S. at 366); *Baker Cnty.*, 763 F.3d at 1280 ("Although the Hospital contends that opting out of Medicare would amount to a grave financial setback, 'economic hardship is not equivalent to legal compulsion . . . .'" (quoting *Garelick*, 987 F.2d at 917)).

Nor are Plaintiffs' efforts to distinguish some of these cases on their facts persuasive. *See* BMS Resp. at 24-25. Plaintiffs assert that the cases dealt with "particular Medicare reimbursement rates," rather than a supposed "mandate" to provide property to others. *Id.* at 24. Plaintiffs are, of course, wrong that the Negotiation Program "mandate[s]" them to provide any property to anyone. *See infra* Section II. But, in any event, the distinction Plaintiffs seek to draw is hollow. As Plaintiffs themselves recognize, the Negotiation Program establishes what the government will ultimately reimburse for certain high-cost pharmaceuticals—placing Plaintiffs' challenge on all fours with the cases they seek to distinguish. *See* BMS Resp. at 24-25.

Further, even a cursory review of the various cases Defendants cited in their opening brief reveals that courts reject challenges to reimbursement rates not because of anything specific to those rates or how they operate—but rather because those rates are part of *voluntary* programs that do not compel participation in the first instance. *See, e.g.*, *Garelick*, 987 F.2d at 917 ("All court decisions of which we are aware that have considered takings challenges by physicians to Medicare price regulations have rejected them in the recognition that participation in Medicare is voluntary."); *Se. Ark. Hospice*, 815 F.3d at 450 ("SEARK voluntarily chose to participate in the Medicare hospice program [and] '[t]his voluntariness forecloses the possibility that the statute could result in an imposed taking of private property.'" (quoting *Minn. Ass'n of Health Care Facilities, Inc. v. Minn. Dep't of Pub. Welfare,* 742 F.2d 442, 446 (8th Cir. 1984))); *see also Baker Cnty.*, 763 F.3d at 1279 ("Just as physicians who voluntarily treat Medicare beneficiaries cannot establish the legal compulsion necessary to challenge Medicare reimbursement rates as

a taking, so too is the Hospital precluded from challenging the rate at which it is compensated for its voluntary treatment of federal detainees.").

Plaintiffs' efforts to evade these cases—and the Negotiation Program generally—ultimately reduce to their claims that a condition cannot be voluntary if their business model makes it financially impractical for them to withdraw from Medicare. BMS Resp. at 25; Janssen Resp. at 10. But courts have considered, and rejected, such claims of involuntariness even where "business realities" create "strong financial inducement to participate"—such as, for example, when Medicaid provides the vast majority of a nursing home's revenue. *Minn. Ass'n of Health Care Facilities*, 742 F.2d at 446. As the *Chamber* court recognized, "participation in Medicare, no matter how vital it may be to a business model, is a completely voluntary choice." 2023 WL 6378423, at *11 (discussing cases); *see also Baker Cnty.*, 763 F.3d at 1280. Plaintiffs offer no principled reason why the same conclusion does not hold here.

* * *

In the end, Plaintiffs' arguments are nothing more than the latest iteration of a familiar playbook employed for decades by hospitals, nursing homes, and other providers who have claimed that limits on Medicare reimbursements take their property. Courts have, for decades, rejected such arguments on the ground that participation in Medicare is fully voluntary. *See, e.g.*, *Baker Cnty.*, 763 F.3d at 1276, 1279-80 (collecting cases); *Garelick*, 987 F.2d at 916. This Court should follow the lead of the court in *Chamber* and do the same.

II. PLAINTIFFS' PHYSICAL TAKINGS ARGUMENTS WOULD FAIL IN ANY EVENT

The absence of legal compulsion is not the only reason Plaintiffs' taking theory fails. As Plaintiffs' response confirms, they do not claim that the Negotiation Program is "so onerous that its effect is *tantamount* to a direct appropriation"—*i.e.*, a "regulatory taking." *Lingle*, 544 U.S. at 537 (emphasis added). Rather, Plaintiffs' only Takings Clause argument is that the Negotiation Program effects a direct "physical taking" because it "order[s]" manufacturers "to provide property [to] . . . Medicare beneficiaries." BMS Resp. at 4-5. Plaintiffs' reading of the IRA as creating an "obligation to *transfer*" drugs is thus the linchpin of their taking theory. *Id.* at 4 (emphasis in original); *see also* Janssen Resp. at 3-4, 25 (arguing that "the IRA obligates Janssen to give third parties access to its drugs"). But it is demonstrably wrong.

