IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

NATIONAL INFUSION CENTER ASSOCIATION *et al.*, Plaintiffs, vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of Health and Human Services, *et al.*, Defendants.	Civil Action No. 1:23-cv-00707

PLAINTIFFS' REPLY IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT AND OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

The government defends the Drug Pricing Program of the Inflation Reduction Act (IRA) on the theory that the Program is a genuine "negotiation." But repeating that word enough times does not make it so. In reality, the IRA delegates unfettered authority to the Centers for Medicare & Medicaid Services (CMS) to *set* drug prices—not as a market participant (CMS is not buying any drugs here), but as a stand-in legislature. While the IRA stages faux "offers," "counteroffers," and "agreements," it exposes those features as a sham by imposing crippling penalties on any manufacturer that declines to participate or "comply" with CMS's decisions. Manufacturers thus have no choice but to "agree" to sell their drugs for below-market prices that CMS unilaterally chooses.

The government's expert declaration—though scarcely referenced in the government's brief, and never for its conclusion—reflects the same misunderstanding of the Program. For all its talk of CMS's "political incentives to avoid" a "failed negotiation," Buchmueller Decl. ¶ 11 (ECF No. 70-1), the declaration ignores that *manufacturers* have no alternative to "accepting" CMS's chosen price. The excise tax, the requirement that noncooperating manufacturers must leave Medicare and Medicaid altogether, and other crippling penalties prevent manufacturers from walking away, so the cost to CMS of a "failed negotiation" does not matter. The declaration does not even *mention* the excise tax, much less explain how it leaves manufacturers with any choice but to accept whatever prices the government dictates.

Stripped of its "negotiation" veneer—and taken for what Congress actually wrote in the statute—the Drug Pricing Program is constitutionally indefensible. First, the statute on its face violates separation-of-powers principles and the nondelegation doctrine by combining a grant of sweeping discretion to an administrative agency with *neither* front-end input *nor* back-end review. The end result is an effective delegation to HHS of boundless power over a massive segment of the economy—the authority not merely to implement the IRA, but to rewrite it with impunity. The government attempts

to justify each element of the statute separately, as if it existed in a vacuum, citing examples where courts have upheld statutes with notice-and-comment procedures and judicial review opportunities. But the government fails to cite a single case upholding a statute that *both* delegated sweeping authority *and* eliminated all procedural guardrails. And for good reason: No such case exists.

Second, under the guise of the so-called "excise tax," the IRA subjects manufacturers to excessive fines for what even the government now admits is entirely innocent conduct. Unable to seriously defend the provision as written, the government invents legal tests and strains to portray the excise tax as much lower than what the statute plainly provides. Failing that, it makes much ado about process, insisting Plaintiffs named the wrong governmental entities in the case caption. But the named defendants have a clear (statutorily mandated) role in enforcing the excise tax provisions, so there is no question that Plaintiffs' claim is redressable in this suit. And the government's theory of the Anti-Injunction Act is even weaker, as it would allow Congress to insulate all manner of unconstitutional laws from judicial scrutiny by enforcing them through "taxes" that no one could ever afford to pay.

Finally, the IRA violates the Fifth Amendment by depriving manufacturers, providers, and patients of core constitutionally protected interests without a modicum of process. The government does not even bother to argue that it can meet the controlling three-factor test for due process challenges under *Mathews v. Eldridge*, 424 U.S. 319 (1976), perhaps because the Fifth Circuit held in this very case that Plaintiffs' allegations regarding the Drug Pricing Program "satisfy the *Mathews* test" for a due process violation. *Nat'l Infusion Ctr. Ass'n v. Becerra*, 116 F.4th 488, 503 (5th Cir. 2024) (*NICA*). The government thus concedes that the private interests at stake are massive, there is a serious risk of erroneous deprivation of those interests, and the government has no legitimate interest in barring front- and back-end review of CMS's implementation of the Program. What the government *does* argue—that Plaintiffs have no protected interests or that the Program does not deprive them of their interests (or both)—is baseless and largely depends on the fiction that the government operates under

the Program like any other "market participant." But the government is not just a market participant; it sets prices for sales to *private* purchasers. And unlike the government here, normal market participants cannot simply dictate the final price by employing an excise tax sledgehammer when the counteroffer comes in higher than they would like.

The Court should grant Plaintiffs summary judgment on each of their claims.

ARGUMENT

I. THE IRA VIOLATES THE SEPARATION OF POWERS AND THE NONDELEGATION DOCTRINE

The government observes (at 1) that "[f]or more than 30 years, Congress has limited how much federal agencies will pay for prescription drugs." But in the IRA, Congress did not exercise power merely over drug reimbursement or procurement. Instead, it delegated price-*setting* authority to HHS to prohibit manufacturers from charging market prices to private Medicare participants. HHS can now legislate drug prices for the entire drug industry; the only "limitation" is that prices must be *lower* than current rates. 42 U.S.C. § 1320f–3(b), (c), (e).

Until the IRA, Congress never delegated price-setting authority without guardrails such as minimum standards of fairness, notice-and-comment rulemaking or other formal hearings, and judicial oversight. But the IRA not only grants sweeping legislative authority to an administrative agency, it removes all of those guardrails, allowing the agency to proceed without the front-end safeguard of notice-and-comment rulemaking, *see* 42 U.S.C. § 1320f Statutory Note (authorizing implementation by "program guidance"), and precluding all meaningful administrative and judicial review, *see id.* § 1320f–7. The statute thus empowers HHS to exceed even the superficial limits the IRA purports to set. Together, these features give HHS "virtually unfettered" discretion to overhaul the $600 billion pharmaceutical market. *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 542 (1935).

1. The government never grapples with the combined effect of the IRA's elements. Instead, it insists (at 14) there is "no support in either Supreme Court or Fifth Circuit precedent" for the proposition that a "collection" of features can combine to create a nondelegation problem. But the *en banc* Fifth Circuit said exactly the opposite just last year: "The Supreme Court has instructed us to review separation-of-powers challenges holistically. And it has held that two or more things that are not independently unconstitutional *can combine* to violate the Constitution's separation of powers." *Consumers' Rsch. v. FCC*, 109 F.4th 743, 778 (5th Cir. 2024) (en banc) (emphasis in original), *cert. granted*, 145 S. Ct. 587 (2024). That is exactly what the IRA does.

The government contends (at 1, 11–12) that "there is nothing particularly special about this statute" because the IRA provides "criteria for selection," "mathematical formulae for calculating ceiling prices," "procedures for negotiation," and "factors" for HHS to "consider" in setting prices. But those criteria are illusory.

To start, the IRA permits HHS to simply *ignore* all of the statutory "criteria," "factors," and "formulae." That's because Congress deprived the public of input on the front end, 42 U.S.C. § 1320f Statutory Note, and eliminated accountability on the back end by foreclosing "administrative or judicial review," *id.* § 1320f–7. These features turn the IRA's broad delegation into an unlimited one. HHS could determine that *all* of a particular manufacturer's drugs actually count as a single "qualifying single source drug," slash the prices of all of those drugs at once, and then tell manufacturers they can do nothing about it. This is not hyperbole. As Plaintiffs explained in their opening brief, HHS has already "interpreted" the IRA to allow the agency to aggregate numerous drugs into one, thus circumventing the statute's ostensible maximum of ten drugs (42 U.S.C. § 1320f–1(a)(1)), *see* Pls.' MSJ 15–16—and belying the government's supposed "criteria . . . for selection," Defs.' Br. 11.

