UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF CONNECTICUT

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., Plaintiff, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES *et al.*, Defendants.	No. 3:23-cv-1103-RNC

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

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INTRODUCTION

Plaintiff's response caricatures the Drug Price Negotiation Program as a coercive "price-setting" regime, in which manufacturers have no choice but to participate. Pl.'s Combined Resp. & Reply Br., ECF No. 92 at 1 (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 Congress chose not to exercise that kind of compulsive regulatory authority here. Instead, it adopted a more flexible approach.

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 healthcare 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 Department of Health and Human Services (HHS) 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, 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 Plaintiff Boehringer Ingelheim's (BI's) Fifth Amendment challenges. *See* Defs.' Mot. Sum. J. Br., ECF No. 48-1 at 19-33 (MSJ). Although manufacturers like BI 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.

As it did in its opening brief, BI continues to claim that the Negotiation Program should not be seen as voluntary because manufacturers face economic pressure to participate. But courts—including the Second Circuit—have uniformly rejected similar challenges to "federal statutory scheme[s] designed to control Medicare costs." *Garelick v. Sullivan*, 987 F.2d 913, 914 (2d Cir. 1993). And BI's attempts to evade this established framework not only misread the underlying legal authorities but also would rewrite decades of established law about Congress's spending powers. There is no basis to do so. Drug manufacturers may choose whether to participate in Medicare—but they do not have a constitutional right to unilaterally dictate how much the government spends on their drugs.

Even aside from this threshold defect, BI's Fifth Amendment claims are untenable. As Defendants previously explained, BI's theory that the Negotiation Program effects a physical taking of its property is irreconcilable with the text and structure of the Inflation Reduction Act (IRA). *See* MSJ at 25-30. Notwithstanding BI's 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, BI's physical-taking theory—the only taking theory it posits—has no foothold. And BI's related claim that the Negotiation Program violates the Due Process Clause ignores that BI has no protected property interest in its Medicare reimbursement rate.

BI gets no further with its First Amendment challenge. The company continues to insist that the agreements it signs with the Centers for Medicare & Medicaid Services (CMS) will force it to adopt the government's message. But that assertion is belied by the plain language and purpose of the agreements, which are purely commercial instruments, and which do not require manufacturers to express or adopt any viewpoint at all. A proper review of those agreements and their role within the Negotiation Program makes clear that the agreements are not expressive, and thus do not give rise to any First Amendment concerns. And a review of the IRA's language likewise makes clear that Congress exempted CMS from notice-and-comment requirements for the first few years of the Program—thus putting to rest BI's Administrative Procedure Act (APA) claim.

Disposing of all these claims leaves only BI's Eighth Amendment challenge to the IRA's excise tax. But BI's response fails to overcome the two justiciability barriers Defendants previously identified. First, as a constitutional matter, the claim is not redressable because BI filed this suit against HHS and CMS but *not* Treasury and the IRS—the only agencies empowered to enforce the tax provision. And although BI protests that HHS and CMS have a supporting role to play in connection with the tax, it offers no basis to conclude that enjoining HHS and CMS would redress any alleged tax-related harm. Second, BI's preemptive challenge to the excise tax is barred by the Anti-Injunction Act (AIA), 26 U.S.C. § 7421(a). BI does not dispute that, on its face, the AIA applies here, requiring BI to pay the tax and then press its constitutional claims in a refund suit—which it can do by paying the tax on a single sale of a single drug. BI nonetheless asks the Court to excuse it from having to comply with that requirement. The Court should reject that invitation because no exception to the AIA applies. In any event, BI's tax claim fails on the merits because the excise tax is not a "fine," let alone an "excessive" fine. BI still does not identify a single case in which a tax was held to be a "fine" under the Excessive Fines Clause. And even if the excise tax here were different, it would not be an unconstitutionally excessive fine for reasons BI fails to rebut.

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

ARGUMENT

I. THE NEGOTIATION PROGRAM IS VOLUNTARY

As much as Congress 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, and after negotiations. *Id.*; *see also* MSJ at 22-24 (detailing the exit options). That is fatal to BI's Fifth Amendment challenge. In the Second Circuit, as elsewhere, a "property owner must be *legally compelled* to engage in price-regulated activity for [those] regulations to" impugn a property interest that the Fifth Amendment protects. *Garelick*, 987 F.2d at 916 (emphasis added); *see also Baker Cnty. Med. Servs., Inc. v. U.S. Att'y Gen.*, 763 F.3d 1274, 1279 (11th Cir. 2014) (hospital cannot bring a takings challenge to "its rate of compensation in a regulated industry for an obligation it voluntarily undertook"). Because "there is no constitutional right (or requirement) to engage in business with the government" at all, Congress was free to make the Negotiation Program a condition of manufacturers' "completely voluntary" participation in Medicare and Medicaid. *Chamber*, 2023 WL 6378423, at *11.

Attempting to resist this result, BI presses a series of old and new objections to the choices Congress put before manufacturers. But BI's efforts to rewrite Congress's bargain misunderstand both the IRA and the underlying authorities. Indeed, BI's legal theory is inconsistent with decades of well-settled precedent about how the government can structure its funding programs. Accepting that theory would require the Court to unjustifiably, and radically, rewrite Spending Clause law.

A. **Manufacturers Are Not Legally Compelled to Participate in the Program**

BI begins by claiming that the Negotiation Program is legally involuntary because CMS's selection of BI's drug "forced" BI into the Program—and took the "decision whether to enter th[e] program[]" out of BI's hands. Resp. at 6-7. But this formulation simply ignores reality.

The IRA was enacted into law in August 2022 and provided that the first selection of drugs would occur by September 2023 based on the criteria that Congress established. *See* 42 U.S.C. § 1320f(d)(1). Manufacturers had no obligations under the Negotiation Program before October 2023. *See id.* § 1320f(d)(4). As Defendants explained in their opening brief, manufacturers of selected drugs that were unwilling to accept the Negotiation Program as a condition of Medicare participation for the 2023 plan year and beyond could have withdrawn from Medicare and Medicaid using procedures that CMS spelled out in its Revised Guidance—all while avoiding both the requirements of the Program and potential tax liability. *See* MSJ at 22-23; CMS, Revised Guidance at 33-34 (June 30, 2023), https://perma.cc/K6QB-C3MM (Revised Guidance) (providing that manufacturers of selected drugs that wish to withdraw from Medicare and Medicaid need only notify CMS of that intent "30 days in advance of the date that excise tax liability otherwise may begin to accrue").[1] Manufacturers that chose *not* to terminate their Medicare and Medicaid agreements did so with the understanding that—going forward—they would be accepting the Negotiation Program's requirements. *See generally* 42 U.S.C. § 1320f-3 (requiring the Secretary to negotiate prices). So manufacturers were never "legally compelled to enter the Program": the decision whether to participate was solely the manufacturers' to make. Resp. at 8.

As a legal matter, the Court need go no further. Manufacturers' ability to decide whether they want to continue participating in Medicare knowing that their drugs had been (or might in the future be) selected for negotiation places the Negotiation Program on all fours with other Medicare conditions—and is sufficient to render the Program fully voluntary under this Circuit's precedent. *See Garelick*, 987 F.2d at 916; *see also Whitney v. Heckler*, 780 F.2d 963, 972 (11th Cir. 1986) ("It is well established that government price regulation does not constitute a taking of property where the regulated group is not required to participate in the regulated industry."). Even if manufacturers are then "subject to the Program for a period of time," that is the natural consequence of the voluntary decision they made. Resp. at 8. Such "consequences . . . cannot be considered a constitutional violation." *Chamber*, 2023 WL 6378423, at *11 (citations omitted).

Because the withdrawal options spelled out in the Revised Guidance are favorable to manufacturers, there is neither any need nor any constitutional basis for this Court to consider BI's claims that those procedures do not align with CMS's statutory authority. *See Bond v. United States*, 564 U.S. 211, 225 (2011) (plaintiffs "have 'no standing to complain simply that their Government is violating the law'" (citation omitted)). But even if they were properly presented, BI's complaints would fail.

