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 United States District Court
for the Western District of Texas

BRIEF FOR APPELLEES

Of Counsel:

ROBERT FOX FOSTER
Acting General Counsel

ELIZABETH C. KELLEY
Acting Deputy General Counsel

JOCELYN S. BEER
Acting Deputy Associate General Counsel for Litigation

KENNETH R. WHITLEY
ANANT KUMAR
Attorneys
U.S. Department of Health and Human Services

ERIC J. HAMILTON
Deputy Assistant Attorney General

JUSTIN R. SIMMONS
United States Attorney

MICHAEL S. RAAB
MAXWELL A. BALDI
Attorneys, Appellate Staff
Civil Division, Room 7513
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530
(202) 532-0211

CERTIFICATE OF INTERESTED PERSONS

A certificate of interested persons is not required, as defendants-appellees are all governmental parties. 5th Cir. R. 28.2.1

STATEMENT REGARDING ORAL ARGUMENT

The Court has scheduled oral argument for October 7, 2025.

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Cases: **Page(s)**

U.S. Constitution:

Statutes:

Regulatory Materials:

Rule:

Legislative Materials:

Other Authorities:

INTRODUCTION

For more than 30 years, Congress has limited how much federal agencies will pay for prescription drugs. Manufacturers that wish to sell their drugs to the Departments of Defense and Veterans Affairs, for example, do so subject to statutorily defined ceiling prices, and both agencies have authority to negotiate prices below those ceilings. *See* 38 U.S.C. § 8126(a)-(h). In 2022, Congress gave the Secretary of Health and Human Services (HHS) similar authority to address the extraordinary and unsustainable increase in the prices Medicare pays for pharmaceutical products that lack generic competition and that account for a disproportionate share of Medicare's expenses. Inflation Reduction Act of 2022, Pub. L. No. 117-169, 136 Stat. 1818 (IRA); *see* 42 U.S.C. §§ 1320f(a), 1320f-1(b), (d), (e). Under the IRA's Drug Price Negotiation Program, the Centers for Medicare & Medicaid Services (CMS) can now negotiate the prices that Medicare will pay for a select group of drugs manufactured by companies that choose to sell drugs to Medicare and Medicaid. The Negotiation Program is a critical tool to achieve the government's policy of "optimiz[ing]" "Federal health care programs[] … to provide access to prescription drugs at lower costs to American patients and taxpayers." Lowering Drug Prices by Once Again Putting Americans First, Exec. Order 14,273, 90 Fed. Reg. 16,441, 16,442, § 2 (Apr. 18, 2025); *see also id.* at 16,442, § 3 (directing HHS to improve Negotiation Program).

Plaintiffs assert that the Negotiation Program violates the nondelegation doctrine, imposes excessive fines, and deprives them of property without due process of law. The district court correctly rejected each of these claims.

Plaintiffs bring a nondelegation challenge to a reticulated scheme in which Congress set forth a clear objective for CMS: to obtain the lowest maximum fair price, told CMS which drugs to select for negotiation; set a ceiling price; and required CMS to consider nine factors in negotiating prices. That level of detail far exceeds the intelligible principles found sufficient in a panoply of other nondelegation challenges. Plaintiffs fare no better in packaging their claim under the same sort of "combination theory" of nondelegation that the Supreme Court rejected just last term.

Plaintiffs' Excessive Fines Clause argument fails three times over. First, plaintiffs seek to enjoin collection of a tax, which the Anti-Injunction Act expressly forbids. Second, plaintiffs have not sued the correct agency defendants to obtain effectual relief. And third, the IRA's excise tax is neither punitive nor excessive. Plaintiffs identify no decision holding a tax to violate the Excessive Fines Clause, and for good reason. Taxes are not punishments.

Plaintiffs' due process challenges similarly fail. No plaintiff has established a cognizable property or liberty interest much less a deprivation of that interest. Drug manufacturers do not have a property right to dictate prices when they participate in a government spending program. Providers are entitled only to reimbursement in the amounts established by Congress; they have no property right in the amount the

government is willing to pay for administering drugs. And patients lack any liberty or property interest in the availability of prescription drugs.

Across five appeals, the Second and Third Circuits have already rejected many of the same arguments that plaintiffs raise here. *See AstraZeneca Pharms. LP v. HHS*, 137 F.4th 116, 125-26 (3d Cir. 2025); *Boehringer Ingelheim Pharms., Inc. v. HHS*, No. 24-2092, 2025 WL 2248727, at *7-8, 10 (2d Cir. Aug. 7, 2025) (published); *Bristol Myers Squibb Co. v. HHS*, Nos. 24-1820, 24-1821, 2025 WL 2537005, at *5-8 (3d Cir. Sept. 4, 2025) (published) (consolidated opinion resolving two cases); *Novartis Pharms. Corp. v. HHS*, No. 24-2968, 2025 WL 2619133, at *5-7 (3d Cir. Sept. 11, 2025) (published). This Court should similarly uphold the constitutionality of the Negotiation Program.

STATEMENT OF JURISDICTION

Plaintiffs invoked the jurisdiction of the district court under 28 U.S.C. §§ 1331 and 1346. ROA.30. The district court entered final judgment in favor of the government on August 7, 2025. ROA.1277. Plaintiffs timely noticed this appeal on August 13, 2025. ROA.1278; *see* Fed. R. App. P. 4(a)(1)(B). This Court has jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES

I. Whether the district court correctly rejected plaintiffs' nondelegation challenge to the Negotiation Program.

II. Whether the district court correctly rejected plaintiffs' excessive-fines challenge to the Negotiation Program.

III. Whether the district court correctly rejected plaintiffs' due process challenge to the Negotiation Program.

PERTINENT STATUTES AND REGULATIONS

Pertinent statutes are reproduced in the addendum to this brief.

STATEMENT OF THE CASE

A. Medicare and the Escalating Cost of Prescription Drug Coverage

Congress created Medicare in 1965. Social Security Amendments of 1965, Pub. L. No. 89-97, tit. I, 79 Stat. 286, 290-353. Medicare provides federally funded health coverage for individuals who are 65 or older or who have certain disabilities or medical conditions. 42 U.S.C. § 1395 *et seq.* CMS administers Medicare on behalf of the Secretary of HHS.

Medicare is divided into "Parts," which establish the terms under which Medicare pays for specific benefits. *See Northeast Hosp. Corp. v. Sebelius*, 657 F.3d 1, 2 (D.C. Cir. 2011). Medicare Part B covers outpatient care as well as the cost of drugs administered as part of that care. *Cares Cmty. Health v. HHS*, 944 F.3d 950, 953 (D.C. Cir. 2019). CMS generally pays Part B providers at a rate of 106% of the average sales price for most separately payable drugs or biologicals. 42 U.S.C. § 1395w-3a(b)(1); *see American Hosp. Ass'n v. Becerra*, 596 U.S. 724, 729 (2022). For nearly four decades, Medicare did not cover the cost of prescription drugs unless they were administered by medical professionals. That changed in 2003, when Congress enacted

Medicare Part D to provide "a voluntary prescription drug benefit program that subsidizes the cost of prescription drugs and prescription drug insurance premiums for Medicare enrollees." *United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 749 (3d Cir. 2017); *see* 42 U.S.C. § 1395w-101 *et seq.* Under Part D, CMS enters into contracts with private entities, known as "sponsors," 42 U.S.C. § 1395w-112(b), and makes payments to them to provide prescription drug plans to Part D eligible individuals, *see id.* § 1395w-115. On average, the government subsidizes 74.5% of expected benefit costs. *See id.* § 1395w-115.

In enacting Part D, Congress initially barred CMS from negotiating Part D drug prices or otherwise interfering in the arrangements between drug manufacturers and insurance plans. 42 U.S.C. § 1395w-111(i); *see also* Michelle Singer, *Under the Influence*, CBS News (Mar. 29. 2007), https://perma.cc/5U9Z-M2YS (documenting extensive pharmaceutical industry efforts to lobby for price-negotiation bar in lead-up to enactment of Part D). But that model led to skyrocketing drug prices that saddled beneficiaries with unaffordable copays and threatened the long-term solvency of the program.

The cost to the federal government of providing prescription drug coverage under Medicare Parts B and D is immense. In 2021 alone, the federal government spent more than $250 billion on drugs covered by these programs. *See* KFF, *10 Prescription Drugs Accounted for $48 Billion in Medicare Part D Spending in 2021, or More Than One-Fifth of Part D Spending That Year* (July 12, 2023), https://perma.cc/4CYL-

KYRM. That figure has risen dramatically over the last decade and is "projected to continue rising during the coming decade, placing increasing fiscal pressure[]" on the federal budget. Office of the Assistant Sec'y for Planning & Evaluation, HHS, *Report to Congress: Prescription Drug Pricing* 8 (May 20, 2020), https://perma.cc/5GEN-LZ7F (2020 Report). Medicare Part D spending in particular "is projected to increase faster than any other category of health spending." S. Rep. No. 116-120, at 4 (2019).

In addition to its effects on the fisc, the high cost of prescription drug coverage directly burdens Medicare beneficiaries by affecting their premiums and out-of-pocket payments. Because Part B premiums are automatically set to cover 25% of aggregate Part B spending, higher total spending on prescription drug coverage results in higher premiums for individual enrollees. *See* 2020 Report 11. Beneficiaries also pay 20% of their Part B prescription drug costs out of pocket. Part D premiums are similarly based on a plan's anticipated costs, and many Part D plans likewise require beneficiaries to pay additional cost-sharing amounts.

