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

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

Plaintiffs,

vs.

XAVIER BECERRA, in his official capacity as Secretary of the U.S. Department of Health and Human Services; the U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of the Centers for Medicare and Medicaid Services; and the CENTERS FOR MEDICARE AND MEDICAID SERVICES,

Defendants.

Civil Action No. 1:23-cv-00707

PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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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 that extend and enhance their lives), 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 attempted to replace 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 the likely backlash, Congress adopted a complex and unprecedented structure that, at every turn, seeks to avoid accountability, obscuring the fact that drug prices are being dictated by government *fiat*. As the Fifth Circuit recently explained, 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 (2024) (*NICA*).

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 500, *compels* manufacturers to accept prices that the Centers for Medicare & Medicaid Services (CMS)—a sub-agency of the Department of Health and Human Services (HHS)—unilaterally chooses. The agency could decide 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.

In any genuine negotiation, the seller would be free to decline to sell at such an unfair price.

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 (not merely its Medicare revenues). 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. That faux "negotiation," backed by the very real threat of a crippling "tax," serves no legitimate purpose other than obscuring Congress's price-fixing scheme.

Next, Congress insulated this scheme from accountability. On the front end, the agency claims that it need not engage in notice-and-comment rulemaking regarding the Program's administration. The agency accordingly has already made key implementation decisions—including decisions that stretch the Program beyond the statutory text—without accounting for the views of affected parties. And on the back end, the IRA's text purports to foreclose altogether administrative and judicial review of critical agency decisions. As a result, the agency can decree any price it wants for a manufacturer's drug and then force the manufacturer to "agree" that it is "fair," without any meaningful ability to reach a different deal, walk away from negotiations, or challenge how the agency reached its decision. Patients and providers are shut out as well, even though government-set prices determine providers' reimbursement rates and patients' access to innovative treatments.

These unprecedented aspects of the Drug Pricing Program render it unconstitutional in at least three ways. *First*, Congress delegated unconstrained authority to the agency, in violation of the separation of powers and the nondelegation doctrine. *Second*, the excise-tax penalty violates the Eighth Amendment's Excessive Fines Clause by inflicting massive penalties on conduct that ordinarily is not considered unlawful or even wrongful. *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). As the Fifth Circuit recently concluded, this "lack of input regarding unanswered implementation questions and inability to challenge particular determinations," coupled with the property interests at stake, "satisf[ies] the *Mathews* test" for finding a due process violation. *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 grant summary judgment, to declare the Program unconstitutional, and to enjoin its implementation.

BACKGROUND

A. Pharmaceutical Innovation Requires Investment in Research and Development

The process of developing new drugs is lengthy, risky, and expensive. *See* Ex. 1, Expert Decl. of Craig Garthwaite ¶¶ 17–30. Today, companies are working on hundreds of new medicines, novel cell and gene therapies, and cutting-edge treatments for cancers, pediatric conditions, and rare diseases.[1] To develop just one new drug, manufacturers spend an average of over $2.5 billion. *See* Garthwaite Decl. ¶ 26. Some drugs for complex conditions require over $10 billion in research and development investment. *See* Alexander Schuhmacher et al., *Changing R&D Models in Research-Based Pharmaceutical Companies*, 14 J. Translational Med., no. 105, at 4–5, (Apr. 27, 2016), bit.ly/2PWRKRC. And the necessary investments are increasing. Over the last 60 years, drug research and development

[1] PhRMA, *Medicines in Development for Cancer: 2023 Report*, 2 (Nov. 2023), bit.ly/3BY59op; PhRMA, *Medicines in Development 2021 Report: Rare Diseases*, 1 (Dec. 2021), bit.ly/3go50j8; PhRMA, *Medicines in Development 2022 Report: Women* 2 (Mar. 2022), bit.ly/3EzupyG; Am.'s Biopharmaceutical Cos., *Medicines in Development 2020 Report: Children*, 1 (Feb. 2020), onphr.ma/2PSX4FN; Am.'s Biopharmaceutical Cos., *Medicines in Development 2020 Update: Cell and Gene Therapy*, 1–2 (Feb. 2020), onphr.ma/3fY6wSX; PhRMA, *Continued Progress Toward New Treatments for Alzheimer's Disease Provides Hope to Millions*, 1 (Mar. 2022), onphr.ma/42zq8pt.

costs have risen 8.6% annually, even after adjusting for 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 will even 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, representing almost 55% of global pharmaceutical research and development spending. *See* Garthwaite Decl. ¶¶ 11, 17. To justify this level of investment, the expected returns for medicines that do make it to market must be high enough to counterbalance the substantial likelihood of failure. And manufacturers must make investment decisions based on predictions about returns a decade or more before a product will earn any revenue. *See id.*

Pharmaceutical innovation benefits not just manufacturers, but providers and patients as well. Providers extend and improve patients' lives by administering treatments, including innovative new drugs and therapies. Ex. 2, Decl. of Brian Nyquist ¶¶ 9–10. Patients, in turn, depend on pharmaceutical innovation to save, extend, and improve their lives. *See* Ex. 3, Decl. of Andrew Spiegel ¶¶ 9–13, 18; Nyquist Decl. ¶¶ 4, 6.

