IN THE 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*.	Civil Action No. 3:23-CV-01103-RNC

COMBINED OPPOSITION TO DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT AND REPLY IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION AND SUMMARY OF ARGUMENT

The Government's brief defends a statute markedly different from the one Congress enacted. On issue after issue, the Government contorts the Inflation Reduction Act's ("IRA") Drug Price Negotiation Program ("Program") into a new, more reasonable regime—one in which the Centers for Medicare & Medicaid Services ("CMS") merely acts as a market participant seeking to negotiate the best possible deal. But that is not how the Program works. The uncomfortable reality for the Government is that CMS acts as a *regulator*: It chooses which drugs are subject to the Program, issues regulatory guidance implementing the Program, and sets the "Maximum Fair Price" for each selected drug. These quintessentially governmental actions are backed by extraordinary enforcement measures, including a confiscatory 1900 percent excise tax, enormous monetary penalties for failing to comply with CMS's directives, and even the power for CMS to unilaterally revise the terms of the "Manufacturer Agreement" after it is signed. Market participants do not have those powers, or anything remotely resembling them.

To be sure, Congress cloaked this price-setting regime in politically palatable terms so it would appear to involve "agreements," "negotiations," and "options" not to participate. But behind that smokescreen, the Program leaves manufacturers no choice but to submit to the Government's demands. To achieve that result, the Program runs roughshod over core constitutional rights. As Plaintiff Boehringer Ingelheim Pharmaceuticals, Inc. ("BI") explained in its opening brief, the Program works an unconstitutional taking of BI's Jardiance® tablets by compelling BI to provide them to Medicare beneficiaries on terms dictated by CMS; violates the Due Process Clause by imposing price controls without bedrock procedural safeguards; abridges BI's First Amendment rights by compelling BI to express the Government's preferred narrative that the Program involves "negotiation" of a "fair" price; and violates the Eighth Amendment by subjecting BI to fines (disguised as a tax) that quickly amount to billions of dollars per week. *See*

BI Opening Brief ("BI Br."), ECF No. 28-1, at 1–4. The Government cannot cut these constitutional corners to achieve its desired ends. *See Horne v. Dep't of Agric.*, 576 U.S. 350, 362 (2015).

Rather than addressing the merits of BI's arguments, the Government's answering brief focuses on the contention that the Program is voluntary and therefore cannot violate the Constitution. In reality, however, the Program is built on legal and economic compulsion that eliminates any true choice and guarantees acquiescence. As to legal compulsion, the Government ignores that CMS's selection of Jardiance®—not any voluntary action on BI's part—triggered the IRA's obligations and penalty provisions, and that the IRA requires BI to participate in the Program for a period of time. The Government waves this compulsion away, arguing that BI has ways to simply "opt out" of the Program after being involuntarily opted in. But those purported "options"—paying an astronomical excise tax, withdrawing *all* of its products from both Medicare and Medicaid, or divesting Jardiance®—were designed to give BI no choice but to remain in the Program. The Government does not respond to BI's undisputed evidence of coercion, but instead relies on Spending Clause and market-participant theories to bypass that evidence entirely. Those responses are meritless and cannot shield the Program from constitutional scrutiny.

The Government's arguments beyond voluntariness fail as well. Regarding BI's due process claim, the Government does not argue that the Program provides the procedural safeguards courts have long held are necessary under the Fifth Amendment. Instead, the Government argues only that BI has no constitutionally protected interest at stake—a retort that falls short because the Program deprives BI of its property interest in its Jardiance® products and associated trade secrets. Precedent also makes clear that even *voluntary* regimes must provide a baseline level of due process.

The Government response to BI's physical takings claim fares no better. By focusing on whether CMS will physically seize Jardiance® tablets, the Government misses the point: A physical taking can occur in numerous ways, including by appropriating a property owner's right to exclude and forcing a transfer of property to third parties, as the Program mandates. The Government also argues that the Program gives third parties only a right to access *prices*, but not the underlying *products*. But that artificial distinction fails to acknowledge that third parties will actually take possession of Jardiance® tablets under the IRA and contradicts the Government's own statements that the IRA obligates BI to *provide drugs* at the Program's prices. Nor does the Government provide any support for its incorrect assertion that a company forced by law to transfer its property to third parties must be treated like a public utility and limited to regulatory takings claims.

Regarding BI's First Amendment claim, the Government does not argue that the Program's requirements can survive any form of heightened scrutiny. Rather, it argues that the Manufacturer Agreement that BI must sign is not speech at all. That contradicts Supreme Court precedent recognizing the First Amendment's broad scope. And at any rate, the IRA and its implementing Manufacturer Agreement go far beyond memorializing the terms of a transaction: They serve to perpetuate the Government's narrative that the Program is a "negotiation" resulting in a "fair price." Finally, the Government's suggestion that BI can simply use more speech to negate the messages communicated through the Program has already been rejected by the Supreme Court.

Even if the Program could be considered voluntary, it would still violate the unconstitutional conditions doctrine. That doctrine applies even when a company like BI voluntarily seeks a government benefit that it is not otherwise entitled to receive. Here, treating Program participation as a "voluntary" condition of Medicare and Medicaid participation would mean conditioning a valuable government benefit on BI relinquishing its First and Fifth Amendment rights. Courts regularly apply the unconstitutional conditions doctrine to government spending programs and have repeatedly invalidated program requirements on that basis. *See, e.g.*, *Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.*, 570 U.S. 205 (2013) ("*USAID*"). The Government quibbles over the proper analytical framework in unconstitutional conditions cases, but it misreads precedent and incorrectly narrows the scope of this established doctrine. Under any reasonable test, the Program imposes unconstitutional conditions on BI's participation in Medicare and Medicaid.

The Government's response to BI's Eighth Amendment claim also falls short. The Government argues that BI lacks standing because it did not join the Internal Revenue Service ("IRS") and Treasury Department as defendants, but the named Defendants are sufficient because they have a statutory role in administering the IRA's excise tax provisions. Moreover, an injunction against Defendants would not only give BI the relief it seeks, but also would cover "persons who are in active concert or participation with" Defendants, i.e., the IRS and Treasury Department. *See* Fed. R. Civ. P. 65(d)(2)(C). Although the Government contends that the Anti-Injunction Act bars this claim, that argument fails because BI has shown a certainty of success on the merits and that denial of review would cause BI irreparable injury. On the merits, it is plain that a 1900 percent tax that Congress acknowledged no one will ever pay is a punitive sanction designed to compel participation in the Program, and thus an excessive fine. Precedent forecloses the Government's argument that only criminal punishments fall within the Excessive Fines Clause, and the Government's efforts to manipulate the size of the excise tax to make it appear less excessive do not withstand scrutiny.

Finally, the Government fails to rebut BI's contention that the Manufacturer Agreement violates the Administrative Procedure Act ("APA") and the Medicare Act. The Government's main argument is that it *did* subject the Agreement to notice and comment procedures. But that is impossible because the Agreement was not published until months *after* the deadline for comments had passed. Moreover, the Government cannot claim that CMS's procedural failures were harmless: Foreclosing BI's opportunity to comment on the text of an agreement—one it was forced to sign and that binds its actions going forward—is certainly prejudicial.

Because the Program is indefensible, the Government opts instead to defend a different, less problematic framework. The Government's brief addresses a statute that (1) imposes "only" a 95 percent excise tax penalty on Medicare sales; (2) authorizes expedited withdrawal from Medicare and Medicaid; (3) allows manufacturers to stop selling selected drugs to Medicare beneficiaries; and (4) grants access to prices but not the underlying drugs.

The Government's litigators may wish that Congress had enacted a law with those characteristics. But the actual statute at issue punishes noncompliant manufacturers with an exorbitant 1900 percent fine on *all* U.S. sales of selected drugs; requires a waiting period of at least 11 months for withdrawal from Medicare and Medicaid, during which the manufacturer remains liable for penalties; forces manufacturers to continue selling selected drugs to Medicare beneficiaries (or else take those drugs off the market entirely); and requires manufacturers to hand over the drugs selected by CMS. Cutting through the Government's theorizing and creative administrative footwork, the on-the-ground reality is that the Program leaves manufacturers with no choice but to comply and deprives them of core procedural safeguards.

At bottom, the Government asks the Court to ignore the Program's obvious real-world effects. But courts "are 'not required to exhibit a naiveté from which ordinary citizens are free.'"

Dep't of Com. v. New York, 139 S. Ct. 2551, 2575 (2019) (quoting *United States v. Stanchich*, 550 F.2d 1294, 1300 (2d Cir. 1977) (Friendly, J.)). The Court should grant BI's motion for summary judgment and deny the Government's cross-motion.

ARGUMENT

I. THE PROGRAM IS NOT VOLUNTARY.

BI has demonstrated that the Program is *not* voluntary. The IRA is structured such that BI is legally compelled to enter the Program and economically coerced to remain in it. Both the text of the IRA and BI's undisputed evidence make this clear. The Government's counterarguments—that legal compulsion is the only relevant consideration; that economic coercion does not matter outside the federalism context or in connection with spending legislation; and that any economic pressure raises no concerns where the Government acts as a market participant—are contrary to controlling precedent and the text and structure of the Program itself.

A. BI Has Demonstrated That It Is Legally Compelled to Participate in the Program.

BI is legally compelled to join, and remain in, the Program. The Government does not dispute that *CMS* selected BI's drug Jardiance® for the Program on August 29, 2023.[1] That selection—not any voluntary action on BI's part—imposed on BI requirements to "enter into agreements," "negotiate to determine … a maximum fair price," provide "access" to Jardiance® at that price, submit confidential data, and "compl[y]" with any other requirements CMS deems "necessary." 42 U.S.C. § 1320f-2(a). If BI does not comply with these requirements, it will face massive penalties for "noncompliance," *see* 26 U.S.C. § 5000D(b), a term that would make no sense if BI were not legally obligated to comply in the first place. The IRA makes this explicit,

[1] *See HHS Selects the First Drugs for Medicare Drug Price Negotiation* (Aug. 29, 2023), https://www.hhs.gov/about/news/2023/08/29/hhs-selects-the-first-drugs-for-medicare-drug-price-negotiation.html.

applying its excise tax provisions to noncompliant manufacturers as soon as CMS "include[s]" their drugs "on the list [it] publishe[s]," not when manufacturers assume the IRA's obligations of their own accord. 26 U.S.C. § 5000D(e)(1). The compulsion is all the more plain when considered against the backdrop of the pre-IRA Medicare Part D, which *prohibited* the Department of Health and Human Services ("HHS") from "interfer[ing] with the negotiations between drug manufacturers[,] pharmacies[,] and [private health plans]" regarding the price of Part D drugs. 42 U.S.C. § 1395w-111(i).

The Government argues that BI can "opt out" of the Program by withdrawing entirely from Medicare and Medicaid. *See, e.g.*, Government Opening Brief ("Gov't Br."), ECF No. 48-1, at 23. The Government's own framing of this argument implicitly acknowledges BI's point: Any need to "opt *out*" of the Program arises only because BI was involuntarily forced into the Program by CMS.