A "relatively small number of drugs are responsible for a disproportionately large share of Medicare costs." H.R. Rep. No. 116-324, pt. 2, at 37 (2019). In 2018, "the top ten highest-cost drugs by total spending accounted for 46 percent of spending in Medicare Part B" and "18 percent of spending in … Part D." 2020 Report 7. By 2021, the top 10 drugs by total spending accounted for 22% of spending under Part D. *See* Juliette Cubanski & Tricia Neuman, *A Small Number of*

Drugs Account for a Large Share of Medicare Part D Spending, KFF (July 12, 2023), https://perma.cc/2PF2-336Z.

These rising costs are in large part attributable to manufacturers' considerable latitude in dictating the prices that Medicare pays for the most expensive drugs. Because drug prices under Medicare Part B and Part D were tied to the price manufacturers charged private buyers, *see* 42 U.S.C. §§ 1395w-3a(b), 1395w-101 *et seq.*, manufacturers of drugs with no generic competition could "effectively set[] [their] own Medicare payment rate[s]" by dictating sales prices in the broader market. Medicare Payment Advisory Comm'n, *Report to the Congress: Medicare and the Health Care Delivery System* 84 (June 2022), https://perma.cc/5X4R-KCHC. Drug companies' substantial leeway in this respect was compounded by the significant legal and practical obstacles to market entry faced by generic competitors, along with the practice of many manufacturers of protecting their market share by entering into "settlements" with generic manufacturers to limit generic marketing. *See, e.g.*, Sarah M.E. Gabriele & William B. Feldman, *The Problem of Limited-Supply Agreements for Medicare Price Negotiation,* 330 JAMA 1223 (2023). As a result of these factors, there are in many instances "no market forces to apply downward pressure to provide lowered prices to the millions who have coverage for such medicines under Medicare." H.R. Rep. No. 116-324, pt. 2, at 37-38.

Other federal agencies, including the Departments of Defense and Veterans Affairs, operate their drug benefit programs differently and have not been subject to

skyrocketing costs. As a condition on Medicaid participation, manufacturers that wish to sell drugs to the government through these programs have long been required to negotiate with the government and reach agreements subject to statutorily defined ceiling prices. *See* 38 U.S.C. § 8126(a)-(h). As a consequence, manufacturers often sell drugs to these agencies for roughly half as much as they charge Medicare Part D. *See* Cong. Budget Office, *A Comparison of Brand-Name Drug Prices Among Selected Federal Programs* 16 (Feb. 2021), https://perma.cc/YY2E-GM97. "[I]f Medicare had received the same discounts as the Departments of Defense and Veterans Affairs, taxpayers would have saved" billions. Staff of H. Comm. on Oversight & Reform, *Drug Pricing Investigation: AbbVie—Humira and Imbruvica* 13-15 (May 2021), https://perma.cc/Z2KG-ZKW3.

B. The IRA's Drug Price Negotiation Program

Through the IRA's Drug Price Negotiation Program, Congress empowered the HHS Secretary, acting through CMS, to negotiate the prices Medicare pays for certain drugs, just as the Department of Defense, the Department of Veterans Affairs, and the Coast Guard have done for decades. *See* IRA §§ 11001-11003, 136 Stat. at 1833-64 (codified at 42 U.S.C. §§ 1320f-1320f-7 and 26 U.S.C. § 5000D). The Negotiation Program applies only to manufacturers that choose to participate in Medicare and Medicaid, and even then, it governs only the prices that Medicare pays for certain drugs. *See* 42 U.S.C. § 1320f-1(b), (d). The Negotiation Program does not dictate the prices paid for sales outside of Medicare Parts B and D.

By statute, only certain drugs are eligible for selection in the Negotiation Program: those that account for the highest Medicare expenditures, that have no generic or biosimilar competitors, and that have been on the market for at least seven years. *See* 42 U.S.C. § 1320f-1(d), (e). For the first negotiation cycle, CMS selects 10 of these drugs with the highest Medicare expenditures for negotiations. *Id.* § 1320f-1(a). Additional drugs will be selected for future negotiation cycles.

After selecting the drugs, CMS signs a Manufacturer Agreement with those manufacturers that are willing to engage in the negotiation process. 42 U.S.C. § 1320f-2. The object of the negotiations is to reach agreement on what the IRA terms a "maximum fair price" that Medicare will pay for each selected drug. *Id.* § 1320f-3. To guide the negotiation process, Congress imposed a "[c]eiling for [the] maximum fair price," which is based on specified pricing data for each drug, *id.* § 1320f-3(c), and directed CMS to "aim[] to achieve the lowest maximum fair price" that the manufacturer will accept, *id.* § 1320f-3(b)(1). If negotiations prove successful, the manufacturer signs an addendum to the Manufacturer Agreement establishing the maximum price at which the drug will be made available to Medicare beneficiaries. *Id.* § 1320f-3.

In enacting the Negotiation Program, Congress revised the terms of its offer to continue purchasing drugs for Medicare and Medicaid. A drug manufacturer that does not wish to participate in the Negotiation Program has several options. Because participation in the Medicare program is a voluntary undertaking, the manufacturer

can withdraw from Medicare and Medicaid and thus not be subject to any of the Negotiation Program's requirements. 26 U.S.C. § 5000D(c)(1); *see also* 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 120-21 (June 30, 2023), https://perma.cc/K6QB-C3MM (Revised Guidance). Alternatively, a manufacturer can transfer its ownership of the selected drug to another entity and continue to sell other drugs to Medicare and Medicaid. *See* Revised Guidance 131-32. A manufacturer that pursues neither of these options may also continue to sell the selected drug to Medicare beneficiaries at non-negotiated prices subject to an excise tax. *See* 26 U.S.C. § 5000D(a)-(h); *see also Excise Tax on Designated Drugs*, 90 Fed. Reg. 31 (Jan. 2, 2025); Internal Revenue Serv. (IRS), Notice No. 2023-52 (Aug. 4, 2023), https://perma.cc/B9JZ-ZG7P (IRS Notice).

C. Implementing the Negotiation Program

1. In addition to the statutory requirements set out above, Congress instructed CMS to implement the Negotiation Program through "program instruction or other forms of program guidance" for the first three negotiation cycles. IRA § 11001(c), 136 Stat. at 1854. In June 2023, CMS published the Revised Guidance that explains, among other things, how CMS determines which drugs may be selected for negotiation and the procedures for participating in the negotiation process. *See* Revised Guidance 91-92. Starting next year, CMS will be subject to notice and

comment requirements in implementing the Negotiation Program. *See* IRA § 11001(c), 136 Stat. at 1854.

The Revised Guidance also sets out procedures for manufacturers that choose not to participate in the Negotiation Program. Revised Guidance 118-21, 129-31. In those circumstances, CMS will "facilitate an expeditious termination of" a manufacturer's Medicare agreement before the manufacturer would incur liability for any excise tax, so long as the manufacturer notifies the agency of its desire to withdraw at least 30 days in advance of when the tax would otherwise begin to accrue. Revised Guidance 33-34. The Treasury Department and the IRS issued a notice explaining that, when excise tax liability is triggered, the tax will be imposed only on the manufacturer's "sales of designated drugs dispensed, furnished, or administered to individuals under the terms of Medicare"—*i.e.*, not on drugs dispensed, furnished, or administered outside of Medicare. IRS Notice 3. That interpretation is effective immediately. *See* IRS Notice 5. The Treasury Department and the IRS have reiterated their understanding of the application of the tax in a proposed rule. *See* 90 Fed. Reg. 31.

2. In August 2023, CMS selected drugs for the first negotiation cycle. *See* HHS, *HHS Selects the First Drugs for Medicare Drug Price Negotiation* (Aug. 29, 2023), https://perma.cc/A36P-Z88Z. The 10 drugs selected accounted for more than $50 billion of gross Medicare Part D spending between June 2022 and May 2023, and Medicare beneficiaries paid a total of $3.4 billion in out-of-pocket costs for those

drugs in 2022 alone. *See id.*; CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026* (Aug. 2023), https://perma.cc/X37F-RC94.

In accordance with the schedule established by Congress, CMS presented the manufacturers of selected drugs with initial offers by February 1, 2024. *See* CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026* (Aug. 15, 2024), https://perma.cc/6MVG-BZP8. The manufacturers responded to the initial offers with counteroffers by March 2. *Id.* CMS subsequently held three negotiation meetings with each company to discuss the offers and relevant evidence. *Id.* Many companies proposed revised counteroffers during these meetings, and CMS accepted four of these revised counteroffers outright. *Id.* All in all, CMS reached price agreements for five of the selected drugs in connection with these meetings. CMS sent final written offers to manufacturers of the five remaining drugs by July 15. By August 1, 2024, CMS and the participating manufacturers had agreed to a negotiated price for each of the 10 selected drugs. *Id.* Assuming that none of the 10 manufacturers withdraws from the negotiation agreement by December 2025, these prices will take effect on January 1, 2026. 42 U.S.C. §§ 1320f(b), (d), 1320f-2(a), 1320f-3(b).

CMS has subsequently selected drugs for the second year of the Negotiation Program and is in the process of negotiating prices. If CMS and the manufacturers reach agreement, these prices will take effect January 1, 2027.

D. Prior Proceedings

1. Plaintiffs are not drug manufacturers. Rather, they are the National Infusion Center Association (NICA), a trade association representing facilities that administer outpatient infusion treatments; the Pharmaceutical Research and Manufacturers of America (PhRMA), the trade association for the pharmaceutical and biotechnology industries; and the Global Colon Cancer Association (GCCA), a group that advocates for colon cancer patients. ROA.30-32. They sued to challenge the constitutionality of the Negotiation Program. ROA.75-79.

Plaintiffs raise three claims. First, they allege that Congress violated the nondelegation doctrine by "grant[ing] HHS virtually unfettered discretion to set drug prices." ROA.75-76. Second, they allege that Congress violated the Eighth Amendment's Excessive Fines Clause by enacting the excise tax. ROA.77. Third, they alleged that Congress violated the Fifth Amendment's Due Process Clause by depriving their members of property without due process. ROA.78.