B. Medicare Traditionally Encouraged Pharmaceutical Innovation

A key driver of pharmaceutical innovation has been the market-based reimbursement traditionally afforded by Medicare. "Medicare stands as the largest federal program after Social Security," providing "health insurance for nearly 60 million aged or disabled Americans, nearly one-fifth of the Nation's population." *Azar v. Allina Health Servs.*, 587 U.S. 566, 569 (2019); *see* Garthwaite Decl. ¶ 88. Medicare includes two major prescription drug programs. First, Medicare Part B covers

medically necessary and preventative healthcare services, including drugs administered by a physician. *See* 42 U.S.C. §§ 1395k(a)(1), 1395x(s)(2)(A); Garthwaite Decl. ¶ 34. Part B is administered by CMS and, with certain exceptions, has long reimbursed providers based on market prices. Part B reimbursement rates generally reflect the drug's "average sales price"—which, with certain exceptions, incorporates the volume-weighted average of all manufacturer sales prices to U.S. purchasers—plus a percentage (currently 6%). *See* 42 U.S.C. § 1395w-3a; Garthwaite Decl. ¶ 39.

Second, Medicare Part D allows beneficiaries to enroll in privately operated plans covering self-administered prescription drugs. *See* 42 U.S.C. § 1395w-102; Garthwaite Decl. ¶ 36. Drug prices in Part D also are market-based and administered by private plan sponsors, which negotiate prices with manufacturers. *See id.* ¶¶ 37–38. 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 [prescription drug plan] sponsors." 42 U.S.C. § 1395w–111(i); *see* Garthwaite Decl. ¶ 50. For decades, Medicare has encouraged innovation through this market-driven approach.

Although Medicare's market-based approach benefits patients globally, it helps Americans most directly. Manufacturers generally launch new drugs in the United States first, so U.S. patients are often the first to receive lifesaving pharmaceuticals. For example, 80% of medicines approved by the FDA in 2021 were available in the United States before any other country. *See* Garthwaite Decl. ¶ 11. Foreign countries with drug-price controls have seen drastic reductions in research and investment, as well as 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 in

reality empowers HHS to control drug prices not by negotiation, but 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 them (first in Part D, later in Part B as well) over a specified twelve-month period. *Id.* § 1320f–1(b)(1)(A). Drugs with the highest total expenditures are to be ranked the highest. *Id.* The IRA defines such "negotiation-eligible drugs," which encompass many of the most innovative drugs and biological products available, 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" is defined differently for drugs and biological products. For drugs, it must (1) be approved and marketed under Section 505 of the 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). For biological products, it must (1) be licensed and marketed under Section 351 of the Public Health Service Act, (2) have been licensed as such for at least eleven years, and (3) not be a reference product for a biosimilar product. *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 and "publish a list." *Id.* § 1320f–1(a). HHS selected the first round of Part D drugs in 2023, with "maximum fair prices" for them scheduled to take effect in 2026; Part B drugs are 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 will be 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). This process is cumulative: A selected drug remains selected until HHS determines that an approved generic or licensed biosimilar has been marketed. *Id.* § 1320f–1(c)(1).

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

Once drugs are ranked and 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). To conduct the "negotiations," the statute directs HHS to "develop and use a consistent methodology and process … to achieve the lowest maximum fair price for each selected drug." *Id.* § 1320f–3(b)(1). That 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, HHS can demand any information it wants on pain of massive penalties. The statute commands manufacturers to give HHS a host of closely guarded trade secrets and other proprietary information, including research and development costs, market data, and costs of production and distribution. *Id.* §§ 1320f–2(a)(4)(B), 1320f–3(e)(1). Manufacturers also must "compl[y] with" whatever *other* 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 then sets no meaningful constraints on what prices HHS can mandate. 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 means a first-year *minimum* discount of 25-to-60%. *See infra*, D.2. For later years, the ceiling can be even more restrictive; the IRA directs HHS to 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 applicable "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). Yet the IRA sets no criteria for how to weigh these considerations, nor does it require HHS to disclose in any meaningful way how it balanced those factors in setting prices. And the statute's low-ceiling, no-floor design gives HHS every incentive to drive prices as low as possible.

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). Manufacturers that fail to do so must pay a penalty of *ten times* the difference between the price charged and the HHS-imposed price, multiplied by the number of units 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. *See* Garthwaite Decl. ¶¶ 43, 82. But the IRA does not give manufacturers that option. Instead, it imposes a steep penalty for every day the manufacturer has not, by the statutory deadline, (1) entered into an "agreement" to negotiate, (2) "agreed" to a maximum fair price, or (3) submitted the information HHS demands for the "renegotiation" process. 26 U.S.C. § 5000D(b). Congress labeled this penalty an "excise tax," but it is intended to coerce rather than raise revenue.

The scope of this "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(d). The applicable percentage starts at 65% and then increases 10% for each quarter of noncompliance until it reaches 95%. *Id.* As the Congressional Research Service explained, "[t]he excise tax rate" thus "range[s] from 185.71% to 1,900% of the selected drug's price depending on the duration of noncompliance." Cong. Rsch. Serv., *Tax Provisions*

in the Inflation Reduction Act of 2022 (H.R. 5376), 4 (2022), bit.ly/3sbHYBy. In other words, the tax *starts* at nearly double the manufacturer's total daily U.S. revenue for the drug, then skyrockets to *19 times* revenue. A summary of predecessor legislation described the excise tax as a "steep, escalating penalty." Title Summary, H.R. 3, at 1 (2022). Indeed, though the statute calls it a "tax," 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'n on Tax'n, *Estimated Budget Effects of the Revenue Provisions of Title XIII – Committee on Ways and Means, of H.R. 5376, The "Build Back Better Act,"* at 8 (Nov. 19, 2021) (*Joint Comm'n*), bit.ly/3plC4cd; *see* CBO, *Estimated Budgetary Effects of Public Law 117-169*, at 5 (Sept. 7, 2022), bit.ly/3JOiq3r. And "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.[2]

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

Withdrawing from Medicare and Medicaid altogether is not feasible for manufacturers. Indeed, "[t]he consequence of" doing so "would be catastrophic for almost any manufacturer."