The government urges the Court (at 17 n.11) to ignore this particular CMS overreach because the "guidance is not challenged in this case." But that is precisely the point. In the cases where CMS's

approach *was* challenged, the government has argued that "[t]he IRA expressly precludes review of [those] statutory claims."[1] So far, the only court to reach the issue agreed that the IRA makes CMS's decisions completely unreviewable. *See Novo Nordisk Inc. v. Becerra*, 2024 WL 3594413, at *3 (D.N.J. July 31, 2024) ("the Court concludes that it lacks subject matter jurisdiction to consider challenges to CMS's underlying determinations"). While the government asserts (at 17 n.11) that "Plaintiffs are mistaken about . . . the definition of 'qualifying single source drug,'" the point is that the IRA, on its face, *allows* CMS to ignore that definition—and every other statutory command—without judicial recourse.[2] That is the very definition of lawmaking authority.

The government does not attempt to disavow the unfettered power that the IRA gives CMS to rewrite the law, or even to downplay the IRA's facial barrier to meaningful input and review. Instead, it takes the categorical position (at 14–15) that total removal of these procedural safeguards is irrelevant to the nondelegation issue. That position defies caselaw and common sense.

A delegation of unchecked discretion is obviously broader than a delegation of checked discretion. To avoid a nondelegation problem, "Congress [must] provide[] an administrative agency with standards guiding its actions such that a *court* could ascertain whether the will of Congress has been obeyed." *Skinner v. Mid-Am. Pipeline Co.*, 490 U.S. 212, 218 (1989) (emphasis added) (quotation omitted). Whether "judicial review is possible," therefore, is a key factor in the nondelegation inquiry. *Touby v. United States*, 500 U.S. 160, 168–69 (1991); *see, e.g.*, *United States v. Gordon*, 580 F.2d 827, 839

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[1] Br. for Appellees, *Novo Nordisk Inc. v. HHS*, No. 24-2510, Doc. 34 at 42 (3d Cir. Dec. 16, 2024); Defs.' Reply Br., *AstraZeneca Pharms. LP v. HHS*, No. 23-cv-931, Doc. 61 at 9–15 (D. Del. Jan. 5, 2024); Br. for Appellee, *AstraZeneca Pharms. LP v. HHS*, No. 24-1819, Doc. 37, 41–47 (3d Cir. Sept. 12, 2024).

[2] The government is also wrong on the definition: The IRA defines "qualifying single source drug" as *one* drug—namely, "*a* drug or biological product" (1) that is FDA-approved "and is marketed pursuant to *such* approval" (i.e., pursuant to a New Drug Application); (2) "for which . . . at least 7 years will have elapsed since the date of *such* approval; and" (3) "that is not *the* listed drug for any [generic]." 42 U.S.C § 1320f–1(e)(1)(A) (emphases added).

(5th Cir. 1978) (noting "the availability of judicial review" can be a factor in assessing a nondelegation challenge); *United States v. Garfinkel*, 29 F.3d 451, 459 (8th Cir. 1994) (citing "[j]udicial review" and "notice and comment" rulemaking as factors in the nondelegation inquiry). In *A.L.A. Schechter Poultry Corp.*, for instance, the Court rejected a delegation of authority to the President to establish "codes of fair competition," stressing the absence of safeguards such as "judicial review to give assurance that the action of the [agency] is taken within its statutory authority." 295 U.S. at 521–22, 533. The *en banc* Fifth Circuit likewise invalidated a statute "so amorphous that no reviewing court could ever possibly invalidate any [agency] action taken in its name." *Consumers' Rsch.*, 109 F.4th at 767. And that statute merely *impeded* meaningful judicial review. The IRA, by contrast, expressly *eliminates* it.

The government's recitation of cases (at 11) only underscores the necessity of procedural guardrails when Congress attempts a delegation as broad as this one. In *American Power & Light Co. v. SEC*, 329 U.S. 90, 105–06 (1946), for example, the Public Utility Holding Company Act ensured that "[p]rivate rights [were] protected by access to the courts" and that "judicial review of the [agency's implementation] safeguard[ed] against statutory or constitutional excesses." The Court in *United States v. Rock Royal Co-op.*, 307 U.S. 533, 576 (1939), emphasized the importance of "procedural safeguards," highlighting that the Agricultural Marketing Agreement Act preserved "the privilege of appeal [of agency action] to the courts." The Fair Labor Standards Act provision at issue in *Opp Cotton Mills v. Administrator of Wage & Hour Division of Department of Labor*, 312 U.S. 126, 144 (1941), set standards sufficient for "the public" and "the courts" to "ascertain whether the agency has conformed." In *Union Bridge Co. v. United States*, 204 U.S. 364, 387–88 (1907), the challenged statute required the agency to "first giv[e] the parties an opportunity to be heard" in an administrative proceeding. The Renegotiation Act at issue in *Lichter v. United States*, 334 U.S. 742, 787 (1948)—which allowed the Under Secretary of War to recover "excessive profits" from private contractors during World War II—expressly provided "for a redetermination of excess profits by the Tax Court de novo." And in *National Broadcasting Co. v.*

United States, 319 U.S. 190, 195, 224 (1943), "96 witnesses" testified over "73 days" in a comprehensive notice-and-comment process, and judicial review was available to ensure that "the action of the [agency] was based upon findings supported by evidence." *See Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 476 (2001) (remanding after upholding the delegation because the statute at issue allowed litigants to challenge agency action "under the judicial-review provisions").

The cases the government cites involving administrative price-setting—the type of delegation at issue here—are particularly clear about the need for such safeguards. The statute in *FPC v. Hope Natural Gas Co.*, 320 U.S. 591, 602 (1944), which required that rates be "just and reasonable," allowed agency action to be "challenged in the courts," to ensure that the "statutory requirements [were] satisfied." *FPC v. Nat. Gas Pipeline Co. of Am.*, 315 U.S. 575, 585–86 (1942). Likewise, in *Yakus v. United States*, 321 U.S. 414, 422–23 (1944), the Court emphasized not only that "[t]he boundaries of the field of the [agency's] permissible action [were] marked by the statute," but "that the courts in an appropriate proceeding" could assess the agency's ultimate decisions. In other words, when Congress *permissibly* delegates price-setting authority, it provides the very guardrails that the IRA omits.

Despite the government's emphasis on "intelligible principles," moreover, it ignores a key purpose of that requirement: to *enable* meaningful judicial review. *See, e.g.*, *Am. Power*, 329 U.S. at 106 ("The legislative policies and standards being clear, judicial review of the [agency action] safeguards against statutory or constitutional excesses."). Because the IRA eliminates such review entirely, it scarcely matters whether CMS's overreach is "ascertain[able]." *Skinner*, 490 U.S. at 218.

Ultimately unable to disclaim the importance of judicial review to the nondelegation inquiry, the government pivots to arguing that although the "*availability*" of judicial review supports "*upholding*" a delegation, the "*preclusion*" of review is still irrelevant. Defs.' Br. 14–15 (government's emphases). But the government cannot have it both ways. Either judicial review matters to the nondelegation question or it does not. And courts have said, time and again, that it does. *See supra* pp.5–6.

Doubling down, the government objects (at 16–17) to the relevance of procedural safeguards on the ground that many Medicare provisions limit judicial review. But in stark contrast to the IRA, the Medicare statute expressly imposes the front-end safeguard of notice-and-comment rulemaking, even above and beyond the traditional rulemaking requirements of the Administrative Procedure Act. *See* 42 U.S.C. § 1395hh(b)(1). The government identifies no statute—in Medicare or otherwise—that delegates broad discretion over a massive segment of the economy, exempts agency decision-making from public input, *and* forecloses administrative and judicial oversight. By attempting to defend each individual feature of the Drug Pricing Program as separately permissible, the government ignores that "two or more things that are not independently unconstitutional *can combine* to violate the Constitution's separation of powers." *Consumers' Rsch.*, 109 F.4th at 778 (emphasis in original).[3]

The government argues (at 15) that considering the availability of judicial review is "inconsistent" with a "line of settled precedent" holding that Congress generally has the power to limit the jurisdiction of the lower federal courts. Again, however, Plaintiffs are not arguing that the preclusion of review *alone* renders the IRA unconstitutional. The statute's nondelegation problem is its sweeping grant of vast discretion *combined with* its affirmative removal of every other key safeguard.