2. The government initially moved to dismiss the claims raised by NICA on two alternative jurisdictional grounds: that the Medicare Act's channeling requirement deprived the district court of subject-matter jurisdiction to consider NICA members' preemptive objections to the Medicare payment amounts they expect to receive and that the complaint failed to demonstrate that any NICA member has Article III standing. ROA.458-69. The district court did not reach the standing argument because it held that NICA's claims are jurisdictionally barred by the Medicare Act's

channeling requirement, which requires that a claim affecting Medicare payments first be presented to HHS before it can be the subject of judicial review. ROA.615-21. And because NICA's presence was necessary to establish venue, the district court dismissed the remaining plaintiffs' claims as well. ROA.621-22.

Plaintiffs appealed, and a divided panel of this Court reversed. *NICA v. Becerra* (*NICA I*), 116 F.4th 488 (5th Cir. 2024). The majority concluded that at least one NICA member had established an economic injury because HHS had selected a member-administered drug for the Negotiation Program, because NICA had sufficiently pleaded that the selection of that drug would "lead to a lower price for that drug," and because that lower price would lead to lower revenue for the member. *Id.* at 498-501. The majority further concluded that NICA had demonstrated an economic injury because it pleaded that the Negotiation Program hampered NICA members' ability to raise debt and equity. *Id.* at 502. And the majority concluded that NICA established a procedural injury as well, accepting that NICA had pleaded a concrete interest in the dispute due to the alleged loss of revenue and had "alleged sufficient facts to satisfy the *Mathews* [*v. Eldridge*] test" and assert a due process violation. *Id.* at 503 (citing 424 U.S. 319, 335 (1976)). Turning to statutory jurisdiction, the majority held that the IRA rather than the Medicare Act provided the substantive basis for NICA's claims and, therefore, that the Medicare Act did not require NICA to raise its claims before CMS in the first instance. *Id.* at 505, 509.

Judge Ramirez would have affirmed the district court's judgment. *NICA I*, 116 F.4th at 509-18 (Ramirez, J., concurring in part and dissenting in part).

3. On remand, the district court granted summary judgment to the government. ROA.1280-1319. The district court first held that "the IRA provides sufficient guidance to [the agencies]" to satisfy the nondelegation doctrine. ROA.1293. It explained that Congress provided CMS both a policy goal—"'achiev[ing] the lowest maximum fair price for each selected drug' for which it is able to persuade manufacturers to sign an agreement" and "detailed criteria" to consider in conducting negotiations. ROA.1293 (quoting 42 U.S.C. § 1320f-3(b)(1)). Those constraints, the district court held, "more than suffice to provide guidance to CMS." ROA.1293. And the district court further rejected plaintiffs' argument that the IRA's preclusion of judicial review creates a nondelegation problem. ROA.1297.

Turning to the Excessive Fines Clause challenge, the district court concluded that it lacked statutory jurisdiction to consider the claim. ROA.1306. The district court explained that the Anti-Injunction Act bars plaintiffs' efforts to enjoin collection of the IRA's excise tax, ROA.1301-02, and that neither of the two narrow exceptions to the Anti-Injunction Act apply, ROA.1302-06. Accordingly, the district court rejected plaintiffs' challenge to the excise tax; it did not reach the government's argument that plaintiffs' excessive-fines claim is not redressable. ROA.1301

Finally, the district court held that plaintiffs' due process claims failed because they "cannot demonstrate any deprivation of a protected interest." ROA.1309. The

district court concluded that providers, like those represented by NICA, do not have a property interest in being reimbursed at any specific level. ROA.1311. It concluded that drug manufacturers, like those represented by PhRMA, do not have a property interest in selling drugs as part of Medicare at their preferred prices. ROA.1317. And it concluded that patients, like those represented by GCCA, have no protected interest in obtaining access to specific products through Medicare. ROA.1318.

SUMMARY OF ARGUMENT

I. The nondelegation doctrine requires only that Congress determine the general policy an agency is to implement and establish the outer boundaries of the agency's delegated authority. Congress did both here, directing CMS to seek to obtain the lowest maximum fair price for selected drugs, requiring CMS to consider a number of factors in formulating offers and counteroffers, and reticulating the scope of the Negotiation Program. The IRA does not violate the minimal requirements of the nondelegation doctrine.

Plaintiffs attempt to aggregate several of their grievances with the Negotiation Program—none of which rises to the level of a constitutional violation—in hopes of stating a nondelegation challenge that way. But the Supreme Court recently rejected the sort of "combination" nondelegation theory plaintiffs offer here. *See FCC v. Consumers' Rsch.*, 145 S. Ct. 2482, 2510-11 (2025). Plaintiffs fail to distinguish that decision.

II. The Anti-Injunction Act prohibits suits to enjoin collection of taxes, subject only to two narrow exceptions. Plaintiffs seek to enjoin collection of the IRA's excise tax. The district court, thus, correctly recognized that it lacks jurisdiction over their Excessive Fines Clause claims. Neither of the judicially created exceptions to the Anti-Injunction Act apply. Plaintiffs seek to enjoin a divisible tax. Because the tax is divisible, the manufacturer may pay the excise tax on a single sale and then bring a refund suit to challenge the legality of the tax. And plaintiffs certainly cannot show that the government has no prospect of success in defending against their novel constitutional argument. Thus, the district court correctly held that it lacked jurisdiction.

Plaintiffs' excise tax challenges also fail for another threshold reason. Treasury and the IRS administer the excise tax, but plaintiffs did not sue those agencies. Thus, a court cannot provide plaintiffs with effective relief.

If this Court were to reach the merits of the excessive fines claims, plaintiffs still would not succeed. A tax is not a fine, which is why plaintiffs can point to no court decision holding a tax unconstitutional under the Excessive Fines Clause. And, in any event, a tax of $65 to $95 on a $100 sale of a drug within Medicare is not excessive.

III. Plaintiffs' due process arguments also lack merit. The basic prerequisite for a due process claim is deprivation of a protected interest. No plaintiff satisfies that first step. The Negotiation Program governs only the prices paid for drugs purchased

as part of Medicare Parts B and D. Manufacturers do not have a property right to dictate the price the government must pay when it offers to subsidize healthcare programs. Similarly, when providers administer drugs to Part B beneficiaries, they have a right to reimbursement at a statutorily prescribed rate. But they have no property right in determining the amount of reimbursement. And patients have no right of access to prescription drugs, nor have plaintiffs offered any theory of how the Negotiation Program would effect a deprivation of such a right.

STANDARD OF REVIEW

"The standard of review on summary judgment is de novo." *Miller v. Michaels Stores, Inc.*, 98 F.4th 211, 215 (5th Cir. 2024).

ARGUMENT

I. The Negotiation Program is fully consistent with the nondelegation doctrine.

A. Congress set the policy for CMS to pursue and bounded CMS's authority in negotiating drug prices.

The Constitution vests legislative power in Congress, U.S. Const. art. I, § 1, but it also permits Congress to "vest discretion in executive agencies to implement and apply the laws it has enacted—for example, by deciding on the details of their execution." *FCC v. Consumers' Rsch.*, 145 S. Ct. 2482, 2491 (2025) (cleaned up); *see also J. W. Hampton, Jr., & Co. v. United States*, 276 U.S. 394, 406 (1928). When Congress leaves implementation of a statute to an agency, it must supply an "intelligible principle," *Hampton*, 276 U.S. at 409, meaning that Congress must "ma[k]e clear both

the general policy that the agency must pursue and the boundaries of its delegated authority." *Consumers' Rsch.*, 145 S. Ct. at 2497 (cleaned up). If Congress meets these undemanding standards, then courts "will not disturb its grant of authority." *Id.*; *see also Mistretta v. United States*, 488 U.S. 361, 372-73 (1989) (a delegation is "constitutionally sufficient if Congress clearly delineates the general policy, the public agency which is to apply it, and the boundaries of this delegated authority.").

The nondelegation doctrine does not impose a demanding test. *See Mayfield v. U.S. Dep't of Lab.*, 117 F.4th 611, 620 (5th Cir. 2024). Congress has delegated authority to the Executive Branch "[f]rom the beginning of the government," *United States v. Grimaud*, 220 U.S. 506, 517 (1911), and the Supreme Court has "found the requisite 'intelligible principle' lacking in only two statutes, one of which provided literally no guidance for the exercise of discretion, and the other of which conferred authority to regulate the entire economy on the basis of no more precise a standard than stimulating the economy by assuring 'fair competition.' " *Whitman v. American Trucking Ass'ns*, 531 U.S. 457, 474 (2001) (first citing *Panama Refin. Co. v. Ryan*, 293 U.S. 388 (1935); and then citing *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495 (1935)). In the more than 90 years since those decisions issued, the Court has upheld a wide variety of challenges to congressional grants of power, including "statutes authorizing the War Department to recover 'excessive profits' earned on military contracts; authorizing the Price Administrator to fix 'fair and equitable' commodities prices; and authorizing the Federal Communications Commission to regulate

broadcast licensing in the 'public interest.'" *Touby v. United States*, 500 U.S. 160, 165 (1991) (citations omitted) (collecting cases).