That characteristic alone distinguishes the Program from the other federal drug programs cited by the Government. *See* Gov't Br. 1, 29. None of those programs involve the Government selecting particular private entities for participation and then levying massive excise tax penalties on the sale of their drugs as a penalty for noncompliance. Unlike the Program here, those other programs also apply to all of a manufacturer's products in Medicare and Medicaid rather than singling out a select few. To be sure, participation in these other programs is often a prerequisite of federal funding, *see, e.g.*, 42 U.S.C. §§ 1396r-8(a)(5)–(6), 1395cc(a)(1)(I)(i), and a manufacturer or provider who withdraws from those programs could incur significant loss of market access. But the decision whether to enter those programs and accept funding conditions in the first place lies squarely in the manufacturer's or provider's hand, not the Government's, and is not backed by a massive excise tax penalty.

In addition to being legally compelled to enter the Program, BI must also remain subject to the Program for a period of time. A manufacturer can avoid the IRA's excise tax only after it has (1) provided notice of termination of all its Medicare and Medicaid agreements and (2) terminated its Medicare agreements, *see* 26 U.S.C. § 5000D(e)—a process that, by statute, takes at least 11 months (and as long as 23 months) to complete, *see* 42 U.S.C. §§ 1395w-114a(b)(4)(B)(ii), 1395w-114c(b)(4)(B)(ii). As a result, BI would still be legally required to fulfill the obligations triggered by CMS's selection of Jardiance® even if it were to try to "opt out."[2]

After several manufacturers filed lawsuits raising this issue,[3] CMS distanced itself from this statutory delay by trying to create a loophole through nonbinding guidance. The Revised Guidance states that CMS will treat any "[t]ermination … [b]y a manufacturer," 42 U.S.C. §§ 1395w-114a(b)(4)(B)(ii), 1395w-114c(b)(4)(B)(ii), as "[t]ermination … [b]y the Secretary" for "good cause," *id.* §§ 1395w-114a(b)(4)(B)(i), 1395w-114c(b)(4)(B)(i). *See* Revised Guidance § 40.6, Ex. B to Declaration of James T. Shearin ("Shearin Decl."), ECF No. 28-5, pp. 129–31. That shift would shorten the withdrawal period to 30 days, but it also contradicts the IRA's plain text. For starters, the IRA suspends the excise tax only when "the manufacturer" provides "notice" to the Government that its Medicaid and Medicare agreements have been "terminat[ed]." 26 U.S.C. § 5000D(c). The Government's position also fails to acknowledge that the IRA limits "good cause" to "knowing and willful violations of the requirements of the agreements" and related malfeasance. 42 U.S.C. §§ 1395w-114c(b)(4)(B), 1395w-114a(b)(4)(B); *see also Owen of*

[2] The Government asserts that "BI has not indicated that it wishes to withdraw from the Negotiation Program or from Medicare and Medicaid," Gov't Br. 22, but in reality BI has consistently maintained that the IRA compels its participation and forecloses withdrawal. BI signed the Manufacturer Agreement *under protest*, and it continues to participate under protest.

[3] *See, e.g.*, *Merck v. Becerra*, No. 23-cv-1615, ECF 1 ¶¶ 6, 82 (D.D.C June 6, 2023); *Dayton Area Chamber of Com. v. Becerra*, No. 23-cv-156, ECF 1 ¶¶ 96, 98–100 (S.D. Ohio June 9, 2023).

Ga., Inc. v. Shelby County, 648 F.2d 1084, 1092 (6th Cir. 1981) ("[T]he phrase 'good cause' must be read ejusdem generis to refer to other factors of the same genre as those enumerated by the specific words."). And at a minimum, the Government's approach collapses the distinction between manufacturer-initiated termination and Government-initiated termination, as reflected by Congress's decision to address those procedures in separate provisions. Regardless, even the Government's incorrect reading would leave BI legally required to participate and remain in the Program for at least 30 days.

The Government argues that temporary participation in the Program (be it for one month or 23) does not matter because "negotiated prices" do not take effect until January 1, 2026. Gov't Br. 23–24. This argument ignores the many injuries BI has suffered and will suffer *before* January 2026 that stem from its compelled participation, including having to convey the Government's message (*see infra* Part IV), submit to an unconstitutional process (Part II), and comply to avoid an unconstitutionally excessive fine (Part VI). The Government's focus on January 2026 also ignores BI's unconstitutional conditions claims (Part V), which are not affected by these timing mechanics: Regardless of how long it takes for an individual to seek (or attempt to walk away from) valuable benefits, the Government cannot coercively condition those benefits on the relinquishment of constitutional rights. And as discussed below (Part I.B), Congress has made the cost of *not* complying so high that BI has no real choice, regardless of how much time it theoretically would take to "opt out."

B. The IRA Also Uses Economic Coercion to Guarantee Continued Participation, Rendering any "Options" to Exit the Program Illusory.

1. Economic compulsion is sufficient to render participation in the Program involuntary. The Government argues that because the IRA does not "*legally compel* manufacturers to negotiate with CMS or to sell their drugs to Medicare beneficiaries," participation in the Program is "a

completely voluntary choice." Gov't Br. 19 (cleaned up; emphasis added). For the reasons given above, legal compulsion *is* present here. But even if it were not, the Supreme Court has rejected the notion that legal compulsion is necessary to establish a constitutional violation. In *Horne*, raisin growers "*voluntarily* cho[se] to participate in the raisin market" and, as a result, were required to turn over a portion of their raisin crops to the Government each year. 576 U.S. at 354, 365 (emphasis added). When the growers claimed that this requirement effected a physical taking, the Government argued that their voluntary participation in the raisin market negated their takings claim—they had "options" to "plant different crops," "sell their raisin-variety grapes as table grapes[,] or for use in juice or wine." *Id.* at 365 (cleaned up). But the Court rejected that argument, holding that it "prove[d] too much" because it would allow property rights to be "easily manipulated." *Id.* (cleaned up). Had legal compulsion been necessary, the Court would have rejected the takings challenge. *See also Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 439 n.17 (1982) (landlord's theoretical ability to "avoid [the challenged law] by ceasing to rent the building to tenants" did not defeat takings claim because property "cannot be so easily manipulated").

Beyond *Horne*, other case law demonstrates that economic compulsion is sufficient to render the Program involuntary. To start, the decision in *National Federation of Independent Business v. Sebelius*, 567 U.S. 519 (2012) ("*NFIB*"), makes clear that "economic dragooning that leaves [BI] with no real option but to acquiesce" in the Program renders participation involuntary, *id.* at 582. The Government is correct that *NFIB* arose in the federalism context. *See id.* at 577–78; Gov't Br. 26–27. But nowhere did the Court adopt the Government's position that coercion principles apply only when states are involved. Instead, *NFIB* is more accurately read as deciding whether coercive legislation violated a specific right. In *NFIB*, the rights in question stemmed from the Tenth Amendment, and here they stem from the First, Fifth, and Eight Amendments. But the coercion principles in *NFIB* are no less relevant simply because different rights are at play.

Earlier decisions confirm this understanding, as they applied the same principles of economic coercion to legislation affecting private parties. For example, in *Union Pacific Rail Road Co. v. Public Service Commission*, the Supreme Court recognized that the Government may not "impose an unconstitutional burden" on a private railroad "by the threat of [even greater] penalties" if the railroad "fail[s] to accept [that burden], and then … declare the acceptance voluntary." 248 U.S. 67, 70 (1918). Such economic "duress" would negate any purported "choice" between compliance and "grave penalties" because it would be "practically impossible *not to comply* with the terms of the law." *Id.* (emphasis added). Likewise, the Court in *United States v. Butler* held that a "regulation [was] not in fact voluntary," and the "asserted power of choice … illusory," where Congress had used "coercion by economic pressure" "to induce [a regulated party] to surrender [its] independence of action." 297 U.S. 1, 70–71 (1936); *see also Carter v. Carter Coal Co.*, 298 U.S. 238, 289 (1936) (finding that "agreement" to participate in coal regulation program was "coerce[d]" because it was backed by provisions imposing substantial taxes for noncompliance, and observing that "[o]ne who does a thing in order to avoid a penalty does not agree"); *Thompson v. Deal*, 92 F.2d 478, 480, 484–85 (D.C. Cir. 1937) (holding that "[t]he asserted power of choice [was] illusory" due to "coercion by economic pressure" where, in order to sell cotton without 50 percent tax and potential fines and imprisonment, farmers had to agree to "limitations on production … as to all [] agricultural commodities" and had to purchase certificates costing almost as much as the tax).

The Government does not address *Butler* or *Carter Coal*, and its attempts to distinguish *Horne*, *Union Pacific*, and *Thompson* fail. The Government argues that the latter three cases are distinguishable because the plaintiffs "were subject to regulatory regimes they could not readily exit," and that those plaintiffs "had to comply with the government's conditions if they wished to sell their products to *anyone*." Gov't Br. 26 (emphasis in original). Those assertions are incorrect. In *Horne*, for example, the growers *could* voluntarily exit the Program or otherwise continue to sell their crops as table grapes, juice, or wine. *See* 576 U.S. at 365. Similarly, in *Thompson*, cotton farmers had the "option" to ignore the Government's production quotas and continue to sell cotton subject to a tax. *See* 92 F.2d at 484. The Government here proffers the same purported options. *See, e.g.*, Revised Guidance § 40.6 (noting manufacturer's "choic[e]" to "opt out of the Negotiation Program and pay the excise tax on the sale of the selected drug"). Those options failed to defeat the plaintiffs' constitutional claims in *Horne* and *Thompson*, and they likewise do not prevail here.[4]

2. The IRA employs economic coercion to ensure that BI, once selected for the Program, continues to comply and cannot exit. BI has shown, for example, that had BI remained in Medicare but not fulfilled its obligations to participate in the Program, it would have soon faced excise taxes of over $5 billion per *week*. Declaration of Christine Marsh ("Marsh Decl."), ECF No. 28-2, ¶ 16. In a year, that noncompliance penalty would top a *quarter trillion* dollars. Alternatively, had BI withdrawn entirely from Medicare and Medicaid, it would have lost over half its U.S. sales. *Id.* ¶¶ 8, 17–18. In addition, BI would have been forced to compromise its core values of "improving human health and responsibility to the community" as 1.3 million patients would have lost coverage for Jardiance®, with many more losing coverage for BI's other products. *Id.* ¶ 18; *cf.*

[4] The Government alludes to another "option": BI could, it asserts, "stop selling [Jardiance®] to Medicare beneficiaries." Gov't Br. 21. But that idea cannot be squared with the IRA's requirement that BI withdraw *all* of its products from Medicare or Medicaid to exit the Program and avoid its penalties. *See* 26 U.S.C. § 5000D(c); *see also* Revised Guidance § 40.6. It also ignores the realities of the Medicare Act, which requires a manufacturer to offer either all or none of its drugs in Medicare Part D. *See* 42 U.S.C. §§ 1395w-153(a), 1395w-114a(b)(1)(A), (g)(2); *see also id.* § 1395w-114c(b).

