No. 25-50661

In the United States Court of Appeals for the Fifth Circuit

NATIONAL INFUSION CENTER ASSOCIATION, on behalf of itself and its members; GLOBAL COLON CANCER ASSOCIATION, on behalf of itself and its members; PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, on behalf of itself and its members,

Plaintiffs-Appellants,

v.

ROBERT F. KENNEDY, JR., Secretary, U.S. Department of Health and Human Services, In his Official Capacity; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; MEHMET OZ, Administrator of the Centers for Medicare and Medicaid Services, In his Official Capacity; CENTERS FOR MEDICARE AND MEDICAID SERVICES,

Defendants-Appellees.

On Appeal from the U.S. District Court for the Western District of Texas
No. 1:23-cv-707 (Hon. David Alan Ezra)

APPELLANTS' REPLY BRIEF

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INTRODUCTION

Unable to defend the system of government-dictated price controls Congress actually established under the Inflation Reduction Act (IRA), the government is reduced to claiming the Drug Pricing Program is something else entirely: a genuine "negotiation" over government purchasing. But repeating that claim enough times does not make it true.

In reality, the IRA delegates unfettered authority to the Centers for Medicare & Medicaid Services (CMS) to *set* drug prices at which manufacturers must provide "access" to 68 million private Medicare "eligible individuals," millions of private providers, and thousands of private pharmacies. 42 U.S.C. § 1320f-2(a)(3). Not as a market participant (CMS is not buying any drugs here), but as a stand-in legislature that can rewrite, with impunity, the law it is supposedly implementing. While the IRA avoids accountability by disguising government price controls with faux "offers," "counteroffers," and "agreements," it exposes the "negotiations" to be a sham by imposing crippling penalties on any manufacturer that does not "comply" with CMS-decreed prices. The Program is constitutionally indefensible. The Court should reverse.

ARGUMENT

I. The IRA Violates the Separation of Powers and Nondelegation Doctrine

The IRA's combination of regulatory features is unprecedented in American history. Never before had Congress delegated price-setting authority—let alone for a massive sector of the economy—with *no* minimum pricing constraints, *no* administrative processes, and *no* judicial oversight. The government touts the Program's superficial limitations, contending (at 20-22) that the IRA provides CMS sufficient "guidance" because it "outlin[es]" procedures for selecting drugs, lists "factors" for the agency to "consider" in setting prices, identifies the "number of drugs" the agency can select, and imposes a "ceiling price." But those are hollow gestures given the IRA's removal of any external constraints, yielding "virtually unfettered" discretion to overhaul the $600-billion-a-year pharmaceutical market. *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 542 (1935).

A. The government's (and district court's) error rests on a fundamental misunderstanding of *FCC v. Consumers' Research*, 145 S. Ct. 2482 (2025). There, the Communications Act delegated (reviewable) authority to the FCC, which "subdelegate[d]" some authority to a private firm. *Id.* at 2491. Because the subdelegation did not enhance the FCC's *own* authority, the Supreme

Court held that "the combination" of "public" and "private" delegations crossed no "constitutional line." *Id.* at 2511. The government (and district court) read *Consumers' Research* as generally precluding courts from *ever* considering statutory features in "combination" when assessing nondelegation challenges. Opp. 22.

But *Consumers' Research* said no such thing. The Court emphasized that the Communications Act's two delegations operated on different "ax[e]s," 145 S. Ct. at 2510, and that fact was essential to its conclusion that the delegations were permissible. The Court acknowledged that features that "exacerbat[e]" or "compound" a single delegation *can* "combine" to cross "a constitutional line." *Id.* at 2510-11.

That is exactly what the IRA does. *See* Br. 35-36. It gives CMS expansive discretion to set prices over a major U.S. market, then "exacerbat[es]" and "compound[s]" that discretion by insulating the agency's pricing decisions from input from affected parties and judicial review. *Consumers' Rsch.*, 145 S. Ct. at 2510-11. Before the IRA, no court ever confronted a nondelegation challenge to this toxic combination—"a lack of historical precedent" that underscores the statute's "severe constitutional problem." *Seila Law v. CFPB*, 591 U.S. 197, 220 (2020) (cleaned up).

B. The government does not deny that the IRA's elimination of administrative input and judicial review permits HHS to ignore Congress's nominal constraints on the agency's decision-making authority, turning the IRA's broad delegation into an *unlimited* one. For example, the government does not dispute that HHS could set drug prices at *zero*, select however many drugs it wants for price controls, and treat *any* product it wishes as a "negotiation eligible drug." Br. 28-31. It thus *concedes* that the agency can rewrite the statute with impunity. Indeed, the government has consistently defended HHS's efforts to do so without "notice-and-comment procedures"[1] or "judicial review of … statutory claims."[2]

C. The government contends "the availability of judicial review and of notice-and-comment procedures is irrelevant to plaintiffs' nondelegation claims." Opp. 24; *see id.* at 25 ("not a relevant consideration"). But the Supreme Court and this Court have emphasized the importance of judicial review and administrative process when a statute grants substantial power to an agency. *See, e.g.*, *Bowles v. Willingham*, 321 U.S. 503, 512-13, 516 (1944);

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[1] Br. for Appellees at 65, *Boehringer Ingelheim Pharms., Inc. v. HHS*, No. 24-2092 (2d Cir. Jan. 15, 2025), Doc. 129-1.