1. Start with the plain text of the statute: that language demonstrates that Congress did not compel manufacturers to sell any drugs in the first instance. As Defendants detailed in their opening brief, manufacturers participating in the Negotiation Program merely undertake an obligation "to provide access to such *price*" as they may negotiate with CMS (which the statute defines as the "maximum fair price" or "MFP"). 42 U.S.C. § 1320f-2(a)(1), (3) (emphasis added); *see also id.* § 1320f-6(a) (defining a "[v]iolation[]" of the agreement as "not provid[ing] access to a price that is equal to or less than the maximum fair price"). In fact, *all* uses of the word "access" in the IRA describe "access to . . . price." *See id.* §§ 1320f-2(a), (d), 1320f-6(a). Not a single provision uses the phrase "access to drugs" or an equivalent. *See generally id.* These drafting choices are not mere "wordplay." BMS Resp. at 5. If Congress wanted to mandate physical access to *drugs*, it would have done so, as it did for copyrighted materials in *Valancourt*.

It pointedly did not. "Given this clear language, it would be improper to conclude that what Congress omitted from the statute is nevertheless within its scope;" after all, "Congress's choice of words is presumed to be deliberate." *Univ. of Texas Sw. Med. Ctr. v. Nassar*, 570 U.S. 338, 353 (2013).

CMS's Revised Guidance confirms what is evident from the plain language of the statute. As CMS detailed, the statutory language means manufacturers that agree to a negotiated price for a selected drug "must provide access *to the MFP*" for Medicare beneficiaries by *either* "prospectively ensuring that the price paid by the dispensing entity when acquiring the drug is no greater than the MFP," or reimbursing "the difference between the dispensing entity's acquisition cost and the MFP" for relevant sales. Revised Guidance at 125-26 (emphasis added). Consistent with the IRA, CMS's guidance explains the mechanisms the agency will establish to ensure that manufacturers comply with the MFP requirements. *See generally* Revised Guidance at 125-129 (sections 40.4 and 40.5), 171-72 (discussing what happens if manufacturer fails "to ensure access to a price less than or equal to the MFP"). Absent from that Guidance—and from the IRA generally—is *any* mention of a mechanism to force manufacturers to actually *make* sales of any drug, or any suggestion that failure to make a sale constitutes a violation. *See id.* at 172-73 (listing "[e]xample of [s]ubstantive [v]iolation"); *see also* 42 U.S.C. § 1320f-6(a) (defining violation of an agreement).

The upshot, to borrow BMS's phrasing, is that if, "after signing the agreement with CMS, BMS were to refuse to transfer Eliquis to Medicare" at all, that *would not be prohibited* by the IRA. BMS Resp. at 5. Plaintiffs cite no provision of the IRA that "force[s] sales" of manufacturers' drugs against their will. *Id.* at 4. And, in the absence

of such compulsion, Plaintiffs' physical taking theory collapses. *See, e.g.*, *Cedar Point*, 141 S. Ct. at 2072 ("The essential question is . . . whether the government has physically taken property for itself or someone else—by whatever means—or has instead restricted a property owner's ability to use his own property."). A limit on the price that manufacturers may charge for drugs sold to Medicare may (or may not) ultimately have an "economic impact" on manufacturers—but it falls on the other side of the "settled difference in [] takings jurisprudence between appropriation and regulation," and thus gives rise to no "physical taking" concerns. *Horne*, 576 U.S. at 362.

2. Unable to accept this result, Plaintiffs grasp for attenuated signs that the statute works differently from how Congress drafted it and how CMS intends to implement it. BMS Resp. at 5-6. This effort fails at the outset in a facial challenge, where Plaintiffs bear the heavy burden of establishing "'that *no* set of circumstances exists under which the Act would be valid,' *i.e.*, that the law is unconstitutional in all of its applications." *Wash. State Grange v. Wash. State Republican Party*, 552 U.S. 442, 449 (2008) (quoting *United States v. Salerno*, 481 U.S. 739, 745 (1987)) (emphasis added). And it is unpersuasive in any event.