Finally, the government argues (at 14) that judicial review would *undermine* accountability by giving courts the final say. But statutory interpretation—which is what the IRA's judicial review bar purports to preclude—is inherent in "the judicial role." *Loper Bright Enters. v. Raimondo*, 603 U.S. 369,

[3] To the extent CMS "voluntarily solicited comments," *see, e.g.*, CMS, *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027*, at 2 (Oct. 2, 2024) (Final Guidance), go.cms.gov/40ttKLJ, that is not relevant here: "an agency can[not] cure an unlawful delegation of legislative power" simply "by declining to exercise some of that power," *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 472–73 (2001). And anyway, formal notice-and-comment rulemaking imposes additional obligations on the government not met by CMS's voluntary solicitation here. *See, e.g.*, *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015) ("An agency must consider and respond to significant comments received during the period for public comment.").

403 (2024). "[T]o the extent that Congress and the Executive Branch may disagree with how the courts have performed that job in a particular case, they are of course always free to act by revising the statute." *Id.* And as to the government's suggestion (at 14) of "accountab[ility] to an elected President" as a *substitute* for judicial review, it ignores that "the Framers crafted the Constitution to ensure that federal judges could exercise judgment free from the influence of the political branches," *Loper Bright*, 603 U.S. at 403. Letting the Executive Branch rewrite statutes with impunity is not accountability.

2. With no procedural safeguards to be found, the government invokes several provisions of the IRA that it calls "limitations." But those provisions only underscore the breadth of the discretion that the IRA delegates—and the glaring lack of procedural guardrails.

To start, the Drug Pricing Program imposes no limit on CMS's ability to set prices as low as it wants. While the government cites "mathematical formulae for calculating *ceiling* prices," Defs.' Br. 11, 13–14 (emphasis added), that offers no protection to Plaintiffs, who are concerned about prices being too *low*. The relevant point is that the IRA contains no price floor; it gives CMS infinite *downward* discretion. For Plaintiffs, the IRA's price "ceiling" is the same as saying nothing.[4]

Similarly, the "factors" that the IRA outlines for HHS to "consider" impose no meaningful constraint on the agency. In fact, the government appears to concede that CMS can give each factor as much or as little weight as it chooses. *Compare* Pls.' MSJ 7–8, 17, *with* Defs.' Br. 12–13. While CMS

[4] And all indications are that the new administration intends to push prices even lower: It has announced plans to "[i]mprov[e]" the Program by "eclips[ing] the 22% in savings achieved in the program's first year." The White House, *Fact Sheet: President Donald J. Trump Announces Actions to Lower Prescription Drug Prices* (Apr. 15, 2025), https://bit.ly/3EUsWao. Indeed, the government says it is considering setting the price for selected drugs for initial price-applicability year 2028 as low as the "unit cost of production and distribution of the selected drug," eliminating all marginal profit. CMS, *Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028*, at 128, 131 (May 12, 2025), https://bit.ly/4k7z66e. The statute provides no principle to guide the clearly legislative decision to strip a manufacturer of any profit on these sales.

may need to "consider" a manufacturer's R&D costs under Section 1320f–3(e)(1)(A), for example, it can then proceed to set whatever price it wants, irrespective of R&D. 42 U.S.C. § 1320f–3(e)(1)(A). Likewise, under Section 1320f–3(e)(1)(B), the agency can "consider" current production costs and then set the same price it would have set had it ignored those costs. *Id.* § 1320f–3(e)(1)(B). And so on.

Finally, the government misplaces its emphasis (at 12) on the IRA's "procedures" for so-called "negotiation," "specific timing deadlines," and "parameters for agreements." The Drug Pricing Program may well specify these administrative steps, but that has no bearing on the constitutional problem, which stems from the total delegation of substantive power to set drug prices without any meaningful input or review. Congress could tell HHS to mail out new drug prices next Wednesday at 3:15 p.m. on letter-sized manilla paper, but that procedural specificity would not validate the delegation.

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The IRA's nondelegation problem is not simply that it gives HHS sweeping discretion to overhaul a massive segment of the economy. Nor is it merely that the IRA limits front-end input and back-end judicial review. The IRA's nondelegation problem is that it *combines* these features, giving HHS legislative discretion without any meaningful checks. *That* is "unprecedented." *Contra* Defs.' Br. 16. And "the lack of historical precedent" for such a delegation is a "most telling indication of [a] severe constitutional problem." *Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 505 (2010).

II. THE IRA VIOLATES THE EXCESSIVE FINES CLAUSE

The so-called "excise tax" is a massive penalty (reaching 1,900% of a manufacturer's U.S. revenues for a drug), which the government admits (at 30) "is not triggered by the commission of *any* offense—reprehensible or otherwise." For all its efforts to invent new legal tests and claim that the excise tax is actually lower than the statute says, the government cannot seriously dispute that the

excise tax is punitive and grossly disproportional. Instead, it insists that Plaintiffs sued the wrong government entities, and the Anti-Injunction Act applies. The government is wrong on all counts.

A. The IRA's Excise Tax Is Punitive

The "excise tax" triggers the Excessive Fines Clause because it is "at least partially punitive." *Timbs v. Indiana*, 586 U.S. 146, 155 (2019). Congress summarized the IRA's predecessor as a "steep, escalating penalty," Title Summary, H.R. 3, at 1 (2022); passed the excise tax despite estimates that it would cripple the business of any manufacturer forced to pay;[5] and codified it in the section on "noncompliance," 26 U.S.C. § 5000D; *see id.* § 5000D(b). The excise tax indisputably serves at "least in part as punishment." *Austin v. United States*, 509 U.S. 602, 610 (1993). The government never actually disclaims that punitive purpose. Instead, it argues that the excise tax is not subject to the Excessive Fines Clause because it (1) is not "[]tethered" to *criminal* conduct, (2) "serves a remedial purpose," and (3) does not relate to an "offense." These arguments defy law and reality.

1. The government claims (at 25) that the excise tax cannot be an excessive fine because it lacks a "connection to either criminal activity or a criminal proceeding." But the Supreme Court has already rejected that argument. *See Austin*, 509 U.S. at 610. "[T]he question is not" whether a fine "is civil or criminal, but rather whether it is punishment." *Id.* And "a civil sanction" "is punishment" when it "cannot fairly be said solely to serve a remedial purpose, but rather can only be explained as also serving either retributive or deterrent purposes." *Id.* (citation omitted).

The government posits (at 25–26) that because the forfeitures in *Austin* and *United States v. Bajakajian*, 524 U.S. 321 (1998), involved property related to criminal activity, penalties "untethered from criminal conduct or criminal proceedings" cannot be excessive fines. But that is a non-sequitur.

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[5] *See* Joint Comm'n on Tax'n, *Estimated Budget Effects of the Revenue Provisions of Title XIII – Committee on Ways and Means, of H.R. 5376, The "Build Back Better Act,"* at 8 (Nov. 19, 2021) (Joint Comm'n), bit.ly/3plC4cd.

