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' OPENING BRIEF

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CERTIFICATE OF INTERESTED PERSONS

Pursuant to Fifth Circuit Rule 28.2.1, undersigned counsel certifies that the following listed persons and entities as described in the fourth sentence of Rule 28.2.1 have an interest in the outcome of these appeals. These representations are made in order that the judges of this Court may evaluate possible disqualification or recusal.

1. **Plaintiff-Appellant the National Infusion Center Association (NICA).** NICA does not have a parent corporation, and no publicly held corporation owns 10% or more of its stock. The following attorneys have represented NICA in this case:

> Tim Cleveland, Austin Krist, Ibituroko-Emi Lawson, McKenzie Edwards and Gerard Bifulco of Cleveland Krist LLC.

2. **Plaintiff-Appellant the Global Colon Cancer Association (GCCA).** GCCA does not have a parent corporation, and no publicly held corporation owns 10% or more of its stock. The following attorneys have represented GCCA in this case:

> Michael Kolber and Megan Thibert-Ind of Manatt, Phelps & Phillips LLP.

3. **Plaintiff-Appellant Pharmaceutical Research and Manufacturers of America (PhRMA).** PhRMA does not have a parent

corporation, and no publicly held corporation owns 10% or more of its stock.

The following attorneys have represented PhRMA in this case:

> Jeffrey Handwerker, John Elwood, Allon Kedem, William Perdue, and Allissa Pollard of Arnold & Porter Kaye Scholer LLP.

4. **Defendant-Appellees Robert F. Kennedy, Jr., the U.S. Department of Health and Human Services, Dr. Mehmet Oz, and the Centers for Medicare and Medicaid Services.** The following attorneys have represented the government in this case:

> Lindsey Powell, Steven A. Myers, David L. Peters, Catherine Padhi, Samuel R. Bagenstos, Paul R. Rodríguez, Joel McElvain, Matthew A. Campbell, Lindsay S. Goldberg, Kenneth Whitley, Eric J. Hamilton, Justin R. Simmons, Brian M. Boynton, Cassandra M. Snyder, Michael Granston, Jaime Esparza, Michael J. Gaffney, Michelle R. Bennett, Stephen M. Pezzi, Christine L. Coogle, and Alexander V. Sverdlov.

Dated: September 2, 2025

/s/ *John Elwood*
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STATEMENT REGARDING ORAL ARGUMENT

Appellants requested oral argument as part of their motion to expedite this appeal. The Court granted the motion. As of this filing, no date has been set for oral argument. Appellants believe oral argument would assist the Court in resolving the issues presented.

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INTRODUCTION

For decades, Medicare has relied on a market-based system for reimbursing drug purchases, helping to make America the world leader in pharmaceutical research and development. This system benefits patients (who receive cutting-edge medicines), manufacturers (who earn competitive returns for successful products), and providers (who receive reimbursement for administering innovative drugs).

In the Inflation Reduction Act of 2022 (IRA), Congress replaced that time-tested system with government-dictated prices. If enacted forthrightly, this new scheme would have come at a high political cost because price controls harm innovation and patient care. To avoid backlash, Congress adopted a complex and unprecedented structure that, at every turn, seeks to avoid accountability, obscuring the fact that drug prices are dictated by government *fiat*. The truth, as this Court recently explained, is that the IRA seeks to replace the "free market" system with "a government-run process" for drug pricing. *Nat'l Infusion Ctr. Ass'n v. Becerra*, 116 F.4th 488, 494 (5th Cir. 2024) (*NICA*). Though the government claims that the IRA just sets the price *it* will pay for drugs, the effect is far more sweeping—setting the maximum prices that manufacturers can charge in entirely private transactions.

Here is how the so-called "Drug Price Negotiation Program" (Drug Pricing Program or Program) works. Contrary to its name, the Program involves no genuine "negotiation." Although "[t]he term 'negotiation' usually implies a process with a variety of possible outcomes," the IRA, by threat of "severe" consequences, *id.* at 499-500, compels manufacturers to accept prices unilaterally chosen by the Centers for Medicare & Medicaid Services (CMS)—a component of the Department of Health and Human Services (HHS). The agency could decree that an innovative, lifesaving medicine that cost $10 billion to develop is worth just $1 per dose. Last August, CMS used this authority to slash list prices for ten drugs by up to 79%, and by an average of 63%. *See* CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026* (Aug. 15, 2024) (*2026 Maximum Prices*), go.cms.gov/48yZiSl. And it has said it is considering setting prices for additional drugs potentially even as low as the unit cost of production and distribution, eliminating all marginal profit.

In any genuine negotiation, the seller would be free to decline to sell at such unfair prices. But not under the IRA. A manufacturer that does not agree to participate in the sham "negotiation," or does not accede to whatever price the agency demands, is subject to a crippling "excise tax." This supposed "tax"

is staggering, starting at a multiple of daily revenues and rapidly escalating to 19 times the manufacturer's *total U.S. revenues* for the drug in question. The manufacturer's only alternative is to withdraw *all* its drugs—not just the one in question—from Medicare and Medicaid altogether, depriving patients nationwide of access to critical medicines and foreclosing nearly half the U.S. drug market. The IRA's faux "negotiation" process serves no purpose other than obscuring Congress's price-fixing scheme.

Congress then insulated this coercive scheme from accountability. On the front end, the agency claims that, in administering the Program, it need not engage in notice-and-comment rulemaking. The agency accordingly has already made key implementation decisions without accounting for the text of the statute or the views of affected parties. And on the back end, the IRA forecloses administrative and judicial review of critical agency decisions. As a result, the agency can decree any price it wants for a manufacturer's drug—indeed, can effectively rewrite the statute however it likes—without any meaningful ability to challenge that decision, including by patients and providers.

These unprecedented aspects of the Drug Pricing Program render it unconstitutional in at least three ways. First, Congress violated the separation of powers and the nondelegation doctrine by delegating unconstrained

authority to HHS. Second, the excise-tax penalty violates the Eighth Amendment's Excessive Fines Clause by inflicting massive penalties on conduct that the government admits is not culpable. Third, exempting key agency implementation decisions from public input and insulating them from judicial review violates the Fifth Amendment's Due Process Clause under *Mathews v. Eldridge*, 424 U.S. 319 (1976). Indeed, this Court has already held that the "lack of input regarding unanswered implementation questions and inability to challenge particular determinations," coupled with the protected interests at stake, "satisf[ies] the *Mathews* [due process] test." *NICA*, 116 F.4th at 503.

If allowed to stand, the Drug Pricing Program will dramatically slow innovation, reduce the availability of new medicines, and undermine public health, causing grave harm to patients, pharmaceutical manufacturers, and healthcare providers. The National Infusion Center Association (NICA), the Global Colon Cancer Association (GCCA), and Pharmaceutical Research and Manufacturers of America (PhRMA) respectfully ask this Court to reverse.

JURISDICTIONAL STATEMENT

The district court had jurisdiction under 28 U.S.C. §§ 1331 and 1346. On August 7, 2025, the district court entered a final order granting summary

judgment to the government and dismissing Plaintiffs' claims. Plaintiffs timely appealed. ROA.1278. This court has jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES

1. Whether the IRA's Drug Pricing Program violates the separation of powers and the nondelegation doctrine.

2. Whether the IRA's "excise tax" violates the Eighth Amendment's Excessive Fines Clause.

3. Whether the IRA's Drug Pricing Program violates the Fifth Amendment's Due Process Clause.

STATEMENT OF THE CASE

A. Pharmaceutical Innovation Requires Investment in Research and Development

The process of developing new drugs is long, risky, and expensive. ROA.750-58. Today, companies are developing hundreds of new medicines, novel cell and gene therapies, and cutting-edge treatments for cancers, pediatric conditions, and rare diseases. To develop just one new drug, manufacturers spend an average of over $2.5 billion. ROA.756. Some drugs for complex conditions require over $10 billion in research and development. *See* Alexander Schuhmacher et al., *Changing R&D Models in Research-Based Pharmaceutical Companies*, 14 J. Translational Med., no. 105, at 3-4,

(Apr. 27, 2016), bit.ly/2PWRKRC. And the necessary investments are increasing. Since 1950, drug research and development costs have risen 8.6% annually after inflation. *See id.* at 3.

Manufacturers also face long odds. Only one in 5,000 compounds that enters preclinical testing achieves FDA approval, a failure rate of 99.98%. *See* Sandra Kraljevic et al., *Accelerating Drug Discovery*, 5 Eur. Molecular Biology Org. Reps. 837, 837 (2004), bit.ly/2Y2gwEK. Of the therapies approved for patient use, only one-third cover their development costs, much less sustain continued investment and innovation. *See* John A. Vernon & Joseph H. Golec, *Pharmaceutical Price Regulation: Public Perceptions, Economic Realities, and Empirical Evidence* 7 (2008), bit.ly/3UR06de.

Despite the low success rate, the U.S. biopharmaceutical industry invested an estimated $153 billion on research and development in 2021 alone. ROA.746. To justify this level of investment, the expected returns for medicines that do make it to market must be high enough to counterbalance the likelihood of failure.

While pharmaceutical innovation benefits manufacturers, it also provides lifesaving and life-enhancing benefits for patients, and more effective treatment options for providers that administer them. Patients depend on

pharmaceutical innovation—prescribed and administered by their providers—to save, extend, and improve their lives. ROA.857-59, 863.

B. Medicare Traditionally Encouraged Pharmaceutical Innovation

A key driver of pharmaceutical innovation has been the market-based reimbursement traditionally afforded by Medicare, which has over 68 million enrollees. CMS, *Medicare Enrollment Dashboard* (2025), http://bit.ly/47Shfgf; *see* ROA.746. Medicare includes two major prescription drug programs. First, Medicare Part B covers medically necessary and preventive healthcare services, including drugs administered by a physician. *See* 42 U.S.C. §§ 1395k(a)(1), 1395x(s)(2)(A); ROA.759. Part B is administered by CMS and, with certain exceptions, has long reimbursed providers based on market prices of supplied medicines. *See* 42 U.S.C. § 1395w-3a; ROA.761.