For example, BMS cites to a provision regulating when insurance plans contracting with Medicare must include the selected Part D drugs as part of their formulary—that is, as part of the coverage they provide. *See* 42 U.S.C. § 1395w-104(b)(3)(I). As noted above, that provision is actually designed as a potential *benefit* to manufacturers: that is, a manufacturer is guaranteed formulary inclusion by all Medicare Part D plans for its selected drug in exchange for reaching an agreement with CMS as to the maximum fair price for the drug. *Id.* § 1395w-104(b)(3)(I)(i). And, contrary to Plaintiffs'

assertion, that statutory provision does not require manufacturers to *make* sales—it merely states that insurance providers shall cover the drugs that manufacturers do, in fact, agree to sell. *See id.*[8] That point is crystallized in CMS's Revised Guidance, where CMS addressed concerns that Part D plans may attempt to "steer Part D beneficiaries away from selected drugs in favor of non-selected drugs that may be associated with higher rebates." Revised Guidance at 84-85. As CMS explained, it will "use its formulary review process to assess" whether Part D plans are improperly disadvantaging selected drugs in their coverage policies. *Id.* at 85. Nothing about that review process or the formulary structure generally contemplates CMS reviewing whether a manufacturer has failed to *make* enough sales of a drug. *See generally id.* at 84-85.

Nor is BMS correct to claim that the excise tax provisions of section 5000D provide grounds for inferring that the IRA compels sales. *See* BMS Resp. at 6. As Defendants explained in their opening brief, Defs.' MSJ Br. at 16-17, section 5000D suspends taxes on applicable sales of a designated drug to Medicare beneficiaries if a manufacturer stops participating in Medicare and Medicaid. *See* 26 U.S.C. § 5000D(c); IRS Notice No. 2023-52, 2023-35 I.R.B. 650 (Aug. 4, 2023), https://perma.cc/B9JZ-ZG7P (addressing interpretation of 26 U.S.C. § 5000D) (IRS Notice). BMS asserts that this suspension makes no sense if manufacturers can just avoid the tax by not selling the selected drug in the first place—something BMS suggests would be a more

[8] Plaintiffs also misunderstand the operation of this provision. Although they contend that all selected drugs must be included on Part D formularies, BMS Resp. at 5, this obligation is imposed on Part D plans only if the manufacturer and CMS have agreed to a negotiated price for the selected drug. *See* 42 U.S.C. § 1395w-104(b)(3)(I)(i) (plan "shall include each covered part D drug that is a selected drug . . . for which a maximum fair price . . . is in effect with respect to the year").

economical option than exiting all of Medicare and Medicaid.[9] But that's just the point: manufacturers have numerous options for exiting or avoiding the Negotiation Program. *See* Defs.' MSJ Br. at 16-18. Some manufacturers may find one option more economically or logistically attractive. Yet the availability of multiple options, even potentially overlapping ones, cannot be taken as *sub silentio* enactment of something that exists nowhere else in the U.S. Code: a *mandate* to sell drugs that manufacturers do not wish to sell. This Court may not infer such a requirement in the absence of clear statutory language. *See, e.g.*, *United States v. Bingert*, 605 F. Supp. 3d 111, 127 (D.D.C. 2022) ("Textual redundancies that are 'subtle or pitted against otherwise plain meanings' are 'feeble interpretive tools.'" (quoting *Mercy Hosp., Inc. v. Azar*, 891 F.3d 1062, 1068 (D.C. Cir. 2018))).

Disposing of these sign-readings leaves Plaintiffs' passing suggestion that Defendants' filings have somehow "concede[d]" the surprising interpretation that Plaintiffs now offer. BMS Resp. at 5; *see also* Janssen Resp. at 26. Defendants did nothing of the kind: an accurate account of the statements Plaintiffs quote and the context in which they appear confirms that Defendants have never departed from the statutory

[9] Plaintiffs separately dispute whether the taxes apply to all sales, or only sales to Medicare. Janssen Resp. at 15; BMS Resp. at 6 n.1. That challenge is not properly presented in this case because Plaintiffs are not contesting the constitutionality of the tax provision or the IRS Notice—a challenge over which this Court would lack subject-matter judgment given that (1) Plaintiffs have not named Treasury or the IRS as a Defendant, (2) the IRS interpretation operates to Plaintiffs' benefit, and (3) the Anti-Injunction Act bars such challenges prior to collection of the tax. *See generally* 26 U.S.C. § 7421(a). But even under Plaintiffs' reading of the tax provision, there would *still* be no indication that the statute compels sales of the selected drug to Medicare. Even if the tax applied to *every* sale of the designated drug, a manufacturer would *still* not be compelled to sell the drug to anyone, and could plausibly incur a tax liability of zero.