The Court in *Austin* held that the Excessive Fines Clause applies to fines—whether "civil *or* criminal"—that are intended in part to punish. 509 U.S. at 610 (emphasis added). It did not remotely endorse the government's nebulous requirement that a punitive fine also must be "[]tethered" to a crime, and other courts have rejected it. *See, e.g.*, *United States v. Schwarzbaum*, 127 F.4th 259, 265, 284 (11th Cir. 2025) (holding that "civil penalties" were excessive fines); *United States v. Mackby*, 261 F.3d 821, 830 (9th Cir. 2001) ("[C]ivil sanctions provided by the False Claims Act are subject to analysis under the Excessive Fines Clause because the sanctions represent a payment to the government, at least in part, as punishment.").[6]

2. In their opening brief, Plaintiffs cited two Double Jeopardy Clause cases for the simple point that "courts determine whether a tax is punitive by considering its size and purpose." Pls.' MSJ 19. The government does not dispute this basic premise, but argues (at 26–27) that under the "analytical framework" of the double jeopardy cases, a tax cannot be a punishment if, in *addition* to being a "deterrent-in-part" or "serv[ing] in part to punish," it *also* has a "remedial purpose." The government then attempts to defend the IRA under that double jeopardy rubric, claiming (at 28) that the excise tax, in addition to punishing noncompliance, also "serves a remedial purpose in compensating the public fisc."

The Supreme Court has rejected the government's argument. Unlike in the double jeopardy context, a fine falls "within the purview of the Excessive Fines Clause" if it is "punitive in part," "[e]ven [if it also] is remedial in some way." *Bajakajian*, 524 U.S. at 329 n.4.[7] "[T]he Supreme Court's

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[6] The only case the government cites (at 24) emphasizing a lack of connection to criminal proceedings—*United States v. Toth*, 33 F.4th 1, 16 (1st Cir. 2022)—relied on outdated precedents and is "difficult to reconcile with" the Supreme Court's more recent guidance. *Toth v. United States*, 143 S. Ct. 552, 553 (2023) (Gorsuch, J., dissenting from denial of certiorari).

[7] *See, e.g.*, *Austin*, 509 U.S. at 610 (the Eighth Amendment is triggered when a fine can be "understood at least in part as punishment"); *Timbs*, 586 U.S. at 155 (2019) (fines trigger "the Eighth Amendment when they are at least partially punitive").

double jeopardy jurisprudence regarding what constitutes 'punishment' diverge[s] sharply from its Excessive Fines jurisprudence," in that "a penalty need not be 'solely remedial' to escape the scope of the double jeopardy clause." *Schwarzbaum*, 127 F.4th at 275. A penalty escapes constitutional scrutiny "in the Excessive Fines context" only when "the purpose of the penalty is *solely* compensatory." *Id.* And as discussed, the government does not (and cannot) dispute that the excise tax is "at least partially punitive." *Timbs*, 586 U.S. at 155.

In any event, the government cannot seriously claim that the excise tax "serves a remedial purpose in compensating the public fisc." Congress knew when it passed the IRA that the excise "tax" was so steep that it would raise no revenue whatsoever (because no manufacturer could endure it). *See* Joint Comm'n at 8. The government nonetheless insists (at 29 n.17) that Congress still might have had a revenue-raising purpose "even if" it knew the excise tax would never raise a penny. But courts need not "shut [their] eyes" to reality. *Miller v. Amusement Enters., Inc.*, 394 F.2d 342, 349 (5th Cir. 1968) (citation omitted). Congress knew what it was doing when it included the excise tax in the Drug Pricing Program—namely, forcing manufacturers to fall into line by imposing a confiscatory penalty on "noncompliance." 26 U.S.C. § 5000D; *see id.* § 5000D(b) (subparagraph entitled "Noncompliance periods"). As predicted, not a single manufacturer has opted to forgo negotiations and instead pay the crippling "tax." *See* CMS, *Fact Sheet: CMS Announces Manufacturer Participation in Second Cycle of Medicare Drug Price Negotiation* (Mar. 14, 2025), https://go.cms.gov/4ks4ITF; CMS, *Medicare Drug Price Negotiation Program: Manufacturer Agreements for Selected Drugs for Initial Price Applicability Year 2026* (Oct. 3, 2023), https://go.cms.gov/3HjwEe8.

3. Finally, the government contends (at 30) that the excise tax is not a punishment because it "is not triggered by the commission of *any* offense—reprehensible or otherwise." But that argument turns Excessive Fines Clause principles on their head. If the severity of a fine must be proportional to

"the gravity of the offense that it is designed to punish," *Bajakajian*, 524 U.S. at 334, then the imposition of an exorbitant fine in the *absence* of an offense (or culpability) is all the more problematic.

In any event, Congress does not agree with the government's argument: It codified the excise tax as a penalty for "noncompliance," 26 U.S.C. § 5000D; *see id.* § 5000D(b), and made it so exorbitant that it would put "noncompliant" manufacturers out of business, *see* Garthwaite Decl. ¶¶ 85–86, 91 (ECF No. 60-1). Further, the "tax" skyrockets exponentially based on the duration of a manufacturer's "noncompliance," 26 U.S.C. § 5000D(b), which clearly evinces a deterrent and punitive purpose. Plaintiffs—and apparently now the government—maintain that declining to "negotiate" is innocent conduct; but that obviously was not Congress's view when it enacted a "steep, escalating penalty." Title Summary, H.R. 3, at 1 (2022).

It is striking that the government now defends the IRA's ruinous penalty on the ground that it applies to *innocent conduct*. That remarkable position—not Plaintiffs' challenge—is what "would lead to absurd results." Defs.' Br. 30. If Congress imposed a multi-billion dollar fine (or even a prison term) for "innocuous conduct like working or shopping," *id.*, that decision would not make the fine (or sentence) any less punitive. Unwarranted punishment is still punishment.

B. The IRA's Excise Tax Is Grossly Disproportional

1. A punitive fine is excessive if it is "grossly disproportional" in "relation[] to the gravity of the offense that it is designed to punish." *Bajakajian*, 524 U.S. at 334. Because the excise tax severely punishes innocent conduct, it lacks any such relationship.

The government ignores this governing rule and instead invents a different test, contending (at 31) that "the excise tax is proportional to the harm to the fisc." But "harm to the fisc" is immaterial when there is no "offense" in the first place. *No* punishment is proportional to "the gravity" of entirely innocent conduct. *Bajakajian*, 524 U.S. at 336. But even if excessiveness were merely a matter of comparing the fine to some "harm to the fisc," there is nothing resembling proportionality here. The

"tax" does not target a manufacturer's "excess" Medicare profits, or even its Medicare sales. It reaches 1,900% of a manufacturer's *total U.S. revenues* for a drug—including revenues on private market sales. Collecting almost *twenty times* a manufacturer's total earnings is not remotely "proportional."[8]

2. Perhaps recognizing that a 1,900% penalty for declining to "negotiate" is indefensible, the government strains to rewrite the law to make it less disproportionate. The government asserts (at 28 & n.16, 31) that the excise tax actually is capped at "95%, not 1900%," and "attaches only to sales of the drug that are reimbursed by Medicare." According to the government (at 31), this "is within the range of constitutionally permissible exactions." The government's attempt to save the IRA by rewriting it is telling—and unavailing.

To begin, penalizing a company 95% of *total U.S. revenues* (rather than just 95% of "excess profits") still would be grossly excessive.[9] But the government miscalculates the excise tax.[10] The "tax" is not a percentage of a drug's base sales price (*i.e.*, a tax-exclusive rate); rather, it is a percentage of the "sum" of the sales price *plus* the excise tax itself (*i.e.*, a tax-*inclusive* rate). 26 U.S.C. § 5000D(a). So when the IRA's "applicable percentage" reaches 95%, the excise tax is not simply 95% of the pre-tax sales price (as the government claims), but 95% of the *sum* of the sales price *and* the excise tax, which comes

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[8] The government (at 30) quotes *Newell Recycling Co. v. EPA*, 231 F.3d 204, 210 (5th Cir. 2000), for the proposition that "if the fine does not exceed the limits prescribed by the statute authorizing it, the fine does not violate the Eighth Amendment." But that is completely circular. Plaintiffs are challenging the IRA *itself* because it prescribes an unconstitutionally excessive fine. The IRA's excise tax cannot be constitutional simply because it "does not exceed the limits prescribed *by the* [*IRA*]"; otherwise, no statutory provision could ever violate the Excessive Fines Clause. *Id.*

[9] Indeed, even under the government's incorrect view, manufacturers would have to turn over $95 for every $100 of their *total revenue* for a drug, not just their excess profits. The government does not attempt to explain how such a requirement would be remotely proportional.