Congress gave CMS far more guidance in how to implement the Negotiation Program than it provided with respect to many other grants of agency authority that have withstood scrutiny under the nondelegation doctrine. *See, e.g.*, *Yakus v. United States*, 321 U.S. 414, 427 (1944) (rejecting challenge to agency's authority to set "fair and equitable" commodity prices); *American Trucking Ass'ns*, 531 U.S. at 472 (rejecting challenge to agency's authority to set air quality standards at a level "requisite to protect the public health"). Congress provided CMS with a general goal in negotiating with manufacturers: CMS is to "aim[] to achieve the lowest maximum fair price for each selected drug" that the manufacturer will agree to. 42 U.S.C. § 1320f-3(b)(1). And Congress told CMS how to go about achieving that goal, outlining how negotiation-eligible drugs are identified, ranked, and selected, *id.* § 1320f-1(b), (d), (e), and requiring the agency to consider in "determining the offers and counteroffers" during the negotiation a set of nine enumerated factors, *see id.* § 1320f-3(e). On top of this guidance, "Congress restricted [CMS]'s discretion by making many of the key regulatory decisions itself." *Big Time Vapes, Inc. v. FDA*,

963 F.3d 436, 445 (5th Cir. 2020); *see, e.g.*, 42 U.S.C. § 1320f-1(a) (number of drugs); *id.* § 1320f-3(c) (ceiling price). Nothing more was required.[1]

The context of this particular grant of authority underscores that conclusion: CMS is engaged in a price negotiation. Federal agencies spend hundreds of billions of dollars every year with far less guidance from Congress over how much to disburse, and Congress has authorized such provisions since the beginning of the republic, *see, e.g.*, Act of Feb. 23, 1795, 1 Stat. 419, 419 (establishing Purveyor of Public Supplies to "conduct procuring and providing of … all articles of supply requisite for the service of the United States" acting "under the direction and supervision of the Secretary of the Treasury"); *United States v. Tingey*, 30 U.S. 115, 126 (1831) ("There is no statute of the United States expressly defining the duties of pursers in the navy."). Indeed, it is difficult to see how the federal government could function if, as plaintiffs posit (at 37), Congress had to specify a floor price before the government could enter agreements to pay for goods. The statutory scheme, of course, imposes another constraint on the floor price: the manufacturer must agree to the price. Manufacturers' ability to pull out of Medicare and Medicaid provide them with

[1] Although plaintiffs argue (at 28, 37-39) that the obligation to consider specified factors does not sufficiently constrain the agency, the Supreme Court reached the opposite conclusion in *Hampton*, rejecting a nondelegation challenge to a statute that required "the President, in so far as he finds it practicable, [to] take into consideration" four factors in setting customs duties. *See* 276 U.S. at 401. The IRA goes even further than the statute at issue in *Hampton*, imposing an affirmative obligation on the agency to consider statutory factors, whether or not practicable. 42 U.S.C. § 1320f-3(e) (the agency "shall consider" nine factors).

significant leverage. *See* ROA.1010 (expert conclusion that "both CMS and manufacturers would bear significant costs from a failed negotiation" and that "both parties have strong incentives to negotiate"); *see also infra* pp. 46-47.

Instead of demanding unrealistic statutory specificity, courts heed "the traditional principle of leaving purchases necessary to the operation of our Government to administration by the executive branch of Government, with adequate range of discretion free from vexatious and dilatory restraints at the suits of prospective or potential sellers." *Perkins v. Lukens Steel Co.*, 310 U.S. 113, 127 (1940). In areas of traditional executive authority, like this one, the already undemanding constraints of the nondelegation doctrine are even more relaxed. *See Loving v. United States*, 517 U.S. 748, 772-73 (1996) (explaining that the ordinary "limitations on delegation do not apply where the entity exercising the delegated authority itself possesses independent authority over the subject matter" (cleaned up)); *see also Bowsher v. Synar*, 478 U.S. 714, 733 (1986) (interpreting and implementing a spending statute "is the very essence of 'execution' of the law).

B. The Supreme Court rejected plaintiffs' combination theory in *Consumers' Research*.

1. Plaintiffs assert that the combination of three elements—the level of guidance the IRA supplies, the IRA's instruction to implement the Negotiation Program through guidance for the first three years, and the IRA's judicial review bar—render the statutory scheme unconstitutional. But "[t]wo wrong claims do not

make one that is right." *See Consumers' Rsch.*, 145 S. Ct. at 2511 (quoting *Pacific Bell Tel. Co. v. linkLine Commc'ns, Inc.*, 555 U.S. 438, 457 (2009)).

In *Consumers' Research*, the Supreme Court rejected a similar "combination" theory in the context of a nondelegation challenge. 145 S. Ct. at 2510-11. There, the Court addressed a statute in which (1) Congress granted authority to the FCC to determine what level of fees would be sufficient to support a program and (2) the FCC relied on a private body to perform calculations and financial projections to set those fees. *See id.* at 2493-95. The Supreme Court held that the combination of these two elements did not amount to a constitutional violation. *See id.* at 2511. The Court explained that the first element implicated the traditional nondelegation doctrine, while the second element implicated the "private nondelegation doctrine," *see generally Carter v. Carter Coal Co.*, 298 U.S. 238, 310-11 (1936). *Consumers' Rsch.*, 145 S. Ct. at 2510. Because "[t]hose doctrines do not operate on the same axis (save if it is defined impossibly broadly)," "a measure implicating (but not violating) one does not compound a measure implicating (but not violating) the other, in a way that pushes the combination over a constitutional line." *Id.* at 2510-11. Each is a separate claim that must rise or fall on its own merits.

The same logic governs here. Congress provided an intelligible principle to CMS, so it did not violate the nondelegation doctrine. *See supra* pp. 18-22. Congress may prohibit judicial review of agency actions. *See Bank of Louisiana v. FDIC*, 919 F.3d 916, 922 (5th Cir. 2019); *see also Sheldon v. Sill*, 49 U.S. (8 How.) 441, 449 (1850). And

there is no constitutional requirement at all for agencies to determine broadly applicable policies only following notice-and-comment procedures. *See Bi-Metallic Inv. Co. v. State Bd. of Equalization*, 239 U.S. 441, 445-46 (1915). Therefore, the availability of judicial review and of notice-and-comment procedures is irrelevant to plaintiffs' nondelegation claims.

2. Plaintiffs' efforts to distinguish *Consumers Research* fall flat. They contend that several features of the Negotiation Program "raise[] structural concerns about expansive delegations that lack any guardrails." Br. 36 (quotation marks omitted) (arguing that the scope of CMS's authority, the lack of notice-and-comment rulemaking, and the judicial review bar all exacerbate the same problem). In so arguing, plaintiffs ignore the Supreme Court's admonition against "defin[ing] impossibly broadly" the "axis" along which their arguments operate. *Consumers' Rsch.*, 145 S. Ct. at 2510-11.

Plaintiffs rely (at 35-36) on *Free Enterprise Fund v. Public Company Accounting Oversight Board*, 561 U.S. 477 (2010), which held that Congress may not grant two layers of tenure protection to certain executive officers. *But see Consumers' Rsch.*, 145 S. Ct. at 2510 (rejecting "analogy and associated logic" of reliance on *Free Enterprise Fund*). In *Free Enterprise Fund*, the Court stated that a "second level of tenure protection" "transforms" an agency's independence by "chang[ing] the nature of the President's review" of an officer's actions. 561 U.S. at 496. "Neither the President, nor anyone directly responsible to him, nor even an officer whose conduct he may

review only for good cause, ha[d] full control over the [agency]." *Id.* That compounding problem bears no resemblance to plaintiffs' arguments against the Negotiation Program. Plaintiffs' argument (at 29-31, 36) that judicial review will prevent agencies from overstepping the authority Congress conferred is not a relevant consideration in nondelegation challenges because the "constitutional question is whether the statute has delegated legislative power to the agency," not how the agency interprets and uses its statutory authority. *American Trucking*, 531 U.S. at 472-73. And notice-and-comment procedures do not impose substantive limits on an agency's exercise of congressionally conferred power. *See Vermont Yankee Nuclear Power Corp. v. Natural Res. Def. Council, Inc.*, 435 U.S. 519, 558 (1978).

Plaintiffs invoke cases (at 40) stressing that the *availability* of "judicial review 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) (emphasis added),[2] but they cite no case holding that *preclusion* of judicial review creates a nondelegation problem. And the Ninth and D.C. Circuits have reached the opposite conclusion. *See Michigan Gambling Opposition v. Kempthorne*, 525 F.3d 23, 33 n.8 (D.C. Cir. 2008) ("Nor are we concerned, for purposes of the non-delegation doctrine, that the Secretary's decision … might be unreviewable in a court of law. [The Act] intelligibly guides the

[2] *Accord Bowles v. Willingham*, 321 U.S. 503, 516 (1944) (judicial review available); *American Power & Light Co. v. SEC*, 329 U.S. 90, 106 (1946) (same); *United States v. Gordon*, 580 F.2d 827, 839 (5th Cir. 1978) (same); *Amalgamated Meat Cutters of N. Am. v. Connally*, 337 F. Supp. 737, 760 (D.D.C. 1971) (same).

Secretary's exercise of discretion, and that is all that the non-delegation doctrine requires." (citations omitted)); *United States v. Bozarov*, 974 F.2d 1037, 1045 (9th Cir. 1992) ("[T]he [Act]'s preclusion of judicial review does not violate the nondelegation doctrine."). *Touby*, is not to the contrary. There, the relevant statute *did* allow for judicial review, *see* 500 U.S. at 168-69, so the Court did not have to (and did not) say whether the nondelegation doctrine required that result. Plaintiffs' citation (at 40) to Justice Marshall's concurrence proves the point—he (and Justice Blackmun) would have gone further, but the majority did not adopt that position. *See id.* at 169-70 (Marshall, J., concurring). Nor does a passing reference to judicial review in *Consumers' Research* transform the well-established requirements for the non-delegation in injury. True, the Supreme Court "ha[s] asked if Congress has provided sufficient standards to enable both 'the courts and the public [to] ascertain whether the agency' has followed the law." 145 S. Ct. at 2497. But this articulation of the level of specificity required to satisfy the intelligible-principle test does not suggest that the presence or absence of judicial review, writ large, is itself a separate part of the nondelegation inquiry.