Mora v. Mejias, 223 F.2d 814, 817 (1st Cir. 1955) (finding it "wholly unrealistic" and "not an honest answer" to suggest that providers of essential commodity can "escape loss by withdrawing from" the market). No rational actor would exercise such "options"—indeed, no manufacturer has.

Ignoring these facts, the Government asserts that BI, in theory, has "options" to exit the Program. *See* Gov't Br. 6. But those "options" are illusory; as BI's uncontroverted evidence shows, none of them is available to BI.

Withdrawing from Medicare and Medicaid. The Government argues that BI "can avoid [the Program] by withdrawing from the Medicare and Medicaid programs" entirely. Gov't Br. 21. The Government ignores BI's showing that this "option" does not exist in reality. The reason is simple: The Medicare and Medicaid market accounts for "more than half of BI's net sales in the United States." Marsh Decl. ¶ 17. Withdrawal from it would impair BI's ability to develop novel products and serve the "[m]illions of Medicare and Medicaid patients [who] depend on BI medications." *Id.* ¶ 18; *see also Mora*, 223 F.2d at 817. Indeed, the degree of coercion here far surpasses that which the Supreme Court found impermissible in *NFIB*, where Congress threatened states with the loss of 10 percent of their budgets if they failed to accept new requirements. *See* 567 U.S. at 582. The magnitude of that penalty distinguished *NFIB* from prior cases in which smaller inducements left program participants with the "prerogative to reject Congress's desired policy, not merely in theory but in fact." *Id.* at 581 (cleaned up).

Paying the excise tax. The Government asserts that BI could "continue selling its drugs to be dispensed or furnished to Medicare beneficiaries at non-negotiated prices and pay an excise tax on those sales." Gov't Br. 6. The Government's discussion of this "option" consists of exactly one sentence, and it is easy to see why: Incurring the excise tax would require BI to suffer even greater losses than if it were to submit to the Government's price. *See* Marsh Decl. ¶¶ 15–16. But a mandate does not become "voluntary" simply because of the introduction of even *more* onerous penalties for non-compliance. *See Union Pacific*, 248 U.S. at 70 (government cannot "impose an unconstitutional burden" on a private party "by the threat of [even greater] penalties" and then "declare the acceptance voluntary" when the party acquiesces).

The Government's attempts to rebrand the excise tax as an empowering "option" is unavailing.

First, the Government seeks to downplay the size of the excise tax by relying on a notice from the IRS advising that it and the Treasury Department "*intend* to *propose* regulations" interpreting 26 U.S.C. § 5000D to apply the excise tax only to "sales of designated drugs dispensed, furnished, or administered to individuals under the terms of Medicare." Gov't Br. 7–8 (emphasis added). But the Government cannot rely on the speculative possibility that these regulations might one day be proposed, let alone promulgated as binding rules. *Murray Energy Corp. v. EPA*, 788 F.3d 330, 334 (D.C. Cir. 2015) ("[p]roposed rules" have no "legal consequences" (citation omitted)). Nor, for that matter, does the statute allow for the Government's narrowing interpretation. *See* 26 U.S.C. § 5000D(a) ("impos[ing]" the tax "on *the sale* by the manufacturer … of any designated drug" (emphasis added)).[5]

Second, the Government seeks to make the tax seem less coercive by arguing that it tops out at 95 percent rather than 1900 percent. Gov't Br. 8. That argument relies on sleight of hand. In the Government's own example, when a manufacturer invoices a wholesaler $100 for a selected

[5] The statute's exclusion for exports, *see* 26 U.S.C. § 5000D(g), reinforces the conclusion that the tax applies to all sales, not just those reimbursed by Medicare and Medicaid: Because Medicare and Medicaid are domestic programs, the exclusion would be surplusage if "the sale[s]" covered by the tax were only sales to those programs. *See Obduskey v. McCarthy & Holthus LLP*, 139 S. Ct. 1029, 1037 (2019) (applying principle that "courts generally presume that statutes do not contain surplusage" (cleaned up)).

drug, the tax makes up $95 of that sum, while the manufacturer retains the remaining $5. Gov't Br. 8. But a $95 tax on a $5 sale and a $1900 tax on a $100 sale reflect exactly the same confiscatory rate of taxation: 1900 percent, or 19 times, the revenue retained by the taxpayer. A true 95 percent tax on a $5 sale would be $4.75—a far cry from the $95 the Government would take from BI. Regardless, the conclusion is the same: Whether the rate is 95 percent or 1900 percent, the tax is so crippling that paying it is not an option (as Congress recognized). *See* BI Br. 32.

Divestiture. The Government last proposes that if BI does not wish to participate in the Program it can simply "divest[] its interest in" Jardiance®. Gov't Br. 2, 7, 21, 23, 28. That "option" defies both common sense and economic reality. Divestiture of Jardiance® would require finding a willing buyer, who would be amply aware of the burdens it would immediately face on account of the inclusion of Jardiance® in the Program and would discount the price it is willing to pay accordingly. The hypothetical transaction would be a "fire sale" that would cause BI to experience the same harm as would participation in the Program. The possibility of such a transaction does not make the Program any more "voluntary." And the Government's shell game of moving the problem around and pretending it doesn't exist is the type of "shorter cut than the constitutional way" the Supreme Court has condemned. *Horne*, 576 U.S. at 362 (cleaned up).

C. The Government Wrongly Asks the Court to Ignore BI's Evidence of Economic Coercion.

The Government gets no further with its additional arguments that (1) the IRA's nature as spending legislation negates the possibility of coercion, and (2) the Government can exert whatever economic pressure it wishes because it is a mere market participant.

1. The Government first argues that because the IRA is Spending Clause legislation, it "operates based on consent," and therefore Program participants "cannot be coerced." Gov't Br.

25 (cleaned up). That is not the law. Although the Supreme Court has at times analogized spending legislation to a contract where parties have the opportunity to "accept[] the terms of that contract," *e.g.*, *Cummings v. Premier Rehab Keller, P.L.L.C.*, 142 S. Ct. 1562, 1570 (2022) (brackets, quotation marks, and citation omitted), the Court's approach in such cases has been to scrutinize the legislation to determine whether it in fact presents a voluntary exchange. Where, as here, a party cannot "voluntarily … accept[]" the conditions imposed by the spending legislation, the Court has struck it down. *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981); *see also NFIB*, 567 U.S. at 580–82 (spending legislation that threatened the loss of all Medicaid funding "le[ft] the States with no real option but to acquiesce"); *South Dakota v. Dole*, 483 U.S. 203, 211 (1987) (spending legislation is unlawful if it is "so coercive as to pass the point at which pressure turns into compulsion" (cleaned up)).

Contrary to the Government's argument, the limits on spending legislation do not apply only when Congress conditions federal funding to states. *See* Gov't Br. 28. The Government's own lead case—*Cummings*—applied the *Pennhurst* framework to private companies, analyzing whether those companies had "voluntarily and knowingly accept[ed]" the conditions associated with their receipt of federal funds. *Cummings*, 142 S. Ct. at 1570–71. The Supreme Court in *Butler* similarly rejected Congress's attempts to use its "taxing and spending" power on private parties "to purchase compliance" through "coercion by economic pressure." 297 U.S. at 71, 74–75. And as already noted, the unconstitutional conditions doctrine frequently operates to prevent the Government from "coercing" private parties, *Koontz v. St. John's River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013), especially when the conditions burden constitutional rights, *see, e.g.*, *USAID*, 570 U.S. at 214 ("[T]he First Amendment supplies a limit on Congress' ability to place conditions on the receipt of funds" (cleaned up)).[6]

2. The Government next argues that any economic "pressure" from the Program is "of no constitutional import" because the Government is acting as a "market participant." Gov't Br. 19, 27–28. The record refutes the Government's argument and shows that CMS acts as a regulator in implementing the Program.

To start, the Government can hardly be analogized to "any well-funded market participant" when it created the Medicare Part D market, inserted itself as the gatekeeper to over half the patients using BI's products, and thus amassed market power by statutory decree. Congress addressed the threat of "price fixing by the CMS bureaucracy" by initially including a "noninterference" provision in the Medicare Act to protect actual market participants from government "dictate[d] … price[s]." 149 Cong. Rec. S15624 (Nov. 23, 2003) (Sen. Grassley); *id.* at S15707 (Nov. 24, 2003) (Sen. Santorum); *see also* 42 U.S.C. § 1392w-111(i) (2022). That all changed when the IRA empowered CMS to set prices "[f]or the first time," Gov't Br. 1; *see also* 42 U.S.C. § 1392w-111(i)(2), and the Government cannot now claim it should be immune from constitutional review when the market power it wields stems from a sovereign act.

A real market participant, unlike CMS, cannot promulgate regulations governing the conduct of its counterparty, impose ruinous taxes and penalties for failure to comply, or unilaterally change the terms of its contract at any time without counterparty consent. Yet CMS exercises *all* of those powers under the Program. *See* 42 U.S.C. § 1320f-6; 26 U.S.C. § 5000D; Revised Guidance §§ 40.1, 40.6, 60.8, 90.1, 100.2; Ex. C to Shearin Decl. ("Manufacturer

[6] The Government also cites (at 27) *Northport Health Services of Arkansas, LLC v. HHS*, 14 F.4th 856 (8th Cir. 2021), but the Eighth Circuit there expressly "d[id] [not] address" plaintiff's claims that the Government's "economic dragooning" left it "no real option but to acquiesce" under *NFIB*, *id.* at 869 n.5.

Agreement") §§ II(e), IV(b), ECF No. 28-6. Courts have repeatedly held that a government agency is not a market participant when it "employs such … coercive mechanism[s], available to no private party." *Am. Trucking Ass'n v. City of Los Angeles*, 569 U.S. 641, 651 (2013); *see also, e.g.*, *United Haulers Ass'n v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 438 F.3d 150, 157 (2d Cir. 2006) ("A governmental entity acts as a market regulator when it employs tools in pursuit of compliance that no private actor could wield, such as the threat of civil fines …."); *Airlines for Am. v. City & County of San Francisco*, 78 F.4th 1146, 1152 (9th Cir. 2023) (collecting authority for the proposition that "civil penalty provisions alone may amount to the force and effect of law rendering a government entity a regulator rather than a market participant").

Even if CMS were considered to be exercising some market power, its simultaneous exercise of sovereign power belies the suggestion that CMS is acting *only* as a market participant. Congress could have authorized CMS to leverage its market power to negotiate drug prices *without* layering on regulations, excise taxes, civil monetary penalties, and the rest of the Program's elaborate structure. But that framework would have left open the possibility that some manufacturers would decline CMS's offer, leaving Medicare beneficiaries without coverage for the selected drugs (which, given the Program's design, are among the most widely prescribed drugs in the market) and all of a manufacturer's other drug products. Congress enacted the coercive provisions described above to augment CMS's economic power with sovereign power and prevent that politically unacceptable outcome. No amount of litigation posturing by the Government can change that fact.