[10] Notably, the government does not rely on its economic expert for this calculation, but instead advances the 95% figure in its briefing. In fact, the government's expert, who fails to recognize that manufacturers cannot walk away from "negotiations," does not even *mention* the excise tax.

out to 1,900% of the price for which the manufacturer ultimately sells the drug. *Id.*[11] For every dollar a manufacturer receives from a sale, it must pay a fine of $19. As the Congressional Research Service explained, therefore, the excise reaches "1,900% of the selected drug's price." Cong. Rsch. Serv., *Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376)*, 4 (2022), https://bit.ly/3sbHYBy. In fact, the government argued in the Fifth Circuit just last year that the excise tax "is 95%, not 1900%," Br. for Defs.-Appellees at 8 n.1, *NICA v. Becerra*, No. 24-50180 (Apr. 19, 2024), but the Fifth Circuit rejected that position, concluding that the excise tax "rises to 1,900%," *NICA*, 116 F.4th at 495 (citing 26 U.S.C. § 5000D(d)).[12]

The statute also refutes the government's claim (at 31) that the excise tax "attaches only to sales of the drug that are reimbursed by Medicare." The excise tax expressly applies to all "sale[s]"—without exception—"of any designated drug." 26 U.S.C. § 5000D(a). In fact, the statute "suspen[ds]" the tax for manufacturers who *exit* Medicare altogether, which would be unnecessary if the tax were already limited to Medicare sales. *Id.* § 5000D(c)(1)(A)(ii). And the excise tax provision expressly carves out "[e]xports," which would be entirely superfluous if it were limited to sales within Medicare—a domestic program. *Id.* § 5000D(g). Indeed, the Fifth Circuit last year rejected the government's claim that "[t]he tax would apply only to drugs administered under Medicare," Br. for Defs.-Appellees at 8 n.1, *NICA v. Becerra*, No. 24-50180, concluding instead that the excise tax applies to "all sales of the drug (not just Medicare sales)," *NICA*, 116 F.4th at 495 (citing 26 U.S.C. § 5000D(d)).

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[11] *See* Gordon Gray, Douglas Holtz-Eakin, & Kenneth Thorpe, *The Medicare Budget Implications of the Inflation Reduction Act* (Oct. 3, 2023) ("[T]he 95 percent rate on the tax-inclusive price translates to a 1900 percent rate on the price received by the [manufacturer]."), https://bit.ly/43kssm0.

[12] That question of statutory interpretation was material on appeal. NICA showed that the Program would inflict Article III injury because "basic economic rationality" would compel manufacturers to submit to MFPs, in turn harming providers. *NICA*, 116 F.4th at 500. As the Fifth Circuit explained, "the penalties the Program imposes make reaching an agreement all but certain." *Id.*

The government bases its contrary position on an IRS "Notice" document that "explain[s] how [the agency] interprets the IRA's excise tax provision." Defs.' Br. 6, 28 n.6 (citing IRS Notice No. 2023-52, 2023-35 I.R.B. 650 (Aug. 4, 2023)). The government argues (at 28 n.16) that Plaintiffs do not (and cannot) challenge the IRS Notice. But in assessing the constitutionality of the IRA, the Court must determine the "best reading" of the statutory language—*i.e.*, "the reading the court would have reached if no agency were involved." *Loper Bright*, 603 U.S. at 400 (citation omitted). Even if the IRS's supposed "interpretation" would save the IRA (which it would not), the agency cannot make a statute constitutional by misinterpreting or rewriting it.

C. The Court Has Jurisdiction Over Plaintiffs' Excise Tax Claim

Unable to seriously defend the excise tax on the merits, the government insists the Court lacks jurisdiction to hear Plaintiffs' claim. Both of its reasons are wrong.

1. Relief Against Defendants Would Redress Plaintiffs' Injury

The government contends (at 18–20) that the Court cannot redress Plaintiffs' Excessive Fines injury because HHS and CMS do not administer the relevant statutory provisions. This argument is wrong because HHS plays an integral part in enforcing the excise tax provisions.

A party has standing if their injury is "fairly traceable to the challenged action of the defendant" and "likely" would "be redressed by a favorable decision." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992) (cleaned up). "[T]o show traceability, there must merely be a causal connection between the plaintiff's injury and the defendant's challenged conduct." *Inclusive Louisiana v. St. James Par.*, 134 F.4th 297, 209 (5th Cir. 2025). And "[w]hen establishing redressability, a plaintiff need only show that a favorable ruling could potentially lessen its injury; it need not definitively demonstrate that a victory would completely remedy the harm." *Sanchez v. R.G.L.*, 761 F.3d 495, 506 (5th Cir. 2014) (cleaned up). A plaintiff thus meets the threshold when a favorable ruling "has the potential, in whole or in part, to redress the claimed injury." *Id.*

"Even though Article III requires a causal connection between the plaintiff's injury and the defendant's challenged conduct, it does not require a showing of proximate cause or that 'the defendant's actions are the very last step in the chain of causation.'" *Inclusive Communities Project, Inc. v. Dep't of Treasury*, 946 F.3d 649, 655 (5th Cir. 2019) (quoting *Bennett v. Spear*, 520 U.S. 154, 168–69 (1997)); *see Maine Lobstermen's Ass'n v. Nat'l Marine Fisheries Serv.*, 70 F.4th 582, 593 (D.C. Cir. 2023) ("[A]n injury may be 'fairly traceable' to an agency action" even when it "is not 'the very last step in the chain of causation.'") (quoting *Bennett*, 520 U.S. at 168–69). For instance, when a statute tasks an agency with proffering information to a separate "action agency," and the "action agency" is charged with making a decision that injures the plaintiff, the injury is redressable by a lawsuit against the antecedent agency tasked with proffering the information. *Bennett*, 520 U.S. at 168. This is true even when the "action agency" is the one that "retains ultimate responsibility for determining whether and how a proposed action shall go forward." *Id.*

Here, an injunction against HHS would protect Plaintiffs from the harms the excise tax inflicts, because HHS fills an integral role in its enforcement. The IRA explicitly requires HHS to provide to "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). That responsibility is part of HHS's "compliance monitoring" obligation, which comes from the IRA's provision directing HHS to "establish [the] Drug Price Negotiation Program." *Id.* § 1320f(a)(4). So even if HHS's role is not "the very last step in the chain of causation," Plaintiffs can obtain redress through a judgment against HHS (1) declaring the excise tax unconstitutional and (2) preventing HHS from carrying out its obligations in the enforcement scheme. *Bennett*, 520 U.S. at 168–69.

Even if the government were right, however, the Court can alleviate any issue simply by adding the necessary parties under Federal Rule of Civil Procedure 21. Under Rule 21, a court may "at any time, on just terms, add or drop a party." Fed. R. Civ. P. 21; *Mullaney v. Anderson*, 342 U.S. 415, 416–

17 (1952) (adding parties); *Adams v. Clinton*, 90 F. Supp. 2d 35, 44 (D.D.C. 2000) (noting that "when necessary to satisfy the redressability component of standing, a court may constructively amend a complaint to include prayers for relief against unnamed defendants"); *Page v. Biden*, 2021 WL 311002, at *4 (D.D.C. Jan. 29, 2021) (noting that it "is within the Court's discretion" to "constructively amend the Complaint to add a defendant" to "fix [a] redressability problem"). So, at most, the Court should add the IRS and the Secretary of Treasury if it believes doing so is necessary to avoid redressability concerns—not dismiss the case.