The exit options CMS articulated in its Guidance derive from statutory provisions authorizing the "Secretary [to] provide for termination of [the relevant] agreement . . . for a knowing and willful

[1] Similarly, manufacturers whose drugs were not selected in the first negotiation cycle could withdraw before the next round of drug selection. *See* 42 U.S.C. § 1395w-114a(b)(4)(B)(ii) (providing that any "manufacturer may terminate" the relevant agreement "for any reason," and that "if the termination occurs before January 30 of a plan year," it shall be effective "as of the day after the end of the plan year"); *id.* § 1395w-114c(b)(4)(B)(ii) (similar).

violation of the requirements of the agreement or *other good cause shown*." 42 U.S.C. § 1395w-114a(b)(4)(B)(i) (emphasis added); *id.* § 1395w-114c(b)(4)(B)(i) (same). BI asks this Court to read the phrase "other good cause shown" as limited to "'knowing and willful violations of the requirements of the agreements' and related malfeasance." Resp. at 8. Tellingly, BI does not volunteer what type of circumstance would be covered by that interpretation—likely because any example would emphasize that its construction would reduce the independent "good cause" clause to a nullity. Yet "one of the most basic interpretive canons" is that "'[a] statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant.'' *Corley v. United States*, 556 U.S. 303, 314 (2009) (quoting *Hibbs v. Winn*, 542 U.S. 88, 101 (2004)). And it is hard to see how a manufacturer indicating that it wishes to withdraw from its agreements early—which would be inconsistent with the agreements' terms—would not constitute "good cause shown" in this context, particularly when BI itself claims 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)).[2]

Further, BI cannot rebut the fact that—even under the more extended withdrawal timeline that BI concedes 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* MSJ at 23-24. After all, the IRA creates a *28-month* delay between when the first drugs are to be selected for negotiation and when any negotiated prices would take effect. *See id.* During that period, a manufacturer can indicate that it intends to withdraw from Medicare—and have that withdrawal take effect before it ever has to sell its drugs at any negotiated prices. *See* 42 U.S.C.

[2] BI makes a passing objection that CMS articulated the withdrawal options "[a]fter several manufacturers filed lawsuits." Resp. at 8. But the rush of some manufacturers to challenge the IRA even before CMS had finalized its Guidance—which the manufacturers knew was forthcoming—can hardly be laid at the feet of the agency. And BI does not deny that the Revised Guidance, which CMS promulgated pursuant to Congress's direction to "implement" the Negotiation Program, forms an authoritative statement of how the agency will conduct the first round of negotiations—and thus can be relied upon by manufacturers planning their business affairs.

§§ 1395w-114a(b)(4)(B)(ii), 1395w-114c(b)(4)(B)(ii). Indeed, manufacturers can notice their termination before, during, or after their negotiations with CMS—as late as January 2025. *Id.*

BI protests that this statutory timeframe does not resolve its concerns about aspects of the Negotiation Program that are currently ongoing—such as participation in the negotiation process and submission of data. Resp. at 9. Of course, if BI were truly concerned about these harms, it could have withdrawn before October 1, 2023—the statutory deadline by which manufacturers of selected drugs had to decide whether they were going to participate in negotiations. Or BI could withdraw *now*. The fact that BI has done neither highlights that—notwithstanding its protestations—BI's objections to the withdrawal timelines are a purely academic exercise.

In any event, BI's supposed harms are unavailing. The Supreme Court has found that being able to withdraw from a price-capped market with a "6 or 12 months" delay is sufficient to defeat a Fifth Amendment claim. *Yee v. City of Escondido*, 503 U.S. 519, 527-28 (1992). Even setting aside the Revised Guidance, BI could have provided notice of its withdrawal from Medicare and Medicaid by January 30 of this year and had that termination take effect by January 2025, squarely within that timeframe. That—along with all the other options available to manufacturers—is fatal to BI's legal-compulsion claim.

B. Economic Incentives Do Not Make the Negotiation Program Coercive

The absence of any legal compulsion to participate in the Negotiation Program requires BI to resort to the supposed *practical* difficulty that a manufacturer would face either in divesting its interest in a selected drug or withdrawing wholesale from Medicare and Medicaid. Resp. at 13-15. But, contrary to BI's repeated claims, the financial feasibility of these options has no bearing on whether the Negotiation Program is *legally* voluntary.

1. *Financial Hardship Does Not Render a Spending Clause Program Involuntary*

Decisions from the Second Circuit and elsewhere dictate that economic or other practical "hardship is not equivalent to legal compulsion for purposes of" a Fifth Amendment analysis, including in the Medicare context. *Garelick*, 987 F.2d at 917; *see also Baker Cnty.*, 763 F.3d at 1280 (explaining that "financial difficulties and perceived inequity" of withdrawing "does not diminish the underlying voluntariness of the Hospital's participation in Medicare"); *St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875 (7th Cir. 1983) (the "fact that practicalities may in some cases dictate participation does not make participation involuntary"). Even where "business realities" create "strong financial inducement to participate"—such as, for example, when Medicare or Medicaid provides the vast majority of a nursing home's revenue—courts have emphasized that the decision to participate in the program "is nonetheless voluntary." *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 Livingston Care Ctr., Inc. v. United States*, 934 F.2d 719, 720 (6th Cir. 1991) (explaining that "participation in the Medicare program is a voluntary undertaking" in the context of a nursing home). Drug manufacturers are no more dependent on federal funds than those facilities. *See, e.g.*, Resp. at 13 (claiming that the "Medicare and Medicaid market accounts for more than half of BI's net sales in the United States" (citation omitted)). So there is no basis for this Court to reach a different result.

Attempting to evade this precedent, BI repeats its prior argument that the Supreme Court's decision in *Horne* somehow overruled those cases and established that "[e]conomic compulsion is sufficient" to "establish a constitutional violation." Resp. at 9-10, 19. But as Defendants explained in their opening brief, *Horne* examined voluntariness in the context of a *regulatory* regime in which parties could avoid the government's property demand only by abandoning their business and "ceasing to" sell their raisins to *anyone*. *Horne*, 576 U.S. at 365 (citation omitted); *see also* Resp. at 12 (noting that plaintiffs in *Horne* would have to switch to selling "table grapes, juice, or wine"). In that context, the Court held that excusing a government's regulatory obligations by positing that the raisin growers were voluntarily participating in the market "proves too much" because exiting the business would deprive the owners of all economic use of its current products in which the owner has a "property right[]." *Horne*, 576 U.S. at 365 (citation omitted).

The same logic animated the other cases that BI cites in support of its financial-hardship coercion argument. *See* Resp. at 10-11; *Thompson v. Deal*, 92 F.2d 478 (D.C. Cir. 1937); *Union Pac. R.R. Co. v. Pub. Serv. Comm'n of Mo.*, 248 U.S. 67 (1918); *United States v. Butler*, 297 U.S. 1 (1936); *Carter v.*

Carter Coal Co., 298 U.S. 238 (1936).[3] As Defendants previously noted, plaintiffs in each of those cases were subject to *regulatory* regimes that put them to the choice of either foregoing their interest in selling goods to private buyers in the market or complying with the government's conditions. *See, e.g. Thompson*, 92 F.2d at 484 (regulatory conditions required plaintiffs "to limit the production of cotton" or to pay a tax); *Union Pac.*, 248 U.S. at 67 (plaintiff was subject to statutory prohibitions against issue of a bond unless the prohibition was waived by a state commission); *Butler*, 297 U.S. at 54 (regulatory scheme establishing limits on production of cotton); *Carter Coal*, 298 U.S. at 289 (analyzing statutory scheme regulating the production of coal and a tax "exacted as a penalty to compel compliance with the regulatory provisions of the act"). Thus, the "coercion by economic pressure" in *Butler*—a phrase BI tries to leverage, but which it notably quotes out of context—referred to a "*tax* [that] plays an indispensable part in the plan of *regulation*" involuntarily imposed on farmers. *Butler*, 297 U.S. at 59, 71, 74-75 (emphasis added); *see also Carter Coal*, 298 U.S. at 289 ("agreement . . . lack[ed] the essential element of consent" when it was "coerce[d]" by a "tax" imposed as part of regulatory regime). That is, coercion existed because, one way or another, the government's *regulatory* regime required the plaintiffs to surrender a protected property interest, be it in the form of money or goods.

But this kind of reasoning does not apply when Congress acts pursuant to its *spending* rather than regulatory powers and offers "federal funds, [if] 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). Unlike the raisins in *Horne* (or the cotton in *Thompson*), federal 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)); *see also Perkins v. Lukens Steel Co.*, 310 U.S. 113, 127 (1940) (government has authority to "determine those with whom it will deal"). And, by setting a condition on how those funds may be paid, the government is neither restricting entities from

[3] Notably, BI has seemingly abandoned its reliance on *Valancourt Books, LLC v. Garland,* 82 F.4th 1222 (D.C. Cir. 2023). Defendants already explained why the logic of that case is inapplicable here. MSJ at 26. But the same is true for the other cases BI cites.

engaging in interstate commerce nor burdening their ability to sell goods to private buyers. Simply put, the government's offer is voluntary because entities are free to decline it and continue their business with *every other* player in the market. This is so even when the government has more resources than private entities or where it serves "as the gatekeeper" to a lucrative profit stream. Resp. at 17.