Second, Medicare Part D allows beneficiaries to enroll in privately operated plans covering self-administered prescription drugs. *See* 42 U.S.C. § 1395w-102; ROA.760. Drug prices in Part D also are market-based, resulting from negotiations among private plan sponsors, pharmacies, and manufacturers. ROA.760-61. The Part D statute provides that, "to promote competition under [Part D]," HHS and CMS "may not interfere with the

negotiations between drug manufacturers and pharmacies and … sponsors." 42 U.S.C. § 1395w-111(i).

Although Medicare's market-based approach benefits patients globally, it helps Americans most directly. Manufacturers generally launch new drugs in the United States first, making U.S. patients the first to receive lifesaving pharmaceuticals. ROA.746. Foreign countries with drug-price controls have seen drastic reductions in research and investment, and delays in patients' access to advanced treatments. *See* Joe Kennedy, *The Link Between Drug Prices and Research on the Next Generation of Cures*, Info. Tech. & Innovation Found. (Sept. 9, 2019), bit.ly/3fSIysc; PhRMA, *Global Access to New Medicines Report* 8, 11-36 (Apr. 2023), bit.ly/3OR7GEx.

C. The IRA Upends Medicare's Market-Based Reimbursement Mechanisms

The IRA upends Medicare's market-based system. Although the statute directs HHS to establish a "Drug Price *Negotiation* Program," 42 U.S.C. § 1320f(a) (emphasis added), the Program actually empowers HHS to *set* drug prices by administrative *fiat*.

1. HHS Ranks and Selects "Negotiation-Eligible Drugs"

The IRA directs HHS to rank "negotiation-eligible drugs" based on Medicare's "total expenditures" for those drugs (first in Part D, later in Part

B). *Id.* § 1320f-1(b)(1)(A). Drugs with the highest total expenditures are ranked highest. *Id.* The IRA defines "negotiation-eligible drugs"—which encompass many of the most innovative drugs and biological products—as the 50 "qualifying single source drugs" with the highest total expenditures under Parts B and D. *Id.* § 1320f-1(d)(1). A "qualifying single source drug" must (1) be approved and marketed under the Federal Food, Drug, and Cosmetic Act, (2) have been approved as such for at least seven years, and (3) not be a reference drug for an approved or marketed generic drug. *Id.* § 1320f-1(e)(1)(A). A parallel definition with a nine-year eligibility threshold applies to biological products. *Id.* § 1320f-1(e)(1)(B).

After "negotiation-eligible drugs" are identified and ranked, the IRA directs HHS to select an increasing number of the highest-ranked drugs for "negotiation." *Id.* § 1320f-1(a). HHS selected the first round of Part D drugs in 2023, with the agency's "maximum fair prices" scheduled to take effect on January 1, 2026; Part B drugs will be added to the selection process beginning in 2026, with maximum prices taking effect in 2028. *Id.* § 1320f-1(a)(1), (3). Ten Part D drugs were selected for 2026, fifteen Part D drugs were selected for 2027, fifteen Part D and Part B drugs will be selected for 2028, and twenty Part D and Part B drugs will be selected for 2029 and each year thereafter.

Id. § 1320f-1(a)(1)-(4). A selected drug remains selected until HHS determines that an approved generic or licensed biosimilar has been marketed. *Id.* § 1320f-1(c).

2. HHS Sets "Maximum Fair Prices" Through Sham "Negotiations"

Once drugs are selected, the IRA directs HHS to "enter into agreements with manufacturers" to "negotiate to determine (and … agree to) a maximum fair price." 42 U.S.C. § 1320f-2(a). The "negotiation" process includes an HHS "offer," a manufacturer "counteroffer," and an HHS "[r]esponse." *Id.* § 1320f-3(b)(2)(B)-(D). But that is where any semblance of negotiation ends.

To start, the IRA commands manufacturers to give HHS a host of closely guarded trade secrets and other proprietary information, including research and development costs, market data, and unit costs of production and distribution. *Id.* §§ 1320f-2(a)(4)(B), 1320f-3(e)(1). Manufacturers must "compl[y] with" whatever requirements HHS deems "necessary for purposes of administering the program." *Id.* §§ 1320f-2(a)(5), 1320f-6(c). These provisions are enforced by $1 million-per-day civil penalties, plus the crippling excise tax discussed below. *Id.* §§ 1320f-2(a)(4)-(5), 1320f-6(c); 26 U.S.C. § 5000D(b)(4).

The IRA sets no meaningful constraints on HHS's price-setting discretion. With one minor exception, the statute does not limit how low a price HHS can demand. 42 U.S.C. § 1320f-3(b)(2)(F). But it does place a "ceiling" on how high a price HHS can offer. *Id.* § 1320f-3(c). For the Program's first year, the ceiling is a percentage of a baseline price (generally, the inflation-adjusted non-federal average manufacturer price in 2021). The ceiling ranges from 75% of that benchmark for recently approved drugs to just 40% for drugs that have been approved for over 16 years. *Id.* § 1320f-3(b)(2)(F), (c)(1)(C)(i). That implies a first-year minimum discount of 25-to-60%. For later years, HHS must use either the calculation above or an alternative calculation if it is lower. 42 U.S.C. § 1320f-3(c)(1)(C)(ii).

Below the "ceiling," HHS has free rein to set prices as it pleases. At most, HHS must "consider" specified "factors," including research and development costs, production and distribution costs, prior federal financial support, data on patents and regulatory exclusivities, market data and revenue and sales volume data, and information about alternative treatments. *Id.* § 1320f-3(e). But the IRA sets no standards for how to weigh these considerations. And it directs HHS "to achieve the lowest maximum fair price for each selected drug." *Id.* § 1320f-3(b)(1).

After a "maximum fair price" becomes effective, the manufacturer must provide "access to such price to" a wide array of individuals and entities participating in Medicare. *Id.* § 1320f-2(a)(1). Otherwise, manufacturers must pay a penalty of ten times the difference between the price charged and the HHS-imposed price for every unit sold. *Id.* § 1320f-6(a)(2).

3. Noncompliant Manufacturers Must Pay a Crippling "Excise Tax"

The hammer the IRA uses to force manufacturers to "agree" to a "maximum fair price" is a so-called "excise tax." In ordinary negotiations, parties that fail to agree can simply walk away. But the IRA does not give manufacturers that option. Instead, it imposes a steep penalty for every day the manufacturer has not (1) entered into an "agreement" to negotiate, (2) "agreed" to a maximum fair price, or (3) submitted the information HHS demands. 26 U.S.C. § 5000D(b). Congress labeled this penalty an "excise tax," but it is intended to coerce rather than raise revenue.

The "tax" is staggering. It applies to all U.S. sales of the drug in question—not just Medicare sales—and is calculated based on a formula representing an "applicable percentage" of the drug's total cost (price plus tax). *Id.* § 5000D(a). The applicable percentage starts at 65% and then increases 10% for each quarter of noncompliance until it reaches 95%.

Id. § 5000D(d). The effective tax rate "starts at 185.7% of the drug's price and rises to 1,900% depending on the duration of noncompliance." *NICA*, 116 F.4th at 495 (citations omitted). The tax thus starts at nearly double the manufacturer's total daily U.S. revenue for the drug, then skyrockets to 19 times that revenue.

A summary of predecessor legislation to the IRA accurately described the excise tax as a "steep, escalating penalty." Title Summary, H.R. 3, at 1 (2022). Both the Joint Committee on Taxation and Congressional Budget Office (CBO) estimated that it would raise "no revenue" because no manufacturer could afford to pay it. Joint Comm. 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.*), bit.ly/3plC4cd; *see* CBO, *Estimated Budgetary Effects of Public Law 117-169*, at 5 (Sept. 7, 2022), bit.ly/3JOiq3r. "CBO's modeling reflects the expectation that manufacturers will comply with the negotiation process because refusing to do so would be costlier than reaching a negotiated price for their Part D sales of a particular drug." CBO, *Alternative Approaches to Reducing Prescription Drug Prices*, at 20 (Oct. 2024) (*Alternative*

Approaches), bit.ly/3YSsKiU. Ultimately, manufacturers have no choice but to "agree" to whatever "maximum fair price" HHS demands.[1]

The IRA provides that the excise tax may be suspended only if the manufacturer stops participating in Medicare Part D, Part B, *and* Medicaid—not just for drugs subject to the Drug Pricing Program, but for *all* of the manufacturer's drugs. *See* 26 U.S.C. § 5000D(c); 42 U.S.C. § 1396r-8(a)(1).

Withdrawing from Medicare and Medicaid altogether is not feasible for manufacturers. "The consequence of" doing so "would be catastrophic for almost any manufacturer." ROA.792-95. Medicare and Medicaid beneficiaries account for almost half the nationwide spending on prescription drugs. *See* CBO, *Prescription Drugs: Spending, Use, and Prices* 8 (2022), https://bit.ly/3HF3IOF. Medicare and Medicaid thus account for an immense portion of manufacturers' revenue. *See* ROA.872; ROA.794. In addition,

[1] The IRS recently proposed a rule purportedly providing that the excise tax applies only to sales of selected drugs within Medicare. *See* IRS Proposed Rules, *Excise Tax on Designated Drugs*, I.B., II.A. (Jan. 2, 2025). The IRS also recently issued guidance providing a "safe harbor" under which manufacturers can report 40% of a drug's U.S. sales as "applicable sales" subject to the excise tax, instead of the actual number of Medicare sales. *See* IRS Rev. Proc. 2025-9 §§ 5-6 (2024). But as this Court explained, the excise tax applies to "all sales of the drug (not just Medicare sales)." *NICA*, 116 F.4th at 495. And the Court is responsible for ascertaining the "best reading" of the IRA. *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 400 (2024). But even under the government's interpretation, the effective tax rate is still 186% to 1,900%.

withdrawing from Medicare and Medicaid would deprive millions of patients of critical medicines, raise serious ethical concerns, and harm manufacturers' reputations. ROA.794-95.