[2] *E.g.*, Br. for Appellee at 41-47, *AstraZeneca Pharms. LP v. HHS*, No. 24-1819 (3d Cir. Sept. 12, 2024), Doc. 37.

Touby v. United States, 500 U.S. 160, 168 (1991)[3]; *United States v. Gordon*, 580 F.2d 827, 839 (5th Cir. 1978); *see also* Br. 24-27.

Judicial review alleviates "structural concerns about expansive delegations." *Consumers' Rsch.*, 145 S. Ct. at 2515 (Kavanaugh, J., concurring); *accord Am. Power & Light Co. v. SEC*, 329 U.S. 90, 106 (1946) ("[J]udicial review of [agency action] safeguards against statutory or constitutional excesses."); *Amalgamated Meat Cutters & Butcher Workmen of N. Am., AFL-CIO v. Connally*, 337 F. Supp. 737, 759 (D.D.C. 1971) (Leventhal, J., for three-judge court).

Confronting those authorities, the government hastily walks back its claim (at 24-25 & n.2) that judicial review is "irrelevant." Instead, it maintains (at 25) that while "the *availability* of judicial review is a factor weighing in favor of *upholding* a statute," "the *preclusion* of judicial review" is irrelevant. But the government cannot have it both ways. If the availability of judicial review is a factor supporting the constitutionality of a delegation, then the absence of judicial review necessarily cuts the other way. Either judicial

[3] The government contends Justice Marshall's concurrence in *Touby* "proves" the majority did not say judicial review matters. Opp. 26. But Marshall was emphasizing *the majority's* point: "*As the Court notes*, judicial review perfects a delegated-lawmaking scheme by assuring that the exercise of such power remains within statutory bounds." 500 U.S. at 170 (emphasis added).

review matters to the nondelegation question or it does not. And courts have said, time and again, that it does. *See* Br. 24-27.

That makes sense. A delegation of unchecked discretion is necessarily more expansive than a delegation of checked discretion. *See* Br. 40-41. Empowering an agency to set "fair" prices is a broader delegation when the agency gets final say on what's "fair." Telling an agency to select "ten" drugs is no constraint when the agency can simply decide to treat multiple drugs as one (as CMS already has). Directing an agency to "consider" specified "factors" is meaningless when the agency's failure to do so is unreviewable. The government does not rebut these points because they reflect what CMS has *actually been doing* for the last three years.

The government cites two out-of-circuit cases for its argument that judicial review is irrelevant. Opp. 25. Even if this Court and the Supreme Court had not already held otherwise, those cases do not support the government's categorical proposition. In *United States v. Bozarov*, the claimant argued that precluding judicial review necessarily violates the nondelegation doctrine. 974 F.2d 1037, 1042 (9th Cir. 1992). Though the court concluded that judicial review is not "*always* constitutionally required," it acknowledged that "*the availability of judicial review is a factor*." *Id.* (emphases added). And the court

"emphasize[d] that [its] holding" upholding that statute was "limited to the [particular statute's] preclusion of judicial review" and not a judgment regarding "the constitutionality of other statutes that prohibit all review." *Id.* at 1045 n.6. Here, by contrast, the IRA's nondelegation problem is its sweeping grant of discretion to set prices for a massive segment of the economy, *combined with* its removal of every safeguard.

Nor does *Michigan Gambling Opposition v. Kempthorne*, 525 F.3d 23, 26 (D.C. Cir. 2008), assist the government. There, the challenged statute said nothing about judicial review, and the scope of the delegation was "not so broad." *Id.* at 32-33. While the two-judge majority noted in dicta that it was not "concerned" about judicial review, *id.* at 33 n.8, it never reconciled that offhand statement with Supreme Court precedent.

Finally, the government accuses Plaintiffs (at 26) of failing to "offer any limiting principle to their argument that the nondelegation doctrine requires judicial review." Leaving aside that *the government* offers no "limiting principle" for *its* claim that judicial review is irrelevant, it mischaracterizes Plaintiffs' position. The lack of judicial review is significant *here* because it exacerbates the sweeping discretion the IRA grants HHS to upend a major industry. The limiting principle for the significance of judicial review is that "the degree

of agency discretion that is acceptable varies according to the scope of the power congressionally conferred." *Am. Trucking*, 531 U.S. at 475. The IRA's scope is staggering; it replaces a massive "free market [with] a government-run process." *Nat'l Infusion Ctr. Ass'n v. Becerra*, 116 F.4th 488, 494 (5th Cir. 2024) *(NICA*). While the government alludes (at 26) to "at least 190 extant statutes" that limit judicial review, it identifies nothing that looks remotely like the IRA.