[2] The IRS recently issued a proposed rule providing that the excise tax applies only to sales of a selected drug within Medicare, *see* IRS Proposed Rules, *Excise Tax on Designated Drugs*, I.B., II.A. (Jan. 2, 2025), a position the government has taken in prior guidance and litigation, *see* IRS Notice 2023-52 § 2 (2023); *see also Merck & Co. v. Becerra*, No. 23-CV-1615 (D.D.C. Sept. 11, 2023), ECF No. 24-1 at 4–5, 22 & n.10; *Bristol Myers Squibb Co. v. Becerra*, No. 23-CV-3335 (D.N.J. Oct. 16, 2023), ECF No. 38-1 at 8. 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). The Court is ultimately responsible for ascertaining the "best reading" of the IRA, *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369, 400 (2024), which applies the excise tax simply to "sales," 26 U.S.C. § 5000D(d)(1)–(4). Even under the government's interpretation, the excise tax would still amount to 186%-1900% of applicable sales.

Garthwaite Decl. ¶ 85; *see id.* ¶¶ 87–89. "Through Medicare and Medicaid, [the federal government] pays for almost half the annual nationwide spending on prescription drugs." *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023). Medicare and Medicaid account for a hefty portion of many manufacturers' revenue. *See* Ex. 4, Decl. of Kristen Bernie ¶ 11; *see also* Garthwaite Decl. ¶ 88. In addition, withdrawing from Medicare and Medicaid would deprive millions of patients of critical medicines, raise serious ethical concerns, and harm manufacturers' reputations. Garthwaite Decl. ¶ 89.

Even if a manufacturer were able, let alone willing, to shoulder those financial, ethical, and reputational costs, the IRA delays manufacturers' ability to exit from Medicare Part D—and thus compels them to participate—for between 11 and 23 months. *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 September 1, 2023.

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, affected parties have no say in how HHS implements key parts of the Program, and they are deprived of legal recourse regarding numerous critical decisions.

On the front end, before implementation decisions are made, there is no right to participate in the implementation process. The Administrative Procedure Act 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." *Id.* § 1320f Statutory Note. CMS has read that language to exempt the Drug Pricing Program from notice-and-comment requirements during the Program's formative years. *See* CMS, *Medicare Drug Price Negotiation Program: Initial Memorandum ,*

Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments, at 2 (Mar. 15, 2023) (*Initial Guidance*), bit.ly/3m0cDPG; CMS, *Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026*, at 8–11 (June 30, 2023) (*Revised Guidance*), bit.ly/4eMvyCO; *see also* CMS, *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027*, at 160–62 (Oct. 2, 2024) (*2027 Guidance*), go.cms.gov/40ttKLJ.

On the back end, after implementation decisions are made, the IRA purports to insulate "key HHS determinations" from review. *NICA*, 116 F.4th at 496. For example, the statute 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, confirming CMS's view that the Program "is not subject to the notice-and-comment requirement of the Administrative Procedure Act or the Medicare statute." *Initial Guidance* at 2. While CMS "voluntarily" solicited comments on some aspects of the Initial Guidance, it adopted others as final. Aspects finalized without notice-and-comment included some of the Program's most critical elements, including "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 4. CMS 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. Among other changes, CMS

altered some aspects of the Initial Guidance that it had previously issued as "final," without any solicitation of comments. *See Revised Guidance* at 97. The Revised Guidance proposes a mechanism to expedite manufacturers' exit from Medicare Part D, purportedly reducing the 11-to-23 month statutory delay to 30 days. *See id.* at 120–21.

In May 2024, CMS issued a draft Program guidance for 2027, and in October it issued the final version. The 2027 Guidance largely mirrors the Revised Guidance and finalizes procedures for effectuating the Program's maximum price requirements in 2026 and 2027.

2. CMS Sets Prices for the First Ten Drugs

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 selected drugs by as much as 79%, with an average discount of 63%. In December 2024, CMS published "explanations" for the prices adopted, which did little more than recite the applicable statutory factors and assert that CMS considered them "holistically." *See* CMS, *Medicare Drug Price Negotiation*, go.cms.gov/3PMAXjv. PhRMA members manufacture eight of these drugs. *See* PhRMA, *About, Members*, phrma.org/About. NICA members administer Stelara®. *See* Dkt. 47-1 ¶ 5:

Drug	Januvia	Fiasp	Farxiga	Enbrel	Jardiance	Stelara	Xarelto	Eliquis	Entresto	Imbruvica
2023 30-Day List Price	$527	$495	$556	$7,106	$573	$13,836	$517	$521	$628	$14,934
New 30-Day List Price	$113	$119	$178.50	$2,355	$197	$4,695	$197	$231	$295	$9,319
Discount	79%	76%	68%	67%	66%	66%	62%	56%	53%	38%

The IRA requires CMS to select drugs for 2027 by February 1, 2025. 42 U.S.C. § 1320f(b)(3). It requires CMS to issue maximum prices for those drugs by November 30, 2025. *Id.* § 1320f-4(a)(1).

E. Procedural History

On June 21, 2023, Plaintiffs sued HHS and its Secretary, as well as CMS and its administrator. Dkt. 1. 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. This 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. Dkt. 53. The Fifth Circuit reversed, holding that NICA does not need to channel its claims. *NICA*, 116 F.4th at 509. The Fifth Circuit also held that NICA has Article III standing based on both economic injury and procedural injury. *Id.* at 501–02.

ARGUMENT

Summary judgment is appropriate where "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Here, Plaintiffs are entitled to judgment as a matter of law on all three of their claims.