language. *See* Defs.' MSJ Br. at 27, 34; *see also* IRS Notice at 2 (stating that manufacturers "agree[ing] to an MFP commit to provide access to selected drugs *at the negotiated prices*" (emphasis added)). And it hardly needs saying that Defendants cannot amend the U.S. Code through a litigation brief.

3. Finally, Plaintiffs still fail to rebut Defendants' observation that, even if Congress *had* forced manufacturers to sell their drugs, that would, at most, place those companies within the framework applied to public utilities. *See* BMS Resp. at 7-8; Janssen Resp. at 26-27. Indeed, Janssen itself observes that the utility framework is applicable *only* when the property is "'partly public, partly private'"—and that would *be exactly the case* if Congress ordered manufacturers to sell their products.[10] Janssen Resp. at 27 (quoting *Duquesne Light Co. v. Barasch*, 488 U.S. 299, 307 (1989) (emphasis removed)). Yet, as Defendants observed, utility rate-setting has never been treated as a *per se* or physical taking. *See, e.g.*, *Verizon Commc'ns, Inc. v. FCC*, 535 U.S. 467, 524-27 (2002); *see also Duquesne Light*, 488 U.S. at 307-15 (discussing evolution of takings jurisprudence with respect to public utilities). Rather, the Supreme Court has made clear that those takings challenges must follow the course for any traditional *regulatory* taking—meaning that they must proceed in an as-applied rather than a facial challenge. *See Verizon*, 535 U.S. at 525 ("[T]he general rule is that any question about the constitutionality of rate-setting is raised by rates, not methods.").

[10] Janssen's observation that it is not a public utility—and that not "a single case" has classified drug manufacturers as public utilities—thus completely misses the point. Janssen Resp. at 27. The reason for that is precisely because manufacturers are *not* ordered to sell their drugs. If they were compelled to make those sales—as both Plaintiffs seem to believe—they would stand on roughly equal footing with utilities.

Plaintiffs attempt to side-step these issues by claiming that the Negotiation Program prices "*necessarily* do not provide market value." BMS Resp. at 7. That is incorrect, at least as a categorical matter.[11] And it is irrelevant in two separate respects. First, in the utility rate-setting context, courts do *not* look to market price as a measure of a taking. *See, e.g.*, *Duquesne Light*, 488 U.S. at 308 (noting that the analysis of what is "just compensation . . . 'and what are the necessary elements in such an inquiry,'" is a difficult question (citation omitted)). Rather, courts look to various factors related to investment-backed expectations—which depend on case- and plaintiff-specific factors that are inimical to a facial challenge, and which Plaintiffs do not even try to establish here. *See, e.g., Verizon*, 535 U.S. at 524-27 (explaining the need to conduct a fact-intensive inquiry). Second, Plaintiffs' objection still fails to overcome the basic fact that utility rate-limits are not seen as physical takings because they do not deprive utilities of the whole "bundle" of rights that are lost when the government physically seizes or invades property. *See, e.g.*, *Horne*, 576 U.S. at 361; *Verizon*, 535 U.S. at 524-25. So too here. In the absence of any obligation to surrender actual drugs, the Negotiation Program is, at

[11] As to the Plaintiffs' particular presentation of this claim, the reason is somewhat technical, but it comes down to the fact that the IRA specifies two possible formulas by which CMS is required to determine a ceiling price—and one of those formulas uses a percentage of the "non-Federal average manufacturer price." 42 U.S.C. § 1320f-3(c)(1)(C). That price, notably, "does not reflect rebates paid by the manufacturer to third-party payers (such as insurance companies or [PBMs])," and so it substantially overstates the net revenue that a manufacturer actually receives from a given drug today. Congressional Budget Office, *A Comparison of Brand-Name Drug Prices Among Selected Federal Programs* at 34 (Feb. 2021), https://perma.cc/BU23-U66U. Because Plaintiffs' drugs Xarelto and Eliquis are already heavily rebated, this calculation may exceed the net revenues Plaintiffs currently receive from those drugs. *See* Inmacula Hernandez, et al., *Estimated Discounts Generated by Medicare Drug Negotiation in 2026*, 29 J. Managed Care Spec. Pharm. 868, 870 (2023).