D. The Government's Medicare Cases Are Inapposite.

The Government points to a handful of cases—including *Garelick v. Sullivan*, 987 F.2d 913 (2d Cir. 1993)—to support its argument that participation in the Program is voluntary, *see* Gov't Br. 19–20, but those cases are inapposite. *First*, none of those cases involved situations remotely similar to the one presented here. None involved programs where the Government selected some, but not all, providers for participation and imposed ruinous penalties on those who did not comply. Instead, the plaintiffs' claims in those cases failed because the plaintiffs chose to take on the obligations they complained of—a choice BI did not receive.[7]

Second, even if the Government's cases were relevant, nearly all of them predate *Horne*.[8] The Supreme Court's subsequent decision in *Horne* refutes the Government's legal compulsion argument and provides the controlling rule of decision for BI's claims. *See supra* pp. 9–10; *see also United States v. Afriyie*, 27 F.4th 161, 168 (2d Cir. 2022) (circuit precedent is not binding when an intervening Supreme Court decision presents a "conflict, incompatibility, or inconsistency"). The Government argues that there is no conflict between *Garelick* and *Horne* because the former only "established the principle that a party lacks a property interest in participation in the Medicare program, and [that] *Horne* casts no doubt on that analysis." Gov't Br. 26 n.5. But that narrow characterization of *Garelick* ignores the Government's repeated argument elsewhere that *Garelick* requires a showing of legal compulsion, *see, e.g.*, *id.* at 20—a theory that *Horne* forecloses. The Government's further suggestion (at 26 n.5) that *Garelick* would control even if in conflict with *Horne* misunderstands the Second Circuit's treatment of intervening Supreme Court precedent. *See Afriyie*, 27 F.4th at 168; *United States v. Emmenegger*, 329 F. Supp. 2d 416, 429 (S.D.N.Y. 2004) (district courts must follow circuit precedent "unless a subsequent

[7] *See, e.g.*, *Baker Cnty. Med. Servs., Inc. v. U.S. Att'y Gen.*, 763 F.3d 1274, 1279 (11th Cir. 2014) (rejecting takings challenge where plaintiff "voluntarily undertook" obligations it complained of).

[8] The only case postdating *Horne* is *Southeast Arkansas Hospice, Inc. v. Burwell*, 815 F.3d 448, 450 (8th Cir. 2016), which mentions *Horne* only in passing and does not analyze the portion of *Horne* that rejects a legal compulsion requirement.

decision of the Supreme Court so undermines it that it will almost inevitably be overruled by the Second Circuit").[9]

Third, several of the Government's cases—including *Garelick*—involved *regulatory* takings claims, and thus are not "controlling precedents" for physical takings claims (much less other constitutional claims). *Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg'l Plan. Agency*, 535 U.S. 302, 323 (2002) (explaining that it is "inappropriate to treat cases involving physical takings as controlling precedents for the evaluation of a claim that there has been a 'regulatory taking,' and vice versa").

Last, some of the Government's cases refute its legal compulsion argument. For example, in *Franklin Memorial Hospital v. Harvey*, 575 F.3d 121, 129–30 (1st Cir. 2009), the court considered whether a "coercive financial incentive," not legal compulsion, made MaineCare involuntary for participating hospitals.

The order in *Dayton Area Chamber of Commerce v. Becerra*, No. 3:23-cv-156, 2023 WL 6378423 (S.D. Ohio Sept. 29, 2023), is unpersuasive for similar reasons. It is a preliminary decision that did not rule on the merits, but instead concluded that "at this initial stage in the litigation process, it is too early to know—with the degree of certainty necessary for a preliminary injunction—that Plaintiffs have a strong likelihood of success on the merits." *Id.* at *12. Moreover, the court's analysis of the Program's voluntariness consists of one cursory paragraph and relies on the same pre-*Horne* cases without addressing *Horne* or the arguments advanced in this brief. *See id.* at *11.

[9] Beyond *Horne*, the Government's cases are also unpersuasive because they do not grapple with other controlling precedent, such as *Butler*, *Carter Coal*, and *Union Pacific*.

II. THE PROGRAM VIOLATES THE DUE PROCESS CLAUSE.

A. The Program Fails to Provide the Procedural Protections Required by the Fifth Amendment.

When the Government sets prices, it must provide the procedural safeguards required by the Fifth Amendment's Due Process Clause. *E.g.*, *In re Permian Basin Area Rate Cases*, 390 U.S. 747, 769–70 (1968). The Program falls well short of minimal due process requirements: It compels BI to hand over its drugs at a price set by an inherently biased government agency, with no ascertainable standards to guide the agency in setting a "maximum fair price" or to ensure that the price it sets is reasonable, and without allowing BI any meaningful opportunity to be heard, to respond to the evidence on which the Government relies, or to obtain review of the agency's decision in court or before any other neutral decisionmaker. BI Br. 14–16. Because the Program deprives BI of protected property interests without *any* meaningful process or limits on CMS's discretion to set whatever "maximum fair price" it chooses, the Program violates the Due Process Clause. Indeed, so far as BI is aware, the near-total absence of guardrails on CMS's discretion sets the Program apart from every other modern federal price-setting program.

Significantly, the Government does not argue that the Program's procedures provide constitutionally adequate protection. Instead, the Government asserts that the Program need not include *any* procedural safeguards because it does not deprive BI of property. Gov't Br. 36–38. The Government thus concedes that, if the Program deprives BI of property, it violates the Fifth Amendment. *See, e.g.*, *Ansell v. D'Alesio*, 485 F. Supp. 2d 80, 86 (D. Conn. 2007) (argument forfeited when not made in opposition to summary judgment motion).

The Government maintains that the Program does not infringe BI's property rights because BI's participation in the Program (and in Medicare) is voluntary and the Program does not deprive BI of any physical doses of its products. Instead, the Government asserts, the Program merely prevents BI from selling its drugs to Medicare beneficiaries at prices chosen by BI. Gov't Br. 37. That argument fails for three principal reasons.

First, as explained earlier, BI's participation is not voluntary, *see supra* Part I, and manufacturers indisputably have a property interest in their medicines. Thus, the issue is not whether BI has a property right to sell its drugs at prices of *its* choosing, but whether BI makes a voluntary choice to hand over its property (its drugs) on terms *the Government* dictates.

Second, even if BI's participation in the Program could be viewed as "voluntary," it does not follow that the Government can set the price of BI's drugs at whatever level it chooses, and through whatever process it deems fit. *See Old Dearborn Distrib. Co. v. Seagram-Distillers Corp.*, 299 U.S. 183, 192 (1936) (recognizing the "well-settled general principle that the right of the owner of property to fix the price at which he will sell it is an inherent attribute of the property itself, and as such is within the protection of the Fifth … Amendmen[t]"). Courts have long considered procedural due process challenges to price-control regimes even where property owners could have avoided price controls by ceasing to engage in the regulated business. BI Br. 12–13. So, for example, in *Bowles v. Willingham*, 321 U.S. 503 (1944), a challenge to wartime rent-control measures, the Court suggested that there was no *taking* because the apartment owners could use their properties for purposes other than residential housing, but went on to consider due process challenges to that regime. *See id.* at 517–21. That analysis would have been unnecessary if the fact that the owners voluntarily rented their property meant that they necessarily had no protected property interest. The Government does not acknowledge *Bowles* or *Yakus v. United States*, 321 U.S. 414, 438 (1944), much less distinguish those decisions. *See also* Thomas W. Merrill, *Constitutional Limits on Physician Price Controls*, 21 Hastings Const. L.Q. 635, 639, 641–50 (1994) (explaining at length why *Bowles* does not support the theory that price controls amount to a deprivation of property "only when someone is subject to a legal obligation to devote their product or services to the public use").

Third, the Government's argument, if accepted, would immunize a huge range of Medicare (and other) decisions from constitutional scrutiny. Freed from the constraints imposed by the Due Process Clause, CMS could exclude providers and drugmakers from these programs, or set prices for their products and services, for wholly arbitrary or even overtly discriminatory reasons. That is not the law. *See Skelly v. INS*, 168 F.3d 88, 91 (2d Cir. 1999) ("[T]here is a well-established equal protection component to the Fifth Amendment Due Process Clause applicable to the federal government."). This point illustrates the sweeping implications of the Government's voluntariness theory: If adopted, it would insulate the Government from a wide range of longstanding substantive and procedural requirements in connection with any program deemed "voluntary."

B. The Program's Compelled Disclosure of Confidential Data Also Violates Due Process.

The Government does not dispute that the Program requires BI to disclose extensive confidential business information to CMS. *See* BI Br. 13; *see generally* 42 U.S.C. §§ 1320f-2(a)(4), 1320f-3(e)(1); Revised Guidance Appx. C, at 188–98 (listing various categories of data CMS expects manufacturers to produce). Nor does the Government dispute that this information constitutes trade secrets, such that BI has a protected property interest in the information. *Compare* BI Br. 13 & n.11, *with* Gov't Br. 38; *see generally Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1001–03 (1984) (company had property interest in trade-secret information submitted to federal agency).

Instead, the Government argues that requiring BI to disclose trade secrets to CMS does not implicate a property interest because CMS has promised to keep them secret. Gov't Br. 38. That argument fails because "the right to exclude others is central to the very definition of the property interest." *Monsanto*, 467 U.S. at 1011. By requiring BI to disclose its trade secrets to CMS, so that CMS can use those secrets to undermine BI's interests in the Program's "negotiations," the Program intrudes on BI's right to exclude—here, its right to exclude *the government* from accessing that data. That remains true even if CMS does not disclose the trade secrets to the public at large.[10]

Monsanto makes clear that an agency can deprive one of property by disclosing trade secrets to the public *or* by using them itself in a manner contrary to the owner's expectations. 467 U.S. at 1011, 1013–14.[11] Indeed, if this were not the case, an agency could requisition confidential data at will without triggering due process protections. That cannot be the law. *Cf. RNR Enters., Inc. v. SEC*, 122 F.3d 93, 97 (2d Cir. 1997) (reviewing due process challenge to administrative subpoena). The flaw in the Government's argument is particularly apparent in the context of real property. By the Government's telling, there would be no intrusion on the owner's right to exclude if a law granted only the Government a right of access without consent. Precedent makes clear that such a law would infringe a protected property right. *See Hendler v. United States*, 952 F.2d 1364, 1374 (Fed. Cir. 1991) ("In the bundle of rights we call property, one of the most valued is the right to sole and exclusive possession—the right to *exclude* strangers, or for that matter friends,

[10] The IRA's provisions requiring drug manufacturers to turn over sensitive business information are yet another example of the ways in which CMS acts as a regulator rather than a market participant. Parties to arms-length negotiations lack the ability to compel their counterparties to turn over highly confidential information.

[11] Moreover, *Monsanto* involved a takings claim, where at issue was the degree to which the Government's access to or use of trade secrets would "frustrate Monsanto's reasonable investment-backed expectation with respect to its control over the use and dissemination of the data." 467 U.S. at 1011. In contrast, any degree of governmental infringement on BI's property rights provides a valid basis for a due process claim.

but especially the Government." (emphasis in original)). The same analysis, and the same result, applies to other forms of protected property such as trade secrets.[12]

III. THE PROGRAM EFFECTS A PHYSICAL TAKING OF BI'S JARDIANCE® TABLETS.

The Program works a physical taking by giving third parties (Medicare Part D beneficiaries and their providers) the right to "access" Jardiance® tablets, at the Government's prices, over BI's objection. *See* BI Br. 20–25. Aside from the Government's attempts to recharacterize the Program as voluntary, the Government offers little response to BI's claim.