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

Article I, section 1 of the Constitution provides that "[a]ll legislative Powers herein granted shall be vested in a Congress of the United States." "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 Supreme Court has twice invalidated statutes for violating these principles. *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). The Fifth Circuit has done so twice in recent years, once *en banc*. *See Consumers' Rsch. v. FCC*, 109 F.4th 743, 786 (5th Cir. 2024) (en banc), *cert. granted*, No. 24-354 (U.S. Nov. 22, 2024); *Jarkesy v. SEC*, 34 F.4th 446, 459–63 (5th Cir. 2022), *aff'd on other grounds*, 603 U.S. 109 (2024). As the Supreme Court recently unanimously confirmed, Congress may not "transfer[] its legislative power to another branch." *Gundy v. United States*, 588 U.S. 128, 132 (2019) (plurality op.); *accord id.* at 147–48 (Alito, J., concurring in the judgment) (similar); *id.* at 152–53 (Gorsuch, J., dissenting) (similar).

The nondelegation doctrine reflects separation-of-powers principles. The Framers "divided the

'powers of the new Federal Government into three defined categories, Legislative, Executive, and Judicial.'" *Seila L. LLC v. CFPB*, 591 U.S. 197, 223 (2020) (citation omitted). "[A]ccountability evaporates if a person or entity other than Congress exercises legislative power." *Jarkesy*, 34 F.4th at 460. Thus, "'the principle of separation of powers that underlies our tripartite system of Government' independently compels the conclusion that Congress, not agencies, must make legislative decisions." *Consumers' Rsch.*, 109 F.4th at 758 (quoting *Mistretta v. United States*, 488 U.S. 361, 371 (1989)).

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). The availability of "judicial review" therefore "is a factor weighing in favor of upholding a statute against a nondelegation challenge." *United States v. Garfinkel*, 29 F.3d 451, 459 (8th Cir. 1994) (citation omitted). Similarly, delegations that restrict "recourse to the judiciary" raise heightened nondelegation concerns. *Consumers' Rsch.*, 109 F.4th at 783. In *Touby v. United States*, 500 U.S. 160 (1991), for example, the Supreme 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. Other Supreme Court decisions underscore that a key feature of a permissible delegation is that "courts would have no trouble testing [the agency's] policies against the law." *Consumers' Rsch.*, 109 F.4th at 765 (discussing cases). And the *en banc* Fifth Circuit recently held a delegation unconstitutional in part because the statute was "so amorphous that no reviewing court could ever possibly invalidate any [agency] action," leaving "reviewing courts … handicapped from redressing the injuries of aggrieved citizens." *Id.* at 767, 784. "[J]udicial review perfects a delegated-lawmaking scheme by assuring that the exercise of such power remains within statutory bounds." *Touby*, 500 U.S. at 170 (Marshall, J., concurring).

Likewise, when Congress delegates authority to an agency to implement a statute, the opportunity for notice-and-comment provides another critical safeguard. Where Congress "mandate[s]

compliance with … requirements for notice and comment," therefore, that may "weigh[] in favor of [upholding] a delegation." *Garfinkel*, 29 F.3d at 459.

Ultimately, "separation-of-powers jurisprudence is done holistically, with an eye to constitutional history and structure." *Consumers' Rsch.*, 109 F.4th at 778. Thus, "two or more things that are not independently unconstitutional *can combine* to violate the Constitution's separation of powers." *Id.* In *Consumers' Research*, for example, the *en banc* Fifth Circuit invalidated the "universal service fund" established under the Telecommunications Act based on its "combination of delegations, subdelegations, and obfuscations." *Id.* at 786. While the court was "highly skeptical" of individual parts of the delegation scheme, *id.* at 778, it invalidated the statute based on a combination of features: Its "double-layered delegation [was] unprecedented," *id.* at 779, it "in [no] way limit[ed] [the agency's] discretion," *id.* at 761 & n.7, and it provided no avenue for meaningful judicial review, *id.* at 766–67.

The IRA epitomizes an unconstitutional delegation. While it grants sweeping legislative power to an administrative agency, it eviscerates the key procedural 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. At the same time, the draconian excise tax prevents manufacturers from protecting themselves against arbitrary agency decision-making during the "negotiation" process. And on the back end, the IRA purportedly *eliminates* judicial review of critical administrative decisions, *see* 42 U.S.C. § 1320f–7, giving HHS unreviewable authority to rewrite the statute or simply ignore statutory constraints. For example, without any public comment, HHS could select a product for negotiation even though it is *not* negotiation-eligible under the IRA. If the manufacturer were to challenge that unlawful decision in court, HHS could invoke the IRA's judicial review bar, which provides that "[t]here shall be no … judicial review" of "[t]he selection of drugs" or "the determination of qualifying single source drugs." 42 U.S.C. § 1320f–7(2)–(3).

Indeed, HHS has already flouted the statutory text by redefining "qualifying single source drug"

to include a combination of *multiple* drugs, thereby allowing the agency to set prices for more products than the IRA permits. The statute limits "qualifying single source drug" to *one* drug, defining the term as "*a* drug or biological *product*" (1) that is FDA-approved "and is marketed pursuant to *such approval*" (*i.e.*, pursuant to *a* New Drug Application); (2) "for which … at least 7 years will have elapsed since the date of *such approval*; and" (3) "that is not *the* listed drug for any [generic]." 42 U.S.C. § 1320f–1(e)(1)(A) (emphases added). Relying on the IRA's judicial review bar and notice-and-comment waiver, however, CMS has read the IRA as a license to redefine "qualifying single source drug" to encompass multiple products. According to CMS, a "qualifying single source drug" actually includes all products "with the same active moiety … , inclusive of products that are marketed pursuant to different NDAs." *Revised Guidance* at 99; *see 2027 Guidance* at 167. The agency took advantage of this rewrite to evade the IRA's limit of "10 negotiation-eligible drugs" in the first price-applicability year, 42 U.S.C. § 1320f-1(a)(1), instead lumping six Novo Nordisk drugs—approved under separate NDAs—into one qualifying single source drug, then selecting nine *more* drugs (for a total of fifteen). *See 2026 Maximum Prices*.