2. The Anti-Injunction Act Does Not Apply

The government has no real answer to Plaintiffs' arguments against applying the Anti-injunction Act (AIA). *See* Pls.' MSJ 22–23. Instead, it attempts to broaden the AIA to the point of absurdity.

a. According to the government (at 21–22), the AIA bars Plaintiffs' excessive fines claim "because Congress labeled" the excise tax a "tax," and that label, even if incorrect, is dispositive. (Cleaned up). The government appears to concede that, under its view, the AIA would bar a lawsuit even if the so-called "tax" violates the Constitution and will not raise any revenue because no manufacturer could afford to pay it. The implications of this argument are striking.

In the government's view of the AIA, the *more* excessive a fine is, the *less* susceptible it is to an excessiveness challenge. Thus, under the government's theory, Congress can evade review by labelling *anything* a "tax" and making it unaffordable. It could impose a "speech tax" requiring anyone who criticizes the government to pay $100 billion. It could impose a $1 trillion tax on church attendance. Or, under the guise of "taxation," it could enact bills of attainder imposing exorbitant monetary penalties on select individuals, making them permanent debtors to the government.

b. Perhaps because such an interpretation would make the AIA itself unconstitutional, *see Webster v. Doe*, 486 U.S. 592, 603 (1988), the government seemingly concedes that the AIA does not

apply if a so-called tax is clearly unlawful *and* unpayable. *See* Defs.' Br. 22–23 (discussing AIA exception articulated in *Enochs v. Williams Packing & Navigation Co.*, 370 U.S. 1 (1962)). For the reasons discussed, however, the excise tax clearly *is* unconstitutional. *See supra* pp.10–17. And the government does not claim that any Plaintiff (or anyone else) could afford to pay the excise tax throughout the entire course of a "refund" litigation. *See Hosp. Res. Pers., Inc. v. United States*, 860 F. Supp. 1554, 1556 (S.D. Ga. 1994) (granting preliminary injunction, despite AIA, because evidence showed that "the collection efforts threatened . . . would effectively force Plaintiff out of business").

Relying on a nonbinding statement of "IRS Policy," the government instead claims (at 22–23) that "a refund suit is an adequate remedy" because the IRS "typically" does not collect the balance of a "divisible tax" while a refund suit is pending. As Plaintiffs explained in their opening brief, however, manufacturers cannot stake their survival on the IRS favorably exercising its discretion—especially when the government will not commit to forbearance *even now*. And while the government says manufacturers "need only pay the excise tax on a single transaction" before suing, Defs.' Br. 23 (citation omitted), it does not dispute that continuing to sell a drug throughout a potentially multi-year refund litigation would generate staggering excise tax *liability*. *See* Garthwaite Decl. ¶ 86 (explaining how "applying the excise tax over a full year" on a drug that "accounts for approximately 13 percent or more of its manufacturer's total net revenues . . . would result in an excise tax liability of 100 percent of the manufacturer's total net revenues"); Bernie Decl. ¶ 10 (ECF No. 60-4) (describing "unsustainable financial liability.").

Rather, the government contends (at 23) that if Plaintiffs ultimately win in a refund suit they will not have to pay the massive liability that accumulates in the meantime. But this misunderstands both the Drug Pricing Program and the nature of liability. The excise tax inflicts irreparable harm not simply because it is unaffordable, but because the prospect of incurring multi-billion-dollar liability compels manufacturers to *instead* submit to the Program. Manufacturers whose business is saving and

improving lives—and who are beholden to investors—are not free to simply bet the company on the outcome of refund litigation, even when the law is clear. If manufacturers cannot litigate the constitutionality of the excise tax without racking up an unpayable balance while the litigation is pending, they are "all but certain" to capitulate. *NICA*, 116 F.4th at 500. And, of course, that is the point of the excise tax in the first place. *See supra* p.13 (explaining that the excise tax would yield "no revenue" because no manufacturer can pay).

The government argues (at 23–24) that the *Williams Packing* exception still does not apply because Plaintiffs' "claim is novel," as there supposedly are no "case[s] in which a court has applied the Excessive Fines Clause to a monetary amount that was not connected to criminal conduct or a criminal proceeding." (Cleaned up). But the unprecedented nature of the excise tax does not cast doubt on its excessiveness—and thus its unlawfulness. Quite the contrary. *E.g.*, *Free Enter. Fund*, 561 U.S. at 484; *Va. Office for Prot. & Advocacy*, 563 U.S. at 260. It is difficult to imagine a clearer excessive-fines violation than a crippling penalty for conduct even the government admits is not "reprehensible" *at all*. And the government is simply wrong that all excessive fines cases are "connected to criminal conduct." *See supra* pp.11–12; *see also Schwarzbaum*, 127 F.4th at 265 (holding that "civil penalties" were excessive fines); *Mackby*, 261 F.3d at 829–30 ("civil sanctions provided by the False Claims Act are subject to analysis under the Excessive Fines Clause").

c. Finally, the government asserts (at 24) that "[t]his case is a far cry from the unique factual pattern" in *South Carolina v. Regan*, 465 U.S. 367 (1984) (quotation marks omitted). But the government never attempts to distinguish the *principle* underlying the *Regan* exception—namely, that the AIA bars a pre-payment challenge only when there is "an alternative legal way to challenge the validity of a tax," which typically means the "availability of a refund suit." 465 U.S. at 373, 375–76; *Westmoreland Coal*, 968 F.3d at 536 (describing *Regan* as requiring "an *adequate*[] alternative remedy") (emphasis added). For the reasons discussed, there is no way to challenge the excise tax *after* paying it, because—by

design—no manufacturer can *afford* to pay it. *See supra* p.13; *NICA*, 116 F.4th at 495. So the typical "alternative avenue for federal court jurisdiction"—"a postpayment refund suit"—is not an "adequate" or "available" option. *Westmoreland Coal*, 968 F.3d at 535.[13]

d. Applying the AIA in this case would create a further constitutional problem. As discussed, the government cannot dispute that the excise tax as written is unaffordable for manufacturers. *See* Garthwaite Decl. ¶¶ 68, 85–86; Bernie Decl. ¶ 10. So requiring manufacturers to "pay" the excise tax before challenging its constitutionality would be the same as preventing manufacturers from challenging its constitutionality altogether. And "deny[ing] any judicial forum for a colorable constitutional claim" would raise "serious constitutional question[s]." *Webster*, 486 U.S. at 603; *see Bowen v. Michigan Acad. of Fam. Physicians*, 476 U.S. 667, 681 n.12 (1986) (noting that the Court's "disposition avoids the 'serious constitutional question' that would arise if [it] construed [a provision] to deny a judicial forum for constitutional claims arising under Part B of the Medicare program"). Whether the Court concludes that the AIA does not apply on its face, or that this case falls within an AIA exception, the AIA cannot constitutionally bar review of the excise tax.

III. THE IRA VIOLATES THE DUE PROCESS CLAUSE

The government disputes none of the three relevant factors for assessing due process challenges under *Mathews v. Eldridge*, 424 U.S. 319 (1976). It thus concedes that Plaintiffs' "'private interests' at stake are immense," Pls.' MSJ 24 (quoting *Mathews*); that "[t]he lack of input regarding unanswered implementation questions and inability to challenge particular determinations create a substantial risk of erroneous deprivation," *id.* at 27 (quoting *NICA*); and that "the government has no legitimate interest in insulating HHS's decision-making from input by affected parties, or in denying

[13] The Declaratory Judgment Act is "coterminous" with the AIA and thus also does not bar Plaintiffs from obtaining declaratory relief. *Z St. v. Koskinen*, 791 F.3d 24, 26 (D.C. Cir. 2015) (citation omitted).

judicial review even for basic statutory-interpretation questions," *id.* That makes resolving this claim easy: Because Plaintiffs have identified constitutionally protected property interests, they are entitled to summary judgment on their due process claim under a straightforward application of *Mathews*.