D. The government invokes several IRA provisions that it calls "guidance." But they only underscore the breadth of the delegated discretion—and the critical lack of procedural guardrails.

To start, the IRA allows HHS to set prices as low as it chooses, which is precisely the sort of unfettered discretion *Consumers' Research* described as "a constitutional problem." 145 S. Ct. at 2502. The government concedes (at 21) the IRA provides only a "ceiling price," and does not attempt to defend the district court's incorrect suggestion (*see* Br. 37-38) that the IRA *implicitly* "sets a floor." ROA.1251. Instead, the government argues (at 21) Congress did not *need* to "specify a floor price" because "the manufacturer must agree to the price" and has "leverage."

But that argument rests entirely on the government's expert declaration, which never addressed the IRA's excise tax and other crippling penalties that prevent manufacturers from walking away, as a party might in an actual negotiation. As *NICA* explained, the IRA's "penalty phase" makes manufacturers "all but certain" to submit to CMS's decreed prices. 116 F.4th at 500. The IRA "*compel*[*s*] [manufacturers] to participate in the Program by threatening them with unavoidable, enterprise-crippling tax liabilities if they refuse[] to sell drugs at prices set by CMS." *Bristol Myers Squibb Co. v. HHS*, No. 24-1820, — F.4th —, 2025 WL 2537005, at *15, (3d Cir. Sept. 4, 2025) (*BMS*) (Hardiman, J., dissenting) (emphasis added). The IRA's faux "negotiation" and "agreement" regime is not fooling anyone, much less constraining CMS.

Similarly unpersuasive is the claim (at 21-22) that "[m]anufacturers' ability to pull out of Medicare and Medicaid provide[s] them with significant leverage." To begin, withdrawal in time to avoid the excise tax was statutorily "*impossible*." *BMS*, 2025 WL 2537005, at *15, 18 (Hardiman, J., dissenting); *see* Br. 15 & n.2. Moreover, "[t]he consequence of" withdrawal "would be catastrophic for almost any manufacturer," requiring abandonment of half the

U.S. drug market and leaving millions of patients without critical medicines. ROA.792-95. Manufacturers have no semblance of "leverage."

Nor does the government elaborate on the "factors" the IRA tells CMS to "consider" in setting prices. Perhaps that is because CMS need not actually give them any weight—a point the government never disputes. Br. 38. While the government notes (at 21 n.1) that the statute upheld in *J.W. Hampton, Jr., & Co. v. United States* also outlined factors for the President to "consider[]" before imposing tariffs, that statute provided for "notice to all parties interested and an opportunity … to be heard." 276 U.S. 394, 405 (1928). There also was no judicial review bar. And it specified a ceiling *and* a floor. *Id.* at 401 ("the total increase or decrease of such rates of duty shall not exceed 50 per centum of [specified] rates").

Citing two cases, the government claims (at 20) the IRA gives "CMS far more guidance … than many other grants of agency authority."[4] But in *Yakus v. United States*, the Court emphasized not only that "[t]he boundaries of the field of the [agency's] permissible action [were] marked by the statute," but

[4] In briefing below, the government listed nine cases for this proposition. As Plaintiffs explained, the statutes at issue in each case allowed for administrative procedures and/or judicial review. ROA.1171-72. Tellingly, the government does not repeat that list before this Court.

"that the courts in an appropriate proceeding" could evaluate the agency's decisions. 321 U.S. 414, 422-23 (1944). The Court thus "noted" that "judicial review" is an "element of the doctrine." *Amalgamated Meat*, 337 F. Supp. at 759. Indeed, "*Yakus* emphasized the importance of regular procedures, and the *Yakus* test reformulated the rule of the delegation doctrine by emphasizing the availability of review." Peter H. Aranson et. al., *A Theory of Legislative Delegation*, 68 Cornell L. Rev. 1, 14 (1982). And in *Whitman v. American Trucking Associations*, the statute *specifically allowed* challenges to agency action "under the judicial-review provisions." 531 U.S. 457, 476 (2001). The IRA, by contrast, eliminates key procedural guardrails.

II. The IRA Violates the Excessive Fines Clause

The so-called "excise tax" is a massive penalty the government has admitted "is triggered by the lawful choices of the taxpayer." Opp. 38. Unable to seriously dispute that the excise tax is punitive and grossly disproportionate, the government insists that the Anti-Injunction Act bars suit and Plaintiffs sued the wrong entities. The government is wrong on all counts.