Even if manufacturers were able, let alone willing, to shoulder those financial, ethical, and reputational costs, the IRA delays their ability to exit from Medicare Part D—and thus compels them to participate—for between 11 and 23 months, depending on the time of year they attempt to exit. *See* 42 U.S.C. §§ 1395w-114a(b)(1)(C)(ii), 1395w-114c(b)(4)(B)(ii), 1395w-153(a)(1). For example, manufacturers whose drugs were "negotiated" in the first round were unable to withdraw from Part D between the IRA's enactment on August 16, 2022, and the selection of their drugs on August 29, 2023.[2]

[2] CMS says it intends to reduce the exit delay under the Secretary's authority to terminate Part D agreements for "a knowing and willful violation of the requirements of the agreement or other good cause shown." 1395w-114c(b)(4)(B)(i); *see Revised Guidance* at 120-21, 129-31. That contradicts the statute, which lays out two separate paths to termination—one after 11-to-23 months at the manufacturer's request, and another with 30 days' notice and a right to a hearing based on the agency's determination of manufacturer misconduct. Treating a manufacturer's own request for termination as the agency's would mean that a manufacturer receives a hearing on its own purportedly voluntary exit from the program. That is contrary to the text and nonsensical.

4. The IRA Limits Notice-and-Comment Rulemaking and Judicial Review

Despite the Drug Pricing Program's unprecedented burdens on manufacturers and serious repercussions for providers and patients, they have no say in how HHS implements key parts of the Program, and the IRA deprives them of legal recourse regarding numerous critical decisions.

On the front end, before implementation decisions are made, the IRA provides no right to participate in the implementation process. The Administrative Procedure Act (APA) sets forth general requirements for notice-and-comment rulemaking, which the Social Security Act requires HHS to follow in substantive rulemaking under Medicare. *See* 5 U.S.C. §§ 553(b)-(c); 42 U.S.C. § 1395hh. The IRA, however, provides that HHS "shall implement [the Drug Pricing Program] for 2026, 2027, and 2028, by program instruction or other forms of program guidance." 42 U.S.C. § 1320f (Statutory Note). CMS has read that language to exempt the Program from notice-and-comment requirements during the Program's formative years. *See, e.g.*, CMS, *Medicare Drug Price Negotiation Program: Initial Memorandum*, at 2 (Mar. 15, 2023) (*Initial Guidance*), bit.ly/3m0cDPG; CMS, *Medicare Drug Price Negotiation Program: Revised Guidance*, at 8-11 (June 30, 2023) (*Revised Guidance*), bit.ly/4eMvyCO; CMS, *Medicare Drug Price Negotiation*

Program: Final Guidance, at 160-62 (Oct. 2, 2024) (*2027 Guidance*), go.cms.gov/40ttKLJ.

On the back end, after implementation decisions are made, the IRA forecloses review of "key HHS determinations." *NICA*, 116 F.4th at 496. It provides that "[t]here shall be no administrative or judicial review" of "[t]he selection of drugs," "the determination of negotiation-eligible drugs," "the determination of qualifying single source drugs," and "[t]he determination of a maximum fair price." 42 U.S.C. § 1320f-7(2)-(3).

D. CMS Implements the IRA

1. CMS Issues Guidance

In March 2023, CMS issued initial guidance on the Drug Pricing Program. While CMS "voluntarily" solicited comments on some aspects of the Initial Guidance, it adopted others as final without receiving comments. *Initial Guidance* at 1-2. Aspects finalized without notice-and-comment included some of the Program's most critical elements, such as "the requirements governing the identification of qualifying single source drugs, the identification of negotiation-eligible drugs, the ranking of negotiation-eligible drugs and identification of selected drugs, and the publication of the list of selected drugs." *Id.* at 5. CMS also claimed the unconditional right to make changes,

"including policies on which CMS has not expressly solicited comment." *Id.* at 2.

In June 2023, CMS issued revised Program guidance for 2026. CMS altered some aspects of the Initial Guidance that it had previously issued as "final," without soliciting comments. *Revised Guidance* at 97.

In October 2024, CMS issued the final 2027 Guidance, and in May 2025, it issued the Draft 2028 Guidance. Those Guidance documents largely mirror the Revised Guidance and finalize procedures for effectuating the Program's maximum price requirements. *See generally Draft 2028 Guidance*.

2. CMS Sets Prices for the First Set of Ten Drugs and Selects the Next Fifteen

In August 2023, CMS selected the first ten drugs for "negotiation." CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026* (Aug. 2023), go.cms.gov/3NRYfmU. In August 2024, it announced the first list of maximum prices, which are scheduled to take effect on January 1, 2026. *See 2026 Maximum Prices*. CMS slashed the list prices of the first ten drugs by as much as 79%, with an average discount of 63%. CMS, *Negotiating for Lower Drug Prices Works, Saves Billions* (Aug. 15, 2024), https://bit.ly/3TJt408. PhRMA members manufacture nine of these drugs. *See* PhRMA, *About, Members*, phrma.org/About.

In January 2025, CMS selected the next fifteen drugs for "negotiation." CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2027* (Jan. 2025), http://bit.ly/4mxQ7Hr. PhRMA members manufacture eleven of them. CMS, *CMS Announces Manufacturer Participation in Second Cycle of Medicare Drug Price Negotiation* (Mar. 14, 2025), bit.ly/4oOPgEe. The IRA requires CMS to determine "maximum fair prices" by November 1, 2025. 42 U.S.C. § 1320f(b)(4).

E. Procedural History

In June 2023, Plaintiffs sued HHS and CMS. ROA.23-80. Plaintiffs contend that the IRA violates (1) the separation of powers and the nondelegation doctrine, (2) the Eighth Amendment's Excessive Fines Clause, and (3) the Fifth Amendment's Due Process Clause. *Id.* The district court dismissed the case for lack of subject-matter jurisdiction and improper venue, concluding that the Medicare statute requires NICA to channel its claims through HHS. ROA.626-39. This Court reversed, holding that NICA need not channel its claims. *NICA*, 116 F.4th at 509. This Court also held that NICA has Article III standing. *Id.* at 501-02.

On remand, the parties cross-moved for summary judgment. The district court granted the government's motion. It first held that the IRA does

not violate the separation of powers and nondelegation doctrine because the statute "provides sufficient guidance to the HHS and CMS" to satisfy the "intelligible principle" standard. ROA.1250. The court next declined to reach Plaintiffs' excessive fines claim, concluding that the excise tax "is a tax for AIA purposes," and neither of the AIA's exceptions apply. ROA.1259. Finally, the court rejected Plaintiffs' due process claim, holding that they have no "entitlement to sell [their] drugs to the Government at any price other than what the Government is willing to pay." ROA.1270. Further, the court concluded, manufacturers lack any protected interest because their "participation in the Program is voluntary." ROA.1274.

SUMMARY OF ARGUMENT

I. The IRA violates the separation of powers and nondelegation doctrine because it grants HHS sweeping discretion to set drug prices without public input or judicial review. The district court erroneously declined to consider the IRA's procedural deficiencies, reasoning that the availability of notice-and-comment rulemaking and judicial review are irrelevant to the constitutionality of a delegation. That holding contravenes controlling precedent and makes no sense; a delegation of *unchecked* price-setting discretion obviously is broader than a delegation of *checked* price-setting

discretion. In any event, the IRA sets a price *ceiling* but no floor; and the superficial "factors" it requires HHS to "consider" do not meaningfully constrain the agency's ability to set prices however low it wants for any drug it chooses. Indeed, the complete absence of front-end and back-end review means that HHS may effectively rewrite the statute with impunity—a power the agency has already exercised by, for example, increasing the number of "negotiation-eligible" drugs.

II. The IRA's so-called "excise tax" violates the Excessive Fines Clause of the Eight Amendment because it is at least partially punitive and grossly disproportionate to the "offense" of declining to "agree" to HHS's prices. The excise tax expressly punishes "noncompliance," and it rapidly escalates to 1,900% of a drug's *total U.S. revenues*. The Joint Committee on Taxation and the CBO both told Congress that it would raise no revenue, since no manufacturer would dare trigger it.

The district court wrongly concluded that the Anti-Injunction Act applies. Plaintiffs cannot pay the excise tax and then litigate a refund suit, because the excise tax is unaffordable. At minimum, manufacturers would need to incur billions of dollars in liability throughout litigation, which is untenable. Applying the AIA amounts to denying any judicial forum for

Plaintiffs' constitutional challenge. Thus, this case falls squarely within the AIA's exceptions.

III. The IRA violates the Fifth Amendment's Due Process Clause because it deprives manufacturers, providers, and patients of constitutionally protected interests without any process. Plaintiffs thus satisfy the three-factor *Mathews* test for due process challenges: 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 Program implementation.

The district court held that the IRA does not deprive Plaintiffs of any protected interest. But the IRA compromises manufacturers' protected interest in selling their products in private transactions to pharmacies and other dispensing entities at market prices; providers' interest in being reimbursed on a non-arbitrary basis at a lawful rate; and patients' interests in maintaining access to essential medicines. Further, the Program is not "voluntary." And even if it were, Plaintiffs still would be entitled to adequate process.

STANDARD OF REVIEW

This Court reviews constitutional challenges to statutes *de novo*. *United States v. Clark*, 582 F.3d 607, 612 (5th Cir. 2009).

ARGUMENT

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

A. Separation of Powers and the Nondelegation Doctrine

Article I of the Constitution provides that "[a]ll legislative Powers herein granted shall be vested in a Congress of the United States." "Accompanying that assignment of power to Congress is a bar on its further delegation: Legislative power … belongs to the legislative branch, and to no other." *FCC v. Consumers' Rsch.*, 145 S. Ct. 2482, 2496 (2025). "That congress cannot delegate legislative power to the [executive branch] is a principle universally recognized as vital to the integrity and maintenance of the system of government ordained by the constitution." *Marshall Field & Co. v. Clark*, 143 U.S. 649, 692 (1892).