The government rests its defense (at 32) on a single flawed argument: that Plaintiffs have purportedly failed to establish that they have been deprived "of any constitutionally protected interest." That is incorrect. The IRA deprives manufacturers, providers, and patients alike of core protected interests.

1. Plaintiffs established that the IRA deprives manufacturers of two distinct constitutionally-protected interests: (1) their "'treasured' common-law right to offer access to their products at prices set by voluntary agreements, not government dictates," Pls. MSJ 26 (quoting *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 149 (2021)); and (2) their full "pecuniary rewards" under their patent rights, Pls.' MSJ 25–26 (quoting *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1372 (Fed. Cir. 2007)). The government's arguments to the contrary are unpersuasive.

a. The government does not meaningfully dispute that manufacturers' right to offer their products at prices set by voluntary agreements is a constitutionally protected interest. Nor could it. Courts have recognized that private parties have a "right . . . to fix the price at which [they] will sell" their products. *Old Dearborn Distrib. Co. v. Seagram-Distillers Corp.*, 299 U.S. 183, 192 (1936). Government interference with that right thus triggers due process requirements. *Bowles v. Willingham*, 321 U.S. 503, 513–14 & n.9 (1944). Rather than dispute that principle, the government instead raises (at 34–37) a factual challenge: that the IRA does not actually deprive manufacturers of their right to offer products at their chosen prices. But neither of the government's rationales withstands scrutiny.

First, the government contends (at 34) that the negotiation program does not limit what manufacturers can charge non-government buyers; rather, the government says that the negotiation program "simply establishes maximum prices the Government will pay for selected drugs." But that

argument is wrong both on the law (the IRA's text) and the facts (how the market actually functions). The government is not purchasing drugs for itself; it is acting as a price regulator, capping the prices of products sold to more than 60 million Medicare-eligible citizens. The IRA requires manufacturers to provide "access" to CMS's imposed price to "eligible *individuals*" and to "pharmac[ies], mail order service[s], or other dispenser[s]," as well as to "hospitals, physicians, and other providers of services and suppliers with respect to" such individuals. 42 U.S.C. § 1320f–2(a)(3) (emphasis added). The statute does not limit the amount of money the government pays for its own purchases; it caps the prices that manufacturers can offer their products to millions of individuals, and their providers and dispensers, in transactions to which the government is not a party. Though the federal government may ultimately bear much of the expense of paying pharmacies and other dispensers for pharmaceutical product costs under Medicare, that does not alter the clear distinction between a procurement or reimbursement schedule and this quintessential price-setting scheme.

Second, the government argues (at 34–37) that the negotiation program does not infringe manufacturers' rights because participation in Medicare and Medicaid is "voluntary." That argument is wrong on multiple levels.

To start, participation in the negotiation program is coercive, not voluntary. Manufacturers face ruinous penalties if they refuse to sell their products at CMS's chosen price, and the only way to avoid the price caps—withdrawing *all* their products from Medicare and Medicaid entirely—is not a meaningful choice. *See Doe v. Univ. of Scis.*, 961 F.3d 203, 213 (3d Cir. 2020) (the "total withdrawal of federal funding" is "economic dragooning," akin to "a gun to the head") (quotation marks omitted). Indeed, the Supreme Court has explained that actions taken under threat of taxes or fines are not voluntary. The government cannot "impose an unconstitutional burden by the threat of penalties worse than [that burden] in case of a failure to accept it, and then [] declare the acceptance voluntary." *Union Pac. R. Co. v. Pub. Serv. Comm'n of Missouri*, 248 U.S. 67, 70 (1918); *see United States v. Butler*, 297

U.S. 1, 70–71 (1936) (the "asserted power of choice is illusory" when Congress uses "coercion by economic pressure"). For example, in *Carter v. Carter Coal Co.*, 298 U.S. 238, 289 (1936), the Court held that an "agreement" to participate in a regulatory program "lack[ed] the essential element of consent" because it threatened substantial taxes for noncompliance.

It is no answer that manufacturers "dissatisfied with the prices that Medicare offers may withdraw from participation." Defs.' Br. 35 (quotation omitted). The Supreme Court has rejected the argument that constitutional constraints disappear when private parties can avoid regulation by exiting the market and not selling their products. *See Horne v. Dep't of Agric.*, 576 U.S. 350, 365 (2015) (rejecting argument that raisin growers could avoid a taking by not selling their raisins). Medicaid and Medicare are a market unto themselves: They account for nearly *half* of all prescription drug sales in the United States. *See Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023).

The government does not dispute (at 36–37) that the negotiation program is *more* coercive than Congress's unconstitutional attempt in *National Federation of Independent Business v. Sebelius*, 567 U.S. 519 (2012) (*NFIB*), to force states to expand their Medicaid programs. The government instead dismisses (at 36–37) *NFIB* as limited to "how federalism principles inform what conditions Congress may attach to money it grants to States." But the government never explains why the federalism concerns in *NFIB* are materially different from the constitutional issues presented here. Regardless, courts have noted that *NFIB*'s reasoning applies "[s]imilarly" to non-state actors. *See Univ. of Scis.*, 961 F.3d at 213.

The government cites (at 34–35) a handful of (mostly) takings cases for the proposition that participation in Medicare and Medicaid is voluntary. Two of those decisions—*Garelick v. Sullivan*, 987 F.2d 919 (2d Cir. 1993), and *Baker County Medical Services, Inc. v. U.S. Attorney General*, 763 F.3d 1274 (11th Cir. 2014)—rejected regulatory takings claims on the theory that price regulation is not a taking "where the regulated group is not required to participate in the regulated industry." *Garelick*, 987 F.2d

at 917; *see Baker*, 763 F.3d at 1276. But the Supreme Court has since rejected that theory. *See Horne*, 576 U.S. at 365. And none of the government's cited cases involved anything resembling the negotiation program here, where participation was coerced by enterprise-threatening penalties, the government has exercised regulatory powers no ordinary market participant could invoke, no due process protections were followed, no standards constrain the agency's price-setting decisions, and the statute bars administrative or judicial review.[14]

b. The government acknowledges (at 32) that "[p]atents are a form of property" but argues that the negotiation program does not deprive manufacturers of any patent rights. But that is precisely what the program does. In enacting the Hatch-Waxman Act, which established the modern framework for drug regulation, Congress recognized that "[p]atents are designed to promote innovation by providing the right to exclude others from making, using, or selling an invention. They enable innovators to obtain greater profits than could have been obtained if direct competition existed. These profits act as incentives for innovative activities." *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1373 (Fed. Cir. 2007) (*BIO*). But that right to exclude is meaningfully diminished if the government can restrict the manufacturer's price, as the government can (and has) under the IRA.

In response, the government attacks a straw man, insisting (at 33) that the right to exclude "does not entitle the patentee to any particular revenue from any particular buyer."[15] But a law that

[14] The government's expert declaration, cited (at 34) for the proposition that "the government is acting as a market participant" because manufacturers supposedly have "negotiating leverage," ignores that the excise tax and other crippling penalties prevent manufacturers from walking away, as a party could in a traditional negotiation. The government's expert does not even mention the excise tax, much less explain how it leaves manufacturers any choice but to accept whatever price the government dictates. No matter the cost to CMS of a failed "negotiation," manufacturers have no "leverage" when they *cannot* reject CMS's ultimate "offer."

[15] The Third Circuit's recent decision in *AstraZeneca Pharmaceuticals LP v. HHS*, No. 24-1819, 2025 WL 1338088 (3d Cir. May 8, 2025), is flawed for the same reason. The court there asserted in dicta that the federal patent laws "do not confer a right to sell at a particular price," but it failed to explain why

authorizes the government to limit prices for an innovative drug during the exclusivity period nonetheless "limit[s] the full exercise of the exclusionary power" to which the manufacturer is entitled. *BIO*, 496 F.3d at 1374. The point is not that the government cannot do so at all, but that it cannot do so without sufficient process.