BI's takings claim is simple. As the owner of Jardiance®, BI retains the sole right to control the "possess[ion], use[,] and dispos[ition] of" each Jardiance® tablet. *Horne*, 576 U.S. at 360 (cleaned up). This gives BI the right "to exclude others" from accessing those tablets against its will. *Kaiser Aetna v. United States*, 444 U.S. 164, 176 (1979). When the Government appropriates BI's rights for the benefit of third parties, a physical taking occurs, and "a simple, *per se* rule applies: The government must pay for what it takes." *Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2071 (2021). That *per se* rule applies here. Once CMS selected Jardiance®, BI became subject to the Program's obligations (*see supra* Part I.A), including the obligation to "enter into [an] agreement[s]" with the Government to "provid[e]" third parties in Medicare "access to the maximum price … with respect to" Jardiance®. 42 U.S.C. § 1320f-2(a)(3). As a practical matter, the IRA thus gives third parties the right "to literally take access" to BI's drugs at the Government's

[12] The Government also faults BI for "not identify[ing] a single procedure related to *data* protection" and instead challenging only the procedures related to CMS's price-setting authority. Gov't Br. 39. But that is the point: The Program gives CMS a blank check to require submission of any "information that the Secretary requires to carry out the negotiation," 42 U.S.C. § 1320f-2(a)(4)(B), while providing *no process* by which BI "[can] be heard at a meaningful time and in a meaningful manner" in opposition to the agency's data demands, *see Mathews v. Eldridge*, 424 U.S. 319, 333 (1976). The Program deprives BI of protected property interests without even a modicum of process.

price. *Cedar Point*, 141 S. Ct. at 2074 (cleaned up). The Act further requires Jardiance® to be covered by every Part D plan formulary—an illusory "benefit" (*see* Gov't Br. 34 n.6) that actually serves to guarantee the right of access to third parties and further strips BI of its ability to control the disposition of its property. *See* 42 U.S.C. § 1395w-104(b)(3)(I).

The Government's responses lack merit. It first suggests there is no taking because CMS will not "send trucks to BI's facility … to haul away drugs." Gov't Br. 34 (cleaned up). That misses the point. Seizing BI's drugs is one way to effect a physical taking, but precedent dictates that an appropriation of property rights (even without a seizure) also effects a physical taking. *See, e.g.*, *Loretto*, 458 U.S. at 435–46 (invading landlord's property—i.e., appropriating the right to exclude—constituted a physical taking); *Cedar Point*, 141 S. Ct. at 2074 (granting third parties access to property—also appropriating the right to exclude—constituted a physical taking). The Supreme Court has explained that the Takings Clause analysis focuses on the challenged law's *effects* on property rights, not *how* the law causes those effects. *See Cedar Point*, 141 S. Ct. at 2071 (collecting cases involving physical takings through various mechanisms). At any rate, the Program *does* result in third parties taking possession of Jardiance® tablets, which is no different than if the Government took possession itself. *See id.* at 2072 (Takings Clause applies "whether the government has physically taken property for itself or someone else—by whatever means"); *Horne*, 576 U.S. at 355, 362 (requirement to "ship … raisins to a raisin handler" who then sets aside "the raisins due the Government" was "essentially" the same as the "the Government h[olding] full title and ownership").

The Government dismisses the effect of the formulary inclusion requirement because it applies only "if the manufacturer reaches an agreement with CMS as to the maximum fair price of the drug." Gov't Br. 34 & n.6. As a statutory matter, the Government is right about when this requirement applies. *See* 42 U.S.C. § 1395w-104(b)(3)(I)(i). But the Government's argument assumes that BI has the choice to reject the Government's price. It does not. Failing to agree would make BI "noncomplian[t]" and subject to the excise tax penalty that can be suspended only by incurring the insurmountable cost of entirely withdrawing from Medicare and Medicaid (which is no real choice either). *See* 26 U.S.C. § 5000D(b)(2)(A); *see also supra* Part I.B. For the same reasons, the Government mischaracterizes the Program in saying that the only "penalty" BI could incur would stem from charging "beneficiaries at prices above" the Government's price. Gov't Br. 35.

The Government next argues that the IRA requires BI to give access only to a specific price, not the Jardiance® tablets themselves. *See* Gov't Br. 35. But the Government does not dispute that the IRA requires that third parties be permitted to take possession of Jardiance® tablets on the Government's terms. Tellingly, the Government does not say how a third party supposedly could access an abstract price without also receiving the underlying product.[13] Moreover, the Government's cramped reading would defeat the Program's core purpose of providing access to *drugs* at lower prices. The Government puts it best: The IRA (through compelled manufacturer agreements) "obligat[es] … manufacturers to *provide selected drugs* at negotiated prices." Gov't Br. 43 (emphasis added).

Finally, the Government argues that even if BI were forced to transfer its drugs to third parties, "that would (at worst) place [BI] in a position similar to public utilities." Gov't Br. 35

[13] The Government's briefs in other IRA cases likewise characterize the Program as mandating access to *drugs*. *See, e.g.*, Defs.' Mem. Supp. Summ. J. at 6, *Janssen Pharms., Inc. v. Becerra*, No. 3:23-cv-3818, ECF No. 33-1, at 6 (D.N.J. Oct. 16, 2023) ("[M]anufacturer will then … provide Medicare beneficiaries access *to the drug* at the negotiated price." (emphasis added)); *id.* at 32 (same). After other manufacturers pointed this out, *see, e.g.*, Pl.'s Opp'n/Reply Br., *Janssen*, No. 3:23-cv-3818, ECF No. 71 (D.N.J. Nov. 24, 2023), the Government silently walked back many (but not all) of its characterizations acknowledging how the Program actually works.

(cleaned up). The Government misunderstands the courts' special treatment of public utilities under the Fifth Amendment: Their takings claims are analyzed differently because of "th[e] *partly public, partly private status* of utility property"—attributes that in no way describe BI's *purely private* property in Jardiance® tablets. *Duquesne Light Co. v. Barasch*, 488 U.S. 299, 307 (1989) (emphasis added); *see also Horne*, 576 U.S. at 358–60 (treating growers' raisins as purely private property under the Takings Clause). The public utility cases are further distinguishable because, as the Government concedes, BI has not brought a regulatory takings claim to challenge "any particular … rate." Gov't Br. 35–36 (cleaned up). To the extent the Government is suggesting that private property somehow transforms into partly public property whenever forcibly transferred to third parties, that proposition has no support in precedent (the Government offers none) and would allow the Government to skirt constitutional scrutiny by doing the very thing that the Fifth Amendment protects against. The Takings Clause is not so toothless.

IV. THE PROGRAM VIOLATES THE FIRST AMENDMENT.

The IRA unlawfully compels BI to endorse the Government's messages about the Program, in violation of the First Amendment. Just as the government may not "prohibit the expression of an idea," *Texas v. Johnson*, 491 U.S. 397, 414 (1989), it also may not tell people that there are things "they must say," *New Hope Fam. Servs., Inc. v. Poole*, 966 F.3d 145, 170 (2d Cir. 2020) (cleaned up); *see also Janus v. AFSCME Council 31*, 138 S. Ct. 2448, 2463 (2018) ("[c]ompelling individuals to mouth support for views they find objectionable violates th[e] cardinal constitutional command" of the First Amendment); *All. for Open Soc'y Int'l, Inc. v. U.S. Agency for Int'l Dev.*, 651 F.3d 218, 225 (2d Cir. 2011) (government compulsion "affirmatively requiring [a party] to adopt a policy espousing the government's preferred message" violates the First Amendment), *aff'd*, 570 U.S. 205 (2013).

Government efforts to "compel speakers to utter or distribute speech bearing a particular message are subject to the … most exacting scrutiny." *Turner Broad. Sys., Inc. v. F.C.C.*, 512 U.S. 622, 642 (1994). These efforts are permissible only in the exceedingly rare circumstances in which the government demonstrates that the compelled speech is "a narrowly tailored means of serving a compelling" government interest. *Pac. Gas & Elec. Co. v. Pub. Utils. Comm'n*, 475 U.S. 1, 17–19 (1986) ("*PG&E*").

Here, the Government forced BI to sign an "agreement" stating that it will "negotiat[e]" with CMS to determine the "maximum fair price" for Jardiance®. 42 U.S.C. § 1320f-2(a); *see also* Manufacturer Agreement at 1. BI disagrees with each of these statements. In BI's view, it has not voluntarily entered into an "agreement" because it has no viable option but to comply with the Program's requirements; there is no "negotiation" because BI must accept whatever price CMS dictates; and the price will not be "fair" because it must (by statute) be set at a below-market level determined by CMS. *Cf. Atl. Coast Line R.R. Co. v. Bhd. of R.R. Trainmen*, 262 F. Supp. 177, 183 (D.D.C. 1967) (explaining that "[i]t is not a genuine negotiation to indicate that the other party has no choice except to accept the offer or accede to the demand," because the "service of an ultimatum does not constitute a negotiation"). BI would not convey any of these messages but for the IRA's compulsion; they are exactly the type of "forced response[s]" that the Supreme Court has found to be "antithetical to the free discussion that the First Amendment seeks to foster." *PG&E*, 475 U.S. at 16.

The Program compels BI to "make statements [it] believe[s] are false" in order to provide support for the Government's preferred narrative that the IRA provides for genuine price negotiations rather than price controls. *See Jackler v. Byrne*, 658 F.3d 225, 241 (2d Cir. 2011). The Government has consistently promoted this misleading narrative. After BI and other manufacturers' signed "agreements" unilaterally drafted by CMS, the President announced that manufacturers were "coming to the negotiating table."[14] Since then, the President has continued to assert that the IRA grants CMS the ability "to negotiate lower prescription drug prices,"[15] a message that is repeated in CMS's guidance and legal briefs.[16] The Government even tries to draw conclusions about BI's subjective intentions from its compelled signature (under protest) of the Manufacturer Agreement. *See* Gov't Br. 22 ("BI has not *indicated that it wishes* to withdraw from the Negotiation Program or from Medicare and Medicaid; to the contrary, BI has signed an agreement to negotiate." (emphasis added)). Although the Government is free to promote its preferred narrative about the Program, it cannot abrogate BI's "right to decide what to say and what not to say," *Burns v. Martuscello*, 890 F.3d 77, 84 (2d Cir. 2018), and cannot constitutionally require BI to endorse its preferred message "by word or act," *W. Va. State Bd. of Educ. v. Barnette*, 319 U.S. 624, 642 (1943).

The Government's responses to BI's First Amendment claim fall short. At the outset, it is important to note that the Government does *not* argue that requiring BI to sign a contract stating that it is engaging in a "negotiation" with CMS to set a "fair price" is narrowly tailored to serve a compelling government interest. Indeed, the Government does not argue that it can survive *any*

[14] President Biden, X (Oct. 3, 2023, 8:05 AM), https://perma.cc/6M4Q-AD6E; President Biden, X (Oct. 5, 2023, 10:55 am), https://perma.cc/55FM-QQ6A; The White House, *Biden-Harris Administration Takes Major Step Forward in Lowering Health Care Costs; Announces Manufacturers Participating in Drug Price Negotiation Program* (Oct. 3, 2023), https://perma.cc/L9BG-EBJ3.