CMS has read the IRA to grant sweeping, unfettered discretion in other 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," such that the reference drug or biological product would not be negotiation-eligible. *See Revised Guidance* at 72–78; *2027 Guidance* at 171–72. 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). "Overly broad delegations" such as these "obscure accountability: When elected representatives shirk hard choices, constituents do not know whom to hold accountable for government action." *Consumers' Rsch.*, 109 F.4th at 759. Nor are these points the sort of minor matters where an administrative agency may be empowered to "fill up the details." *Wayman*, 23 U.S. (10 Wheat.) at 43. They are "important subjects, which must be entirely regulated by the legislature itself." *Id.*

Such blatant assertions of legislative power by an administrative agency would crumble under judicial scrutiny. As the government reads the IRA, however, HHS is immune. Faced with Administrative Procedure Act challenges to its redefinition of "qualifying single source drug," 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. *See* Br. for Appellee, *AstraZeneca Pharms. LP v. HHS*, No. 24-1819, Doc. 37, 41–47 (Sept. 12, 2024). As the government sees it, "reviewing courts are handicapped from redressing the injuries of aggrieved citizens." *Consumers' Rsch.*, 109 F.4th at 784. Congress gets to avoid political accountability by delegating its legislative authority to HHS, and HHS gets to avoid judicial scrutiny thanks to Congress. But the Constitution bars Congress from delegating such sweeping, unchecked power to "unelected bureaucrats." *Id.* at 759.

The IRA also violates the separation of powers by delegating to HHS unconstrained discretion to set Medicare drug prices as low as it chooses. While the statute directs HHS to "consider" certain "factors," it provides *no* guidance on how to weigh those factors and sets *no* concrete limits on the agency's discretion—other than a minimum discounted "ceiling" price and a general instruction to "achieve the *lowest* maximum fair price." 42 U.S.C. § 1320f–3(b)(1), (c), (e) (emphasis added). As the Fifth Circuit observed, "there is no limit to how low HHS's offer can be." *NICA*, 116 F.4th at 495. The agency's "discretion is limited only by the most amorphous of standards." *Consumers' Rsch.*, 109 F.4th at 781. Congress cannot give CMS such untrammeled discretion to wield command-and-control authority over vast swaths of the economy. *See Jarkesy*, 34 F.4th at 462.

Finally, "'[p]erhaps 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.'" *Consumers' Rsch.*, 109 F.4th at 779 (quoting *Seila L.*, 591 U.S. at 220). 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. And unlike historical federal price-setting

statutes, the IRA is not limited to wartime exigencies or the unique problems of common carriers, nor does it require prices to be "just and reasonable." *See, e.g.*, Pub. L. No. 421, §§ 2, 302, 56 Stat. 23 (1942); 15 U.S.C. § 717c; 16 U.S.C. § 824d. Rather, like the unconstitutional statute in *Consumers' Research*, the IRA's "delegation is unprecedented." *Consumers' Rsch.*, 109 F.4th at 779.

Standing alone, each of these defects undermines separation-of-powers principles. Taken together, they create a "novel structure," *Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 496 (2010), that concentrates "significant governmental power" in an administrative agency "accountable to no one," *Seila L.*, 591 U.S. at 224, to set prices for nearly half of nationwide prescription drug sales. These features of the Drug Pricing Program "*combine* to violate the Constitution's separation of powers." *Consumers' Rsch.*, 109 F.4th at 778.

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 Clause: It is designed to punish noncompliance with the IRA's sham negotiation process, and is wildly disproportionate to the "offense" of refusing to agree that a government-dictated price is "fair."

A. The IRA's Excise Tax Is Punitive

The IRA's excise tax triggers the Excessive Fines Clause because it is punitive. As the Fifth Circuit described it, the "tax" is part of the IRA's "penalty phase." *NICA*, 116 F.4th at 495; *see id.* at 500 (discussing "the penalties the Program imposes"). In assessing whether a "tax" operates as a

penalty, the Supreme Court uses a "functional approach," under which labels are not dispositive. *NFIB v. Sebelius*, 567 U.S. 519, 565 (2012). In the related context of the Double Jeopardy Clause, courts determine whether a tax is punitive by considering its size and purpose. *See Dep't of Revenue of Mont. v. Kurth Ranch*, 511 U.S. 767, 780 (1994); *Dye v. Frank*, 355 F.3d 1102, 1105 (7th Cir. 2004). "It matters not whether the scheme has a remedial purpose, even a predominantly remedial purpose," because "the Excessive Fines Clause applies to *any* statutory scheme that serves *in part* to punish." *Tyler v. Hennepin Cnty., Minnesota*, 598 U.S. 631, 648 (2023) (Gorsuch, J., concurring) (cleaned up).