Nor do plaintiffs offer any limiting principle to their argument that the nondelegation doctrine requires judicial review to be available. Congress has "plenary" control over the jurisdiction of the lower federal courts, *Patchak v. Zinke*, 583 U.S. 244, 252 (2018), and Congress has exercised that power to bar judicial review in at least 190 extant statutes, Laura E. Dolbow, *Barring Judicial Review*, 77 Vand. L. Rev. 307, 380-400 (2024) (collecting statutes). Agencies have rendered some decisions that were

not reviewable in court since the earliest days of the Nation. *See, e.g.*, *Hayburn's Case*, 2 U.S. 408 (1792); *Decatur v. Paulding*, 39 U.S. 497, 516-17 (1840); *see generally* Nicholas Bagley, *The Puzzling Presumption of Reviewability*, 127 Harv. L. Rev. 1285, 1295-1303 (2014). And the Supreme Court has repeatedly upheld statutes barring judicial review of nonconstitutional claims. *E.g.*, *Block v. Community Nutrition Inst.*, 467 U.S. 340, 352-53 (1984).

II. The district court correctly rejected plaintiffs' excise-tax claims.

The district court lacked jurisdiction to consider plaintiffs' excise-tax claims. If this Court disagrees, it should remand to allow the district court to consider the merits of plaintiffs' claims in the first instance. *See Utah v. Su*, 109 F.4th 313, 320 (5th Cir. 2024). But in any event, plaintiffs' claims fail on the merits because the excise tax is not punitive and is reasonable.

A. The Anti-Injunction Act and the tax exception to the Declaratory Judgment Act bar plaintiffs' excise-tax claims.

1. "Under the Anti-Injunction Act, Congress has provided that, absent limited exceptions, 'no suit for the purpose of restraining the assessment or collection of any tax shall be maintained in any court by any person.'" *Franklin v. United States*, 49 F.4th 429, 434 (5th Cir. 2022) (quoting 26 U.S.C. § 7421(a)). "Federal courts lack subject-matter jurisdiction over suits to which the [Anti-Injunction Act] applies." *Hotze v. Burwell*, 784 F.3d 984, 996 (5th Cir. 2015). The tax exception to the Declaratory

Judgment Act similarly bars courts from issuing declaratory judgments "with respect to Federal taxes," 28 U.S.C. § 2201(a).

The Anti-Injunction Act "could scarcely be more explicit" *Bob Jones Univ. v. Simon*, 416 U.S. 725, 736 (1974). "Because of the Anti-Injunction Act, taxes can ordinarily be challenged only after they are paid, by suing for a refund." *National Fed'n of Indep. Bus. v. Sebelius* (*NFIB*), 567 U.S. 519, 543 (2012) (lead opinion). "Courts have zealously guarded this rule" "that a taxpayer must 'pay first and litigate later.'" *Franklin*, 49 F.4th at 434 (citation omitted). The same rule governs in constitutional and statutory challenges. *Alexander v. Americans United Inc.*, 416 U.S. 752, 759 (1974) ("[D]ecisions of this Court make it unmistakably clear that the constitutional nature of a taxpayer's claim[] … is of no consequence under the Anti-Injunction Act.").

This blanket prohibition against pre-enforcement challenges "also extends to declaratory judgments." *Bob Jones*, 416 U.S. at 732 n.7. As "there is 'little practical difference' between an injunction and anticipatory relief in the form of a declaratory judgment" against a taxing provision, *Jefferson Cty. v. Acker*, 527 U.S. 423, 433 (1999), the Declaratory Judgment Act excludes cases "with respect to Federal taxes," 28 U.S.C. 2201(a). There is "no dispute … that the federal tax exception to the Declaratory Judgment Act is at least as broad as the Anti-Injunction Act." *Bob Jones*, 416 U.S. at 732 n.7.

2. A claim is barred by the Anti-Injunction Act—and therefore by the tax exception to the Declaratory Judgment Act—if (a) the exaction at issue is a "tax"

within the meaning of these statutes, and (b) the purpose of the claim is to "restrain[] the assessment or collection" of that tax. 26 U.S.C. § 7421(a). Because both conditions are met, the district court correctly dismissed plaintiffs' excise-tax claim for lack of jurisdiction. *See Novartis Pharms. Corp. v. HHS*, No. 24-2968, 2025 WL 2619133, at *5-7 (3d Cir. Sept. 11, 2025) (published).

a. In determining whether a payment qualifies as a "tax" for these purposes, courts defer to the language Congress used to describe the exaction at issue. That is because the challenged statute and the "Anti-Injunction Act … are creatures of Congress's own creation"—thus, "[h]ow they relate to each other is up to Congress." *NFIB*, 567 U.S. at 544 (lead opinion). As "the best evidence of Congress's intent is the statutory text," *id.*, Congress's decision to call something a tax—or not—is all but conclusive.

The Supreme Court's decision in *NFIB* illustrates this reasoning. In reviewing the constitutionality of the Affordable Care Act's individual mandate, the Court considered whether the Anti-Injunction Act barred a suit that challenged the payment levied on those without health insurance. *NFIB*, 567 U.S. at 543-46 (lead opinion). The Court concluded that it did not: the Affordable Care Act "describe[d] the payment as a 'penalty,' not a 'tax,'" and "that label [was] fatal to the application of the Anti-Injunction Act." *Id.* at 564. The *NFIB* Court explained that this dispositive reliance on "Congress's choice of label on th[e] question" was grounded in longstanding precedent. 567 U.S. at 564 (lead opinion). For over a century, the Court

has consistently deferred to congressional labels in determining whether the Anti-Injunction Act applies—even when it ultimately disagreed with the label. For instance, in *Bailey v. George*, 259 U.S. 16, 20 (1922), the Court held that the Act barred a claim challenging a "tax" intended to discourage the use of child labor. But on the same day, the Court also held that this "so-called" child labor tax was, constitutionally speaking, not a tax. *Child Labor Tax Case*, 259 U.S. 20, 38 (1922). Similarly, in *NFIB*, the Supreme Court held that the Affordable Care Act individual mandate penalty was not a tax for purposes of the Anti-Injunction Act but then upheld Congress's imposition of the penalty under the taxing power. 567 U.S. at 564, 574 (lead opinion). The Court has "thus applied the Anti–Injunction Act to statutorily described 'taxes' even where that label was inaccurate." *Id.* at 544. This result follows from the Court's committed deference to the congressional label in this context: where Congress calls something a "tax," it "intend[s] the Anti–Injunction Act to apply." *Id.* at 564.

The Court's reasoning is controlling here, for the statutory text and structure leave no doubt that Congress considered the excise tax to be a "tax" and thus subject to the Anti-Injunction Act. The IRA provision concerning the excise tax is codified in the Tax Code (Title 26 of the U.S. Code), *see* 26 U.S.C. § 5000D; the tax is enforced by the IRS; and—most importantly—Congress describes the exaction as a "tax." *Id.* § 5000D(a) ("There is hereby imposed on the sale by the manufacturer … of any designated drug … a tax …."); *id.* § 5000D(a)(1) (referring to "such tax"); *id.* § 5000D(a)(2) (same); *id.* § 5000D(c) ("Suspension of tax"); *id.* § 5000D(f)(2) (referring

to "the tax imposed by this section"). "Because Congress labeled the exaction a 'tax,' it is a tax within the meaning of the Anti-Injunction Act." *Novartis*, 2025 WL 2619133, at *5.

Plaintiffs' assertion (at 44) that the excise tax is not a "tax" because it is not intended to collect revenue is without merit. Plaintiffs' argument cannot be squared with the statute's "plain text," *Novartis*, 2025 WL 2619133, at * 6, and is foreclosed by decades of Supreme Court precedent making clear that the Anti-Injunction Act "draws no distinction between regulatory and revenue-raising tax rules," *CIC Servs., LLC v. IRS*, 593 U.S. 209, 225 (2021). Contrary to plaintiffs' suggestion, the Act applies as long as "the dispute is about a tax rule," and "[t]hat is just as true when the tax in question is a so-called regulatory tax—that is, a tax designed mainly to influence private conduct, rather than to raise revenue." *Id.* at 224-25.[3]

b. Because the excise tax is plainly a "tax" for these purposes, plaintiffs' excise-tax claim is barred by the Anti-Injunction Act and thus by the tax exception to the Declaratory Judgment Act as long as the purpose of the claim is to "restrain[] the assessment or collection" of that tax. 26 U.S.C. § 7421(a). In addressing that question,

[3] Plaintiffs' reliance on a Congressional Budget Office estimate that the excise tax would raise no revenue is misplaced for several reasons. First, "the [Congressional Budget Office] is not Congress, and its reading of the statute is not tantamount to congressional intent." *Sharp v. United States*, 580 F.3d 1234, 1239 (Fed. Cir. 2009). Second, plaintiffs' argument confuses purposes and effects. The excise tax is still a tax even if, by plaintiffs' telling, a manufacturer would not engage in the conduct that would cause the harm the excise tax is designed to remedy. *Cf. United States v. Sanchez*, 340 U.S. 42, 44 (1950) (tax is valid "even [if it] definitely deters the activity taxed").

courts "inquire not into a taxpayer's subjective motive, but into the action's objective aim." *CIC Servs.*, 593 U.S. at 217. That aim is "best assessed" by "look[ing] to the face of the taxpayer's complaint" and, "most especially, … to the relief requested." *Id.* at 217-18 (quotation marks omitted). If the relief requested runs against implementation or collection of the tax itself, the suit is prohibited. *Id.* at 219.