Given this distinction—between demands that imperil property interests in the context of a regulatory regime and conditions that Congress sets for voluntary participation in lucrative federal spending programs—it is not surprising that courts have never looked to plaintiffs' financial circumstances to evaluate the voluntariness of Medicare or Medicaid conditions. *See, e.g.*, *Baker Cnty.*, 763 F.3d at 1279-80 (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. v. Harvey*, 575 F.3d 121, 129-30 (1st Cir. 2009); *Burditt v. HHS*, 934 F.2d 1362, 1376 (5th Cir. 1991). Rather, courts have consistently recognized that conditions the government attaches to Medicare and Medicaid participation are inherently "voluntary" because there is no "right (or requirement)" to conduct business with the government in the first instance. *Chamber*, 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.").[4] And this has not changed since *Horne*. Indeed, as Defendants observed in their opening brief, some of the cases rejecting Fifth Amendment challenges to Medicare conditions postdate *Horne*—and correctly find it inapplicable. *See, e.g., 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). By contrast, BI fails to identify a *single* case applying the reasoning of *Horne* to find Medicare conditions involuntary.

In a last-ditch effort to avoid this well-established precedent, BI protests that *Garelick* and other decisions that rejected Fifth Amendment challenges to Medicare conditions on grounds of

[4] BI protests that the First Circuit in *Franklin Memorial Hospital* analyzed whether a condition that a state attached to its healthcare payments was voluntary based on whether the state's laws created a "coercive financial incentive." Resp. at 20 (quoting 575 F.3d at 130). This misstates the analysis. The court found there could be "no coercive financial incentive to participate" under the relevant regulations. *Franklin Mem'l Hosp.*, 575 F.3d at 130. The court therefore had no occasion to opine on whether "financial incentive[s]" could make a program involuntary.

voluntariness did not involve conditions like the ones here, which BI claims are imposed on "some, but not all, providers." Resp. at 18-19. To be clear, the Negotiation Program does not do that either: although only a certain number of drugs are *selected* each year, *all* drug manufacturers that choose to participate in Medicare do so in recognition that they are subject to the Program's selection criteria—which may or may not cause their drugs to be chosen in a particular year. *See generally* 42 U.S.C. § 1320f-1 (setting forth the selection criteria). More fundamentally, however, BI fails to understand the reasoning of the cases it seeks to distinguish. The courts in those cases rejected constitutional challenges not because of anything specific to the challenged Medicare rates but rather because they found those rates are part of programs that do not *legally* compel participation in the first instance. *See, e.g.*, *Garelick*, 987 F.2d at 917; *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,* 742 F.2d at 446)); *see also Baker Cnty.*, 763 F.3d at 1279. In doing so, those courts expressly rejected BI's contention that a condition cannot be voluntary if a plaintiff's business model makes it financially impractical to decline. *See, e.g.*, *Minn. Ass'n of Health Care Facilities*, 742 F.2d at 446.

In short, BI has failed to demonstrate that the law established in the Second Circuit and beyond is inapplicable to the Negotiation Program. BI's economic-coercion theory thus fails.

2. *"Coercion" Does Not Apply to the Government Purchasing Goods in the Market*

Even setting aside established precedent, BI's suggestion that "economic compulsion" can render the federal government's offer to purchase goods or services "involuntary" is a radical concept that fails on its own terms. Resp. at 9.

First, outside the context of regulatory conditions, BI's only authority for its economic-coercion theory remains the Supreme Court's decision in *National Federation of Independent Business v. Sebelius*, 567 U.S. 519 (2012) (*NFIB*). *See* Resp. at 10-11, 13. As Defendants previously explained, that decision is inapposite because federalism was the animating concern of the Court's "coercion" inquiry. *NFIB*, 567 U.S. at 577 (plurality opinion) (explaining the need to protect "the status of the States as independent sovereigns in our federal system"). That inquiry was derived exclusively from cases addressing how principles of federalism limit Congress's authority to attach funding conditions on grants to States—and, in performing that inquiry, the lead opinion did not cite to any Spending Clause decision concerning private parties. *See id.* at 579-81 (discussing, *inter alia*, *South Dakota v. Dole*, 483 U.S. 203 (1987)). Not surprisingly then, the Supreme Court has also not relied on *NFIB*'s "coercion" test when analyzing the application of Spending Clause legislation to private parties. The very next year after deciding *NFIB*, for instance, the Court decided *Agency for International Development v. Alliance for Open Society International, Inc.*, which considered whether the First Amendment permitted the government "to leverage funding to regulate speech outside the contours of the federal program" at issue. 570 U.S. 205, 214-15 (2013). More recently, the Court decided *Cummings* which, as BI notes, discussed the "voluntar[iness]" of terms imposed by Spending Clause legislation in the context of identifying remedies available to private parties. 596 U.S. at 219 (quotes and citations omitted). In neither of those cases did the Court so much as cite *NFIB*, much less employ its analysis. *Agency for Int'l Dev.*, 570 U.S. at 214; *Cummings*, 596 U.S. at 219. The same result should hold here.

Second, and even more fundamentally, 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. Or. Dep't of Agric.*, 553 U.S. 591, 598 (2008) (quoting *Cafeteria & Rest. 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, 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."). 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 Consciousness, Inc. v. Lee*, 505 U.S. 672, 678 (1992) (emphasis added); *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. & Constr. Trades Dep't, AFL-CIO v. Allbaugh*, 295 F.3d 28, 35 (D.C. Cir. 2002). 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.

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. & Constr. 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). BI fails to acknowledge those cases. *See* Resp. at 17-18. But they make clear 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 BI's claims, these distinctions do not vanish merely because the government can also regulate the relevant market (in often-unrelated ways). Resp. at 17-18. As the authority Defendants previously identified makes clear—and as BI fails 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"). Imposing taxes or restrictions to "regulate[] the [] market is not sufficient to preclude [the State's] 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 efficient and equitable federal procurement of high-cost prescription drugs. MSJ at 5-6. These steps to limit government outlays on selected drugs are 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 government expenditures 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.").

Third, and finally, BI's economic-coercion argument proves too much. According to BI, what makes the Negotiation Program "coercive" is the fact that it puts manufacturers to the choice of accepting Congress's condition or forgoing Medicare and Medicaid funding generally, which accounts for a large portion of BI's "net sales." Resp. at 13-14 (citation omitted). But the same could be said about numerous conditions that have long been understood as voluntary, not coercive.

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"). BI's argument would 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).

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]articipation 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 to have "effective governing body"); *id.* § 482.21 (requiring hospitals to "maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement 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. All such conditions would be "coercive" under BI's logic.

Fortunately, the Supreme Court has recently made clear that it does not view things this way. As Defendants noted 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. *Biden v. Missouri*, 595 U.S. 87, 94 (2022). 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.* As Defendants explained, MSJ at 29, the Court did this even in the face of the challengers raising a "coercion" argument similar to the one BI presents here. *See Becerra v. Louisiana*, Nos. 21A240, 21A241, Resp. to Stay App., 2021 WL 8939385 at *27 (Dec. 30, 2021).

BI does not address the *Missouri* decision. And it does not even attempt to wrestle with the logical outcomes of its economic-coercion theory. But there is a reason no court has embraced such a theory. If accepted, it would require rewriting a mass of Spending Clause precedent. BI does not come close to justifying that result.

C. The Negotiation Program Does Not Violate the Unconstitutional Conditions Doctrine

Finally, BI cannot transform the practical inconvenience of divesting its drug or withdrawing from Medicare and Medicaid into a Fifth Amendment problem merely by invoking the phrase "unconstitutional conditions doctrine." Resp. at 35-36.

1. As Defendants explained in their opening brief—and as the cases BI itself cites demonstrate—the unconstitutional-conditions doctrine comes into play only when a plaintiff can show that the government seeks waiver of a concrete constitutional right (such as a vested property interest) in exchange for a separate discretionary benefit. *See, e.g.*, *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 612 (2013) (explaining that the "predicate for any unconstitutional conditions claim is that the" plaintiff have a protected constitutional right such that the "government could not have constitutionally ordered the person asserting the claim to do what it attempted to pressure that person into doing"); *Bd. of Comm'rs v. Umbehr*, 518 U.S. 668, 674–75 (1996) (analyzing whether termination of a government contractor impinged a separate First Amendment right); *R.S.W.W., Inc. v. City of Keego Harbor*, 397 F.3d 427, 434 (6th Cir. 2005) (explaining that while the unconstitutional conditions doctrine can "prohibit the government from conditioning benefits on a citizen's agreement to surrender due process rights," the plaintiff must first establish an underlying property interest). As the Second Circuit explained in a case BI invokes, *O'Connor v. Pierson*, to "determine whether the [government] violated [plaintiff's] constitutional rights by insisting on the [condition], we first identify the right at stake." 426 F.3d 187, 201 (2d Cir. 2005). Applying this framework in the context of the Fifth

Amendment, the Second Circuit in *O'Connor* considered whether a school board could condition a teacher's return to work on his waiver of privacy over his medical records only *after* it concluded that the privacy of medical records was a protected interest—one that stood wholly apart from the government benefit (resumption of duties) the teacher was trying to obtain. *Id.*

Here, however, there is no such distinction between the property right being claimed and the benefit. In BI's formulation, Congress allegedly infringed on BI's due process right because it didn't provide adequate procedures for setting the price of a selected drug as part of its overall offer to continue reimbursing manufacturers' *other* products. *See* Resp. at 37. But BI has no underlying property interest in *any* of those reimbursement rates. *See infra* Section II.B. So BI's complaint is not that the government is leveraging a benefit against a cognizable constitutional right; rather, it is that the government's offer is not sufficiently lucrative (though still lucrative enough that it is costly to decline). As Defendants previously observed, an unconstitutional-conditions theory cannot be bootstrapped in this way. MSJ at 31. Were it otherwise, plaintiffs dissatisfied with their rate of Medicare reimbursement could *always* challenge that rate as an unconstitutional condition. That is not the law. *See, e.g.*, *Garelick*, 987 F.2d at 917 (noting that courts have uniformly rejected Fifth Amendment challenges "to Medicare price regulations"); *Baptist Hosp. E. v. Sec'y of HHS*, 802 F.2d 860, 869 (6th Cir. 1986) (rejecting due process challenge to Medicare reimbursement rates on voluntariness grounds).