The excise tax is punitive. A summary of predecessor legislation described it as a "steep, escalating *penalty*." Title Summary, H.R. 3, at 1 (2022) (emphasis added). Not only does the statutory scheme serve "in part" to punish; that appears to be its *sole* purpose. Before the IRA's passage, the Joint Committee on Taxation and the CBO both told Congress that the tax would raise no revenue, since no manufacturer would dare trigger it. *See supra*, *Joint Comm'n* at 8. And CBO recently reiterated "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." *Alternative Approaches* at 20. 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) (subparagraph entitled "Noncompliance periods"). "Deter[ring]" noncompliance "has traditionally been viewed as a goal of punishment." *Bajakajian*, 524 U.S. at 329. At the very least, the excise tax "cannot fairly be said *solely* to serve a remedial purpose." *Tyler*, 598 U.S. at 648 (Gorsuch, J. concurring) (cleaned up). Therefore, "the Excessive Fines Clause applies." *Id.*

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, reaches 1,900%. 26 U.S.C. § 5000D(b)(1)–(4). That enormous levy would cause significant financial harm to manufacturers. *See* Garthwaite Decl. ¶¶ 68, 85–86; Bernie Decl. ¶ 10. Indeed, for every $1 billion in annual net revenues for a drug, a manufacturer

would incur *$19 billion* in penalties after a year. Garthwaite Decl. ¶ 68. And if the 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." *Id.* ¶ 86. 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, *Tyler*, 598 U.S. at 648 (Gorsuch, J. concurring). *See Bajakajian*, 524 U.S. at 337–40 (finding a far less onerous excise tax grossly disproportionate and punitive).

While the excise tax punishes noncompliant manufacturers, its harms extend more broadly. Without it, manufacturers could more effectively resist lowball HHS "offers" that do not reflect a medicine's value, allowing prices and reimbursement rates to continue to reflect market forces. *See NICA*, 116 F.4th at 499–500 (describing harm to providers). In other words, the excise tax is an integral part of the IRA's scheme for imposing government-dictated prices. It not only punishes manufacturers, but also reduces provider reimbursements and limits patients' access to treatments.

B. The IRA's Excise Tax Is Grossly Disproportionate

The IRA's excise tax violates the Excessive Fines Clause because it is wildly disproportionate to the "offense" it seeks to punish. While the Eighth Amendment does not require strict proportionality between the punishment and the gravity of the offense, it forbids "gross disproportionality." *Bajakajian*, 524 U.S. at 336. The Supreme Court has considered three general 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 Group, Inc.*, 532 U.S. 424, 435 (2001) (citations omitted). Courts have applied these factors to many kinds of 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). These factors establish that 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" being punished—a manufacturer's refusal to express its agreement to the HHS-imposed price—does not entail any "reprehensibility or culpability." *Cooper Indus.*, 532 U.S. at 435. Noncompliant conduct under the IRA 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). Indeed, failing to agree on a price for a lawful sale ordinarily is not even considered wrongful, much less unlawful. At a minimum, such conduct is less culpable than that at issue in *Bajakajian*, where the Supreme Court held that forfeiting $357,444 was grossly disproportionate to the offense of failing to report that same amount of currency to customs inspectors. *See* 524 U.S. at 337–40. The Court held that the defendant had "a minimal level of culpability" because his "crime was solely a reporting offense," since "[i]t was permissible to transport the currency out of the country so long as he reported it." *Id.* at 337, 339. Here, a manufacturer's refusal to accept an offer it views as unfairly low is not culpable at all.

Second, there is no reasonable relationship between the size of the penalty and any harm caused. As in *Bajakajian*, the "offense" at issue is "unrelated to any other illegal activities," it "affect[s] only … the Government," and it does not involve "fraud on the United States." *Id.* at 338–39. Even if the government has an interest in ensuring that drugs are sold for no more than 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 actual sales price, and which is significantly more disproportionate than the penalty struck down 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," and "any relationship between the Government's actual costs and the

amount of the sanction is merely coincidental." *Austin*, 509 U.S. at 621–22 & n.14 (brackets omitted).

Third, Plaintiffs are not aware of *any* other statute that imposes similarly severe sanctions on comparable "misconduct." No other statutes impose any penalty—much less on this scale—for mere failure to agree to a government-mandated price. That alone shows that the excise tax is grossly disproportionate and unconstitutional. Considered with the other novel and punitive features of the excise "tax," this 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 Anti-Injunction Act (AIA) does not bar Plaintiffs' excessive fines claim. 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 excise "tax" does not even seek to collect revenue—even the government estimates that it "would raise no revenue because no manufacturer could afford to pay it." *NICA*, 116 F.4th at 495 (citing *Joint Comm'n* at 8). Thus, applying the AIA here would make no sense—it would simply compound the nondelegation problem by insulating a disproportionate penalty from judicial scrutiny.

In any event, the excise tax satisfies two AIA exceptions. One applies 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). 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 that would arise 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. *Bob Jones Univ. v. Simon*, 416 U.S. 725, 737 (1974). Here, as discussed, the excise tax is punitive and grossly disproportionate, so the government cannot prevail. *See supra*, II.A–B. 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," Garthwaite Decl. ¶ 86. *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)).

The government has argued elsewhere that the AIA applies because the excise tax is a "divisible tax" that "is imposed on each 'sale' of a designated drug," *Dayton Area Chamber of Commerce et al v. Becerra*, 23-CV-156, Dkt. 71 at 28 (S.D. Ohio, Dec. 15, 2023) (quoting 26 U.S.C. § 5000D(a)), "the IRS typically does not collect the balance of any divisible tax that would otherwise be due" during litigation, and the IRS *might* "exercise [such] forbearance" with respect to the excise tax, *id.* (quoting IRS Policy Statement 5-16, IRM § 1.2.1.6.4(6)). Apparently, the government believes manufacturers could sell a single unit of a single drug, pay the excise tax on that sale, and then sue for a refund. But this defies reality. Manufacturers cannot stake their survival on the IRS favorably exercising discretion. And even if the IRS were to forbear, additional drug sales would still generate billions in excise tax liability, which manufacturers cannot feasibly incur. *See* Garthwaite Decl. ¶¶ 68, 86. Alternatively, *stopping* subsequent sales during litigation would be financially catastrophic for manufacturers and would deprive patients of critical medication. *See Fam. Rehab., Inc. v. Azar*, 886 F.3d 496, 504 (5th Cir. 2018) ("The combined threats of going out of business and disruption to Medicare patients are sufficient for irreparable injury."). Thus, the AIA does not bar Plaintiffs' excessive fines claim.