A. The Excise Tax Is Punitive

The "excise tax" is "at least partially punitive." *Timbs v. Indiana*, 586 U.S. 146, 154-55 (2019). Congress described the IRA's predecessor bill as a

"steep, escalating penalty," Title Summary, H.R. 3, at 1 (2022); passed the excise tax despite estimates showing it would cripple any manufacturer forced to pay, *see* Br. 13; and codified it in the statute's "noncompliance" section, 26 U.S.C. § 5000D; *see id.* § 5000D(b) ("Noncompliance periods"). It indisputably serves "deterrent purposes" and thus operates at "least in part as punishment." *Austin v. United States*, 509 U.S. 602, 610 (1993) (cleaned up).

The government never disclaims that punitive purpose. Instead, it argues (at 38) that the excise tax is not subject to the Excessive Fines Clause because it "lacks any connection to criminal conduct." That reasoning would perversely give the government *greater* ability to punish innocent conduct than serious crimes. The Supreme Court has already rejected it: "[T]he question is not" whether a fine "is civil or criminal, but rather whether it is punishment." *Austin*, 509 U.S. at 610. 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 38) that because the forfeitures in *Austin*, *Timbs*, and *United States v. Bajakajian*, 524 U.S. 321 (1998), involved property related to criminal activity, penalties for "lawful choices" cannot be

excessive fines. But that is a non-sequitur. *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 proposed requirement that a punitive fine *also* must be "connect[ed] to criminal conduct," which other courts have rejected. *E.g.*, *United States v. Schwarzbaum*, 127 F.4th 259, 265, 284 (11th Cir. 2025); *United States v. Mackby*, 261 F.3d 821, 830 (9th Cir. 2001).[5]

The government falsely suggests (at 38) that a fine labeled a "tax" *cannot* violate the Excessive Fines Clause. While the "tax" label can matter for purposes of the Anti-Injunction Act—because both the tax and AIA "are creatures of Congress's own creation"—that statutory label "does not determine" the merits of a *constitutional* challenge. *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 544, 564-65 (2012) (*NFIB*). Congress cannot evade constitutional scrutiny by calling a fine a "tax."

[5] The government cites *United States v. Jalaram, Inc.*, 599 F.3d 347, 354 (4th Cir. 2010), and *United States v. Toth*, 33 F.4th 1, 16 (1st Cir. 2022). But those cases relied on outdated precedents and are "difficult to reconcile with" more recent Supreme Court guidance. *Toth v. United States*, 143 S. Ct. 552, 553 (2023) (Gorsuch, J., dissenting from denial of certiorari).

B. The IRA's Excise Tax Is Grossly Disproportionate

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. The Court thus must compare the size of the excise tax to "the degree of [Plaintiffs'] reprehensibility or culpability." *Cooper Indus., Inc. v. Leatherman Tool Grp., Inc.*, 532 U.S. 424, 435 (2001). As the government admits, the excise tax is "is not triggered by the commission of *any* offense—reprehensible or otherwise," ROA.982, but instead "by [manufacturers'] lawful choices," Opp. 38. And the tax is massive, reaching 1,900% of a drug's *total* U.S. revenues. 26 U.S.C. § 5000D(b)(1)-(4). Thus, it is grossly disproportionate.

The government contends (at 39) that "[t]he excise tax bears a close and proportional relationship to the burdens on the fisc." Even if true, that would be immaterial, since there is no "offense" (or culpability) in the first place: *Any* punishment is disproportional to the "reprehensibility or culpability" of entirely innocent conduct. *Cooper*, 532 U.S. at 435.

In any event, there is nothing resembling proportionality here. The "tax" does not target a manufacturer's "excess" Medicare profits, its Medicare profits generally, or even its Medicare revenues. It reaches 1,900% of a

manufacturer's *total U.S. revenues* for a drug—including revenues from private market sales. Collecting almost *twenty times* a manufacturer's total earnings from a drug is not remotely "proportional."

2. The government strains to rewrite the statute to make it seem less disproportionate. The government asserts (at 39-40) the tax actually is capped at "95%" of "the amount charged by the manufacturer" and applies "only to sales … that are reimbursed by Medicare." The government's need to rewrite the IRA to save it is revealing—and unavailing.

To begin, the government made the same argument last year, *see* Br. for Appellees at 8 n.1, *NICA*, 116 F.4th 488 (5th Cir. 2024) (No. 24-50180), Doc. 60-1, and this Court rejected it. In upholding Plaintiffs' standing to challenge the excise tax, this Court held that it applies to "all sales of the drug (not just Medicare sales) … and rises to 1,900%." *NICA*, 116 F.4th at 495.