The analogy to government contracts Defendants offered in their opening brief is sound: by failing to identify an interest *apart* from the very benefit BI is seeking, BI is akin to a sophisticated defense contractor asking a court to ensure that the contract it signed with the Pentagon offers sufficient compensation to avoid a Fifth Amendment taking. *Contra* Resp. at 37. Courts are not in the business of conducting this kind of oversight. *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)).

2. BI fares no better in its attempt to have the Court evaluate the Negotiation Program under the "proportionality test" of *Koontz*. Resp. at 38-39. As Defendants previously explained, the

Supreme Court has—time and again—explicitly rejected extending the "rough proportionality" standard BI advocates beyond "the special context of [] land-use decisions conditioning approval of development on the dedication of property to public use." *City of Monterey v. Del Monte Dunes at Monterey, Ltd.*, 526 U.S. 687, 702-03 (1999); *see also Koontz*, 570 U.S. at 604-05 (discussing the doctrine); *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 538 (2005) (noting the "special context of land-use exactions"). BI protests this limitation—but it cannot overcome the Supreme Court's repeated (and recent) holdings. *See* Resp. at 38. Nor can BI establish that the "realities of the [land-use] permitting process," which leverage applicants' vested property interests, have anything in common with Congress setting the terms on which the government will pay out its own funds. *Koontz*, 570 U.S. at 604-05.

BI may be unhappy that Congress created the Negotiation Program as a condition of future Medicare and Medicaid participation. But BI's dissatisfaction does not mean the condition is unconstitutional. 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). BI cannot claim that having to decide whether to continue participating in those federal programs under a new condition puts manufacturers to an improper choice.

*   *   *

Throughout its briefing, BI has failed to cite a single case finding conditions on Medicare participation to violate the Fifth Amendment. That is not surprising. Courts have, for decades, rejected such challenges. *See, e.g.*, *Garelick*, 987 F.2d at 916; *Baker Cnty.*, 763 F.3d at 1276, 1279-80 (collecting cases); *Chamber*, 2023 WL 6378423, at *11. This Court should do the same.

II. Even if it Were Not Voluntary, the Negotiation Program Would Not Violate the Fifth Amendment

Even setting aside the voluntary nature of the Negotiation Program, BI's response still fails to establish any Fifth Amendment problem.

A. The Negotiation Program Does Not Give Rise to a Physical Taking

BI does 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, BI's response confirms that its only Takings Clause argument is that the Negotiation Program effects a "physical taking" because it "gives third parties the right 'to literally take access' to BI's drugs at the Government's price." Resp. at 25-26. This theory fails outright, however, because—even if participation in Medicare were not voluntary—the IRA does not require BI to sell its drugs or otherwise give "access" to them "against its will." *Id.* at 25.

1. Start with the plain text of the statute, which demonstrates that Congress did not compel manufacturers to sell any drugs in the first instance. 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.* If Congress wanted to mandate physical access to *drugs*, it would have done so—but 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 Tex. 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 id.* at 125-29 (sections 40.4 and 40.5), *id.* at 171-72 (discussing what happens if manufacturer fails "to ensure access to a price that is 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 is that if, after signing the agreement with CMS, BI were to refuse to sell Jardiance to Medicare beneficiaries, that *would not be prohibited* by the IRA—and would subject BI to no "penalty." Resp. at 27. BI cites no provision of the IRA that forces sales of manufacturers' drugs against their will. And, in the absence of such compulsion, BI's physical-taking theory collapses. *See, e.g.*, *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 149 (2021) ("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 beneficiaries may (or may not) ultimately have an "economic impact" on manufacturers—but it falls squarely 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.

Unable to accept this result, BI grasps for signs that the statute works differently from how Congress drafted it and how CMS intends to implement it. In particular, BI cites to a provision regulating when insurance plans contracting with Medicare must include the selected 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). Contrary to BI's suggestion, that statutory provision does not require manufacturers to *make* sales—it merely states that Part D insurance plans shall cover the drugs subject to a price agreement that manufacturers do, in fact, agree to sell. *See id.* 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.

BI makes a passing suggestion that Defendants' filings in this case and in others have somehow conceded the contrary interpretation on which BI's takings theory hinges. Resp. at 27 n.13. Defendants did nothing of the kind: an accurate account of the statements BI quotes and the context in which they appear confirms that Defendants have never departed from the statutory language. *See id.* (quoting Defendants' briefs); *see also* IRS Notice No. 2023-52 at 2 (Aug. 4, 2023), https://perma.cc/B9JZ-ZG7P (stating that manufacturers "agree[ing] to an MFP commit to provide access to selected drugs *at the negotiated prices*" (emphasis added)) (IRS Notice). And it hardly needs saying that Defendants cannot amend the U.S. Code through a litigation brief.

2. Separately, BI still fails 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* Resp. at 27-28. Indeed, BI 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.[5] *Id.* at 28 (quoting *Duquesne Light Co. v. Barasch*, 488 U.S. 299, 307 (1989)); *Duquesne Light*, 488 U.S. at 307 (explaining that what creates the "partly public, partly private status of utility property" is the fact that those private "assets are employed in the public interest to provide consumers of the State with electric power"). 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 ratesetting is raised by

[5] BI's observation that, unlike utilities, its property is "purely private" thus misses the point. Resp. at 28 (emphasis removed). The reason BI's drugs are private is precisely because manufacturers are *not* ordered to sell their drugs. If BI were compelled to make those sales—as BI seems to believe—that *would* make their property partially public, and BI would stand on roughly equal footing with utilities. Such a transformation would, of course, not "skirt constitutional scrutiny," Resp. at 28, because public utilities have their own forms of constitutional protection that reflect their unique "partly public, partly private" nature, *Duquesne Light*, 488 U.S. at 307.

rates, not methods."). 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. The same is true here.

Ultimately, however, because Congress did *not* obligate manufacturers to surrender their drugs, the Negotiation Program is (at most) a form of price regulation—except that it regulates only 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."). BI's physical takings theory thus fails.

B. The Negotiation Program Raises No Due Process Concerns

BI's response likewise cannot rescue its due process theory. BI treats the viability of that theory as depending solely on whether its participation in the Negotiation Program is voluntary. Resp. at 21-23. But the other threshold "inquiry in every due process challenge is whether the plaintiff has been deprived of a *protected interest* in property or liberty." *Am. Mfrs. Mut. Ins. Co. v. Sullivan*, 526 U.S. 40, 59 (1999) (citing *Mathews v. Eldridge*, 424 U.S. 319, 332 (1976)) (emphasis added). And, regardless of whether the Program is voluntary, BI fails to establish any protected property interest at stake here.

1. For all the reasons discussed in the prior subsection, the Negotiation Program does not impinge on manufacturers' interest in their physical drugs because it does not compel sales of any drug in the first instance. *See supra* Section II.A. BI thus cannot point to its interest in those drugs as the relevant interest. Resp. at 21. Rather, what is at stake with the Negotiation Program is the potential future rate of reimbursement that a manufacturer can receive for a selected drug. Yet BI no longer even *attempts* to claim that its rate of Medicare reimbursement can qualify as a protected interest. *See id.* at 21-22. And rightly so. As courts have repeatedly emphasized, "providers do not have a property interest in a particular reimbursement rate." *Managed Pharmacy Care v. Sebelius*, 716 F.3d 1235, 1252 (9th Cir. 2013); *see also 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"); *see also Shah*, 920 F.3d at 998 (continued "participation in the federal Medicare reimbursement program is not a property interest"). This rule reflects the well-settled principle that it is Congress, not private parties, that has "control over the use of federal funds." *NFIB*, 567 U.S. at 579; *see also Sabri*, 541 U.S. at 608.