The government argues (at 33–34) that "[i]n negotiating" drug prices it is simply "acting as a market participant," and "[j]ust like private individuals and businesses," it can decide with whom to transact and on what conditions. Again, however, the IRA regulates the prices at which manufacturers may offer their products *to third-parties*. *See supra* pp.2–3. When a government exercises powers "tantamount to regulation," it is no mere market participant. *Cardinal Towing & Auto Repair, Inc. v. City of Bedford*, 180 F.3d 686, 691 (5th Cir. 1999); *see also S.-Cent. Timber Dev., Inc. v. Wunnicke*, 467 U.S. 82, 98 (1984) (state may not leverage role as a market participant to evade constitutional limits on its regulatory powers); *Keystone Chapter, Associated Builders & Contractors, Inc. v. Foley*, 37 F.3d 945, 955 n.15 (3d Cir. 1994) (state not a "market participant" when acting with an "interest in setting policy").

In fact, the Fifth Circuit in this case already rejected the idea that the government is just any participant in the marketplace. As the *NICA* court explained, "[m]anufacturers who fail to reach an agreement with [CMS] are subject to escalating fines ranging from [185.71]% to 1,900% of the drug's price that can only be suspended if the manufacturer terminates Medicare coverage for all drugs that it produces." *NICA*, 116 F.4th at 494. No ordinary buyer in the marketplace has the power to economically cripple a private party that declines to agree to its dictated terms. Nor is the "opt-out" a real option: "[B]asic economic rationality" dictates that a manufacturer is more likely to agree to an unprofitable price for a selected drug than to refuse and "lose[]the Medicare [and Medicaid] market

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the IRA's severe limits on what manufacturers can earn under their patents does not implicate constitutionally protected rights. 2025 WL 1338088, at *6.

for all of its drugs." *Id.* at 500.

The government also attempts (at 33) to defend the program on the ground that "other federal agencies have for decades negotiated with drug manufacturers over the price paid for patented drugs in other government programs." The government cites 38 U.S.C. § 8126, under which the Department of Veterans Affairs administers a program allowing it and certain other federal agencies—including the Department of Defense—to purchase drugs from manufacturers at discounted prices. But comparing the drug-pricing program in § 8126 with the negotiation program under the IRA only underscores Plaintiffs' point. Unlike CMS, those agencies actually *are* purchasers of drugs in the marketplace, so it makes sense that they negotiate the prices that they pay as buyers. Moreover, purchases by the VA or DOD are not subject to anything like the hammer of the IRA's excise "tax" to force manufacturers to acquiesce to its pricing demands. And, unlike here, the government's decisions in that program are subject to judicial review. *See, e.g.*, *Coal. for Common Sense in Gov't Procurement v. Sec'y of Veterans Affs.*, 464 F.3d 1306, 1312, 1316–19 (Fed. Cir. 2006).

2. Patients, like those represented by GCCA, indisputably have a protected liberty interest in their health and their very lives. U.S. Const. amend. V. Many of the first ten selected drugs are life-saving medicines. As the government's expert puts it, these drugs "treat serious health conditions, including blood clots, diabetes, heart disease, arthritis and cancer," such that "there could be serious health and financial consequences if patients lost access to one or more of the selected drugs." Buchmueller Decl. ¶ 11. The government does not dispute that the Program could result in millions of Americans losing access to their critical medicines. Indeed, the government repeatedly suggests that if a manufacturer is unwilling to accept the Hobson's choice of unfair price controls or a crippling excise tax, it should simply withdraw from Medicare and Medicaid entirely. *See, e.g.*, Defs.' Br. 35.

The government argues (at 40) that Plaintiffs cite no authority suggesting that "patients have a constitutional right to have all current Medicare and Medicaid products remain available through

those programs forever—let alone some speculative right to the fruits of some possible future innovation." But to say that patients do not have a right to have *all* Medicare and Medicaid products remain available *forever*, does not mean that patients do not have a liberty interest in preserving access to *some* life-saving medicines *now*.

3. Finally, the IRA deprives providers like NICA of their constitutionally protected interest in being reimbursed on a non-arbitrary basis at a lawful rate. Pls.' MSJ 25. The government's response is unconvincing. As before, it devotes most of its brief to dismantling an argument Plaintiffs never advanced. The government argues (at 38) that "providers have no protected interest in being reimbursed at their preferred levels." So stipulated. By contrast, the protected interest providers *do* have—and the only one Plaintiffs have ever asserted—is to be reimbursed on a non-arbitrary basis at a lawful rate. *That* protected interest is well established. *See Rock River Health Care, LLC v. Eagleson*, 14 F.4th 768, 773–74 (7th Cir. 2021); *Furlong v. Shalala*, 156 F.3d 384, 393 (2d Cir. 1998).[16]

The government's attempt to commandeer *Rock River Health Care* and *Furlong* does not make it out of the harbor. The government contends those cases "confirm[] the lack of a property interest here" because they held "only" that providers "have a property interest in reimbursement 'at the legally prescribed rate.'" Defs.' Br. 38 (quoting *Rock River Health Care*, 14 F.4th at 774). That acknowledgment dooms the government's argument: Here, the IRA unlawfully deprives providers of the pre-IRA "legally prescribed rate" via its unconstitutional Drug Pricing Program. The government asserts (at 38) that the IRA does not deprive providers of that property interest because the negotiation program

[16] For similar reasons, the government is wrong when it argues that "the Seventh Circuit explicitly rejected the theory on which Plaintiffs rely here: that the providers were 'entitled to a *particular* reimbursement rate' or 'to whatever rate [the providers] believe is appropriate,' divorced from any actual legal prescription." Defs.' Br. 39 (quoting *Rock River Health Care*, 14 F.4th at 774). Plaintiffs do not claim entitlement to "a particular reimbursement rate" or the rate they "believe is appropriate." Plaintiffs' argument is much more modest—that the government cannot impose unlawful price controls through an arbitrary program that diminishes providers' reimbursement revenues.

"does not alter [the] statutory reimbursement formula"—as though altering the formula were the only way to deprive providers of their protected interest. Even if it were accurate that the IRA does not alter the reimbursement formula (in fact, the IRA alters the statutory reimbursement formula under both Parts B and D),[17] that the Program deprives providers of their property interest in a different way—by imposing price controls that in turn decrease providers' revenues—does not diminish providers' asserted right.

The government devotes (at 39) two sentences to argue that the Drug Pricing Program "passes even Plaintiffs' test" because, the government says, providers "will be" reimbursed on a non-arbitrary basis at a lawful rate. The Court should give this argument as much attention as the government did: For the reasons discussed, the government's price-setting scheme is both arbitrary and unlawful.

The government likewise dismisses Plaintiffs' argument that the negotiation program threatens to wipe out the "enormous resources" they have invested in "building facilities and processes for administering Medicare-reimbursed drugs effectively and efficiently," Pls.' MSJ 25, arguing that Plaintiffs failed to explain how the program deprives providers of those interests. But Plaintiffs did explain, *id.* at 24–25, and it is obvious in any event. As the Fifth Circuit held, the negotiation program "substantially impacts" providers' "ability to stay in business." *NICA*, 116 F.4th at 503. A provider driven out of business has been deprived of protected interests.

CONCLUSION

For the foregoing reasons, this Court should deny the government's motion for summary judgment, grant summary judgment to Plaintiffs, declare the IRA's Drug Pricing Program unconstitutional, and enjoin Defendants from implementing it.

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[17] *Compare* Garthwaite Decl. ¶ 79, *with* 42 U.S.C. § 1395w–3a(b)(1)(B); *compare* Final Guidance at 39–40, *with* 42 U.S.C. § 1395w–102(d)(1)(D).

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