The nondelegation rule reflects separation-of-powers principles. "The purpose of the nondelegation doctrine is to enforce limits on the degree of policy judgment that can be left to those executing or applying the law." *Consumers' Rsch.*, 145 S. Ct. at 2501 (quotation marks omitted).

"[A]ccountability evaporates if a person or entity other than Congress exercises legislative power." *Jarkesy v. SEC*, 34 F.4th 446, 460 (5th Cir. 2022), *aff'd on other grounds*, 603 U.S. 109 (2024).

The Supreme Court has twice invalidated statutes for violating this principle. *See A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495 (1935); *Panama Ref. Co. v. Ryan*, 293 U.S. 388 (1935). And the Court has unanimously confirmed in recent years that Congress may not "transfer[] its legislative power to another branch." *Gundy v. United States*, 588 U.S. 128, 132 (2019) (plurality op.); *id.* at 148 (Alito, J., concurring in the judgment); *id.* at 152-53 (Gorsuch, J., dissenting); *see Consumers' Rsch.*, 145 S. Ct. at 2496; *id.* at 2512-18 (Kavanaugh, J., concurring); *id.* at 2518 (Jackson, J., concurring); *id.* at 2519-39 (Gorsuch, J., dissenting).

To avoid exceeding its authority to delegate, 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) (cleaned up). Typically, providing an "intelligible principle" ensures that a delegation does not violate the constitutional separation of powers in two key ways: it "ensures [both] … that important choices of social policy are made by Congress" and "that courts

charged with reviewing the exercise of delegated legislative discretion will be able to test that exercise against ascertainable standards." *Indus. Union Dep't, AFL-CIO v. Am. Petroleum Inst.*, 448 U.S. 607, 685-86 (1980) (Rehnquist, J., concurring).[3] "The legislative policies and standards being clear, judicial review of the [agency action] safeguards against statutory or constitutional excesses." *Am. Power & Light Co. v. SEC*, 329 U.S. 90, 106 (1946).

Accordingly, "the availability of judicial review" is an important factor in nondelegation analysis as a "safeguard[] against arbitrary [agency] action." *United States v. Gordon*, 580 F.2d 827, 839 (5th Cir. 1978). Indeed, "[t]he safeguarding of meaningful judicial review is one of the primary functions of the doctrine prohibiting undue delegation of legislative powers." *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); *see United States v. Garfinkel*, 29 F.3d 451, 459 (8th Cir. 1994) ("Judicial review is a factor weighing in favor of upholding a statute against a nondelegation challenge.")

[3] *See Arizona v. California*, 373 U.S. 546, 626 (1963) (Harlan, J., dissenting in part) (nondelegation doctrine "serves two primary functions vital to preserving the separation of powers": ensuring that "fundamental policy decisions" are made "by the body immediately responsible to the people," and "providing the courts with some measure against which to judge the official action").

(brackets and citation omitted); Peter H. Aranson et. al., *A Theory of Legislative Delegation*, 68 Cornell L. Rev. 1, 14 (1982) (the Supreme Court has "reformulated the rule of the delegation doctrine by emphasizing the availability of review"). Congress must "provide[] sufficient standards to enable both *the courts* and the public to ascertain whether the agency has followed the law." *Consumers' Rsch.*, 145 S. Ct. at 2497 (emphasis added) (cleaned up); *id.* at 2515 (Kavanaugh, J., concurring) (availability of plenary judicial review "substantially mitigate[s]" "structural concerns about expansive delegations" (citing, *e.g.*, *Loper Bright*, 603 U.S. at 394-96, 404)).

Likewise, when Congress delegates authority to an agency to implement a statute, notice-and-comment rulemaking provides another critical safeguard. *See Garfinkel*, 29 F.3d at 459. A "claim of undue delegation of legislative power … thus naturally involves consideration of the interrelated questions of the availability of appropriate restraints through provisions for administrative procedure and judicial review." *Amalgamated Meat Cutters*, 337 F. Supp. at 759.

The Supreme Court has repeatedly relied on these safeguards in upholding statutes against nondelegation challenges. In *Bowles* v. *Willingham*, 321 U.S. 503 (1944), the Court emphasized the importance of

judicial review in upholding a wartime statute that empowered an agency to "fix maximum rents" in designated "defense rental area[s]." *Id.* at 512-13, 516. Crucially, the statute allowed "for the filing of a protest with the Administrator" and then for "any person 'aggrieved'" by the agency's decision to "secure judicial review." *Id.* at 516. The "standards prescribed by the Act" were acceptable because they were "adequate for the judicial review *which ha*[*d*] *been accorded*." *Id.* (emphasis added).

Similarly, in *Touby v. United States*, 500 U.S. 160 (1991), the Court upheld a delegation scheme limiting judicial review only because the statute merely "postpone[d] legal challenges … until the administrative process ha[d] run its course." *Id.* at 168. As Justice Marshall noted in concurring, "judicial review perfects a delegated-lawmaking scheme by assuring that the exercise of such power remains within statutory bounds." *Id.* at 170 (Marshall, J., concurring).

B. The IRA Fails the Nondelegation Test

The IRA fails to "clear[] the nondelegation bar." *Consumers' Rsch.*, 145 S. Ct. at 2507. While it grants sweeping legislative power to an administrative agency, it eviscerates the safeguards necessary to preserve accountability. On the front end, the statute does not require notice-and-comment rulemaking—

or any external input from regulated parties or the public. Meanwhile, the draconian excise tax prevents manufacturers from protecting themselves during the "negotiation" process. And on the back end, the IRA eliminates judicial review of critical administrative decisions, *see* 42 U.S.C. § 1320f-7, giving HHS unreviewable authority to "turn [the Drug Pricing Program] into anything [it] wants," *Consumers' Rsch.*, 145 S. Ct. at 2502.

To see how the IRA vests HHS with unchecked power, start with the law's mandate to set drug prices as low as the agency chooses. While HHS must "consider" certain "factors," the statute neither guides nor meaningfully limits the agency's discretion. 42 U.S.C. § 1320f-3(e). Rather, it broadly instructs the agency to "achieve the *lowest* maximum fair price," *id.*, § 1320f-3(b)(1), (c), (e) (emphasis added), and "there is no limit to how low HHS's offer can be," *NICA*, 116 F.4th at 495. The excise tax and other crippling penalties mean manufacturers have no alternative but to accede to whatever price CMS decrees. *See supra* pp. 12-15; *see also NICA*, 116 F.4th at 500 (IRA's penalties make manufacturers "all but certain" to submit). Indeed, CMS says it is considering setting the 2028 price for selected drugs potentially even as low as the "unit cost of production and distribution of the selected drug," eliminating all marginal profit. *See* CMS, *Draft Guidance on the Medicare Drug Price*

Negotiation Program 131 (May 12, 2025) (*2028 Draft Guidance*), https://bit.ly/4k7z66e.

But here's the rub: Even if delegating broad discretion to reduce prices were permissible standing alone, the statute "compounds" that delegation "exponentially" by eliminating all meaningful guardrails. *Consumers' Rsch.*, 145 S. Ct. at 2510. As discussed, the IRA dispenses with notice-and-comment rulemaking, 42 U.S.C. § 1320f (Statutory Note), and precludes administrative and judicial review of its key features, *id.* § 1320f-7(2)-(3). The statute thus empowers HHS to "turn [the Drug Pricing Program] into anything [it] wants." *Consumers' Rsch.*, 145 S. Ct. at 2502.

Consider how the IRA's features work in combination. Without any public comment, HHS could set a price of *zero* for a given drug and claim that it "considered" the statutory factors and deemed that price "fair." If the manufacturer were to challenge CMS's decision in court, the government could invoke the IRA's provision barring judicial review of "[t]he determination of a maximum fair price." 42 U.S.C. § 1320f-7(3). And that would be that.

Or, CMS could select a product for negotiation even though it is not negotiation-eligible under the "best reading" of the IRA—that is "the reading

the court would have reached if no agency were involved." *Loper Bright*, 603 U.S. at 400 (quotation marks omitted). A manufacturer challenging that decision in court would again face the judicial review bar, which equally applies to "[t]he selection of drugs" and "the determination of qualifying single source drugs." 42 U.S.C. § 1320f-7(2).

Indeed, that has already happened. Recall that the statute limits the number of qualifying single source drugs for which CMS may set prices each year (ten in 2026, fifteen in 2027, etc.). Then, it defines "qualifying single source drug" as *a* drug (1) that is FDA-approved "and is marketed pursuant to *such approval*" (*i.e.*, pursuant to a New Drug Application (NDA)); (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]." *Id.* § 1320f-1(e)(1)(A) (emphases added). Despite the "best reading" of that definition (a "drug" is *one* drug), *Loper Bright*, 603 U.S. at 400, CMS has elected to treat multiple drugs as the *same* qualifying single source drug if they share "the same active moiety," even if they "are marketed pursuant to different NDAs." *Revised Guidance* at 99; *see 2027 Guidance* at 167. In the first round of "negotiations," for example, CMS treated *six* Novo Nordisk drugs approved under separate NDAs as one qualifying single source drug, and then selected nine more drugs,

circumventing the statutory limit of ten. *See 2026 Maximum Prices*; 42 U.S.C. § 1320f-1(a)(1).

CMS has read the IRA to grant the agency unfettered discretion in other significant ways as well. For instance, the agency interprets the statute not to specify what it means for a generic drug or biosimilar product to be "marketed" for purposes of exempting the reference drug from negotiation-eligibility. *See Revised Guidance* at 72-78; *2027 Guidance* at 170-71. And CMS has asserted wide discretion to decide what is included in the "total expenditures" that determine HHS's rankings. *See Revised Guidance* at 97 & n.29; *2027 Guidance* at 165-78 & nn.54, 75; 88 Fed. Reg. 22,120, 22,260 (Apr. 12, 2023).