BI's tacit concession of this point is fatal, however, because without a protected property interest in the rate of Medicare reimbursement its due process theory collapses. Simply put, BI cannot claim that the procedures for setting its rate of reimbursement are inadequate when it has no protected interest in that rate. As courts have repeatedly explained, due process protections do not exist in the abstract: "[o]nly after finding the deprivation of a protected interest do [courts] look to see if the [challenged] procedures comport with due process." *Am. Mfrs. Mut. Ins.*, 526 U.S. at 59. BI identifies no case requiring that the government follow any particular procedures when there is no underlying property or liberty right at stake. *See* Resp. at 22-23. And precedent dictates otherwise. *See, e.g.*, *Bd. of Regents of State Colls. v. Roth*, 408 U.S. 564, 578 (1972) (untenured professor, whose appointment was for only one year, did not possess a protected property interest in continued employment, and university was therefore not required "to give him a hearing when they declined to renew his contract of employment").

2. BI cannot overcome this central flaw in its due process theory by pointing to a supposed property interest in the business data that it would submit to CMS. Resp. at 23-24. As BI itself notes, an intrusion on a protected property interest in data can occur *either* when data is improperly disclosed *or* when the government uses that data in a manner "contrary to the owner's expectations." *Id.* at 24; *see also Monsanto*, 467 U.S. at 1011, 1013-14 (applying this test). Thus, in *Monsanto*, the Supreme Court considered whether the petitioner was "aware of the conditions under which the data [were] submitted" to determine whether the petitioner's property interest had been infringed. *Id.* at 1007.[6] But BI does not suggest that CMS will improperly disclose trade secrets—and both the IRA and the Revised Guidance expressly assure that CMS will not. *See, e.g.*, Revised Guidance at 33 ("CMS will

[6] BI protests in a footnote that *Monsanto* applied this test in the context of a takings, rather than a due process, claim. Resp. at 24 n.11. But BI identifies no authority to suggest that the test for whether a property right exists is different depending on which clause of the Fifth Amendment the court is applying. *See id.*

protect the confidentiality of any proprietary information from Primary Manufacturers or Secondary Manufacturers . . . as required under section 1193(c) of the Act and other applicable law."); *id.* at 123 ("CMS will implement a confidentiality policy that is consistent with existing federal requirements for protecting proprietary information[.]"). And, as Defendants explained, manufacturers have long disclosed confidential data to CMS for purposes of CMS calculating reimbursements, so they cannot claim that the submission of data runs contrary to their expectations. *See, e.g.*, 42 U.S.C. § 1396r-8(b)(3) (requiring participating manufacturers to report drug pricing data).

Even more fundamentally, BI cannot point to its *data* as the relevant interest because—as Defendants previously noted—the procedures BI has challenged as inadequate in this case relate to the *prices* that the IRA authorizes CMS to negotiate, rather than the submission of data. *See, e.g.*, Resp. at 21 (claiming that "[w]hen the Government sets *prices*, it must provide the procedural safeguards" (emphasis added)). Attempting to overcome this mismatch, BI asserts that it has an interest in withholding its business data from the government to ensure that the government does not use that information "to undermine BI's interests" during price negotiations. *Id.* at 24. But again, the establishment of a *price*—with or without BI's desired procedures—does not impinge on BI's interest in its *data*. And further processes for protecting BI's *data* would not limit CMS's "discretion" to negotiate a price. *Id.* at 21. So BI's complaints about lack of procedures for data submission cannot form the basis for the type of due process claim it presses. *See, e.g.*, *Mathews*, 424 U.S. at 334-35 (explaining that, in a due process challenge, the plaintiff must establish "the risk of an erroneous deprivation of such interest through the procedures used," and "the probable value, if any, of additional or substitute procedural safeguards").

* * *

The IRA does not infringe on BI's interests in its physical drugs and BI has no protected property interest in its rate of Medicare reimbursement. BI's Fifth Amendment takings and due process claims thus fail for those independent reasons.

III. The Negotiation Program Does Not Violate the First Amendment

BI's First Amendment arguments likewise repeat the same conceptual errors that animated BI's opening brief. In particular, BI continues to assert that signing agreements with CMS is a form of expression that it is "compel[led]" to undertake. Resp. at 28. But that is not true.

A. As a starting point, BI's speculation about the agreements' supposed purpose—which BI claims is "to provide support for the Government's preferred narrative" and "tap into a politically popular concept," *id.* at 29, 35—fails to overcome the reality that the agreements are purely commercial arrangements. 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. Healthcare providers and other entities execute similar agreements to memorialize their acceptance of the terms for participation across a range of federal healthcare programs. *See, e.g.*, 42 U.S.C. §§ 1395cc, 1396r-8(a)-(b), 1395w-112(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/U69K-MTJR. Contrary to BI's insistence, such agreements are "not directed at the communication of information" about the signatories' views 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 these agreements is thus "plainly incidental to the . . . regulation of conduct" that the agreements govern: namely, the establishment of future prices that the government will pay for drugs. *Rumsfeld 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). Put another way, the only thing these agreements regulate are the actual *prices*, and the words used in the agreements are merely a means by which that regulation of prices 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 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."); *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.").

Notably, BI does not even acknowledge that the agreements it protests have *any* commercial purpose. *See generally* Resp. at 29-32. Instead, it continues 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. *Id.* at 29. Of course, the agreement itself includes an explicit disclaimer to the contrary—precisely to avoid the kind of misunderstanding Plaintiffs seem intent on creating. *See* CMS, Medicare Drug Price Negotiation Program Agreement ("Template Agreement"), https://perma.cc/6VG4-KKF6. Contrary to Plaintiffs' cramped reading, the point of that disclaimer is not to "cure" some defect in the agreement or statute by "disclaim[ing]" the otherwise expressive content of the agreement. Resp. at 33-34. Rather, the point is to underscore the 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."

It is this absence of expressive content in the agreement that distinguishes the IRA from the precedent BI cites in its response. *See, e.g.*, *Expressions Hair Design*, 581 U.S. at 47 (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" (emphasis added)); *Sorrell*, 564 U.S. at 567 (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"); *Tinker v. Des Moines Indep. Cmty. Sch. Dist.*, 393 U.S. 503, 508 (1969) (students wearing armbands was "a silent, passive expression of opinion"); *Texas v. Johnson*, 491 U.S. 397, 404-405 (1989) (evaluating challenge to statute prohibiting flag burning in light of "decisions recognizing the communicative nature of conduct relating to flags" and accepting as undisputed that respondent's "conduct was expressive"). Indeed, BI identifies no case in which a court found that the words of a contract are expressive merely because they were written and could be incorrectly understood as conveying a message. That is not surprising. 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 BI's argument is only highlighted by its efforts to analogize manufacturers' signatures on agreements with CMS to voters' signatures on political petitions and to students' wearing of armbands to protest the Vietnam War. *See* Resp. at 31-32 (citing *John Doe No. 1 v. Reed*, 561 U.S. 186, 195 (2010); *Tinker*, 393 U.S. at 505). BI asserts that its signing of an agreement carries the same expressive content as those activities. *Id.* That would doubtlessly come as a surprise to the plaintiffs in those cases—who signed petitions and expressed unpopular viewpoints not to open a new bank account or pay for a car but rather to engage in core First Amendment activity of political expression. *See, e.g.*, *Reed*, 561 U.S. at 195 (noting that "the individual's signature" on a petition "expresses [a] political view"). Ultimately, BI's categorical claims that its commercial agreements with CMS convey the same type of "message" is nothing more than an unsupported assertion that all contracts are necessarily expressive speech. Resp. at 35.

BI tries to distance itself from this result by claiming that the "IRA's statutory scheme is unique." Resp. at 35. But BI's objection is to the statute's use of specific terms like "agree," "fair," or other terms that it views as potentially expressive. *Id.* And BI offers no principled reason why the same logic wouldn't require the Department of Defense to scrub every one of its contracts to ensure that they never employ those terms, or others like them. *See id.*; *Cf.* Cong. Resch. Serv., *Defense Primer: Dep't of Defense Contractors* (Jan. 17, 2023), 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, of course, is not the law. As the D.C. Circuit has observed, "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)). BI's "extraordinary argument, if accepted, would extend First Amendment protection to every commercial transaction"—contrary to current law. *Id.*

B. BI's 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 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 BI's claims, viewing the Negotiation Program this way does not raise the specter of it being an unconstitutional condition. *See* Resp. at 37-39. 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. 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, Inc.*, 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)).

Indeed, no portion of the agreement that BI protests (nor the IRA generally) purports to "regulate speech outside the contours of the [Negotiation] [P]rogram" 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"). BI does not deny that manufacturers are free to continue saying anything they want about the IRA, CMS, or the Negotiation Program—both in the course of negotiations and in public. So even if BI were correct that the agreements are expressive, BI would *still* be unable to establish that they attach an improper condition on government funds.

In the end, BI's objection to the agreements boils down to the claim that it dislikes the Negotiation Program and does not want to be perceived as supporting it. *See* Resp. at 29. But BI remains free to express its viewpoint—as it has. And "Congress is not required by the First Amendment to subsidize" BI's 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)). If BI fears that participating in the Negotiation Program puts it in conflict with its firmly held principles, it is free to withdraw from the program. *See Chamber*, 2023 WL 6378423, at *11. The IRA does not compel unwilling manufacturers to take the government's funds.