That was correct. The "tax" is not capped at 95% of "the amount charged by the manufacturer," *contra* Opp. 40, but at 95% of that amount *plus* the excise tax itself (*i.e.*, the 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 out to 1,900% of the price. *Id.*

For every dollar a manufacturer receives from a sale, it must pay $19 in fines. As the Congressional Research Service explained, the excise reaches "1,900% of the selected drug's price." Cong. Rsch. Serv., R47202, *Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376)*, at 4 (2022), https://bit.ly/3sbHYBy.

Statutory text and context support this Court's conclusion that the excise tax applies to "all sales of the drug (not just Medicare sales)." *NICA*, 116 F.4th at 495. The excise tax applies to *all* "sale[s] … of any designated drug." 26 U.S.C. § 5000D(a). The statute also "suspen[ds]" the excise tax for manufacturers who *exit* Medicare, which would be unnecessary if the tax were limited to Medicare sales. *Id.* § 5000D(c)(1)(A)(ii). And the excise tax provision exempts "[e]xports," which again would be superfluous if limited to sales within Medicare—a domestic program. *Id.* § 5000D(g).

The government rests its contrary position on an IRS "Notice." Opp. 40 (citing IRS Notice No. 2023-52 (Aug. 4, 2023), https://perma.cc/B9JZ-ZG7P (IRS Notice)). But an agency cannot render a statute constitutional by misinterpreting or rewriting it. Plaintiffs challenge the statute, not the IRS's interpretation. In assessing the IRA's constitutionality, the Court must determine the "best reading" of the statutory language—*i.e.*, "the reading the court

would … reach[] if no agency were involved." *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 400 (2024) (citation omitted).

And anyway, the IRS Notice is just the agency's *current* interpretation, on which "taxpayers may rely" *only* "[u]ntil the Treasury Department and the IRS issue further guidance." IRS Notice 5. Taxpayers cannot rely on an agency interpretation that contravenes the words of the statute and could change tomorrow.

C. The Court Has Jurisdiction Over Plaintiffs' Excessive Fines Claim

1. The Anti-Injunction Act Does Not Apply

The government focuses on whether the AIA applies facially, Opp. 27-32, and has little to say about the two AIA exceptions at issue. Those exceptions apply, and to hold otherwise would extend the AIA to the point of absurdity.

a. As Plaintiffs explained, Br. 48, a suit is exempt from the AIA when Congress has not provided "an alternative legal way to challenge the validity of a tax," *South Carolina v. Regan*, 465 U.S. 367, 373 (1984), meaning the challenger could not feasibly pay the tax and then bring a "postpayment refund suit," *In re Westmoreland Coal Co.*, 968 F.3d 526, 535 (5th Cir. 2020). While some courts have incorrectly treated "the *Regan* exception [as] 'very narrow,'"

this Court "view[s] the exception more broadly." *Id.* at 536 (citations omitted). It applies whenever a "postpayment refund suit" would not be "an adequate[] alternative" to an otherwise-barred challenge. *Id.* (cleaned up).

That is true here: As this Court explained, "no manufacturer could afford to pay" the excise tax. *NICA*, 116 F.4th at 495. So a "postpayment refund suit" is not an option at all, let alone an adequate alternative.

The government argues (at 34) the AIA applies *even when* a "tax" is so exorbitant that *nobody* has the "ability to pay." That is absurd. As the government claims, the AIA bars even "constitutional claims" whenever "Congress label[s] [an] exaction a 'tax.'" Opp. 31-35 (citation omitted). So, under the government's theory, the AIA would preclude judicial review of even flagrantly unconstitutional laws so long as Congress enforces them through unaffordable "taxes." Indeed, the *more* excessive the "tax," the *less* susceptible the law would be to challenge: Congress could impose a $100-billion tax on church attendance, or a similarly exorbitant "speech tax" for criticizing the government, and the AIA would preclude review. The *Regan* exception prevents just such absurdity.

The exception articulated in *Enochs v. Williams Packing & Navigation Co.* also applies, because (i) "the Government [cannot] ultimately prevail" on

the merits, and (ii) Plaintiffs would suffer "irreparable injury" if required to pay the unaffordable excise tax before suing. 370 U.S. 1, 6-7 (1962). The government contends (at 33) that "the excise tax is []defensible," so Plaintiffs' likelihood of success is not certain. But there is nothing remotely defensible about a crippling financial penalty for conduct even the government agrees is completely lawful.

b. The government seeks to evade both AIA exceptions on the theory (at 32-34) that the excise tax is "divisible," meaning Plaintiffs could pay the tax "on a single transaction" and *hope* "the IRS [would] not collect the remainder of the excise tax that would otherwise be due" throughout a refund litigation. Not so.