Such blatant assertions of legislative power by an administrative agency would crumble under judicial scrutiny. Faced with APA challenges, however, HHS has insisted that the IRA's judicial-review bar strips the judiciary of any power to even consider whether the agency has overstepped its statutory authority.[4] So far, the only court to reach the issue agreed with the government that the IRA makes CMS's decisions unreviewable. *See Novo*

[4] *See, e.g.*, Br. for Appellees at 42, *Novo Nordisk Inc. v. HHS*, No. 24-2510 (3d Cir. Dec. 16, 2024), Dkt. No. 34 ("The IRA expressly precludes review of [those] statutory claims.").

Nordisk Inc. v. Becerra, 2024 WL 3594413, at *3 (D.N.J. July 31, 2024) ("[T]he Court concludes that it lacks subject matter jurisdiction to consider challenges to CMS's underlying determinations."). As the government sees it, Congress gets to avoid political accountability by delegating its legislative authority to HHS, and HHS gets to avoid judicial scrutiny thanks to Congress. The IRA thus grants broad policymaking discretion upfront and then turns it into potentially *infinite* policymaking discretion by prohibiting review.

"Perhaps the most telling indication of a severe constitutional problem" with the structure of a government program "is a lack of historical precedent to support it." *Seila Law v. CFPB*, 591 U.S. 197, 220 (2020) (cleaned up). Plaintiffs are aware of no other statute that grants such sweeping power to an administrative agency while also barring both front-end notice-and-comment rulemaking and back-end accountability via judicial review. Throughout this litigation, the government has not identified a single comparable example.

Standing alone, each of these defects undermines separation-of-powers principles. Together, they create a "novel structure," *Free Enter. Fund v. Pub. Cos. Acct. Oversight Bd.*, 561 U.S. 477, 496 (2010), that concentrates "significant governmental power" in an administrative agency "accountable to no one," *Seila Law*, 591 U.S. at 224, to set prices for nearly half of nationwide

prescription drug sales. The result is an unconstitutional delegation of legislative authority that contravenes core separation-of-powers principles.

C. The District Court Misapplied the Nondelegation Doctrine

The district court misapplied the nondelegation doctrine in numerous ways.

1. At the outset, the court erroneously rejected the premise of Plaintiffs' nondelegation challenge—*i.e.*, the IRA compounds an already-broad delegation by eviscerating procedural safeguards—"[b]ecause the Supreme Court declined to adopt a 'combination' analysis in a delegation challenge [in *FCC v. Consumers' Research*]." ROA.1248-49. But *Consumers' Research* supports, rather than undermines, Plaintiffs' nondelegation claim.

In *Consumers' Research*, the Supreme Court held that the "universal service" provision in the Communications Act of 1934 "clears the nondelegation bar." 145 S. Ct. at 2507. That provision directs the FCC to collect payments from communications carriers that are "sufficient" to support communications services in underserved communities. The FCC, in turn, has instructed a private administrator to calculate the program's expenses and advise the agency on the payment amounts to collect. *See id.* at 2495; *see also* 47 C.F.R. §§ 54.709(a)(2) and (3). In upholding those delegations, the Court

reaffirmed "the Constitution's nondelegation rule," reiterating that Congress must "provide[] sufficient standards to enable both the courts and the public to ascertain whether the agency has followed the law." *Id.* at 2495, 2497 (cleaned up).

The Court focused on the "public" delegation first. It observed that a delegation of revenue-raising power with no "ceiling" "would pose a constitutional problem." *Id.* at 2502. The Communications Act raises no such concern, the Court explained, because "the word 'sufficient' sets a floor and a ceiling alike"; "[a]n amount of money is 'sufficient' for a purpose if it is 'adequate' or 'necessary' to achieve that purpose." *Id.* Further, the Communications Act adequately circumscribes the universal service program itself, "instruct[ing] the Commission to provide to an identified set of recipients a defined sort of benefit." *Id.* at 2504. Thus, the statute prevents the FCC from "turn[ing] [the service] into anything [it] wants" by "collecting contributions 'sufficient' for[ ]either the most barebones or the most extravagant program." *Id.* at 2502. This "limited conception of universal service is rooted in its history." *Id.* at 2504.

Next, the Court considered whether "the '*combination*' of Congress's grant of authority to the FCC and the FCC's reliance on the Administrator for financial projections violates the Constitution, even if neither one does so

alone." *Id.* at 2510. In rejecting that conclusion, the Court distinguished *Free Enterprise Fund*, which struck down a statute on separation-of-powers grounds "because it gave an executive officer two 'layers of protection' from the President's removal authority"—restricting "his ability to remove a principal officer, who was in turn restricted in his ability to remove an inferior officer." *Id.* (quoting 561 U.S. at 483-84).

The *Consumers' Research* Court explained that, in *Free Enterprise Fund*, "each of the two layers of for-cause protection limited the same thing—the President's power to remove executive officers." *Id.* Thus, "the two layers of restrictions operated on a single axis with the one exacerbating … the other." *Id.* By contrast, when a statute delegates authority to an agency and the agency then delegates a portion of that authority to a private entity, the delegations "do not operate on the same axis." *Id.* "So a measure implicating (but not violating) [the private nondelegation doctrine] does not compound a measure implicating (but not violating) the [public nondelegation doctrine], in a way that pushes the combination over a constitutional line." *Id.* at 2510-11.

Unlike the Communications Act, the IRA contains multiple features that *do* "operate on the same axis," *do* "exacerbat[e]" a single delegation to one agency, and accordingly *do* "push[] the combination over a constitutional line."

Id. The Drug Pricing Program is not the product of two separate, independently lawful delegations to distinct entities. Rather, it grants HHS broad discretion to set drug prices (or even rewrite the statute), then amplifies that same authority by foreclosing public input and judicial review of the agency's decisions. The statute thus raises "structural concerns about expansive delegations" that lack any guardrails. *Id.* at 2515 (Kavanaugh, J., concurring). And unlike the universal service fund, there is no "limited conception" of HHS's authority "rooted in [the] history" of the unprecedented Drug Pricing Program. *Id.* at 2504. *Consumers' Research* thus underscores the IRA's nondelegation problems.[5]

[5] The district court also relied on *National Broadcasting Co. v. United States*, 319 U.S. 190 (1943), *FPC v. Hope Natural Gas Co.*, 320 U.S. 591 (1944), and *Whitman v. American Trucking Associations*, 531 U.S. 457 (2001), which denied nondelegation challenges despite apparently broad delegations. But the court overlooked key differences between the statutes at issue in those cases and the IRA. In *National Broadcasting*, the statute required notice-and-comment and judicial review, ensuring that "the action of the [agency] was based upon findings supported by evidence." 319 U.S. at 195, 224. In *American Trucking*, the statute allowed challenges to agency action "under the judicial-review provisions." 531 U.S. at 476. And the statute at issue in *Hope Natural Gas* permitted agency action to be "challenged in the courts" to ensure that the action "meets the requirements of the Act." 320 U.S. at 602. But none of the upheld delegations lacked accountability at both the front and the back end as the IRA does.

2. Having started from the wrong premise, the district court never got back on track. It concluded that the IRA provides the requisite "intelligible principle" because it supplies "mathematical formulae for calculating ceiling prices," lists "factors" CMS must "consider" in setting prices, establishes certain criteria for selecting drugs, sets "parameters for agreements," and defines some terms. ROA.1249. But the IRA's "definitions," "criteria," "formulae," "parameters," and "factors" provide no meaningful constraint, because the agency can interpret them as "extravagantly" as it wants and then hide behind the judicial review bar. *Consumers' Rsch.*, 145 S. Ct. at 2507. Indeed, the agency has already started doing so. *See supra* pp. 29-31.

Regardless, the district court's reasoning fails even on its own terms. To start, the court erroneously focused on the IRA's "mathematical formulae for calculating *ceiling* prices," ROA.1249 (emphasis added), when the statute's problem is that it contains no price *floor*. CMS has infinite downward discretion. It could—and has suggested it may—set prices as low as the "unit cost of production and distribution of [each] selected drug," eliminating all marginal profit. *2028 Draft Guidance* at 128, 131.

The district court excused the lack of a price floor because the IRA alludes to "fair" prices, purportedly resembling the requirement in

Consumers' Research that the FCC make "sufficient" collections. ROA.1251. But "sufficient" has a definite meaning in the Communications Act: "An amount of money is 'sufficient' for a purpose if it is 'adequate' or 'necessary' to achieve that purpose." *Consumers' Rsch.*, 145 S. Ct. at 2502. "[T]he FCC cannot raise *more* than" is necessary to fund the program. *Id.* If the agency were free to adopt a different "statutory construction," there would be "a constitutional problem." *Id.* at 2507, 2502. Under the IRA, by contrast, "[t]here shall be no administrative or judicial review of … [t]he determination of a maximum fair price," 42 U.S.C. § 1320f-7(3), so the meaning of "fair" is entirely up to the agency.

Similarly, the "factors" HHS must "consider" when setting prices impose virtually no constraint on the agency, which can give each factor as much or as little weight as it chooses. While CMS may need to "consider" a manufacturer's R&D costs under Section 1320f-3(e)(1)(A), it could simply decline to give those costs any weight in setting the ultimate price. 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—with no judicial review.

As for the "detailed criteria for the selection of negotiation-eligible drugs," ROA.1249, CMS has already demonstrated the impotence of that supposed constraint by *rewriting it*. Again, CMS "interpreted" the IRA to allow the agency to aggregate numerous drugs into one. When called into court to defend that purported "interpretation," the government successfully argued that "[t]he IRA expressly precludes review of [those] statutory claims." *See supra* n.4.

Finally, the district court misplaced its emphasis on the IRA's "specific timing deadlines" and "parameters for agreements." ROA.1249. 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 manila paper, but that procedural specificity would not protect against abuses of power.