[15] President Biden, X (Nov. 20, 2023, 10:45 AM), https://perma.cc/RX5C-6JH6; The White House, *FACT SHEET: Biden-Harris Administration Announces Dozens of Pharma Companies Raised Prices Faster than Inflation, Triggering Medicare Rebates* (Dec. 14, 2023), https://perma.cc/X6UL-S2C5.

[16] *See, e.g.,* Gov't Br., *Merck & Co. v. Becerra*, No. 23-cv-1615, ECF No. 24-1, at 12, 15-18 (D.D.C. Sept. 11, 2023); Gov't Br., *Dayton Area Chamber of Commerce v. Becerra*, No. 23-cv-156, ECF No. 34, at 4–6, 10 (S.D. Ohio Aug. 11, 2023).

form of heightened scrutiny. Any such argument would be doomed because the Government has no valid interest, let alone a compelling interest, in conscripting manufacturers to amplify its political message, and the Government could achieve its goal of lowering drug prices through a variety of means that do not infringe manufacturers' First Amendment rights. *See* BI Br. 28–29.

Having tacitly conceded its inability to withstand First Amendment scrutiny, the Government repeats its argument that the First Amendment is not implicated by BI's "choos[ing] to sign an agreement with CMS" and "undertak[ing] a voluntary obligation to negotiate prices." Gov't Br. 40. But the Program is not "voluntary," *see supra* Part I, and, in any event, the Supreme Court has "rejected th[e] [v]alidity of limitations on First Amendment rights as a condition to the receipt of public benefits," *Elrod v. Burns*, 427 U.S. 347, 359 (1976) (plurality opinion); *see also infra* Part V.

The Government next asserts that BI's signing of the Agreement is not "speech" or "expressive conduct" protected by the First Amendment at all. Gov't Br. 39. This argument runs into a wall of Supreme Court precedent recognizing that the scope of First Amendment-protected speech is sweeping and includes expressive conduct in addition to spoken and written language. *See, e.g.*, *Tinker v. Des Moines Indep. Cmty. Sch. Dist.*, 393 U.S. 503, 505 (1969) (wearing armbands to protect Vietnam War is protected by First Amendment); *Johnson*, 491 U.S. at 406 (flag burning "sufficiently imbued with elements of communication" to implicate First Amendment (cleaned up)). That such expressive conduct pertains to a transaction does not strip it of First Amendment protection. *See, e.g.*, *Expressions Hair Design v. Schneiderman*, 581 U.S. 37, 47 (2017) (law that regulates "how sellers may communicate their prices" implicates First Amendment). Government mandates applicable to "the written or spoken word" are subject to even more demanding First Amendment scrutiny. *Johnson*, 491 U.S. at 406.

There can be no real debate that signing the Manufacturer Agreement constitutes "speech" protected by the First Amendment. *See Sorrell v. IMS Health Inc.*, 564 U.S. 552, 570 (2011) (recognizing that "the creation and dissemination of information are speech within the meaning of the First Amendment"). The Agreement does much more than merely set the terms of a transaction; it repeats and amplifies the Government's message—a *political* message—that the Program is a "negotiation" that will result in a "fair price," rather than top-down government price-setting. In the same way that an individual "expresses a view on a political matter when he signs a petition," *John Doe No. 1 v. Reed*, 561 U.S. 186, 194–95 (2010), a manufacturer amplifies the Government's political message when it signs an "agreement" to "negotiate" a "maximum fair price."

The Government does not cite a single case holding that agreements are not speech protected by the First Amendment.[17] Instead, it argues that where a "law's effect on speech would be only incidental to its primary effect on conduct," the law does not regulate speech and is thus not subject to First Amendment scrutiny. Gov't Br. 40 (citing *Expressions Hair Design*, 581 U.S. at 47); *see also* Abrams Inst. Amicus Br. 9, ECF No. 72-1 (arguing that the Agreement merely defines "what plaintiff must *do*"). The Program, however, is not a "typical price regulation." *Expressions Hair Design*, 581 U.S. at 47. It goes well beyond such regulation because it forces BI to endorse the Government's message that the Program involves "negotiations" and a "fair price." The IRA could mandate that BI *do* everything set forth in the Agreement without also

[17] One of the government's amici asserts that *Ohralik v. Ohio State Bar Association*, 436 U.S. 447 (1978), "provides numerous examples of regulations of commercial activity where speech is a component of the activity… that do not offend the First Amendment." Abrams Inst. Amicus Br. 11 n.8, ECF No. 72-1. But *Ohralik* never suggested that the government can immunize restrictions on *speech* from First Amendment scrutiny simply by bundling them into regulations of "commercial activity." *See* 436 U.S. at 456.

compelling it to call these actions a "negotiation" that results in a "fair" price in service of the Government's own political objectives.

The validity of the Government's message, moreover, is an issue of public concern that is not merely incidental to the regulatory aspects of the Program, as demonstrated by the title of the "Drug Price Negotiation Program," debate regarding the Program in Congress,[18] and the repeated statements of government officials, including the President, prominently employing the same message. The Program differs markedly from a statute requiring universities to grant military recruiters with access to their campuses. *See Rumsfeld v. Forum for Acad. & Institutional Rts., Inc.*, 547 U.S. 47, 62 (2006). Nor is this case like *Nicopure Labs, LLC v. FDA*, which involved a statutory ban on distribution of free e-cigarette samples—thus effectively prohibiting manufacturers from stating that they were providing e-cigarettes at "zero dollars." 944 F.3d 267, 292 (D.C. Cir. 2019). Here, unlike in *Nicopure*, the IRA's requirements do not bear "only on product price," *id.*, but instead convey that the process leading to the price is a "negotiation" that will achieve a "fair" result. Congress could have structured the Program as an ordinary price-setting program in which the agency hears the evidence and then establishes a maximum price, *see, e.g.*, 15 U.S.C. § 717c(a), but that sort of program would have left the Government without the political benefits of the "negotiation" framing, *see* BI Br. 28–29 & n.17. The Government cannot escape the consequences of that calculated choice.

The Government next invokes the "disclaimer" in the Manufacturer Agreement, but that provision does not cure the First Amendment violation. For one thing, the compelled speech arises

[18] *See, e.g.*, 168 Cong. Rec. S4155–56 (Aug. 6, 2022) (remarks of Sen. Crapo) (advocating against Program's "system of bureaucratic drug price controls" because it involves "negotiation in name only" and makes manufacturers "an offer [they] can't refuse"); 168 Cong. Rec. S5400 (Sept. 8, 2022) (remarks of Sen. Thune) (advocating against IRA because the Program's "price controls … will discourage medical innovation and reduce the number of new treatments and cures").

from the text of the IRA itself. According to the statute, the Program is based on "agree[ments] to "negotiat[e]" a "maximum fair price." 42 U.S.C. § 1320f-2(a); *see also Nat'l Ass'n of Mfrs. v. SEC*, 800 F.3d 518, 530 (D.C. Cir. 2015) (statutory definition does not cure First Amendment violation). Moreover, the Government cannot insulate a speech mandate from First Amendment scrutiny merely by including a disclaimer (which is, in effect, additional compelled speech) stating that the speaker might not agree with the message it is being compelled to convey. As the Third Circuit explained in another case involving a disclaimer, "the fact that the schools can issue a general disclaimer along with the [required] recitation does not erase the First Amendment infringement at issue here, for the schools are still compelled to speak the Commonwealth's message. Otherwise, the state may infringe on anyone's First Amendment interest at will, so long as the mechanism of such infringement allows the speaker to issue a general disclaimer." *Circle Sch. v. Pappert*, 381 F.3d 172, 182 (3d Cir. 2004).[19]

The Government's argument that manufacturers have the "ability to say whatever they wish about the Negotiation Program or to criticize CMS or the IRA," Gov't Br. 41, likewise does not solve the First Amendment problem. The Government cannot "require speakers to affirm in one breath that which they deny in the next." *PG&E*, 475 U.S. at 16; *see also New Hope*, 966 F.3d at 170 (when the government "mandat[es] that persons explicitly agree with government policy on

[19] One of the Government's amici cites *PruneYard Shopping Center v. Robins*, 447 U.S. 74, 88 (1980), for the proposition that the owner of a private shopping mall is "free to publicly dissociate [himself] from the views of the speakers" distributing political pamphlets on the property. Abrams Inst. Amicus Br. 17. But one of the bases for *PruneYard*'s holding was that the mall owner was "*not* … being compelled to affirm their belief in any governmentally prescribed position or view," which is precisely what the Program compels BI to do. *See PruneYard*, 447 U.S. at 88 (emphasis added). Moreover, while the *PruneYard* Court buttressed its conclusion by reasoning that it was unlikely that the views expressed by individuals leafletting in a public shopping mall would be "identified with those of the owner" of that mall, *id.* at 87, the Program threatens just such misattribution by compelling BI to endorse a message with which it disagrees, *see supra* p. 30 & n.14.

a particular matter, it plainly violate[s] the First Amendment" (citation omitted)); *see also Miami Herald Publ'g Co. v. Tornillo*, 418 U.S. 241, 256 (1974). If such a requirement were permissible, the Government could compel people to endorse any message, so long as it did not bar them from uttering their true opinions in addition to the compelled speech.

The Government's argument that recognizing the validity of BI's First Amendment claim will lead to a flood of First Amendment challenges to government contracts, Gov't Br. 2, is equally unfounded. The IRA's statutory scheme is unique, and therefore a ruling in BI's favor will not cast all government contracts or price-regulation schemes into doubt. This is the first time the Government has utilized sham "negotiations" and coerced "agreements" on what is "fair" to tap into a politically popular concept and avoid the reputational costs of a top-down price-setting regime.[20] The Program is thus easily distinguishable from other agreements that the Government cites, which lack these problematic features. *See* Gov't Br. 39; 42 U.S.C. §§ 1395cc, 1396r-8(b), (c) (governing typical Medicare provider agreements and Medicaid rebate agreements, which do not require counterparties to "agree" that the price CMS pays is "fair" or the result of "negotiations").

V. THE PROGRAM VIOLATES THE UNCONSTITUTIONAL CONDITIONS DOCTRINE.

The Government hinges its defense on its contention that a manufacturer's entry into the Program and continued participation in Medicare are "completely voluntary." Gov't Br. 2. But even if the Program were "voluntary" (it is not), the Government's attempt to leverage BI's ability

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[20] Other laws charge federal agencies with setting prices without relying on agreements or negotiations between regulator and regulatee. *See, e.g.*, 15 U.S.C. § 717c(a) (directing Federal Energy Regulatory Commission to determine the "just and reasonable rate[]" of natural gas for resale in interstate commerce); 49 U.S.C. § 10704 (granting Surface Transportation Board the power to "prescribe the maximum rate" a rail carrier may charge "after a full hearing").

to continue participating in Medicare and Medicaid to force the company to surrender various constitutional rights would still violate the Constitution.