most, a form of price regulation—except that it is a regulation only of the price that the *government* pays. That is not a taking at all, and it is certainly not a *physical* taking. *See, e.g., FCC v. Fla. Power Corp.*, 480 U.S. 245, 253 (1987) ("It is of course settled beyond dispute that regulation of rates chargeable from the employment of private property devoted to public uses is constitutionally permissible.").

* * *

In their eagerness to challenge the IRA, Plaintiffs have disregarded the language of the statute and its context. But Plaintiffs' desire to bend the IRA to match their legal theory does not make the statute constitutionally suspect. Even if the Negotiation Program were not fully voluntary—which it is—Plaintiffs' takings challenge would run aground on the established difference between physical takings and economic regulation.

III. PLAINTIFFS' FIRST AMENDMENT CHALLENGE LACKS MERIT

Plaintiffs' First Amendment arguments likewise repeat the same conceptual errors that animated their opening motion. In particular, Plaintiffs continue to assert that signing agreements with CMS is a form of expression that they are "compelled" to undertake. Janssen Resp. at 28; BMS Resp. at 27, 29. But that is not true.

1. As a starting point, Plaintiffs' speculation about the secret "point" of the agreements—which they claim are designed to "conceal government mandates as voluntarily assumed commitments"—fails to overcome the reality that the agreements are purely commercial arrangements. BMS Resp. at 34-35; *see also* Janssen Resp. at 28. As Defendants detailed in their opening brief, these agreements exist solely to memorialize

manufacturers' voluntary undertaking of a commitment to participate in the Negotiation Program—and, ultimately, to charge Medicare beneficiaries no more than the negotiated prices. *See* Revised Guidance at 118-20.

Health care providers and other entities execute similar agreements to memorialize their acceptance of the terms for participation across a range of federal health care programs. *See, e.g.*, 42 U.S.C. §§ 1395cc, 1396r-8(b), (c), 1395w-102(b)(1). For example, the Medicare Participating Physician or Supplier Agreement uses the word "agreement" 29 times to indicate that the parties are entering a commercial arrangement and share a common understanding of their obligations. *See* CMS, Medicare Participating Physician or Supplier Agreement (CMS-460), https://perma.cc/WG64-ZNPL. Contrary to Plaintiffs' insistence, such agreements are "not directed at the communication of information" at all, and any conduct restriction "is imposed 'for reasons unrelated to the communication of ideas.'" *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 291 (D.C. Cir. 2019) (quoting *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 569 (2001)). Any speech implicated by the execution of the agreement "is plainly incidental to the . . . regulation of conduct" that the agreements govern: namely, the establishment of future prices that the government will pay for drugs. *Rumsfield v. Forum for Acad. & Institutional Rts., Inc. (FAIR)*, 547 U.S. 47, 62 (2006); *see also Expressions Hair Design v. Schneiderman*, 581 U.S. 37, 47 (2017) (a "law's effect on speech [that is] only incidental to its primary effect on conduct" does not draw First Amendment scrutiny). Such arrangements do "not implicate the First Amendment" at all. *Nicopure*, 944 F.3d at 291; *see also Sorrell v. IMS Health Inc.*, 564 U.S. 552, 567 (2011) ("[T]he First Amendment does not prevent

restrictions directed at commerce or conduct from imposing incidental burdens on speech.").

Notably, Plaintiffs do not even acknowledge that the agreements they protest have *any* commercial purpose. *See generally* BMS Resp. at 29-30, 32-34; Janssen Resp. at 28-31. Instead, pointing to media reports and press statements, Plaintiffs continue to argue that Congress's use of terms like "negotiation[]" "agreement" and "maximum fair price"—which Congress employed as statutory terms of art—compels manufacturers to endorse colloquial understandings of the words and phrases. BMS Resp. at 33-35; Janssen Resp. at 30-31. Of course, CMS's agreement includes an explicit disclaimer to the contrary—precisely to avoid the kind of misunderstanding Plaintiffs seem intent on making. Contrary to Plaintiffs' cramped reading, the point of that disclaimer is not to "cure[]" some defect by "disclaim[ing]" the otherwise expressive content of the agreement. BMS Resp. at 36; *see also* Janssen Resp. at 33-34. Rather, the point is to highlight the obvious fact that the terms of the agreement are used solely as statutory terms of art, not as forms of colloquial expression about what is "fair."