3. The district court said *nothing* about the IRA's lack of front-end notice-and-comment rulemaking. And the court concluded that "preclusion of judicial review is not related to the nondelegation doctrine." ROA.1252-54 (citation omitted). But as to judicial review, the Supreme Court has said

otherwise. *See, e.g.*, *Am. Power*, 329 U.S. at 106; *Bowles*, 321 U.S. at 512-13, 516; *Touby*, 500 U.S. at 168-69. So has this Court. *See, e.g.*, *Gordon*, 580 F.2d at 839. So have other courts. *See, e.g.*, *Amalgamated Meat Cutters*, 337 F. Supp. at 759; *Garfinkel*, 29 F.3d at 459. So have scholars. *See, e.g.*, Aranson, *supra*, at 14; Michael Herz, *Deference Running Riot: Separating Interpretation and Lawmaking Under Chevron*, 6 Admin. L.J. 187, 188 & n.9 (1992). As Justice Marshall put it in his concurrence in *Touby*, "judicial review perfects a delegated-lawmaking scheme by assuring that the exercise of such power remains within statutory bounds." 500 U.S. at 170 (Marshall, J., concurring).

That makes sense. A delegation of unchecked discretion is obviously broader than a delegation of checked discretion. That is why "many of the broader structural concerns about expansive delegations [are] substantially mitigated by" judicial review. *Consumers' Rsch.*, 145 S. Ct. at 2515 (Kavanaugh, J., concurring).

Restricting both administrative procedures and judicial oversight compounds delegations to agencies by placing "the limits on an agency's power in that agency's own self-interested hands." *Szonyi v. Barr*, 942 F.3d 874, 876 (9th Cir. 2019) (Collins, J., dissenting from denial of rehearing en banc).

"Unsurprisingly," *id.*, removing external guardrails invites self-serving and "extravagant[]" "statutory construction[s]" by agencies, *Consumers' Rsch*, 145 S. Ct. at 2507, that differ drastically from how courts would apply the same statutes "if no agency were involved," *Loper Bright*, 603 U.S. at 400. Courts cannot simply "leave it to the agency to decide when it is in charge." *Arlington v. FCC*, 569 U.S. 290, 327 (2013) (Roberts, C.J., dissenting). Under "constitutional separation-of-powers principles," it is the "province of the Judiciary" to "interpret[] statutes and determin[e] agency jurisdiction and substantive agency powers." *Pereira v. Sessions*, 585 U.S. 198, 221 (2018) (Kennedy, J., concurring).

By combining a sweeping delegation of discretion with insulation from administrative and judicial checks, the IRA unconstitutionally confers legislative authority on an administrative agency, undermining the separation of powers.

II. The IRA Violates the Excessive Fines Clause

Under the Eighth Amendment, "[e]xcessive bail shall not be required, nor excessive fines imposed." The Excessive Fines Clause "limits the government's power to extract payments … as punishment." *United States v. Bajakajian*, 524 U.S. 321, 328 (1998) (citation omitted). It applies not only to

criminal fines but also civil fines designed "in part to punish." *Austin v. United States*, 509 U.S. 602, 610 (1993). "[T]he touchstone of the constitutional inquiry under the Excessive Fines Clause is the principle of proportionality: The amount of the [fine] must bear some relationship to the gravity of the offense that it is designed to punish." *Bajakajian*, 524 U.S. at 334. The IRA's "excise tax" violates the Excessive Fines Clause: It is designed to punish noncompliance with the IRA's "negotiation" process and is wildly disproportionate to the "offense" of refusing to agree to government-dictated prices.

A. The 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). In an excessive fines claim, "the question is not" whether a fine "is civil or criminal, but rather whether it is punishment." *Austin*, 509 U.S. at 610. "[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.* (emphases added). In assessing whether a "tax" is partly punitive, the Supreme Court uses a "functional

approach," under which labels are not dispositive. *NFIB v. Sebelius*, 567 U.S. 519, 565 (2012).

The excise tax is at least partially punitive. The "tax" is part of the IRA's "penalty phase." *NICA*, 116 F.4th at 495. A summary of predecessor legislation described it as a "steep, escalating penalty." Title Summary, H.R. 3, at 1 (2022). The relevant section of the tax code is entitled, "Designated drugs during *noncompliance* periods." 26 U.S.C. § 5000D (emphasis added); *see id.* § 5000D(b) ("Noncompliance periods"). "Deter[ring]" noncompliance "has traditionally been viewed as a goal of punishment." *Bajakajian*, 524 U.S. at 329.

The sheer size of the penalty underscores its punitive nature. The tax rate starts at 186% of a drug's total U.S. revenues, and, after 271 days of "noncompliance," reaches 1,900%. 26 U.S.C. § 5000D(b)(1)-(4); *see NICA*, 116 F.4th at 495. A manufacturer with $1 billion in sales would incur $19 billion in penalties. ROA.778-79.

That enormous levy would cause significant financial harm to manufacturers. *See* ROA.778-79; ROA.792-93; ROA.871. If a drug "accounts for approximately 13 percent or more of its manufacturer's total net revenues, applying the excise tax over a full year … would result in an excise tax liability

of 100 percent of the manufacturer's total net revenues." ROA.793. By any measure, that is an "exceedingly heavy burden," *NFIB*, 567 U.S. at 565, confirming that the tax is punitive and does not "solely" serve a remedial purpose, *Austin*, 509 U.S. at 610; *see Bajakajian*, 524 U.S. at 337-40 (finding a far less onerous fine grossly disproportionate and punitive).

In fact, deterrence and punishment are the *whole point*. Before the IRA's passage, the Joint Committee on Taxation and the CBO both told Congress that the "tax" would raise no revenue, because no manufacturer would dare trigger it. *See supra*, *Joint Comm.* at 8. CBO has since reiterated its "expectation that manufacturers will comply with the negotiation process because refusing to do so would be costlier than reaching a negotiated price." *Alternative Approaches* at 20. 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. At minimum, the excise tax is "at least partially punitive." *Timbs*, 586 U.S. at 155.

B. The IRA's Excise Tax Is Grossly Disproportionate

The excise tax violates the Excessive Fines Clause because it is "gross[ly] disproportiona[te]" to the "offense" it seeks to punish. *Bajakajian*, 524 U.S. at 337. In assessing proportionality, the Supreme Court considers three criteria: "the degree of the defendant's reprehensibility or culpability; the relationship between the penalty and the harm to the victim caused by the defendant's actions; and the sanctions imposed … for comparable misconduct." *Cooper Indus., Inc. v. Leatherman Tool Grp., Inc.*, 532 U.S. 424, 435 (2001) (citations omitted). Courts have applied these factors to various penalties. *See, e.g.*, *Yates v. Pinellas Hematology & Oncology, P.A.*, 21 F.4th 1288, 1314-16 (11th Cir. 2021) (treble damages and statutory penalties); *United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 387-90 (4th Cir. 2015) (punitive damages and civil penalties). Applied here, the excise-tax penalty is grossly disproportionate to the "offense" of failing to participate in the IRA's compelled-negotiation process.

First, the supposed "offense"—a manufacturer's refusal to "agree" to HHS-imposed prices—does not entail *any* "reprehensibility or culpability." *Cooper Indus.*, 532 U.S. at 435. "Noncompliance" under the IRA, 26 U.S.C. § 5000D, involves no "threat of violence," "trickery," or "deceit," nor

"indifference to or reckless disregard for the health and safety of others," *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 576 (1996). Such conduct is considerably less culpable than the conduct in *Bajakajian*, where a fine of $357,444 was grossly disproportionate to the offense of failing to report that amount of currency to customs inspectors. *See* 524 U.S. at 337-40. The government concedes as much, admitting that the excise-tax penalty "is not triggered by the commission of *any* offense—reprehensible or otherwise." ROA.982.

Second, there is no reasonable relationship between the size of the penalty and any harm caused. Even if the government has an interest in ensuring that drugs are sold for HHS's mandated prices, the tax vastly exceeds any alleged harm. A noncompliant manufacturer faces a penalty of multiple times its total daily revenues for *all* U.S. sales of the drug—a figure that dwarfs the difference between HHS's price and the market price, and which is significantly more disproportionate than the unconstitutional penalty in *Bajakajian*. The excise tax also has no aggregate limit; it is assessed for each day of noncompliance. It thus "has absolutely no correlation to any damages sustained by society or to the cost of enforcing the law." *Austin*, 509 U.S. at 621-22 (brackets omitted).

Third, no other statute imposes similarly severe sanctions for comparable "misconduct." Indeed, no other statute imposes *any* penalty for mere failure to agree to a government-mandated price. That alone shows that the excise tax is grossly disproportionate. The IRA's unprecedented use of "the power to destroy," *M'Culloch v. Maryland*, 17 U.S. (4 Wheat.) 316, 431 (1819), is plainly unconstitutional.

C. The Anti-Injunction Act Does Not Apply

The district court erred in rejecting Plaintiffs' excessive fines claim on the ground that the Anti-Injunction Act (AIA) applies.

1. The AIA "protects the Government's ability to collect a consistent stream of revenue" by "requir[ing] taxes to be challenged 'only after they are paid.'" *In re Westmoreland Coal Co.*, 968 F.3d 526, 533 (5th Cir. 2020) (quoting *NFIB*, 567 U.S. at 543). But the IRA's excise "tax" does not seek to collect revenue at all; even the government estimates that it "would raise no revenue because no manufacturer could afford to pay it." *NICA*, 116 F.4th at 495 (citation omitted). Thus, applying the AIA here would make no sense; it would simply compound the nondelegation problem by further insulating a disproportionate penalty from judicial scrutiny.