IV. BI's APA Challenge Fails

BI's APA arguments are no more successful. BI centers its response on disputing whether manufacturers had actual notice of—and opportunity to comment on—the "text of" the manufacturer agreements. *See* Resp. at 45-46. This effort is doomed at the outset because, as Defendants previously explained, no such notice or opportunities for comment were required. MSJ at 52-54. Congress expressly authorized CMS to dispense with notice-and-comment requirements when it directed CMS to "implement [the Negotiation Program] for 2026, 2027, and 2028 by program instruction or other forms of program guidance," § 11001(c), 136 Stat. at 1854. So, for the current negotiation cycle, CMS was not required to provide manufacturers any comment opportunities at all.

Confining its response to one conclusory sentence accompanied by a half-page footnote, BI claims that the IRA is not sufficiently clear about Congress's intent to abrogate the notice-and-comment provisions of the APA and the Medicare Act—and that manufacturer agreements should be excluded from that abrogation. Resp. at 44 & n.25. Neither assertion is tenable. BI's argument is built on the observation that, when directing CMS to proceed through guidance, Congress did not use the specific phrase "[n]otwithstanding any other provision of law." *Id.* But the Supreme Court has held that Congress need not "use any 'magical passwords' to exempt a later statute from the" APA's background procedural requirements. *Dorsey v. United States*, 567 U.S. 260, 274 (2012) (citation omitted). Rather, the requisite intent can be found when, for example, Congress "specifie[s] procedures . . . that cannot be reconciled with the notice and comment requirements of" the APA or the Medicare Act. *Asiana Airlines v. FAA*, 134 F.3d 393, 398 (D.C. Cir. 1998).

BI fails to address this standard. *See* Resp. at 44 & n.25. Yet it is controlling here. As Defendants have explained, Congress expressly instructed CMS to proceed outside of normal notice-and-comment procedures in the Negotiation Program's early years because lawmakers recognized that CMS was required to make numerous determinations on a tight timeframe—timeframes which did not allow for traditional notice-and-comment rulemaking. MSJ at 53-54. *Cf. Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1816 (2019) (recognizing Congressional authority to alter notice-and-comment requirements for rulemaking under the Medicare Act). BI provides no basis to believe that manufacturer *agreements* should be treated any differently than other elements of the program that Congress authorized CMS to "implement . . . by program instruction or other forms of program guidance." IRA, § 11001(c), 136 Stat. at 1854. Indeed, there is no basis to distinguish the two.[7]

V. THE COURT LACKS JURISDICTION OVER BI'S EXCISE-TAX CLAIM

BI's response likewise fails to overcome two, independent jurisdictional bars that prevent the Court from reaching the merits of its excise-tax claim: the redressability requirement of Article III standing and the Anti-Injunction Act. As to the former, BI does not explain how the Court can

[7] In any event, CMS in fact did provide opportunity to comment on the contents of the agreement, *see* Revised Guidance at 30, and BI chose not to avail itself of this opportunity, *see* MSJ at 55 n.14. Neither the APA nor the Medicare Act would require anything more, even if the IRA hadn't prescribed different procedures. Moreover, the agreements do not impose any substantive requirements apart from what is stated in the Revised Guidance, which BI (apparently) recognizes was validly promulgated. The particular details of the agreements that BI now protests (such as the disclaimer making clear that terms of art are not used in a colloquial sense) are clarifying points that do not alter manufacturers' legal obligations. Revised Guidance at 30; *see generally* MSJ at 54-55.

redress its alleged tax-related injuries by enjoining only HHS and CMS—but not Treasury and the IRS—from enforcing § 5000D of the Internal Revenue Code. BI's redressability problem is particularly pronounced here where enjoining HHS and CMS would likely exacerbate—not alleviate—a manufacturer's tax liability. As to the latter, BI does not dispute that the AIA, on its face, precludes its tax claim. And BI's attempt to contort and broaden the two narrow exceptions to that bar on preemptive challenges to tax provisions should be rejected.

A. **BI's Excise-Tax Claim is Not Redressable**

BI does not dispute that (setting aside the AIA) it would have been proper to sue Treasury and the IRS in connection with its challenge to the enforcement of § 5000D. Similarly, BI does not dispute that Treasury and the IRS are the only agencies empowered to assess and collect the excise tax. Accordingly, enjoining HHS and CMS—but not Treasury and the IRS—would not redress BI's tax-related injuries, and BI therefore lacks standing to press its excise-tax claim. *See* MSJ at 10-12.

In response, BI offers three reasons to disregard its failure to bring its tax challenge against the agencies that administer the tax code. *See* Resp. at 40. None of them establishes that BI has standing to pursue its tax claim against HHS and CMS.

First, BI misstates the statutory role of HHS in connection with the excise tax. BI asserts that the excise tax "can only be imposed after HHS" shares the information described in 42 U.S.C. § 1320f-5(a)(6). Resp. at 40. That is incorrect. Section 5000D of the Internal Revenue Code establishes that the excise tax accrues for manufacturers, producers, and importers of designated drugs that choose not to sign a negotiation agreement or to agree to a maximum fair price—without any action by HHS or CMS. 26 U.S.C. § 5000D. The excise tax is "imposed on the sale by the manufacturer, producer, or importer of any designated drug during a day described in subsection (b)." *Id.* § 5000D(a). Subsection (b) then defines the periods during which the tax is assessed. *Id.* § 5000D(b). For example, for initial price applicability year 2026, the tax is imposed beginning on October 2, 2023, and "*ending* on the earlier of" "the first date on which the manufacturer of such designated drug has in place [a negotiation agreement]" or "the date that the [HHS Secretary]" determines the standards for deselection found in 42 U.S.C. § 1320f-1(c) have been satisfied. 26 U.S.C. § 5000D(b)(1) (emphasis added);

see also 42 U.S.C. § 1320f-1(c) (describing deselection standards). The tax is also imposed, for initial price applicability year 2026, beginning on August 2, 2024, and "*ending* on the earlier of" "the first date on which the manufacturer of such designated drug and the [HHS Secretary] have agreed to a maximum fair price" or "the date that the Secretary of Health and Human Services" determines the standards for deselection have been satisfied. 26 U.S.C. § 5000D(b)(2) (emphasis added). For each of these periods, *see id.* § 5000D(b)(1), (2), the HHS Secretary may play a role, but that role is to make determinations that would stop—not start—accrual of the excise tax.

Section 1320f-5(a)(6) does not make HHS responsible for assessing the excise tax—or even necessary for the IRS's assessment of it. That section states that HHS is empowered to "carry out" various "administrative duties," including sharing "such information as is necessary to determine the tax imposed by [§] 5000D." 42 U.S.C. §§ 1320f(a)(4), 1320f-5(a)(6). However, "[f]or purposes of the preceding sentence, such information" includes "the date on which the Secretary receives notification of any termination of an agreement under the Medicare coverage gap discount program," "the date on which the Secretary receives notification of any termination of an agreement under the manufacturer discount program," and "the date on which the Secretary receives notification of any termination of a rebate agreement described in section 1396r-8(b)." *Id.* § 1320f-5(a)(6)(A)-(C). Accordingly, the HHS Secretary is authorized to provide Treasury with information that would *terminate* tax liability; that information is not necessary to the tax "be[ing] imposed." Resp. at 40.

That is especially so in the context of the excise tax, where the IRS has proposed regulations regarding a taxpayer's obligations to self-report its excise-tax liability. *Excise Tax on Designated Drugs; Procedural Requirements*, 88 Fed. Reg. 67,690 (Oct. 3, 2023) (proposing "how taxpayers will report liability for the excise tax imposed on manufacturers, producers, or importers of certain designated drugs"). In other words, a manufacturer, producer, or importer that makes sales of a designated drug to Medicare during a period set forth in § 5000D(b) would be responsible for self-reporting and paying the tax, and potentially subject to examination with respect to the accuracy of its return—regardless of whether HHS or CMS shares any information with the IRS.