But even absent the disclaimer, Plaintiffs' reasoning is supported by neither law nor logic. In no case that Plaintiffs identify did a court find that the words of a contract are expressive merely because they were written and *could* be incorrectly understood as conveying a message. *See* BMS Resp. at 33-34; Janssen Resp. at 31-33. Rather, the Supreme Court has found an abridgement of expression where regulations target speech directly.

Thus, for example, in *Expressions Hair Design*, the Court found the First Amendment implicated by a law that did not regulate "the amount [merchants] are allowed to

collect from a cash or credit card payer" but instead directly targeted "how sellers may *communicate* their prices." 581 U.S. at 47 (emphasis added). Similarly, in *Sorrell*, the Court found that the prohibition on the sale of doctors' prescribing information violated the First Amendment because it "impose[d] a burden based on the content of speech and the identity of the speaker." 564 U.S. at 567. But here, the only thing being *regulated* are the actual *prices*, not anyone's speech: the words used in the agreements are merely a means by which the regulation is given effect. These types of commercial arrangements in the service of "ordinary price regulation do[] not implicate constitutionally protected speech." *Nicopure*, 944 F.3d at 292 (citing *Expressions Hair Design*, 581 U.S. at 47); *see also Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence*, 731 F.3d 71, 77 (1st Cir. 2013) ("[P]rice regulations and other forms of direct economic regulation do not implicate First Amendment concerns."). As the Supreme Court has emphasized, "'it has never been deemed an abridgment of freedom of speech or press to'" regulate conduct "'merely because the conduct was in part initiated, evidenced, or carried out by means of language, either spoken, written, or printed.'" *Expressions Hair Design*, 581 U.S. at 47 (quoting *FAIR,* 547 U.S. at 62).

The flaw in Plaintiffs' argument is highlighted by their efforts to analogize manufacturers' signatures on CMS agreements to voters' signatures on political petitions. *See* BMS Resp. at 33 (citing *John Doe No. 1 v. Reed*, 561 U.S. 186, 195 (2010)). Plaintiffs assert that both types of signatures carry the same expressive content. *Id.* That would doubtlessly come as a surprise to the voters who sign petitions to engage in the core First Amendment activity of political advocacy, not to open a new bank account or pay for a car. *See, e.g.*, *Reed*, 561 U.S. at 195 (noting that "the individual's signature" on a

petition "expresses [a] political view"). Notwithstanding their assertions to the contrary, Plaintiffs' categorical claim that the commercial agreements between them and CMS convey a "message" is nothing more than an unsupported assertion that all contracts are necessarily expressive speech.

By that logic, the Department of Defense would have to scrub every one of its contracts to ensure that those contracts do not use terms like "agree," "fair," or other terms that Plaintiffs view as objectionable. *Cf.* Cong. Resch. Serv., *Defense Primer: Depart of Defense Contractors* (Jan. 17, 2023), available at https://crsreports.congress.gov/product/pdf/IF/IF10600 (noting that in fiscal year 2021, "DOD obligated more money on federal contracts ($397 billion in current dollars) than the contract spending of all other government agencies combined"). That cannot be correct. After all, "the Supreme Court has long rejected the 'view that an apparently limitless variety of conduct can be labeled 'speech'" even when "'the person engaging in the conduct intends thereby to express an idea.'" *Nicopure*, 944 F.3d at 291 (quoting *United States v. O'Brien*, 391 U.S. 367, 376 (1968), citing *Barnes v. Glen Theatre, Inc.*, 501 U.S. 560, 570 (1991)). And Plaintiffs' "extraordinary argument, if accepted, would extend First Amendment protection to every commercial transaction"—contrary to the current view of the law. *Id.* at 291.

2. Plaintiffs' First Amendment concerns are all the more inapt given that participation in the Negotiation Program is a voluntary undertaking. *See supra* Section I. If manufacturers are truly concerned that their signing of an agreement to negotiate will be incorrectly perceived as their adoption of the government's message, they can simply decline to participate in the program. In this way too, there is no compulsion for manufacturers to say—or to be perceived as saying—anything at all.