In any event, the excise tax satisfies two AIA exceptions. One applies when—aside from a prepayment lawsuit—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). Because "no manufacturer could afford to pay" the excise tax, *NICA*, 116 F.4th at 495, the typical "alternative avenue for federal court jurisdiction"—"a postpayment refund suit"—is not available here, *Westmoreland Coal*, 968 F.3d at 535. To hold otherwise would perversely allow the government to preclude an excessive-fines challenge by intentionally making the fine *too* excessive to pay beforehand. That illogical interpretation would render the AIA itself unconstitutional. *See Webster v. Doe*, 486 U.S. 592, 603 (1988) (noting "serious constitutional question … if a federal statute were construed to deny any judicial forum for a colorable constitutional claim" (cleaned up)).

Another AIA exception applies when (i) "it is clear that under no circumstances could the Government ultimately prevail" in defending the challenged tax, and (ii) the plaintiff would suffer "irreparable injury" if required to pay the tax before suing. *Enochs v. Williams Packing & Nav. Co.*, 370 U.S. 1, 7 (1962). Here, the excise tax is punitive and grossly disproportionate to the concededly non-reprehensible conduct it punishes. *See*

supra pp. 42-46. And attempting to pay the excise tax before suing would cause irreparable economic injury, in some cases "liability of 100 percent of the manufacturer's total net revenues." ROA.793; *see, e.g.*, *Atwood Turnkey Drilling, Inc. v. Petroleo Brasileiro, S.A.*, 875 F.2d 1174, 1179 (5th Cir. 1989) (irreparable injury exists "where the potential economic loss is so great as to threaten the existence of the movant's business" (collecting sources)).

2. In refusing to apply either exception, the district court erred twice over. First, the court declined to apply the *Regan* exception on the theory that "Plaintiffs can bring a refund suit after incurring the tax on a single transaction" because the excise tax is "divisible." ROA.1259-61. The court relied on a nonbinding statement of "IRS Policy" specifying that, during a refund suit, "the IRS typically does not collect the balance of any divisible tax that would otherwise be due." *See* ROA.1260.

But manufacturers cannot stake their survival on the IRS benevolently exercising its discretion. And even if manufacturers "need only *pay* the excise tax on a single transaction" before suing, ROA.1260 (emphasis added; quotation marks omitted), continuing to sell a drug throughout a potentially multi-year refund litigation would generate multi-billion-dollar excise-tax *liability*, *see* ROA.793; ROA.871 (describing "unsustainable financial

liability"). Manufacturers whose business is saving and improving lives—and who are beholden to investors—are not free to bet the company on the outcome of refund litigation, however clear the law. 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 submit to the Program instead. *NICA*, 116 F.4th at 500. And, of course, that is the *very point* of the excise tax. *See supra* p. 44.

Second, the district court declined to apply the *Williams Packing* exception "[f]or the same reasons" it rejected the *Regan* exception—*i.e.*, Plaintiffs supposedly "can bring a refund suit after incurring the tax on a single transaction," and thus cannot show "irreparable injury." ROA.1262. The district court also opined that Plaintiffs will not clearly prevail on the merits. ROA.1263. But for the reasons discussed, incurring the excise tax *would* cause manufacturers irreparable harm. *See supra* pp. 49-50. And again, the excise tax indisputably violates the Excessive Fines Clause. *See supra* pp. 42-47.

On the merits, the district court reasoned that Plaintiffs' "Eighth Amendment claim is novel and far from certainty," and no "court has applied the Excessive Fines Clause to a monetary amount that was not connected to criminal conduct or a criminal proceeding." ROA.1263. But there is nothing

"[un]certain[]" about Plaintiffs' challenge to a crippling financial penalty for conduct everyone agrees is completely lawful. And the Supreme Court was unequivocal when it held that "the question is not" whether a fine "is civil or criminal, but rather whether it is punishment." *Austin*, 509 U.S. at 610. Numerous cases have applied the Clause to purely civil penalties. *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) (acknowledging that civil sanctions under the False Claims Act "are subject to analysis under the Excessive Fines Clause" because they are designed in part to punish). The Drug Pricing Program may itself be "novel," but Plaintiffs' excessive fines claim relies on a body of established law and is meritorious.

III. The IRA Violates the Due Process Clause

The Fifth Amendment provides that no person shall "be deprived of life, liberty, or property, without due process of law." The government thus may not deprive a person of a protected interest without adequate procedures. *See Swarthout v. Cooke*, 562 U.S. 216, 219-20 (2011). The IRA deprives manufacturers, providers, and patients of protected interests, while affording them *no* opportunity to be heard.

A. The IRA Deprives Plaintiffs of Protected Interests

The Due Process Clause protects a "broad" class of property and liberty interests. *Bd. of Regents of State Colls. v. Roth*, 408 U.S. 564, 571-72 (1972). The government can create such protected interests through statutes, contracts, "policies and practices," or "rules and understandings" that are "promulgated and fostered by [government] officials." *Perry v. Sindermann*, 408 U.S. 593, 601-03 (1972). Protected "'property' interests … are not limited by a few rigid, technical forms," *id.* at 601, and "extend well beyond actual ownership of real estate, chattels, or money," *Roth*, 408 U.S. at 571-72; *see Hignell-Stark v. City of New Orleans*, 46 F.4th 317, 323 (5th Cir. 2022) (test for protected interests is "quite broad"). The liberty interests the Due Process Clause protects are similarly broad, encompassing "not merely freedom from bodily restraint but also the right of the individual to contract, to engage in any of the common occupations of life, [and] to acquire useful knowledge." *Meyer v. Nebraska*, 262 U.S. 390, 399 (1923).

1. The IRA deprives manufacturers of their protected interest in the "treasured" common-law right to offer access to their products at market prices. *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 149 (2021). The Supreme Court has long recognized that private parties have the "right … to fix the

price at which [they] will sell" products. *Old Dearborn Distrib. Co. v. Seagram-Distillers Corp.*, 299 U.S. 183, 192 (1936).

The IRA deprives manufacturers of that protected interest by capping prices at which they can sell their products to over 68 million Medicare beneficiaries. It requires manufacturers to provide "access" to CMS's imposed price not to the government but to "eligible *individuals*," "pharmac[ies], mail order service[s], or other dispenser[s]," as well as to "hospitals, physicians, and other providers of services and suppliers." 42 U.S.C. § 1320f-2(a)(3) (emphasis added). The IRA thus directly infringes manufacturers' protected interest in selling their products to private parties at market prices.

That deprivation is particularly acute here, because pharmaceutical manufacturers hold patents that entitle them to seek supracompetitive profits.[6] "The federal patent system … embodies a carefully crafted bargain": In return for "the creation and disclosure of new, useful, and nonobvious advances in technology," inventors obtain "the exclusive right to practice the invention for a period of years." *Bonito Boats, Inc. v. Thunder Craft Boats,*

[6] The Supreme Court has "indisputably established" that "rights secured under the grant of letters patent … [are] property," *William Cramp & Sons Ship & Engine Bldg. Co. v. Int'l Curtis Marine Turbine Co.*, 246 U.S. 28, 39-40 (1918).

Inc., 489 U.S. 141, 150-51 (1989). "[T]he fundamental purpose of the patent grant" is to "encourag[e] innovation" by allowing the patentee a time-limited "right to exclude" in which to earn "above-market profits." *Biotech. Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1372 (Fed. Cir. 2007) (*BIO*) (quotation marks omitted).

"By penalizing high prices," the IRA "re-balance[s] the statutory framework of rewards and incentives … as it relates to inventive new drugs." *Id.* at 1374. Because of the long lead times for developing cutting-edge medicines, manufacturers must make investment decisions based on the prospect of future sales. ROA.750-51. For products patented or in development when the IRA was enacted, manufacturers invested in reliance on the principle that, "[u]pon grant of the patent, the only limitation on the size of the carrot should be the dictates of the marketplace." *King Instruments Corp. v. Perego*, 65 F.3d 941, 950 (Fed. Cir. 1995); *see BIO*, 496 F.3d at 1372 (patent system "provides incentive … to continue costly development efforts"). Having a drug selected for IRA "negotiation" will have significant economic ramifications for the manufacturer, ROA.781-83; ROA.800-02; ROA.871-73; *see NICA*, 116 F.4th at 500. The IRA thus deprives manufacturers of their protected interest in selling their products to private parties at market prices.

2. With respect to providers, "[t]he Drug Pricing Program substantially impacts [their] revenue and ability to stay in business." *NICA*, 116 F.4th at 503. "The path from a decrease in market price to loss of revenue for NICA members is a predictable result of the formula for reimbursement." *Id.* at 500-01. Providers have a protected interest in being reimbursed on a non-arbitrary basis at a lawful rate. *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). Thus, there is a "clear link between the decisions being made and NICA's concrete interests." *NICA*, 116 F.4th at 503-04. Further, providers have invested enormous resources developing facilities and processes for administering Medicare-reimbursed drugs. ROA.858. Thus, the IRA strips providers of protected property interests.

3. For patients—such as those served by NICA members and those represented by GCCA—the drug-selection decision may be one of life and death. ROA.857. HHS's decisions may determine whether existing products remain available to Medicare and Medicaid beneficiaries and whether future products are brought to market for patients. ROA.857; ROA.864.

B. The IRA's Procedures Are Constitutionally Insufficient

The government has never even attempted to argue that the Drug Pricing Program affords constitutionally sufficient process. And for good reason. The IRA exempts the Program from notice-and-comment rulemaking while barring administrative and judicial review. A government program that "provides *no process* whatsoever" creates "a glaring [due process] problem," which "alone" compels the conclusion that it is unconstitutional. *Schepers v. Comm'r*, 691 F.3d 909, 915 (7th Cir. 2012).

Because *no* process cannot constitute *due* process, there is no need for this Court to address the full *Mathews* balancing test. Moreover, this Court already concluded that the Complaint "allege[s] sufficient facts to satisfy the *Mathews* test." *NICA*, 116 F.4th at 503.

In any event, the IRA flunks the *Mathews* test. Under *Mathews*, courts balance (1) "the private interest … affected by the official action," (2) "the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards," and (3) "the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural

requirement[s] would entail." 424 U.S. at 335. Each factor weighs in Plaintiffs' favor.