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 plaintiff of a protected liberty or property interest without adequate procedures. *See Swarthout v. Cooke*, 562 U.S. 216, 219 (2011).

A. The IRA Deprives Plaintiffs of Protected Interests Without Due Process

The Drug Pricing Program violates the Due Process Clause. The statute deprives manufacturers, providers, and patients of protected interests, while purportedly exempting the Program from notice-and-comment rulemaking and facially barring administrative and judicial review. The Program thus has "a glaring problem" under the Due Process Clause: It "provides *no process* whatsoever." *Schepers v. Comm'r*, 691 F.3d 909, 915 (7th Cir. 2012). Because *no* process cannot constitute *due* process, that "alone" warrants judgment in Plaintiffs' favor. *See id.*

But even if the Court applies the three-factor test articulated in *Mathews v. Eldridge*, 424 U.S. 319 (1976), the IRA flunks it. As the Fifth Circuit recently concluded, Plaintiffs' allegations describing the Drug Pricing Program "satisfy the *Mathews* test" for a due process violation. *NICA*, 116 F.4th at 503. Because the Complaint accurately describes the Program, that conclusion is dispositive.

First, "the private interests" at stake are immense. *Mathews*, 424 U.S. at 334–35. In concluding that the Complaint "allege[s] sufficient facts to satisfy the *Mathews* test," *NICA*, 116 F.4th at 503, the Fifth Circuit necessarily determined that Plaintiffs have a property interest that triggers the protections of the Due Process Clause. *See, e.g.*, *Richardson v. Texas Sec'y of State*, 978 F.3d 220, 228 (5th Cir. 2020) (treating protected interest as a prerequisite to a due process claim). The evidence supports the allegations: The IRA deprives providers, manufacturers, and patients of core property rights.

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. "NICA has established with sufficient certainty that the selection of one of its members' drugs will lead to a lower price for that drug," and

"[t]he 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. Because 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), 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 building facilities and processes for administering Medicare-reimbursed drugs effectively and efficiently. *See* Nyquist Decl. ¶ 9. As the Fifth Circuit concluded, the IRA thus strips providers of protected property interests.

The IRA likewise deprives manufacturers of their protected property interests. The government can create property interests through statutes, express or implied 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). Federal law provides that "patents shall have the attributes of personal property," 35 U.S.C. § 261, and 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). The Court has reaffirmed this principle numerous times since. *See, e.g.*, *Horne v. Dep't of Agric.*, 576 U.S. 351, 359 (2015) (a patent "confers upon the patentee an exclusive property in the patented invention" (quotation marks omitted)); *Hartford-Empire Co. v. United States*, 323 U.S. 386, 415 (1945) ("That a patent is property … has long been settled."). In granting property rights, "[t]he 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, Inc.*, 489 U.S. 141, 150–51 (1989).

While the government "may elect not to confer a property interest" in the first place, "it may not constitutionally authorize the deprivation of such an interest, once conferred, without appropriate

procedural safeguards." *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 541 (1985) (cleaned up). The time-limited "right to exclude" gives the patentee "pecuniary rewards," thereby "encouraging innovation. Indeed, the encouragement of investment-based risk is the fundamental purpose of the patent grant." *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1372 (Fed. Cir. 2007) (*BIO*) (quotation marks omitted).

"By penalizing high prices—and thus limiting the full exercise of the exclusionary power that derives from a patent—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. *See* Garthwaite Decl. ¶¶ 15, 17, 78(d). For products that were 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 ("the patent system provides incentive to the innovative drug companies to continue costly development efforts"). In upending that principle, the selection of a manufacturer's drug for government price controls under the IRA deprives that manufacturer of its property rights.

The IRA also disrupts manufacturers' "treasured" common-law right to offer access to their products at prices set by voluntary agreements, not government dictates. *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 149 (2021). That right is more than "a mere subjective 'expectancy,'" *Perry*, 408 U.S. at 603 (citation omitted). For decades, Congress and the Executive Branch allowed and encouraged manufacturers to sell their products at market prices. When Congress created Medicare Part D, Congress even *prohibited* HHS from "interfer[ing] with the negotiations between drug manufacturers and pharmacies and [prescription drug plan] sponsors." 42 U.S.C. § 1395w–111(i). As the Fifth Circuit concluded with respect to providers, *see NICA*, 116 F.4th at 501–04, manufacturers thus have a

"legitimate claim of entitlement" based on years of "rules and understandings, promulgated and fostered by" the federal government, *Perry*, 408 U.S. at 602–03.

Ultimately, having a drug selected for "negotiation" under the IRA will have significant economic ramifications for the manufacturer. *See* Garthwaite Decl. ¶¶ 73, 99–100; Bernie Decl. ¶¶ 10, 16–17. Selection of a drug "will lead to a lower price for that drug." *NICA*, 116 F.4th at 500. In some instances, the economic viability of a product may turn *entirely* on HHS's decision whether the product is selected for "negotiation"—or is grouped with other products as one qualifying single source drug. *See* Garthwaite Decl. ¶¶ 73, 106–07; *supra*, p.16.