To start, the IRS has *never* promised to refrain from collecting the excise tax on additional transactions while a refund suit is pending. No IRS guidance document on the excise tax says anything of the sort. The government cites (at 33) a nonbinding policy statement of the IRS's "general[]" discretionary practice. In other words, the government's argument rests on the notion that the IRS *might* exercise forbearance, even though it has been unwilling to make any such commitment. "Cold comfort, indeed." *Cf. BMS*, 2025 WL 2537005, at *22 (Hardiman, J., dissenting).

But even if the IRS refrains from collecting taxes throughout protracted refund litigation, manufacturers would incur "unsustainable financial *liability*" during that time. ROA.871 (emphasis added); *see* ROA.793. Betting a company's survival on litigation is not "an adequate[] alternative" for purposes of the *Regan* exception. *Westmoreland Coal*, 968 F.3d at 536. Likewise, 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. *See NICA*, 116 F.4th at 500. That is the *entire point* of the excise tax.

Finally, the government is wrong (at 34 n.4) that Plaintiffs' inability to incur unlimited financial liability signals weakness in their merits argument. Manufacturers owe fiduciary duties to their shareholders and occupy a position of trust with patients who rely on their medicines. No matter how strong a litigant's position, litigation comes with inherent risks. At minimum, a manufacturer would have to devote enormous resources—tens if not hundreds of billions of dollars—to finance such fines pending the lawsuit's eventual outcome. Manufacturers cannot simply ante "100 percent of [their] total net revenues" simply because they will eventually be proven right on the law. ROA.793.

c. Applying the AIA in this case would create a *further* constitutional problem, because 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 v. Doe*, 486 U.S. 592, 603 (1988). The AIA thus cannot be read "as precluding all judicial review." *Westmoreland Coal*, 968 F.3d at 535. But that is the implication of the government's position.

2. Relief Against Defendants Would Redress Plaintiffs' Injury

The government argues (at 35-37) that Plaintiffs' excessive fines claim is not redressable because HHS and CMS supposedly do not administer the relevant statutory provisions. That is incorrect.

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). "When 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 meets that threshold

when a favorable ruling "has the potential, in whole or in part, to redress the claimed injury." *Id.* The enjoined act need not be "the very last step in the chain of causation." *Bennett v. Spear*, 520 U.S. 154, 168-69 (1997).

The IRA requires HHS to provide the Treasury Secretary "such information as is necessary to determine the tax imposed by section 5000D." 42 U.S.C. § 1320f-5(a)(6). Plaintiffs can accordingly obtain redress through a judgment against HHS preventing it from carrying out its obligations in the unconstitutional enforcement scheme.

The government (at 36 n.5) cites a July 2024 regulation requiring manufacturers to "self-report their excise tax liability." But Plaintiffs brought this suit in June 2023, so, contrary to the government's position (*id.*), "standing … exist[ed] when the complaint was filed." And if needed, the Court can alleviate any issue that has arisen since, simply by adding necessary parties. Fed. R. Civ. P. 21; *Novartis Pharms. Corp. v. HHS*, No. 24-2968, — F.4th —, 2025 WL 2619133, at *4-5 (3d Cir. Sept. 11, 2025) (adding Treasury and IRS).

III. The IRA Violates the Due Process Clause

The government does not even attempt to defend the IRA's woefully deficient procedures. It concedes that the statute flunks all three *Mathews v. Eldridge* factors, 424 U.S. 319 (1976): (1) Plaintiffs' "'private interests' at stake

are immense," Br. 57 (quoting *Mathews*, 424 U.S. at 334-35); (2) "[t]he lack of input regarding unanswered implementation questions and inability to challenge particular determinations create a substantial risk of erroneous deprivation," *id.* (quoting *NICA*, 116 F.4th at 503); and (3) "the government has no legitimate interest in insulating HHS's decision-making from input by affected parties, or in denying judicial review," *id.* at 58 (citing *Mathews*, 424 U.S. at 335). That makes resolving this claim straightforward: Because Plaintiffs have identified constitutionally protected property interests, they have established a due process violation.

A. The government argues manufacturers lack any protected interest because the government is a market participant and "no one has a right to sell to the government that which the government does not wish to buy." Opp. 42 (cleaned up). And, regardless, Medicare is "voluntary." Opp. 45. Both arguments are meritless.

1. The government attempts to redefine manufacturers' property interests by falsely asserting that the IRA simply sets the prices at which the government buys drugs from manufacturers—once again, a revealing misrepresentation of the statute. In fact, the IRA empowers CMS to set prices at which manufacturers must provide "access" to *private* "pharmac[ies], mail

order service[s], or other dispenser[s]" and *private* "hospitals, physicians, and other providers of services and suppliers" that serve 68 million *private* Medicare "eligible individuals." 42 U.S.C. § 1320f-2(a)(3) (emphasis added). The Program thus deprives manufacturers of a "protected interest in the treasured common-law right to offer access to their products at market prices" to *private* parties. Br. 52 (cleaned up).