"It is settled law that the government may not, as a general rule, grant even a gratuitous benefit on condition that the beneficiary relinquish a constitutional right." *O'Connor v. Pierson*, 426 F.3d 187, 201 (2d Cir. 2005) (cleaned up); *accord Koontz*, 570 U.S. at 606; *Dolan v. City of Tigard*, 512 U.S. 374, 385 (1994); BI Br. 39–43. This doctrine prevents the Government from requiring BI to give up its constitutional rights "in exchange for a discretionary benefit conferred by the government." *Dolan*, 512 U.S. at 385.

The Government errs in arguing that the unconstitutional conditions doctrine does not apply because BI assertedly lacks a vested property interest in selling drugs to Medicare and Medicaid beneficiaries. *E.g.*, Gov't Br. 30–31. Whether BI has a right to participate in Medicare and Medicaid is "immaterial" to the unconstitutional conditions doctrine. *Perry v. Sindermann*, 408 U.S. 593, 598 (1972). As *Dolan* makes clear, the "well-settled doctrine of 'unconstitutional conditions'" forbids the government from requiring a person to surrender constitutional rights "in exchange for a *discretionary* benefit conferred by the government." 512 U.S. at 385 (emphasis added). Here, the Government acknowledges that the Program forces BI to "choose between," *id.*, continued participation in the critically important Medicare and Medicaid markets, on the one hand, and asserting its rights under the First and Fifth Amendments, on the other.[21] The unconditional conditions doctrine forbids the Government from conditioning BI's access to a valuable privilege on "the relinquishment of constitutional rights." *Frost v. R.R. Comm'n of Cal.*, 271 U.S. 583, 593–94 (1926).

[21] *See, e.g.*, Gov't Br. 2 (Plaintiff "may be dissatisfied with the *conditions* Congress imposed on future Medicare spending[.]"), 6 ("These *conditions* parallel those that Congress has long attached to other government health care programs."), 21 ("If a provider dislikes the *conditions* offered by the government, it can simply withdraw from the program.") (all emphases added).

The Government's remaining contentions are no more persuasive. The Government makes a convoluted argument that it can condition BI's participation in Medicare and Medicaid on BI's surrender of procedural due process rights because the benefit and rights are one and the same. Gov't Br. 31. That assertion mischaracterizes BI's claim. The Program is unconstitutional because it seeks to condition BI's ability to sell *any drugs* to Medicare *or Medicaid* beneficiaries on its surrender of a distinct constitutional right: BI's right not to have CMS set the terms for sales of *one drug* (Jardiance®) to *Medicare* beneficiaries through an arbitrary and self-serving process. Because the Government thus seeks to leverage a much broader benefit to induce BI to give up a particular right, "the lack of process" does *not* "concern[] the very same Medicare sales that BI is seeking as a benefit." *See id.*

Similarly, the Government's attempt to analogize BI to a government contractor who "claim[s] that the denial of a contract improperly infringed on his procedural rights to negotiate that contract," Gov't Br. 32, is inapt. Instead, BI's situation is analogous to a contractor that is asked to surrender its constitutional rights in order to receive a government contract—which would plainly violate the unconstitutional conditions doctrine. *See Bd. of Comm'rs v. Umbehr*, 518 U.S. 668, 674 (1996). The Government offers no reason why it supposedly is helped by the fact that the right at stake derives from the Fifth Amendment's Due Process Clause, and the cases it cites hold that the doctrine protects due process rights. *See R.S.W.W., Inc. v. City of Keego Harbor*, 397 F.3d 427, 434 (6th Cir. 2005) (citing *Vance v. Barrett*, 345 F.3d 1083, 1089 (9th Cir. 2003)).[22]

With respect to BI's First Amendment right to refrain from endorsing messages it opposes, the Government argues that the Program's speech mandates merely "pertain to the nature of [the]

[22] To the extent the Government relies on *Keego Harbor* and *Vance* for the proposition that the unconstitutional conditions doctrine applies only when a constitutional right is at stake, that proposition is not in dispute. *See* BI Br. 40–43 (identifying three ways program is unconstitutional).

government program" and therefore permissibly "define" the Program. Gov't Br. 42–43 (quoting *USAID*, 570 U.S. at 217). *USAID* does not support the Government's position. Although the Court noted there that the line between conditions that properly "define the federal program" and conditions that improperly "reach outside it … is not always self-evident," the Court was "confident" that when the Government "compel[s]" the recipient of a benefit to "adopt … the Government's view on an issue of public concern, the condition *by its very nature* affects protected conduct outside the scope of the federally funded program." *Id.* at 217, 218 (emphasis added). That is exactly what is happening here: The Government is attempting to "leverage" its control over the prescription drug market to coerce BI to espouse a message with which it disagrees. *See supra* Part IV.

With respect to the Takings Clause, the Government likewise cannot justify the taking of BI's Jardiance® products as a condition on BI's participation (for all of its products) in Medicare and Medicaid. That requirement violates the unconstitutional conditions doctrine because it is not proportional to the benefit sought. *See Koontz*, 570 U.S. at 605–06 (setting out this test); BI Br. 41–42 (applying the test). Although the Government contends that the proportionality principle is limited to the land-use context, Gov't Br. 32, that argument proves too much. While cases articulating the proportionality test involved "misuse of the power of land-use regulation," *Koontz*, 570 U.S. at 599, that does not mean the test is inapplicable to other types of governmental action. Indeed, the land-use cases relied on precedent across the range of enumerated constitutional rights, *see Dolan*, 512 U.S. at 385 (citing cases), and cases outside the land-use context have applied similar proportionality principles, *see, e.g.*, *Mem'l Hosp. v. Maricopa County*, 415 U.S. 250, 258–59 & n.13 (1974).

Regardless, even if the proportionality test is not applicable, it is clear that the unconstitutional conditions doctrine *does* apply. *See, e.g.*, *Koontz*, 570 U.S. at 604 (explaining that the unconstitutional conditions doctrine "reflect[s] an overarching principle … that vindicates the Constitution's enumerated rights"); *O'Connor*, 426 F.3d at 201 (noting that the unconstitutional conditions doctrine is "settled law"). Thus, at a minimum, the Program is unlawful if the condition it imposes—requiring BI to grant Medicare participants "access" to Jardiance® products—would violate the Fifth Amendment if required outright. *See, e.g.*, *Maricopa County*, 415 U.S. at 258 (applying same test to condition burdening constitutional right as law infringing that right directly); *O'Connor*, 426 F.3d at 201 (same).[23] The Program fails that test, *see supra* Part III, and thus violates the unconstitutional conditions doctrine even if it is voluntary.

VI. THE IRA IMPOSES EXCESSIVE FINES IN VIOLATION OF THE EIGHTH AMENDMENT.

The Government challenges BI's Eighth Amendment claim on jurisdictional grounds as well as on the merits. The Government's arguments fail on all fronts.

A. The Court Has Jurisdiction Over BI's Claim.

1. BI Has Standing.

According to the Government, the Court should reject BI's Eighth Amendment claim concerning the excise tax because BI supposedly sued the wrong agency. Because the "tax" is codified in Title 26 of the U.S. Code and is "administer[ed]" by the IRS and the Treasury Department, the Government argues that any injunctive relief the Court might award against HHS and CMS will not redress BI's injuries flowing from its exposure to the tax. *See* Gov't Br. 10–11. This argument fails for three reasons.

[23] *Horne* suggests an even more stringent test: When the Government requires the "relinquish[ment of] specific, identifiable property as a 'condition'" on market participation, it effects a "per se taking." 576 U.S. at 364–65.

First, contrary to the Government's contention, the IRA assigns HHS an essential role in administering the excise tax: The tax can only be imposed after HHS "shar[es] with the Secretary of the Treasury [] such information as is necessary to determine the tax imposed by section 5000D." 42 U.S.C. § 1320f-5(a)(6) (defining this duty); *id.* § 1320f(a)(4) (assigning this duty to HHS). The Government offers no reason why Defendants could not be enjoined from taking that step, nor any reason why doing so would not redress BI's injury.

Second, the Government errs in asserting that the reach of an injunction necessarily is limited to the named parties, especially in the context of federal agencies. The Federal Rules of Civil Procedure expressly allow an injunction to bind not only "the parties" and their agents but also "other persons who are in active concert or participation with" the parties. Fed. R. Civ. P. 65(d)(2)(C). On any reasonable interpretation, administration of the excise tax is a joint undertaking by HHS and the Treasury Department. Thus, even if it were necessary to bind the IRS or the Treasury Department to deliver relief, this Court could do so.

Third, *Haaland v. Brackeen*, 599 U.S. 255 (2023), does not warrant a different result. There, unlike here, the plaintiff had sued the wrong sovereign; the Court held that an injunction barring *federal* defendants from enforcing the Indian Child Welfare Act "would not remedy the alleged injury, because *state courts* apply the [adoption] placement preferences, and *state agencies* carry out the court-ordered placements." *Id.* at 292 (emphasis added). Here, by contrast, BI has challenged a single act of Congress that commands two federal agencies to collaborate to implement a single tax.

2. The Anti-Injunction Act Does Not Bar This Claim.

The Government does not dispute that under *Enochs v. Williams Packing & Navigation Co.*, 370 U.S. 1 (1962), a plaintiff can seek advance review of a tax where there is "certainty of success on the merits" and denying such review would work irreparable injury. BI Br. 34; Gov't Br. 15–17. Both prongs of this test are met here.

First, because of the extraordinary magnitude of the tax, BI would be irreversibly damaged by having to pay the tax for any meaningful period of time. As BI's undisputed evidence shows, if subjected to this tax BI would face liability of $500 million *per week*, later increasing to more than $5.5 *billion* per week. Marsh Decl. ¶ 16. This case is thus a far cry from *Larson v. United States*, 888 F.3d 578 (2d Cir. 2018), where the plaintiff faced a payment of $61 million that arose from criminal activity. *See id.* at 579. The burden the tax imposes on BI is staggering, particularly given that it stems entirely from conduct that the Government acknowledges is entirely legal, *see* Gov't Br. 6.

The Government's "divisible tax" argument is a red herring. Even assuming for purposes of argument that (1) the excise tax would operate as a divisible tax, (2) review would be available after a single sale transaction, and (3) the IRS would exercise forbearance in collection of the excise tax until resolution of that suit, *see* Gov't Br. 16–17, the irreparable harm to BI still would not be mitigated. This is because the exact timing of the payment of the excise tax is not the fundamental problem. Instead, the real problem arises from the ruinous *magnitude* of the potential tax liability BI would accrue while litigation (reviewing a "test transaction") ran its course. That is not a risk any rational actor could knowingly undertake. And while BI is confident it would prevail on the merits in such a case, the Government vigorously asserts otherwise, rendering disingenuous its suggestion that this approach to seeking review is reasonable.

Second, as to certainty of success on the merits, the Government recognizes that this criterion is intertwined with BI's arguments on the merits of its claim. *See* Gov't Br. 17. As explained below, the claim will succeed on the merits, and as a result, the Court may adjudicate it.