First, "the private interests" at stake are immense. *Id.* at 334-35. As detailed above, the Program caps the prices at which manufacturers can sell their products to over 68 million Medicare beneficiaries. Having a drug selected for "negotiation" will thus have significant economic ramifications for manufacturers. ROA.781-83; ROA.801-02; ROA.871-73. Indeed, in some instances, the economic viability of a product may turn entirely on whether CMS selects a product for "negotiation." ROA.781; ROA.801-02. For providers, this Court has already recognized that "[t]he Drug Pricing Program substantially impacts [their] revenue and ability to stay in business." *NICA*, 116 F.4th at 503. The stakes are no less significant for patients, whose access to critical medicines hangs in the balance.

Second, "[t]he lack of input regarding unanswered implementation questions and inability to challenge particular determinations create a substantial risk of erroneous deprivation." *Id.* According to CMS, the IRA leaves many key questions unanswered, allowing the agency to fill in the gaps. Yet CMS also maintains that the Program is exempt from notice-and-comment rulemaking, and the statute bars judicial review of key implementation

decisions. *See* 42 U.S.C. §§ 1320f (Statutory Note), 1320f-7. Without any mechanism for external input or accountability, the risk of misapplying a novel, complex statutory scheme is immense.

Third, the government has no legitimate interest in insulating HHS's decision-making from input by affected parties, or in denying judicial review of basic statutory-interpretation questions. *See Mathews*, 424 U.S. at 335. Rather, "the burden on the government consists of the fiscal and administrative burdens inherent in any review process." *NICA*, 116 F.4th at 503. And anyway, giving interested parties the opportunity to comment on the law's implementation and to seek review of legal questions would impose only minimal "fiscal and administrative burdens." *Mathews*, 424 U.S. at 335. On the other hand, external input would substantially reduce "the risk of an erroneous deprivation" of protected interests. *Id.*

C. The District Court's Reasoning Is Mistaken

The district court erred in concluding that "Plaintiffs cannot demonstrate any deprivation of a protected interest." ROA.1266.

1. Manufacturers

The district court concluded that manufacturers have "no legitimate claim of entitlement to sell [their] drugs to the Government at any price other

than what the Government is willing to pay." ROA.1270. The court further held that manufacturers lack a protected interest because participation in Medicare and Medicaid is voluntary. ROA.1274. Neither rationale withstands scrutiny.

First, the district court's premise is wrong: The statute does not limit the amount of money *the government* pays for its own purchases; it sets the prices individuals, providers, and dispensers pay in private transactions to which the government is not a party. *See* 42 U.S.C. § 1320f-2(a)(3). Indeed, under Medicare Part D, CMS never buys a single drug. *See, e.g.*, 42 U.S.C. § 1395w-112(b)(1). Rather, plans submit bids and CMS selects plans for the Medicare Part D program based on their bids. While the government subsidizes insurers, CMS does not reimburse insurers for the actual or "negotiated" price of any drug; reimbursement rates are set by a complex statutory formula consisting of direct subsidies and "reinsurance." 42 U.S.C. § 1395w-115(a) (direct subsidy); § 1395w-115(b) (reinsurance).[7]

Second, Plaintiffs have never argued manufacturers have a right to sell their products at their "preferred price" to anyone. Rather, manufacturers'

[7] *AstraZeneca Pharms. LP v. HHS*, 137 F.4th 116 (3d Cir. 2025), made the same error, wrongly concluding that the Program "only sets prices for drugs *that CMS pays for*." *Id.* at 126.

common-law rights, coupled with their patents, grant them a protected interest in seeking "above-market profits during the patent's term." *BIO*, 496 F.3d at 1372. By establishing "maximum fair prices," the Drug Pricing Program deprives manufacturers of core interests in setting their prices.

Third, contrary to the district court's reasoning, there is nothing "voluntary" about being forced to choose between acceding to price controls, incurring massive penalties, and withdrawing from nearly half of the national market for prescription drugs. "[T]he consequences of failing to reach an agreement with HHS are [so] severe" that "[m]anufacturers are all but certain to adopt the price" HHS imposes, even when doing so would "ma[k]e sales of a particular drug unprofitable." *NICA*, 116 F.4th at 500. That is exactly what has happened. "[A]ll manufacturers of all ten drugs selected for negotiation have signed agreements to participate." The White House, *Biden-Harris Administration Takes Major Step Forward in Lowering Health Care Costs; Announces Manufacturers Participating in Drug Price Negotiation Program* (Oct. 3, 2023), https://bit.ly/46fRYLD.

The Supreme Court rejected a similar voluntariness theory in *NFIB*. There, the Affordable Care Act attempted to coerce states into expanding their Medicaid programs by "threatening to withhold all of [their] Medicaid

grants." 567 U.S. at 575. The Court held that scheme unconstitutional, rejecting the government's argument that states "voluntarily and knowingly accept[ed] the terms" of the Medicaid program. *Id.* at 577. The court explained that, "[i]nstead of simply refusing to grant new funds to States that will not accept the new conditions, Congress … also threatened to withhold those States' existing Medicaid funds." *Id.* at 579-80. The sheer size of the Medicaid program made that threat coercive—"a gun to the head." *Id.* at 581.

Just as the ACA threatened to withhold all Medicaid funds to coerce states into accepting new conditions, the IRA threatens to withhold Medicare and Medicaid coverage for all of a manufacturer's drugs to coerce price concessions under an entirely new program. The IRA's conditions on participation in Medicare and Medicaid thus "take the form of threats to terminate other significant independent grants." *Id.* at 580. And withdrawing coverage for all of a manufacturer's products under Medicare and Medicaid is at least as coercive as withdrawing federal Medicaid funding from the states. *Cf. Doe v. Univ. of Scis.*, 961 F.3d 203, 213 (3d Cir. 2020) ("total withdrawal of federal funding" can be "economic dragooning" and "a gun to the head").

The district court concluded that the "anti-commandeering" principles underlying *NFIB* do not apply here because "the government is dealing with

private parties instead of state agencies." ROA.1272 (cleaned up). But government coercion can be even more effective against private businesses than against sovereign states. The district court did not explain its contrary conclusion. In any case, *NFIB* illustrates the degree of coercion the Supreme Court believes renders a federal program involuntary—regardless of the particular coerced party.

Moreover, even if participation in the Program were a voluntary benefit to manufacturers, the government still would be required to afford them constitutionally adequate process. The Due Process Clause applies equally to voluntary benefit programs. In *Goldberg v. Kelly*, 397 U.S. 254 (1970), for instance, the Supreme Court recognized that the government was *not* obligated to provide "public assistance benefits," which were a "privilege and not a right." *Id.* at 262 (quotation marks omitted). Yet if it *did* provide them, it could not terminate them without providing constitutionally sufficient process. *Id.* at 263-65. At minimum, that meant the government had to take steps to ensure that "payments [would] not be erroneously terminated." *Id.* at 266. Here, it means that HHS cannot be allowed to administer—or even to rewrite—the Drug Price Negotiation Program at will.

To the extent "voluntariness" is a barrier to Fifth Amendment claims, it bars takings claims, not due process claims. Indeed, "there's a big difference between saying that something is property for purposes of procedural due process and saying that it is property for purposes of the Takings Clause." *Hignell-Stark*, 46 F.4th at 323. When a party voluntarily submits property to the government, it "can hardly be called a taking." *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1007 (1984). So while the Takings Clause may not protect "statutory entitlements" under voluntary government programs, *Pittman v. Chi. Bd. of Educ.*, 64 F.3d 1098, 1104 (7th Cir. 1995), the Due Process Clause does, *see, e.g.*, *Goldberg*, 397 U.S. at 263-64.

Bowles is instructive. The statute there did not effect a taking, the Court held, because landlords had voluntarily submitted to rent regulation by choosing to lease their apartments. 321 U.S. at 517. Nevertheless, the government was required to provide landlords due process in setting rents. *Id.* at 519-21. That is because the Due Process Clause is a "constitutional limitation[] safeguarding essential liberties" "that even the war power does not remove." *Id.* at 521 (cleaned up). The price-cap statute supplied adequate

process because it "provided for judicial review"—precisely what the IRA fails to do. *Id.*[8]

2. Providers and Patients

Relying on the *NICA* dissent, the district court concluded that providers lack a "constitutionally protected interest in being reimbursed at their *preferred* levels in the Medicare program." ROA.1268-69. But providers *do* have a protected interest in being reimbursed on a non-arbitrary basis at a lawful rate. *See Rock River Health Care, LLC*, 14 F.4th at 773-74; *Furlong*, 156 F.3d at 393. The IRA creates an arbitrary and unlawful price-setting scheme, and this court has already recognized that the Program will decrease providers' revenues. *NICA*, 116 F.4th at 500-01, 503. Thus, any reimbursements providers receive based on government-decreed "maximum fair prices" implicate due process interests.

Finally, patients indisputably have a protected interest in their health and their very lives. U.S. Const. amend. V. Many of the first ten selected drugs are life-saving medicines. They "treat serious health conditions, including blood clots, diabetes, heart disease, arthritis and cancer," such that "there

[8] The Second Circuit thus erred in rejecting a manufacturer's due process challenge to the Program on "voluntariness" grounds. *Boehringer Ingelheim Pharms., Inc. v. HHS*, No. 24-2092, 2025 WL 2248727, at *10 (Aug. 7, 2025).

could be serious health and financial consequences if patients lost access to one or more of the selected drugs." ROA.1000. The Program could result in millions of Americans losing access to their critical medicines. While patients may not have a right "to have *all* current Medicare and Medicaid products remain available through those programs *forever*," ROA.1274 (emphasis added), they do have a protected interest in preserving access to *some* life-saving medicines *now*.

CONCLUSION

This Court should reverse.

Dated: September 2, 2025

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CERTIFICATE OF SERVICE

I hereby certify that on September 2, 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 2, 2025

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CERTIFICATE OF COMPLIANCE

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