It has been "well-settled" for decades that "the right of the owner of property to fix the price at which he will sell it" is "within the protection of the Fifth … Amendment[]." *Old Dearborn Distrib. Co. v. Seagram-Distillers Corp.*, 299 U.S. 183, 192 (1936) (citations omitted). The Program strips manufacturers of that right, compelling them to offer their products to private purchasers at steep discounts—up to 79% for the first ten drugs—costing manufacturers billions.

That right is crucial to manufacturers of innovative medicines, whose hard-earned patents afford an interest in seeking higher prices "than could have been obtained if direct competition existed." *Biotech. Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1373 (Fed. Cir. 2007) (citation omitted). Indeed, affording a patent-holder a time-limited right to pursue "pecuniary rewards" to recoup investments and encourage further discovery is "the

fundamental purpose of the patent grant." *Id.* at 1372 (citation omitted). By imposing price caps for products patented years before the IRA's enactment—and years before existing patent rights expire—the statute impairs manufacturers' protected interests.

The government's example (at 42) of other federal drug-benefit programs underscores the IRA's fundamental differences. Under 38 U.S.C. § 8126, the Department of Veterans Affairs administers a "procurement" program allowing it and other federal agencies, including the Department of Defense, to purchase drugs *directly* from manufacturers at discounted prices. *Id.* § (a)(1). But unlike CMS, those agencies *do* "purchase" drugs in the marketplace, *id.* § 8126(a)(4), so it makes sense that they "negotiate" the prices they pay as buyers. Moreover, those agencies do not have any mechanism like the IRA's excise tax to force manufacturers to accept their price demands. And, crucially, their decisions 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).[6]

[6] The government's analogy to military contractors selling weapons is inapt for the same reasons.

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 S.-Cent. Timber Dev., Inc. v. Wunnicke*, 467 U.S. 82, 98 (1984). This Court explained as much in *NICA*. No ordinary purchaser has the power to impose "escalating fines" to economically cripple a counterparty that declines its proposals. 116 F.4th at 494. And "even if HHS offered a price that made sales of a particular drug unprofitable, the manufacturer still might agree to the unprofitable price because doing so is preferable to losing the Medicare market for all of its drugs." *Id.*

The government's argument (at 43) that manufacturers "have no right to force the government to pay for their drugs on specific terms" is also ironic. *The government* is the one forcing "specific terms" on manufacturers by leveraging its regulatory powers to fine them into ruin for refusing to "agree" to government-decreed prices for private transactions.

The government defends the Program (at 43) on the theory that it "does not control the price paid for a drug by any person who is not a Medicare beneficiary or by any private insurance plan." But that is a concession that the Program controls the price paid by millions of *private* individuals, pharmacies, and hospitals in private transactions to which the government is not a party.

And it does so without any pretense of minimally sufficient procedures. *Cf. Bowles*, 321 U.S. at 521 (upholding rent-fixing statute that "provided for judicial review"); *Mathews*, 424 U.S. at 333 ("The fundamental requirement of due process is the opportunity to be heard at a meaningful time and in a meaningful manner." (quotation marks omitted)).

The government's attempt to distinguish *Old Dearborn* fails. Stopping short of claiming it has been overturned, the government argues (at 44) the "Supreme Court has since held that the Constitution does not substantively constrain a legislature's ability to fix the price of goods." That is a radical overstatement. But even the government's few cited authorities emphasize the importance of features that the IRA lacks: a "judicial determination to th[e] effect" that "the requirements of due process are satisfied." *Nebbia v. New York*, 291 U.S. 502, 537 (1934). In any event, Plaintiffs are not challenging "a *legislature's* ability to fix the price of goods." *Contra* Opp. 44 (emphasis added). Congressionally enacted price controls would be subject to democratic accountability. But the government cannot empower an *administrative agency* to set prices without minimally sufficient protections.

The government likewise seeks (at 47) to distinguish *Bowles* on the ground that, there, Congress "sought to regulate the price at which any person

could lease his property to *any* buyer," whereas the Drug Pricing Program regulates prices only "where a buyer uses Medicare." The government apparently concedes (at 47) that protected interests are implicated when the government imposes "market-wide price restrictions," but argues that is not the case when laws purportedly "determine the price the government itself is willing to pay." Again, however, that argument rests on the false premise that the government buys prescription drugs subject to the Program (it does not) and that the IRA does not dictate prices in private market transactions (it does). *See supra* pp. 23-24; Br. 53, 59.

2. Though manufacturers have literally billions of dollars on the line, the government argues (at 45) the IRA does not deprive them of "anything" because they are not "compelled to participate" in the Program or in Medicare. Nonsense.