As 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. Nyquist Decl. ¶ 4. HHS's decisions may determine whether existing products remain available to Medicare and Medicaid beneficiaries and whether future products are brought to market for *any* patients. *Id.* ¶ 10; s*ee* Spiegel Decl. ¶¶ 14–18.

Second in the *Mathews* test, "[t]he lack of input regarding unanswered implementation questions and inability to challenge particular determinations create a substantial risk of erroneous deprivation." *NICA*, 116 F.4th at 503; *see Mathews*, 424 U.S. at 335. According to CMS, the IRA leaves many key questions unanswered, allowing the agency to fill in the gaps. Yet CMS also maintains that the Drug Pricing Program is exempt from notice-and-comment rulemaking through 2028, and the statute purportedly bars judicial review of key implementation decisions. *See* 42 U.S.C. § 1320f Statutory Note; *id.* § 1320f–7. These features combine to preclude regulated entities and the public from offering views on key determinations before they are made, having their views considered, or seeking judicial review after those decisions become final. 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 even for basic statutory-interpretation questions.

See Mathews, 424 U.S. at 335. The government has identified no emergency requiring suspension of ordinary administrative processes. Rather, "the burden on the government consists of the fiscal and administrative burdens inherent in any review process." *NICA*, 116 F.4th at 503. But giving interested parties the opportunity to comment on decisions about the law's implementation, and to seek review of statutorily impermissible or irrational choices, would impose only minimal "fiscal and administrative burdens." *Mathews*, 424 U.S. at 335. And external input would substantially reduce "the risk of an erroneous deprivation" of public and private interests. *Id.*

B. Participation in the Drug Pricing Program Is Not Voluntary

The IRA's due process problem cannot be excused on the fiction that "participation in the Medicare program is voluntary." *Texas Clinical Labs, Inc. v. Shalala*, 1999 WL 1243200, at *4 (N.D. Tex. Dec. 21, 1999). "For an abandonment option to render" compliance with a government program "a voluntary choice, the option would have to at least be cognizable to [property] owners." *Valancourt Books, LLC v. Garland*, 82 F.4th 1222, 1235 (D.C. Cir. 2023).

Withdrawal from Medicare and Medicaid to avoid the IRA is not a cognizable option. Manufacturers spent billions of dollars developing innovative medicines long before the IRA was enacted, so they were not "on notice" and did not "assume[] the risk" that pricing would later be decided by government *fiat*. *Texas Clinical Labs*, 1999 WL 1243200, at *5. And there is nothing "voluntary" about being forced to choose between acceding to the government's demands on pain of massive penalties or withdrawing from nearly half of the national market for prescription drugs. Indeed, "the 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 do would "ma[k]e sales of a particular drug unprofitable." *NICA*, 116 F.4th at 500. And that is exactly what has happened. Despite receiving nothing new in exchange for substantial price reductions, "all 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), bit.ly/3JtAkbl.

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 found that scheme unconstitutional, rejecting the federal government's argument that states "voluntarily and knowingly accept[ed] the terms" of the Medicaid program. *Id.* at 577. The seven-justice majority 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. And Congress "surpris[ed] participating States with post-acceptance or 'retroactive' conditions," which states "could hardly anticipate" when they "developed intricate statutory and administrative regimes over the course of many decades … under existing Medicaid." *Id.* at 581, 584 (citation omitted).

Just as the Affordable Care Act threatened to withhold *all* Medicaid funds to coerce states into accepting *new* conditions, the IRA threatens to withhold coverage for *all* of a manufacturer's drugs to coerce price concessions in 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 if withdrawing federal Medicaid funding was a "gun to the head" of states, then withdrawing coverage for *all* of a manufacturer's products under Medicare and Medicaid is, if anything, even more coercive. *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").

Exiting from Medicare and Medicaid also could stifle providers' and patients' access to the most-frequently prescribed medicines. Beneficiaries who rely on "high-spend" Medicare drugs—which often lack satisfactory alternatives—could no longer use federal funding to access their

medications. That would devastate millions of patients, contradict manufacturers' core mission, and tarnish manufacturers' reputations. *See* Garthwaite Decl. ¶ 89; Bernie Decl. ¶ 14.

In any event, manufacturers could not exit Medicare and Medicaid immediately even if they wanted to. As explained, the Medicare Part D statute delays a manufacturer's ability to terminate its relevant agreements with HHS for 11 to 23 months. *See* 42 U.S.C. §§ 1395w-114a(b)(4)(B)(ii), 1395w-114c(b)(4)(B)(ii), 1395w–153(a)(1). While CMS has represented that it will take administrative action to reduce the delay to 30 days, *see Revised Guidance* at 120–21; *2027 Guidance* at 190, this representation is expressly nonbinding. And CMS previously issued parts of the Initial Guidance as "final," only to turn around and change them in the Revised Guidance. *See Revised Guidance* at 97.

Further, CMS's statutory basis for reducing the exit delay is dubious at best. The statutory provision allowing termination "[b]y the Secretary [of HHS]" upon 30 days' notice requires "a knowing and willful violation of the requirements of the agreement or other good cause shown." 42 U.S.C. § 1395w-114a(b)(4)(B)(i), (ii); *id.* § 1395w-114c(b)(4)(B)(i), (ii). In other words, HHS may terminate a manufacturer's agreements only for serious misconduct. Yet CMS asserts that it will find "good cause" at a manufacturer's request, even if it has committed *no* misconduct. *See Revised Guidance* at 120–21; *2027 Guidance* at 190. That attempted rewrite is not a "permissible" interpretation of the statute. *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369, 400 (2024) . Manufacturers thus must assume that termination will take up to 23 months, during which time continued participation in Medicare Part D and the IRA's Drug Pricing Program is expressly involuntary.

CONCLUSION

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

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