The excise-tax claim squarely targets the tax. *See, e.g.*, ROA.60-65, 77. And the relief requested here to "[e]njoin HHS from enforcing the IRA excise tax" seeks to restrain the assessment or collection of that tax. ROA.79. "These allegations leave little doubt that a primary purpose of this lawsuit is to prevent the [IRS] from assessing and collecting" the excise tax. *Bob Jones*, 416 U.S. at 738.

3. Courts have crafted two exceptions to the Anti-Injunction Act. Neither applies here.

a. In *Enochs v. Williams Packing & Navigation Co.*, the Supreme Court held that the Anti-Injunction Act does not apply when two conditions are met: (1) if the plaintiff will suffer irreparable injury and (2) "if it is clear that under no circumstances could the Government ultimately prevail" even "under the most liberal view of the law and the facts." 370 U.S. 1, 7 (1962). "Unless both conditions are met, a suit for preventive injunctive relief must be dismissed." *Americans United*, 416 U.S. at 758. Plaintiffs' claim fails both prongs.

First, because a refund suit is an adequate remedy, plaintiffs cannot establish that they will suffer irreparable harm absent preemptive injunctive relief. "This is not

a case in which an aggrieved [taxpayer] has no access at all to judicial review." *Bob Jones*, 416 U.S. at 746. A manufacturer that wishes to challenge the excise tax could pay it, seek a refund from the IRS, then sue for a refund in district court or the Court of Federal Claims. *See* 26 U.S.C. § 7422; 28 U.S.C. §§ 1346(a)(1), 1491. And a taxpayer need only pay "the excise tax on a single transaction" before challenging the tax in court. *Rocovich v. United States*, 933 F.2d 991, 995 (Fed. Cir. 1991); *see also Flora v. United States*, 362 U.S. 145, 171-75 nn.37-38 (1960). While such a suit is pending, the IRS generally does not collect the remainder of the excise tax that would otherwise be due. IRS, *Internal Revenue Manual* § 1.2.1.6.4(6), 2007 WL 9790655.

Second, plaintiffs have fallen well short of establishing a "certainty of success on the merits," *Bob Jones*, 416 U.S. at 737; *see infra* pp. 35-41. That bar is not easily met. *See, e.g.*, *Minnesota ex rel. Spannaus v. United States*, 525 F.2d 231, 234-35 (8th Cir. 1975) (holding that second prong of *Williams Packing* test was not met because "[a]lthough the government's analysis may ultimately be found incorrect, we cannot say at this juncture that the argument is made in bad faith"); *Shannon v. United States*, 521 F.2d 56, 61 (9th Cir. 1975) (holding that second prong of *Williams Packing* test was not met where "the court could not have inferred a complete lack of merit in the government's case"). Plaintiffs have not shown that the excise tax is indefensible. *See Novartis*, 2025 WL 2619133, at *7 ("far from certain that Novartis would win on the merits of its [excise tax] claim").

b. A second exception to the Anti-Injunction Act is embodied in *South Carolina v. Regan*, which applies only when Congress has not "provided an alternative avenue for an aggrieved party to litigate its claims," necessitating the party harmed by the tax to find a third party to assert the legal issues. 465 U.S. 36, 381 (1984). Plaintiffs point to no case to support their argument that the *South Carolina* exception can apply based on a taxpayer's ability to pay a tax. The law supports the opposite conclusion. *See Flora*, 362 U.S. at 175 (hardship of prepaying tax does not justify equitable relief against enforcement of tax); *see also id.* at 175 n.38 (applying holding to divisible excise tax). And even putting aside a manufacturer's obvious ability to pay a single instance of this divisible tax, here, plaintiffs have "an adequate remedy; [they] simply [don't] like it." *Larson v. United States*, 888 F.3d 578, 589 (2d Cir. 2018) (requiring the plaintiff to pay a $61 million tax, then seek a refund, before pressing Excessive Fines claim even though the plaintiff alleged he was unable to pay). But preferring to avoid the uncertainty of litigation does satisfy the limited exception provided by *South Carolina*.[4]

c. Finally, to the extent plaintiffs suggest (at 48) that the Anti-Injunction Act itself is unconstitutional as applied to their claims, that novel argument is without merit. The Anti-Injunction Act has been applied for more than 150 years—often to

[4] Plaintiffs' assertion that no manufacturer would pay a single instance of an excise tax and then "bet the company on the outcome of refund litigation," Br. 50, undermines their assertion of "certainty of success on the merits," *Bob Jones*, 416 U.S. at 737. If such a course of action carries risk for the manufacturer, then, by definition, success on the merits is less than certain.

constitutional claims—without any hint of a constitutional problem. *See, e.g.*, *United States v. Clintwood Elkhorn Min. Co.*, 553 U.S. 1, 10 (2008) ("[T]he taxpayer must succumb to an unconstitutional tax, and seek recourse only after it has been unlawfully exacted"). Congress acts well within its power when it postpones the availability of judicial review. *See Weinberger v. Salti*, 422 U.S. 749, 762 (1975).

B. Plaintiffs excise-tax claims are not redressable.

Plaintiffs' Eighth Amendment claims would fail for lack of standing were they not otherwise barred. To show Article III standing, a plaintiff must establish "that [it] suffered an injury in fact that … would likely be redressed by judicial relief." *TransUnion LLC v. Ramirez*, 594 U.S. 413, 423 (2021). Redressability must be established "for each claim that [the plaintiff] press[es] and for each form of relief that [it] seek[s]." *Id.* at 431.

As the Supreme Court recently reaffirmed in *Haaland v. Brackeen*, 599 U.S. 255, 291-96 (2023), a plaintiff lacks standing to seek declaratory or injunctive relief if it fails to sue the entities responsible for its injuries. *Brackeen* concerned a dispute over the constitutionality of a federal law requiring that Native American children in adoption proceedings be preferentially placed with Native families over non-Native families. *Id.* at 262-63. Certain plaintiffs sought a declaration that these placement preferences were unconstitutional and an injunction preventing their application. The Court held that this claim failed for lack of standing because the entities that implement the statute's placement preferences—state courts and agencies—were not parties to the

lawsuit. *Id.* at 292-94. Neither an injunction nor a declaratory judgment would prevent the non-party state officials from applying the placement preferences. *Id.* And a declaratory judgment against the defendants would thus amount to "little more than an advisory opinion." *Id.* at 293.

Plaintiffs have similarly failed to sue the entities responsible for the alleged harm. Plaintiffs' alleged injury arises from a tax that is assessed and collected by the IRS, which is not a party to the lawsuit. The IRA's tax provisions are codified in the Internal Revenue Code, 26 U.S.C. § 5000D, and the Treasury, of which the IRS is a part, is charged with enforcing Section 5000D and interpreting its provisions. *See id.* § 5000D(h); *see also id.* § 7701(a)(11)(B). Under this authority, the IRS has published notices and regulations implementing the Section 5000D tax. 90 Fed. Reg. 31; IRS Notice.

Treasury and the IRS are thus the only entities responsible for enforcing the excise-tax provisions, but plaintiff have sued neither.[5] The Court cannot enter

[5] The Third Circuit erred in concluding that CMS is partially responsible for enforcing the excise tax. *See Novartis*, 2025 WL 2619133, at *4. Tax liability accrues under the statute without any action by CMS, 26 U.S.C. § 5000D, and the only role for CMS is sharing information that may stop, but not start, the accrual of liability, *see* 42 U.S.C. §§ 1320f(a)(4), 1320f-5(a)(6). Additionally, taxpayers must self-report their excise tax liability, *Excise Tax on Designated Drugs; Procedural Requirements*, 89 Fed. Reg. 55,507 (July 5, 2024) (codified at 26 C.F.R. pts. 40, 47), regardless of whether CMS shares any information with the IRS. And the Third Circuit's joinder of IRS and Treasury, *Novartis*, 2025 WL 2619133, at *5, cannot create standing that did not exist when the complaint was filed, *see Lujan v. Defenders of Wildlife*, 504 U.S. 555, 569 n.4 (1992) (plurality opinion).

judgment against these agencies because they are "not parties to the suit," and they would not be "obliged to honor an incidental legal determination the suit produced." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 569 (1992) (plurality opinion); *see also id.* at 570-71 ("The short of the matter is that redress of the only injury in fact respondents complain of requires action … *by the individual funding agencies*; and any relief the District Court could have provided in this suit against the Secretary was not likely to produce that action." (emphasis added)). Any injunctive or declaratory judgments issued against HHS and CMS, the only defendants in this action, would not redress plaintiffs' excise-tax injury. Therefore, that claim is not redressable.

C. The excise tax complies with the Eighth Amendment.

Plaintiffs' excessive fines claim lacks merit because the excise tax is not a "fine" that implicates the Excessive Fines Clause, nor is it "excessive." These deficiencies provide alternate grounds for affirmance but would best be addressed by the district court in the first instance.

1. The Eighth Amendment provides that "[e]xcessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted." U.S. Const. amend. VIII. "Taken together, these Clauses place parallel limitations on the power of those entrusted with the criminal-law function of government." *Timbs v. Indiana*, 586 U.S. 146, 151 (2019) (quotation marks omitted). The Excessive Fines Clause accordingly "limits the government's power to extract payments … as punishment for some offense." *Id.* (quotation marks omitted). Although the form of

proceeding, "civil or criminal," is not entirely dispositive, the question remains whether a particular payment is "punishment for some offense" against the sovereign. *Austin v. United States*, 509 U.S. 602, 610, 622 (1993).