Second, BI argues that "even if it were necessary to bind the IRS or the Treasury Department" to redress its tax claim, "this Court could do so" by issuing an injunction binding the absent agencies. Resp. at 40. That is so, BI asserts, because Treasury and the IRS are "in active concert or participation" with Defendants. *Id.* (quoting Fed. R. Civ. P. 65(d)(2)(C)). BI's argument—which is not supported by citation to any caselaw—quickly unravels. The "general principle" governing remedies is "that a court cannot 'make a decree which will bind any one but a party.'" *Doctor's Assocs., Inc. v. Reinert & Duree, P.C.*, 191 F.3d 297, 302 (2d Cir. 1999) (injunctions that attempt to bind absent parties are "improper") (quoting *Alemite Mfg. Corp. v. Staff*, 42 F.2d 832, 832 (2d Cir. 1930)). Rule 65(d)(2)(C) does not undo that cardinal rule of remedies, but rather serves to prevent those aiding and abetting a named defendant from violating a court order on the defendant's behalf. *See id.* at 303 (injunction "not authorized by Rule 65(d) because the injunction bars" nonparty conduct "that do[es] not aid or abet the federal defendants in violating the injunctions entered against them"); *see also Next Invs., LLC v. Bank of China*, 12 F.4th 119, 134 (2d Cir. 2021) ("relevant inquiry under Rule 65(d) is whether the non-part[ies] aided or abetted the Defendants' violations of the court's orders"); *NML Cap., Ltd. v. Republic of Argentina*, 727 F.3d 230, 243 (2d Cir. 2013) (nonparties "could become liable through Rule 65 if they assist [defendant] in violating the district court's orders"). Given the rule's role, it is unsurprising that BI does not cite a case in which a district court relied on Rule 65(d) to enjoin an absent federal agency. After all, an injury is not redressable in a suit in which the plaintiff fails to sue the agency directly responsible for the alleged harm—even if that agency is "in consultation with" the defendant agency. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 558, 570-71 (1992) (plurality opinion) ("redress of the only injury in fact respondents complain of requires action (termination of funding until consultation) by the [absent] individual funding agencies").

Third, BI attempts to distinguish *Haaland v. Brackeen*, 599 U.S. 255 (2023), noting that the named defendants there were federal agencies while the absent parties were state agencies. Resp. at 40. That is a correct description of the facts, but the requirement that a plaintiff must sue the proper defendant is not limited to cases in which a plaintiff sues the wrong sovereign. *Brackeen* itself makes that clear when it cites *Lujan*—a case in which plaintiffs sued a federal agency, but not the right one—

for the proposition that when defendants are "not parties to the suit, [] there is no reason they should be obliged to honor an incidental legal determination the suit produced." *Brackeen*, 599 U.S. at 293 (quoting *Lujan*, 504 U.S. at 569 (plurality opinion)).

Because BI failed to sue Treasury and the IRS—the only agencies empowered to collect the tax—in connection with its excise-tax claim, BI has "not shown that [its] injury is 'likely' to be 'redressed by judicial relief'" in this suit. *See Brackeen*, 599 U.S. at 292 (citation omitted).

B. The AIA and DJA Preclude Review of BI's Excise-Tax Challenge

BI does not contest that the AIA, on its face, applies to bar BI's excise-tax claim. *See generally* Resp. at 40-41. That concession is unsurprising given that Congress labeled the excise tax a "tax" and the purpose of BI's excise-tax claim is to "restrain[] the assessment or collection" of that tax. 26 U.S.C. § 7421(a); *see also* 26 U.S.C. § 5000D (labeling excise tax a "tax"). That is all that matters for AIA purposes. *NFIB*, 567 U.S. at 544, 564 (AIA precludes preemptive challenge to exaction Congress has "label[ed]" as a "tax"). *See generally* MSJ at 12-15.

Nonetheless, BI asserts that the *Williams Packing* exception to the AIA applies.[8] That exception does not apply because BI has failed to carry the "double burden" of establishing that "there is no adequate remedy at law and 'it is clear that under no circumstances could the Government ultimately prevail.'" *Botta v. Scanlon*, 314 F.2d 392, 394 (2d Cir. 1963) (quoting *Enochs v. Williams Packing & Navigation Co., Inc.*, 370 U.S. 1, 7 (1962)).

As to whether there is an adequate remedy at law, BI has multiple avenues to press its constitutional challenges in court. BI could file a refund suit in federal district court or in the Court of Federal Claims after the tax is imposed on just a single sale of a single drug. *See* 26 U.S.C. § 7422; 28 U.S.C. §§ 1346(a)(1), 1491.[9] Or, if the IRS takes any collection action in connection with unpaid

[8] Defendants previously explained why the *Williams Packing* and *South Carolina* exceptions do not apply here. *See* MSJ at 15-18. BI does not contest the inapplicability of the latter exception.

[9] BI would file a return at the end of the quarter that accurately reported its various sales, pay the tax owed on at least one of those sales, file an administrative claim for a refund, and then—if the IRS denies that claim or if six months elapse without a decision—file a refund suit. 26 U.S.C. §§ 6511, 6532(a)(1), 7422(a). BI would only have to pay the tax on a single sale to bring a refund suit.

excise-tax amounts, BI could raise its constitutional challenge during a collection due process ("CDP") hearing and, if unsuccessful, petition the Tax Court for review, *see* 26 U.S.C. § 6330(d)(1).[10] "The issue here is when—not if—[BI] may challenge" the excise tax. *Fla. Bankers Ass'n v. U.S. Dep't of the Treasury*, 799 F.3d 1065, 1067 (D.C. Cir. 2015).

BI's assertions that this judicial review would be inadequate rely on a misunderstanding of how the excise tax will be assessed and a policy disagreement with Congress about how the AIA should operate. As a threshold matter, BI again ignores the IRS's interpretation of the excise tax's rate and reach. *See* Resp. at 4, 41, 43. In a notice that "taxpayers may rely on" now, the IRS has made clear that it interprets the tax to apply only to a manufacturer's "sales of designated drugs dispensed, furnished, or administered to individuals *under the terms of Medicare*"—*i.e.*, only those drugs dispensed, furnished, or administered to Medicare beneficiaries. IRS Notice at 3, 5 (addressing interpretation of 26 U.S.C. § 5000D) (emphasis added). The IRS Notice also explains that, after 271 days, the maximum ratio of the tax to the total amount the manufacturer charges for a drug is 95% (not 1900%, as BI claims). *Id.* at 4. BI's estimates of potential tax liability, *see* Resp. at 41, therefore rest on significant miscalculations (against their own interests).

BI also asserts that the fact that the tax is a "divisible tax" is irrelevant. Resp. at 41. But this fact matters because, as a divisible tax, it is imposed on each "sale" of a designated drug, 26 U.S.C. § 5000D(a), which means that a taxpayer who wishes to challenge such a tax need only pay "the excise tax on a single transaction" before bringing a refund suit, *Rocovich v. United States*, 933 F.2d 991, 995 (Fed. Cir. 1991). And "[w]hen a refund suit is pending on a divisible assessment, the [IRS] will exercise forbearance with respect to collection provided that the interests of the government are adequately protected and the revenue is not in jeopardy." IRS Policy Statement 5-16, IRM 1.2.1.6.4(6).

[10] If BI filed an accurate return, reported its sales and the tax owed, but paid only a portion of the tax owed and the IRS later took some collection action (*e.g.*, issued notice that it intended to levy), BI could then contest the constitutionality of the excise tax in a CDP hearing before an impartial officer in the IRS Independent Office of Appeals. *See* 26 U.S.C. § 6330(c)(2)(B) (if taxpayer had not yet had an opportunity to do so, it may "raise . . . challenges to the existence or amount of the underlying tax liability" at a CDP hearing); *id.* § 6330(b)(1) (describing CDP hearing); *see also id.* § 7803(e)(3) (describing function of IRS Appeals). If necessary, BI could then file suit in Tax Court.

BI nonetheless maintains that even if the tax is divisible, even if it could thus bring a refund suit after paying the tax on just a single sale, and even if the IRS would not seek to collect any further tax payments during the pendency of that refund suit, BI would *still* need a preemptive injunction now because it would not know whether future sales ultimately would be subject to the excise tax. Resp. at 41. But that is just another way of saying BI would like to challenge the constitutionality of the excise tax before paying it—exactly what the AIA forbids. *RYO Mach., LLC v. Dep't of Treasury*, 696 F.3d 467, 471 (6th Cir. 2012) ("The AIA has been interpreted broadly to encompass almost all premature interference with the assessment or collection of any federal tax."). BI's argument effectively boils down to a policy disagreement with Congress: in BI's eyes, large corporate taxpayers that are engaged in sizeable or frequent transactions that may trigger substantial tax liability should not have to wait to challenge the constitutionality of a tax until after paying it. *See* Resp. at 41. Congress chose a different path wherein BI's "sole recourse is to pay the tax and seek a refund." *CIC Servs., LLC v. IRS*, 593 U.S. 209, 225 (2021). Corporate taxpayers often must engage in large transactions without fully knowing the tax consequences, setting aside reserves to pay any amount of tax that is ultimately due. And, if anything, BI is better positioned than most, because the excise tax is divisible such that it will not have to pay the excise tax on more than a single transaction before it can press its constitutional challenge. At that point, if BI prevails—which BI (wrongly) believes it is certain to do, *see* Resp. at 41—no further excise tax would be assessed or collected.

Even if these opportunities for judicial review were inadequate, the *Williams Packing* exception would not apply here because BI cannot show that, "under the most liberal view of the law and the facts," "it is clear that under no circumstances could the Government ultimately prevail" on the merits. *Williams Packing*, 370 U.S. at 7. As set forth below, *see infra* Section VI.D.1, the excise tax is neither a "fine" nor an "excessive" one. At the very least, BI has not established a "certainty of success on the merits," *Bob Jones Univ. v. Simon*, 416 U.S. 725, 737 (1974)—a high bar, and one not met here, where BI has failed to identify a single decision finding a tax to constitute a "fine" for Excessive Fines Clause purposes or to be an "excessive" fine in violation of the Eighth Amendment. *See infra* Section VI.D.