As Plaintiffs explained, Br. 60-62, participation in the Program is not voluntary simply because the government gives manufacturers the Hobson's choice between massive price cuts and exiting nearly *half* the market for prescription drugs, leaving patients without needed medicines. Even that "choice" was illusory. Because of the IRA's statutory deadlines, manufacturers could not have declined to participate in the Program's first

year without facing the crippling excise tax. "To avoid being subject to the excise tax [when the noncompliance period began], they had to do the impossible: terminate their Medicare agreements by January 29, 2022, months before the Act became law." *BMS*, 2025 WL 2537005, at *21 (Hardiman, J., dissenting). Even if manufacturers provided withdrawal notice when drugs were first selected on August 29, 2023, they still "would have incurred excise tax liability for the 15 months between October 2, 2023, and December 31, 2024." *Id.*[7]

The IRA's excise tax is as coercive as the challenged provisions of the Affordable Care Act in *NFIB*. *See* Br. 60-62. The government argues (at 46) that *NFIB* does not apply because it addressed only "federalism-based limits on the conditions that Congress may attach to money it grants to States." But Congress's "economic dragooning" is at least as coercive when deployed against private entities. 567 U.S. at 578, 582. The key question is whether "persuasion [has] give[n] way to coercion." *Id.* at 585. If it has, the target of the regulation—whether a state or private party—is not acting voluntarily.

[7] "Apparently recognizing this Catch-22," *id.* at *22, the government claims (at 46) CMS created an escape hatch whereby manufacturers could "withdraw in as little as 30 days." But as Judge Hardiman explained—and as Plaintiffs already noted, Br. 15 n.2—"CMS lacks authority to offer this expedited exit option," 2025 WL 2537005, at *23.

But even if participation in the Program were somehow voluntary, the Due Process Clause "applies equally to voluntary benefit programs." Br. 62. The government does not even mention, let alone distinguish, *Goldberg v. Kelly*, 397 U.S. 254 (1970), in which the government was barred from terminating voluntary "public assistance benefits" without providing constitutionally sufficient process. Indeed, *Goldberg* recognized that even "government contractor[s]" deserve due process. *Id.* at 264. In short, even a government program that is truly voluntary (unlike the IRA) requires basic procedural protections.

B. The IRA likewise deprives providers of protected interests. The government argues (at 49-50) this Court should ignore what it said in *NICA* about this issue because that decision addressed standing. But the Court's analysis applies here. Noting that "key determinations [under the IRA] are made without notice and comment and insulated from administrative or judicial review," the Court concluded "there is a substantial risk that [providers] will be erroneously deprived *of important property interests.*" 116 F.4th at 503 (emphasis added). Further, Plaintiffs "alleged sufficient facts to satisfy the *Mathews* test" for identifying a due process violation, which necessarily requires showing a protected property interest. *Id.* This Court

could not have reached that conclusion if it agreed with the government that providers *lack* any protected interest.

The government contends that providers are entitled only "to be paid for Part B drugs … under the statutory reimbursement formula," Opp. 48, which "depends entirely on the Medicare Act," Opp. 47. But that is precisely Plaintiffs' point: Despite that statutory entitlement, the IRA gives HHS unfettered discretion to *ignore* the Medicare Act. *See supra* p. 4. So while the government *says* (at 48) a provider "might have a viable claim if CMS deprived it of payment for services already rendered and refused the provider a meaningful opportunity to be heard," the IRA bars providers from "challeng[ing] particular determinations." *NICA*, 116 F.4th at 503. That is how the Program "create[s] a substantial risk of erroneous deprivation" of the providers' interest in obtaining "revenue and … stay[ing] in business." *Id.*

C. Patients' protected interests are equally at stake. The government never contests that patients have a protected interest in preserving access to some life-saving medicines, Br. 65, but argues (at 50) that patients lack a protected interest in accessing *experimental* drugs and *physician-assisted suicide* (neither of which would be likely to be covered by the IRA). The government then insists (at 50) that the Drug Pricing Program will not cause

Americans to lose access to critical medicines. But the government has repeatedly stated (*e.g.*, at 45-46) that manufacturers unwilling to accept government price controls should withdraw from Medicare and Medicaid. That would be "devastating for millions of patients." ROA.794. The Program undeniably implicates patients' protected interests.

CONCLUSION

This Court should reverse.

Dated: September 24, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on September 24, 2025 the foregoing document was electronically filed with the Court via the appellate CM/ECF system, and that copies were served on counsel of record by operation of the CM/ECF system on the same date.

Dated: September 24, 2025

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CERTIFICATE OF COMPLIANCE

This document complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B)(ii) because it contains 6,481 words excluding the parts exempted by Fed. R. App. P. 32(f) and Fifth Circuit Rule 32.2. This document complies with the typeface and type style requirements of Fifth Circuit Rule 32.1 and Fed. R. App. P. 32(a)(5) and 32(a)(6), respectively, because it has been prepared in a proportionately spaced typeface using Microsoft Word in Century Expanded BT 14-point font.

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