In keeping with the Eighth Amendment's focus on excessive punishment, every Supreme Court case applying the Excessive Fines Clause has involved a forfeiture ordered as a sanction for criminal conduct after an adjudication of guilt in a criminal proceeding, *see United States v. Bajakajian*, 524 U.S. 321, 325-26 (1998); *Alexander v. United States*, 509 U.S. 544, 547-548 (1993), or a civil action brought after the property owner had already been convicted of a crime, seeking forfeiture of property used in the commission of the crime, *see Timbs*, 586 U.S. at 148; *Austin*, 509 U.S. at 605; *see also United States v. Jalaram, Inc.*, 599 F.3d 347, 354 (4th Cir. 2010) ("[T]he [Supreme] Court consistently focused on whether the forfeiture stemmed, at least in part, from the property owner's criminal culpability."); *United States v. Toth*, 33 F.4th 1, 16 (1st Cir. 2022) (rejecting excessive fines challenge where "civil penalty [was] not tied to any criminal sanction"), *cert. denied*, 143 S. Ct. 552 (2023).

The excise tax here, by contrast, lacks any connection to criminal conduct. Liability does not depend on the commission of any crime; it is instead triggered by the lawful choices of the taxpayer in connection with drug sales to Medicare. To defendants' knowledge, neither the Supreme Court nor any other court has ever held that a tax—let alone one that lacks any connection to a criminal offense—implicates

the Excessive Fines Clause. This Court should reject plaintiffs' invitation to break new ground.

2. Even if the excise tax was a fine, it would not be "excessive." A fine violates the Excessive Fines Clause only "if it is grossly disproportional to the gravity of a defendant's offense." *Bajakajian*, 524 U.S. at 334. In conducting this inquiry, the Supreme Court has emphasized that "judgments about the appropriate punishment for an offense belong in the first instance to the legislature." *Id.* at 336. Because "Congress is a representative body, its pronouncements regarding the appropriate range of fines … represent the collective opinion of the American people as to what is and is not excessive." *United States v. 817 N.E. 29th Drive*, 175 F.3d 1304, 1309 (11th Cir. 1999). "No matter how excessive (in lay terms) an administrative fine may appear, if the fine does not exceed the limits prescribed by the statute authorizing it, the fine does not violate the Eighth Amendment." *Newell Recycling Co. v. EPA*, 231 F.3d 204, 210 (5th Cir. 2000). That presumption would apply with even greater force in the tax context, as "the appropriate level or rate of taxation is essentially a matter for legislative, and not judicial, resolution." *Commonwealth Edison Co. v. Montana*, 453 U.S. 609, 627 (1981).

The excise tax bears a close and proportional relationship to the burdens on the fisc. The tax is imposed only if the manufacturer continues to sell the selected drug to Medicare at a non-negotiated price and only on sales of the selected drug that are reimbursed by Medicare. 26 U.S.C. § 5000D(b); IRS Notice 3. And the ratio of the tax

to the amount charged by the manufacturer falls between 65% and 95%, *see* 26 U.S.C. § 5000D(d); IRS Notice 3-4, which is within the range of constitutional exactions. *See, e.g.*, *United States v. Alt*, 83 F.3d 779, 782-83 (6th Cir. 1996) (81% civil fraud penalty). Indeed, because the tax attaches only to sales of the drug that are reimbursed by Medicare, the tax necessarily recoups only a portion of the outlays that the Medicare program or Medicare beneficiaries have paid for the drug.

Moreover, plaintiffs seek to enjoin their own interpretation of the excise tax, even though the IRS has explained that the tax is far lower than plaintiffs allege. *But see United States v. Hansen*, 599 U.S. 762, 781 (2023) (courts should not "manufacture conflict" between statutory text and Constitution). The IRS has made clear, in a notice that "taxpayers may rely on" now, that a covered taxpayer would owe a $95 tax out of $100 charged for a drug by a manufacturer.[6] *See* IRS Notice at 3, 5. In any event, because plaintiffs bring a facial challenge—before any tax has been assessed or collected—it must establish that the tax is "unconstitutional in all of its applications." *City of Los Angeles v. Patel*, 576 U.S. 409, 418 (2015) (quotation marks omitted). Therefore, to the extent the parties have a dispute about the applicable rate of tax that would apply, plaintiffs are entitled to relief only if the excise tax is unconstitutional applying IRS's interpretation of its scope and rate.

[6] The 95% rate applies only after 270 days have passed, 26 U.S.C. § 5000D(d)(4), and the IRS guidance assumes that the manufacturer does not separately state the tax on its invoice, IRS Notice 3-4.

III. The Negotiation Program complies with the Due Process Clause because it does not deprive plaintiffs any protected interests.

The Negotiation Program does not implicate plaintiffs' due process rights. The Due Process Clause protects against the deprivation "of life, liberty, or property, without due process of law." U.S. Const. amend. V. The threshold "inquiry in every due process challenge is whether the plaintiff has been deprived of a protected interest in 'property' or 'liberty.'" *American Mfrs. Mut. Ins. Co. v. Sullivan*, 526 U.S. 40, 59 (1999). Plaintiffs have not.

Property interests arise from an independent source, such as state or federal law. *See Board of Regents v. Roth*, 408 U.S. 564, 577 (1972). To have a constitutionally protected property interest, "a person clearly must have more than an abstract need or desire for" and "more than a unilateral expectation of" the property. *Id.* Rather, he must have an "individual entitlement" to the property, which "cannot be removed except 'for cause.'" *Logan v. Zimmerman Brush Co.*, 455 U.S. 422, 430 (1982); *see also Memphis Light, Gas & Water Div. v. Craft*, 436 U.S. 1, 11-12 (1978)

A. Manufacturers lack any a protected property interest in selling their drugs as part Medicare at particular price.

1. Plaintiffs assertion (at 51-54) that they have a right to sell their drugs as part of Medicare at their preferred price lacks merit. The Second and Third Circuits have correctly rejected parallel claims. *See AstraZeneca Pharms. LP v. HHS*, 137 F.4th 116, 125-26 (3d Cir. 2025); *Boehringer Ingelheim Pharms., Inc. v. HHS*, No. 24-2092, 2025 WL 2248727, at *10 (2d Cir. Aug. 7, 2025) (published).

a. "[N]o one has a 'right' to sell to the government that which the government does not wish to buy." *Coyne-Delany Co. v. Capital Dev. Bd.*, 616 F.2d 341, 342 (7th Cir. 1980) (per curiam). "Like private individuals and businesses, the Government enjoys the unrestricted power to produce its own supplies, to determine those with whom it will deal, and to fix the terms and conditions upon which it will make needed purchases." *Perkins*, 310 U.S. at 127.

Pursuant to the government's power to determine the prices it will pay for goods and services, other federal agencies have for decades negotiated with drug manufacturers over the price paid for drugs in other government programs. *E.g.*, 38 U.S.C. § 8126(a)-(h). Similarly, as a condition of Medicaid participation, drug manufacturers have long entered into agreements to provide drugs to certain healthcare facilities subject to statutory price ceilings. *See Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 113 (2011) (describing requirements under Section 340B of the Public Health Service Act). And the government regularly negotiates the price it will pay for other goods. *See, e.g.*, 48 C.F.R. pts. 15, 215. Just as military contractors have no right to sell their products to the Department of Defense at prices above what the government is willing to pay, "[t]here is no protected property interest in selling goods to Medicare beneficiaries (through sponsors or pharmacy benefit plans) at a price higher than what the government is willing to pay when it reimburses those costs." *AstraZeneca*, 137 F.4th at 125-26.

In negotiating the price that Medicare will pay for drugs, the government is acting as a market participant. The IRA sets the terms of the government's offer to pay for certain drugs. While manufacturers may use their market power to negotiate with the government, they have no right to force the government to pay for their drugs on specific terms. Plaintiffs' contrary view does not reflect how the market works, nor is it consistent with Congress's undoubted authority to control federal spending. The Negotiation Program reflects Congress's judgment that American taxpayers have been spending too much on high-cost prescription drugs, and the government has a strong interest in controlling federal spending to promote the general welfare. *See Sabri v. United States*, 541 U.S. 600, 608 (2004) ("The power to keep a watchful eye on expenditures … is bound up with congressional authority to spend in the first place ….").

Plaintiffs' argument, in part, rests (at 59) on a misunderstanding of the relationship between the Negotiation Program and the rest of the market for prescription drugs. A negotiated price applies only to drugs purchased through Medicare Part B or D. Thus, the Negotiation Program does not control the price paid for a drug by any person who is not a Medicare beneficiary or by any private insurance plan. Nor does the Negotiation Program even control the price paid for Medicare beneficiaries who, for whatever reason, chose to purchase their drugs without using their Part B or D benefits—*i.e.*, who choose to pay cash when filing their prescriptions. *See, e.g.*, 42 C.F.R. § 423.120(c)(3) (permitting an individual at an

in-network pharmacy to request that the pharmacy not bill the individual's Part D plan). "[T]he Negotiation Program only sets prices for drugs *that CMS pays for* when it reimburses sponsors" of Parts B and D plans. *AstraZeneca*, 137 F.4th at 126. And the government may decide how much it is willing to spend on prescription drug coverage.

b. Contrary to plaintiffs' contention, *Old Dearborn Distributing Co. v. Seagram-Distillers Corp.*, 299 U.S. 183 (1936), does not support their asserted property interest in deciding "the price at which [they] will sell products." Br. 52-53 (quoting *Old Dearborn*, 299 U.S. at 192). Citing a line of cases that have since been overruled, *Old Dearborn* asserted that legislatures generally may not impair "the right of the owner of property to fix the price at which he will sell" his property in the broader marketplace. 299 U.S. at 192. But the Supreme Court has since held that the Constitution does not substantively constrain a legislature's ability to fix the price of goods. *Olsen v. Nebraska ex rel. Western Reference & Bond Ass'n*, 313 U.S. 236, 247 (1941); *see also Nebbia v. New York*, 291 U.S. 502, 516 (1934) ("So far as the requirement of due process is concerned, and in the absence of other constitutional restriction, a state is free to adopt whatever economic policy may reasonably be deemed to promote public welfare….."). And *Old Dearborn* itself expressly affirmed the validity of legislation that allowed parties to fix the price of goods by contract. 299 U.S. at 192. Even on its terms, it did not recognize a freestanding property right to force a price on an unwilling buyer.