Contrary to Plaintiffs' claims, viewing the Negotiation Program this way does not raise the specter of it being an unconstitutional condition. *See* Janssen Resp. at 38; BMS Resp. at 38-39. Even if the negotiation agreements raised First Amendment questions—which they do not, for all the reasons above—Congress is free to attach "conditions that define the limits of the government spending program." *Agency for Int'l Dev.*, 570 U.S. at 214-15. Here, of course, the program that Plaintiffs protest is the *negotiation* of prices. *See* 42 U.S.C. § 1320f-3(a). So, signing something termed an "agreement" after the completion of that negotiation—and promising to give Medicare beneficiaries the benefit of the agreed-upon price—is nothing more than "the activit[y] Congress wants to subsidize." *Agency for Int'l Dev.*, 570 U.S. at 214-15; *see also United States v. Am. Libr. Ass'n*, 539 U.S. 194, 211 (2003) ("Within broad limits, 'when the Government appropriates public funds to establish a program it is entitled to define the limits of that program.'" (quoting *Rust v. Sullivan,* 500 U.S. 173, 194 (1991)). No portion of the agreement that Plaintiffs protest (nor the IRA generally) purports to "regulate speech outside the contours of the [Negotiation] program" or places restrictions on the manufacturers themselves. *Agency for Int'l Dev.*, 570 U.S. at 214-15; *see also Rust*, 500 U.S. at 197 (explaining that the Court's "'unconstitutional conditions' cases involve situations in which the Government has placed a condition on the *recipient* of the subsidy . . . thus effectively prohibiting the recipient from engaging in the protected conduct outside the scope of the federally funded program"). As Plaintiffs do not deny, they are free to continue saying anything they want about the IRA, CMS, and the Negotiation Program—both in the course of negotiations and in public. So even if Plaintiffs were correct that the agreements are expressive, or that they "create the misimpression that

[manufacturers] consent[]" to the IRA, Plaintiffs would *still* be unable to establish that those agreements constitute an improper condition on the receipt of government funds. BMS Resp. at 40.

Indeed, Plaintiffs' objection to the agreements boils down to the claim that they dislike the Negotiation Program and do not want to be *perceived* as supporting it. *See id.* at 39-40. Put another way, Plaintiffs want to receive government money without the fear that some members of the public may conclude (plainly incorrectly) that Plaintiffs like how the government has made the money available. As a business model, this aspiration may be understandable. But "Congress is not required by the First Amendment to subsidize" Plaintiffs' preferred messaging. *Regan v. Tax'n With Representation of Wash.*, 461 U.S. 540, 546 (1983); *see also Am. Libr. Ass'n*, 539 U.S. at 212 ("'A refusal to fund protected activity, without more, cannot be equated with the imposition of a "penalty" on that activity.'" (quoting *Rust*, 500 U.S. at 193)); *see Regan*, 461 U.S. at 546 (dismissing "the notion that First Amendment rights are somehow not fully realized unless they are subsidized by the State." (citation omitted)).

Ultimately, if Plaintiffs fear that their publicity campaign against the IRA is insufficient, and fear that participating in the Negotiation Program puts them in conflict with their firmly held principles, they are free to withdraw from the program. *See Chamber*, 2023 WL 6378423, at *11. The IRA does not compel unwilling manufacturers to take—or be perceived as taking—the government's funds.

CONCLUSION

For these reasons, and those articulated in Defendants' opening brief, the Court should deny Plaintiffs' motion for summary judgment, grant Defendants' cross-motion, and enter judgment for Defendants on all claims.

Dated: December 22, 2023

Respectfully submitted,

BRIAN M. BOYNTON
Principal Deputy Assistant
Attorney General

MICHELLE R. BENNETT
Assistant Branch Director

/s/ Alexander V. Sverdlov
ALEXANDER V. SVERDLOV
CHRISTINE L. COOGLE
Trial Attorneys
STEPHEN M. PEZZI
Senior Trial Counsel
United States Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, NW
Washington, DC 20005
Tel: (202) 305-8550
Email: alexander.v.sverdlov@usdoj.gov

Counsel for Defendants