Because the AIA applies, and because the "federal tax exception to the Declaratory Judgment Act is at least as broad as the [AIA]," *Bob Jones Univ.*, 416 U.S. at 732 n.7, the Court must dismiss BI's tax claim.

VI. The Excise Tax Does Not Violate the Eighth Amendment

The excise tax does not run afoul of the Excessive Fines Clause of the Eighth Amendment because it is neither a "fine" nor an "excessive" one. *See* MSJ at 43-52. In response to Defendants' brief, BI mostly rehashes arguments it has already made. *See* Resp. at 42-43. Most noteworthy, however, is what BI does not say and what cases it is not able to muster: BI still has not cited a single case in which a tax was deemed to be "punishment for some offense"—that is, a "fine"—under the Excessive Fines Clause. Similarly, BI still had not identified any tax other than those with a connection to criminal conduct or criminal proceedings that was held to be "punishment for some offense" under any provision of the Constitution. BI is thus asking this Court to break new ground by holding that the IRA's excise tax—which has no connection to any criminal conduct or criminal proceedings, and which does not turn on any particular level of culpability—is an excessive fine in violation of the Eighth Amendment. But BI does not come close to justifying such a result.

A. BI faults Defendants for starting at the beginning and asserts that the Court need not decide at the outset whether the excise tax is deemed to be "punishment for an offense" before proceeding to the excessiveness inquiry. *See* Resp. at 42 (citing MSJ at 43-50). BI does not cite a single case in which a court took such a shortcut, and binding precedent—both from the Supreme Court and the Second Circuit—are clear that the first step in the Excessive Fines Clause analysis is to ask whether the exaction at issue constitutes "punishment for an offense." *See United States v. Bajakajian*, 524 U.S. 321, 328 (1998) ("Forfeitures—payments in kind—are thus 'fines' if they constitute punishment for an offense."); *Austin v. United States*, 509 U.S. 602, 609–10 (1993) ("The Excessive Fines Clause limits the government's power to extract payments . . . 'as *punishment* for some offense.'" (emphasis in original) (quoting *Browning–Ferris Indus. v. Kelco Disposal, Inc.*, 492 U.S. 257, 265 (1989))); *United States v. Davis*, 648 F.3d 84, 96 (2d Cir. 2011) ("A fine refers to 'a payment to a sovereign as punishment for some offense.'" (quoting *Browning–Ferris*, 492 U.S. at 265)). Against this unbroken line of precedent, BI points to a decision it admits "did not reach the plaintiff's Excessive Fines Clause claim." *See* Resp. at 42 (citing *Tyler v. Hennepin Cnty*, 598 U.S. 631 (2023)). And the two-Justice concurrence on which BI relies does not in any event disavow the requirement that an exaction be deemed "punishment" to come within the ambit of the Excessive Fines Clause. *See Tyler*, 598 U.S. at 649 (Gorsuch, J., concurring) (stating that, in the view of the two concurring Justices, "a scheme producing fines that punishes some individuals" should be subject to excessiveness analysis).

Next, BI states that "civil *penalties* may be fines within the meaning of the Eighth Amendment." Resp. at 42 (emphasis added). But BI still does not identify—and Defendants are not aware of—any *tax* that has been held to be a "fine" under the Eighth Amendment. *See id.* Conceding that "few cases addressing the Excessive Fines Clause" involve civil—as opposed to criminal—fines, BI asserts that "courts have repeatedly concluded that civil exactions fall within the scope of the Eighth Amendment." *Id.* at 42-43. In support, BI cites three out-of-circuit decisions. *Id.* None of them was cited in BI's opening brief—and for good reason, as none involves taxes and, in all of them, the sanctions at issue were those the legislature actually referred to as "fines," "penalties," or treble damages assessed in connection with a statutory penalty. *See Pimentel v. City of Los Angeles*, 974 F.3d 917, 920 (9th Cir. 2020) ("civil fines for parking meter violations"); *WCI, Inc. v. Ohio Dep't of Pub. Safety*, 774 F. App'x 959, 960 (6th Cir. 2019) ("fine" for "nude dancing" "in contravention of Ohio law and liquor-controlled regulations"); *United States v. Mackby*, 261 F.3d 821, 830 (9th Cir. 2001) (analyzing False Claims Act liability provision, 31 U.S.C. § 3729(a)(1), which states any person who knowingly presents a false claim "is liable to the [government] for a civil penalty" and treble damages). Similarly, all of these "fines" applied only to culpable conduct. *See Pimentel*, 974 F.3d at 923 ("[P]laintiffs are indeed *culpable* [for violating] Municipal Code § 88.13 for failing to pay" use fee (emphasis added)); *WCI, Inc.*, 774 F. App'x at 967 (analyzing fine imposed for violation of Ohio Admin. Code 4301:1-1-52(B)(2), which states that "no [liquor] permit holder . . . shall *knowingly or willfully* allow in and upon his licensed permit premises any persons to . . . [a]ppear in a state of nudity" (emphasis added)); *Mackby*, 261 F.3d at 830 (analyzing False Claim Act's scienter element). Accordingly, none of these newly cited cases involve exactions similar to the excise tax.

Finally, BI fails to respond to most of Defendants' arguments as to why the excise tax is not a "fine." Despite citing the decision in its opening brief, BI does not attempt to rebut Defendants' argument that the decision in *Dep't of Revenue of Montana v. Kurth Ranch*, 511 U.S. 767 (1994), rested on features—a state drug tax imposed on criminal activity—that are wholly absent here. Similarly, BI has no response to Defendants' observation that *Kurth Ranch* squarely rejected the deterrent-in-part test on which BI relies—a test that has never been applied by the Supreme Court in the tax context. *See* MSJ at 47-48. Finally, BI is silent in response to Defendants' arguments distinguishing *Austin* and *Bajakajian*—the only cases BI cited in its opening brief in which a court held that an exaction constituted a "fine" for purposes of the Excessive Fines Clause. As explained, the exactions in those cases—the *in rem* civil forfeiture in *Austin* and the criminal forfeiture in *Bajakajian*—bear no resemblance to the excise tax. *See* MSJ at 45-46. The net result of the various points BI has left unrebutted is that, to the parties' knowledge, no court has held that a tax—or even another exaction similar to the excise tax—was a "fine" under the Excessive Fines Clause.

B. Even if BI could establish that the excise tax is a "fine" for Excessive Fines Clause purposes, it is not an "excessive" one. BI offers nothing new on this front. It again characterizes the IRS's interpretation of the scope and reach of the excise tax as "misleading," and as "a sleight of hand," Resp. at 14, 43—mischaracterizations that Defendants have already corrected. *see* MSJ at 8, 49. BI then attempts to distinguish an 81 percent penalty, which was held not to be constitutionally excessive, on the basis that the penalty was "for fraud," not "perfectly legal" conduct. Resp. at 43 (citing *United States v. Alt*, 83 F.3d 779, 784 (6th Cir. 1996)). But Defendants have already explained why the nature of the conduct at issue here reinforces why the Court should not reach the excessiveness inquiry in the first place. MSJ at 50 ("That is precisely the point: Because the tax is not triggered by the commission of any offense—reprehensible or otherwise—it is not 'punishment for some offense' and therefore is not a 'fine' under the Excessive Fines Clause." (emphasis omitted)); *see also Davis*, 648 F.3d at 96-97 (discussing *Austin* and explaining why an exaction that is "unconnected to any criminal prosecution" and that does not turn on any particular level of "culpability" is not a fine in the first instance).

BI also points again to predictions based on pieces of the statute's legislative history, Resp. at 43, without saying a word about arguments Defendants have already offered in response, MSJ at 49-50.

Finally, BI fails to engage with Defendants' analysis of the proportionality test. For example, BI does not dispute that, in applying that test, a court must afford "substantial deference" to Congress. *Solem v. Helm*, 463 U.S. 277, 290 (1983); *see also Bajakajian*, 524 U.S. at 336 (same). That is a high bar given that, at this stage, before any excise tax has been assessed or collected, BI is challenging whether assessment of the excise tax at a rate equal to the rate established by Congress would violate the Excessive Fines Clause. BI does not identify a single case in which a civil penalty assessed within or below the range set forth by Congress was deemed excessive. And BI does not even attempt to refute Defendants' analysis of the *Bajakajian* factors. *See* MSJ at 51-52.

Because the excise tax is neither a "fine" nor an "excessive" one, if the Court reaches the merits of BI's Eighth Amendment claim, that claim should be rejected.

CONCLUSION

For these reasons, and those articulated in Defendants' opening brief, the Court should deny Plaintiff's motion for summary judgment and grant Defendants' cross-motion.

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Respectfully submitted,

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