B. The Excise Tax Is a Fine and Is Unconstitutionally Excessive.

The Government's primary argument on the merits of BI's Eighth Amendment claim is that Excessive Fines Clause arguments are essentially off the table in all circumstances other than when the fine is "punishment for an offense." Gov't Br. 43–50. Not so. In *Tyler v. Hennepin County*, 598 U.S. 631 (2023), the Court held that a plaintiff could state a Takings Clause claim where a county government seized and sold a taxpayer's residence to satisfy a tax debt (including accrued penalties) and also pocketed the sales proceeds in excess of the debt. *See id.* at 634, 647. The Court's majority opinion did not reach the plaintiff's Excessive Fines Clause claim, but the concurring Justices recognized that the exaction—an unquestionably civil matter—likely ran afoul of the Eighth Amendment, concluding: "Economic penalties imposed to deter willful noncompliance with the law are fines by any other name. And the Constitution has something to say about them: They cannot be excessive." *Id.* at 648–50 (Gorsuch, J., joined by Jackson, J., concurring).

Elsewhere, the Court has made clear that civil penalties may be fines within the meaning of the Eighth Amendment: "[T]he question is not, as the United States would have it, whether [an exaction] is civil or criminal, but rather whether it is punishment." *Austin v. United States*, 509 U.S. 602, 610 (1993). That is because "the notion of punishment … cuts across the division between the civil and the criminal law" and "civil proceedings may advance punitive as well as remedial goals." *Id.* Although there are relatively few cases addressing the Excessive Fines Clause in a civil context, that does not suggest that the Clause does not apply in that context—and nothing the Government cites holds otherwise. Indeed, courts have repeatedly concluded that civil exactions fall within the scope of the Eighth Amendment. *See, e.g.*, *Pimentel v. City of Los Angeles*, 974 F.3d 917, 921–22, 925 (9th Cir. 2020) (analyzing whether $63 parking fine is "grossly disproportional to the underlying offense of overstaying the time at a parking space");

WCI, Inc. v. Ohio Dep't of Pub. Safety, 774 F. App'x 959, 960–61, 966–67 (6th Cir. 2019) (analyzing whether $25,000 fine on adult entertainment venue, as penalty for performers' unlawful conduct, violated Eighth Amendment); *United States v. Mackby*, 261 F.3d 821, 830–31 (9th Cir. 2001) (remanding to consider whether False Claims Act civil penalty and treble damages, together totaling about 12 times the underlying Medicare overbilling, was unconstitutionally excessive).[24]

Moreover, "Congress cannot change whether an exaction is a tax or a penalty for *constitutional* purposes simply by describing it as one or the other." *NFIB*, 567 U.S. at 544. Thus, because the excise tax here is a penalty that is "punitive in part," it is "within the purview of the Excessive Fines Clause." *United States v. Bajakajian*, 524 U.S. 321, 330 n.4 (1998).

As for the *excessive* nature of the fine here, the Government has little to say. *See* Gov't Br. 51–52. The Government relies primarily on the same misleading calculation discussed above to argue that the rate of the tax is only 95 percent, *see supra* pp. 14–15; Gov't Br. 8, 17, and musters only a single case finding a comparable rate constitutional, *see* Gov't Br. 52 (citing *United States v. Alt*, 83 F.3d 779, 784 (6th Cir. 1996)). But that case involved a penalty for fraud, not conduct that the Government insists is perfectly legal. *See Alt*, 83 F.3d at 782–83. The excessive nature of the fine is only underscored by the Congressional Budget Office's conclusion that no one will ever incur the tax because of its enormous cost. *See* BI Br. 32. If the Government could avoid Eighth Amendment scrutiny merely by labeling such an extortionate fine a "tax," that would open an enormous loophole in the Eighth Amendment.

[24] The relative dearth of caselaw may be due in part to the fact that the Supreme Court did not determine that the Excessive Fines Clause applies to the States until 2019. *See Timbs v. Indiana*, 139 S. Ct. 682 (2019).

VII. THE MANUFACTURER AGREEMENT VIOLATES THE APA AND THE MEDICARE ACT.

The Government did not provide notice and an opportunity for comment on the Manufacturer Agreement, in violation of the APA and the Medicare Act. Although the Government tries to excuse CMS's circumvention of these notice and comment requirements, its arguments are unavailing.

The Government begins by attacking a strawman, arguing that CMS *guidance* need not be subject to notice and comment and relying on statutory language providing that CMS shall implement the IRA "for 2026, 2027, and 2028 by program instruction or other forms of program guidance." Gov't Br. 52–53. BI's argument is that the *Manufacturer Agreement*—not the guidance—was improperly excluded from notice and comment. BI Br. 53–56. Nothing in the statute exempts the Manufacturer Agreement from the APA's notice and comment requirements.[25]

[25] The Government's argument fails even on its own terms. The IRA does not displace the APA's notice and comment requirements because a "[s]ubsequent statute may not be held to supersede or modify" these requirements "except to the extent that it does so expressly." 5 U.S.C. § 559; *see also Yale-New Haven Hosp. v. Leavitt*, 470 F.3d 71, 78 (2d Cir. 2006). To be considered "express," Congress must have "established procedures so clearly different from those required by the APA that it must have intended to displace the norm." *Marcello v. Bonds*, 349 U.S. 302, 310 (1955). The IRA cannot clear that bar. Even when "Congress unambiguously intended" for an agency to proceed by "guidance," the agency was still "probably … *required* to promulgate such rules only through APA rulemaking procedures" if such guidance was binding. *NRDC v. EPA*, 22 F.3d 1125, 1147 (D.C. Cir. 1994) (emphasis in original). Here, moreover, Congress knew how to provide that guidance could be issued without notice and comment notwithstanding the APA, but included no such language in the IRA. In the Medicare and Medicaid contexts, Congress has repeatedly enacted provisions stating that program instructions or guidance may be issued "[n]otwithstanding any other provision of law." *E.g.*, 42 U.S.C. § 1320a-7c(a)(6)(J) ("Notwithstanding any other provision of law, the Secretary may implement the partnership established by subparagraph (A) by program instruction or otherwise"); *id.* § 1395cc-7(c); *id.* §1395m(u)(7)(G); *id.* § 1395w-4(k)(2)(A); *id.* § 1395-3a(c)(5)(C). The IRA contains no such provision. Because "Congress legislates against the backdrop of existing statutes," this omission shows that Congress did not intend to exempt IRA guidance from the APA's notice and comment requirements. *See Orton Motor, Inc. v. HHS*, 884 F.3d 1205, 1214 (D.C. Cir. 2018).

Next, the Government asserts that it *did* subject the Manufacturer Agreement to notice and comment, because in soliciting comment on the guidance, CMS asked for comment on "[t]erms and conditions contained in the manufacturer agreement." This argument ignores the fact that the draft Manufacturer Agreement was not published until July 3, 2023—months after the April 14, 2023 deadline for commenting on the draft guidance. *See* Ex. D to Shearin Decl., ECF No. 28-7. The Government also ignores CMS's categorical statement, when it issued the Revised Guidance, that it "will not provide a comment period on the Agreement." Revised Guidance at 30. Clearly, CMS did not provide adequate notice or an opportunity for comment.

That failure was significant. As a matter of common sense, there is a difference between seeking general comments about the terms of an agreement and actually subjecting the text of an agreement to public comment. That conclusion is confirmed by the Agreement itself, which contains numerous terms not found in the guidance. To start, the Agreement confers sweeping authority on CMS by providing that "CMS retains authority to amend th[e] Agreement" at any time without the manufacturer's consent. Manufacturer Agreement §§ II(e), IV(b). The Agreement also includes new language attempting to insulate CMS from First Amendment challenges. *Id.* § IV(f). The Agreement further limits manufacturers' rights by providing that "[a]ctions by the Manufacturer for damages are not permitted pursuant to this Agreement, and the Manufacturer's remedies for any breach are limited to termination of the Agreement or other action consistent with applicable statutes, regulations, or guidance." *Id.* § IV(i). These are only a handful of examples of substantive provisions of the Agreement that are nowhere reflected in the guidance.

Thus, the Manufacturer Agreement goes well beyond the guidance, by changing manufacturers' existing rights and by imposing new duties, which—like violations of the IRA itself—the Agreement asserts can be enforced through imposition of enormous excise tax penalties and civil monetary penalties. *See* Manufacturer Agreement § II ("the Manufacturer agrees to comply with … all applicable guidance"); *id.* § IV(j) ("the Manufacturer may be subject to civil monetary penalties and an excise tax, as applicable, for failure to meet the requirements of the Negotiation Program, including violations of this Agreement"); *Gonnella v. SEC*, 954 F.3d 536, 546 (2d Cir. 2020) (noting that the creation of "new law, rights, or duties" constitutes a "legislative rule" which "must go through Notice and Comment procedures").

In this context, failure to provide for notice and comment on the Agreement itself was prejudicial. "Agency mistakes constitute harmless error only where they clearly had no bearing on the procedure used or the substance of decision reached." *N.Y. Pub. Int. Rsch. Grp. v. Whitman*, 321 F.3d 316, 334 n.13 (2d Cir. 2003). Moreover, "an utter failure to comply with notice and comment cannot be considered harmless if there is any uncertainty at all as to the effect of that failure." *Am. Pub. Gas Ass'n v. U.S. Dep't of Energy*, 72 F.4th 1324, 1338 (D.C. Cir. 2023). Here, CMS utterly failed to take comment on the Agreement itself.

It is also significant that the Agreement diverges from, and goes far beyond, CMS's Guidance. That characteristic creates sufficient uncertainty about the effect that BI's comments, if it had been given an opportunity to file them, might have had on the Agreement's terms. Even if BI had an opportunity to generally comment on a hypothetical agreement, it had no opportunity to comment on the actual text of the Agreement or the provisions that are not in the guidance. For instance, if given the opportunity, BI would have commented that CMS's ability to make unilateral changes to the Agreement at any time is coercive and at odds with the statutory construct of a negotiated agreement. It is at least plausible that CMS, given its goal of portraying the Program as a "negotiation," would have revised this language; at the very least, the agency would have had to contend with BI's suggestion. For these reasons, the error here is far from harmless. *See Sugar*

Cane Growers Coop. of Fla. v. Veneman, 289 F.3d 89, 96 (D.C. Cir. 2002) (holding that it was not harmless error for an agency to "skip [APA] procedures" by "engag[ing] in informal consultation" instead of taking comment); *see also Sprint Corp. v. FCC*, 315 F.3d 369, 377 (D.C. Cir. 2003) (holding that FCC should have taken comment on a modified version of a former rule, which itself had gone through notice and comment procedures, and that its failure to do so was not harmless). Simply put, "any contract provisions that are legislative," such as those in the Agreement, "are subject to [the APA's] notice and comment requirements." *Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1053–54 (D.C. Cir. 1987). CMS failed to comply with those requirements here.

CONCLUSION

For the foregoing reasons, and those set forth in BI's Opening Brief, the Court should grant summary judgment in favor of BI.

Respectfully submitted,

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