Plaintiffs fare no better in gesturing to manufacturers' patent rights. "[F]ederal patent laws do not create any affirmative right to … sell anything," *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1372 (Fed. Cir. 2007) (quotation marks omitted), much less a right to command a particular price, *AstraZeneca*, 137 F.4th at 125. While a patentee may use its exclusive right to sell a drug as leverage in the marketplace, the freedom from competitive pressure conferred by the period of exclusivity does not entitle the patentee to any particular revenue from any particular buyer. Plaintiffs fail to allege any deprivation of patent rights, so those rights may not form the basis of a due process claim.

2. Even if manufacturers could establish a protected interest, the Negotiation Program does not deprive them of anything. Plaintiffs have failed to develop, and thus to preserve, any argument about how the Negotiation Program deprives manufacturers of property beyond their reliance on *Old Dearborn*. But in any event, such arguments would be meritless.

No manufacturer is compelled to participate in the Negotiation Program. As every court to consider the question has concluded, participation in Medicare is a voluntary choice. *See, e.g.*, *Burditt v. HHS*, 934 F.2d 1362, 1376 (5th Cir. 1991); *Baptist Hosp. E. v. HHS*, 802 F.2d 860, 870 (6th Cir. 1986). Participation does not become involuntary just because participation is particularly lucrative. *See, e.g.*, *Garelick v. Sullivan*, 987 F.2d 913, 917 (2d Cir. 1993). A manufacturer with a drug selected for the Negotiation Program has a choice: it may remain in Medicare because it concludes

that the benefits still outweigh the burdens or it may withdraw in as little as 30 days, *see* 42 U.S.C. §§ 1395w-114a(b)(4)(B)(i), 1395w-114c(b)(4)(B)(i); Revised Guidance 33-34; *Bristol Myers Squibb Co. v. HHS*, No. 24-1820, 24-1821, 2025 WL 2537005, at *7-8 (3d Cir. Sept. 4, 2025) (published). Nor is *NFIB* to the contrary. That decision addressed federalism-based limits on the conditions that Congress may attach to money it grants to States. *See NFIB*, 567 U.S. at 578-79 (lead opinion); *see also Bristol Myers*, 2025 WL 2537005, at *6 (rejecting similar argument by highlighting "*NFIB*'s explicit and repeated focus on federalism and the States' role as distinct sovereigns"); *Boehringer*, 2025 WL 2248727, at *8 ("[T]he Supreme Court's holding in NFIB very clearly derived from federalism concerns, *i.e.*, the scope of the federal government's authority to regulate the states."). These limits on Congress's ability to "encourage a State to regulate in a particular way," *NFIB*, 567 U.S. at 576 (lead opinion) (quotation marks omitted), do not similarly restrict the government's ability to procure goods from private companies or support the contention that such offers to pay for goods can be coercive in any constitutional sense.

Plaintiffs' insistence that manufacturers' participation in Medicare is involuntary would be relevant to the due process analysis only to the extent they argue that the government coercion is the mechanism by which manufactures are deprived of their purported interests. Despite plaintiffs' assertion (64 n.8) to the contrary, the Second Circuit in *Boehringer* did not conclude that the Due Process Clause contains an exception for voluntary government programs. Instead, the court held that a

manufacturer cannot allege a deprivation of property because it is coerced to sell drugs at a government-set price when that manufacturer has the option to withdraw from the government program. *Boehringer*, 2025 WL 2248727, at *10. Plaintiffs' reliance (at 63-64) on cases concerning market-wide price-control regimes underscores the lack of a protected property interest in these circumstances. Unlike the provisions challenged in *Bowles*, 321 U.S. at 519-21, in which Congress sought to regulate the price at which any person could lease his property to *any* buyer, the Negotiation Program does not regulate the price at which manufacturers may sell their drugs except in circumstances where a buyer uses Medicare Part B or D to pay for the drugs. *See AstraZeneca*, 137 F.4th at 126 ("These are not private market transactions, regardless of the private hands through which CMS's funds pass."). And plaintiffs offer no sound reason to extend the analysis that applies to market-wide price restrictions to a law that governs only the procedures used to determine the price the government itself is willing to pay.

B. The Negotiation Program will not deprive providers of any protected property interests.

1. Plaintiffs assert that "[p]roviders have a protected interest in being reimbursed [for drugs they administer] on a non-arbitrary basis at a lawful rate," Br. 55, but they fail to recognize that a provider's right to Medicare reimbursement depends entirely on the Medicare Act. The very cases plaintiffs rely on rest on this principle. *See Rock River Health Care, LLC v. Eagleson*, 14 F.4th 768, 774 (7th Cir. 2021)

("The Providers do not have a legitimate claim of entitlement to whatever rate they believe is appropriate, but they do have a legitimate claim of entitlement to reimbursement *at the rate as established under the law*." (emphasis added)); *Furlong v. Shalala*, 156 F.3d 384, 393 (2d Cir. 1998) ("[P]rofessionals who provide services under a federal program such as Medicaid or Medicare have a property interest in reimbursement for their services *at the* '*duly promulgated reimbursement rate*.'" (emphasis added)). A provider might have a viable claim if CMS deprived it of payment for services already rendered and refused the provider a meaningful opportunity to be heard. But a provider has no due process right to weigh in on what CMS is willing to pay for future administrations of drugs. Indeed, a provider does not even have "a property interest in continued participation or reimbursement" in "federal health care programs." *Shah v. Azar*, 920 F.3d 987, 998 (5th Cir. 2019).

Providers are entitled to be paid for Part B drugs at under the statutory reimbursement formula. *See* 42 U.S.C. § 1395w-3a(b)(1)(A)-(B), (b)(3) (providing the reimbursement formula as 106% of "the volume-weighted average formula of the average sales price" for non-negotiated drugs and 106% of the maximum fair price for drugs selected for the Negotiation Program). Congress has thus established the rate at which plaintiffs are entitled to be reimbursed, and plaintiffs have no "legitimate claim of entitlement" to anything more. *See Rock River*, 14 F.4th at 774; *see also Personal Care Prods., Inc. v. Hawkins*, 635 F.3d 155, 159 (5th Cir. 2011) (Medicaid supplier has no "property interest in its present reimbursement claims while past claims are under

investigation for fraud" because regulations permit reimbursements to be withheld pending investigations). And plaintiffs reference to their investment of resources into "developing facilities and processes for administering Medicare-reimbursed drugs," Br. 55, is a non-sequitur. Plaintiffs do not allege that the government is depriving them of their facilities and processes. Nor can a contractor who builds a facility expecting future government contracts claim entitlement to enough government largess to make good its investment. *See College Sav. Bank v. Florida Prepaid Postsecondary Educ. Expense Bd.*, 527 U.S. 666, 672 (1999) (explaining that a "generalized right to be secure in one's business interests" is not "a property right protected by the Due Process Clause").

2. This Court's decision in *NICA I* does not command a different result. At that stage in the proceedings, this Court reversed an order dismissing this suit for improper venue. *See* 116 F.4th 488, 496, 509 (5th Cir. 2024). To resolve that venue question, this Court first considered a subsidiary question of NICA's Article III standing. As part of that standing analysis, at the motion-to-dismiss stage, this Court concluded that NICA "has a concrete interest in not seeing its members' revenue decrease as a result of allegedly unconstitutional government action." *Id.* at 503. But "whether a party bringing a due process claim has a 'colorable claim' to a protected property interest for purposes of standing is a different question from whether, on consideration of the merits, the party in fact has a protected property interest." *Boehringer*, 2025 WL 2248727, at *10 n.12 (citing *Booker-El v. Superintendent, Ind. State*

Prison, 668 F.3d 896, 899-901 (7th Cir. 2012) (holding that the plaintiff had adequately pleaded an injury-in-fact based on "a substantial risk in losing benefits" but also holding on the merits that the plaintiff lacked a property interest in those same benefits)). *NICA I* did not resolve that merits question, which the government never briefed, during an appeal about standing and venue. And the clear answer is that providers have suffered no deprivation of property.

C. Patients have no protected interests implicated by the Negotiation Program.

Plaintiffs assert (at 55, 64-65) that which drugs are selected for the Negotiation Program matters to some patients. The Due Process Clause, however, does not protect any right of access to prescription drugs. *See Abigail All. for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 703-11 (D.C. Cir. 2007) (Due Process Clause does not protect right to experimental drugs); *id.* at 710 n.18 (collecting cases); *cf. Washington v. Glucksberg*, 521 U.S. 702, 735 (1997) (Due Process Clause does not protect substantive right to assisted suicide). Plaintiffs provide no authority to the contrary. And even if plaintiffs could establish a protected interest in the availability of drugs, they fail to show any deprivation of that interest. Plaintiffs' offer only the *ipse dixit* that the Negotiation Program "could result in millions of Americans losing access to their critical medicines," Br. 65, without citation or evidentiary support. That conclusory allegation cannot support a due process claim.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be affirmed.

Respectfully submitted,

ERIC J. HAMILTON
Deputy Assistant Attorney General[*]
JUSTIN R. SIMMONS
United States Attorney

MICHAEL S. RAAB

/s/ Maxwell A. Baldi
MAXWELL A. BALDI
Attorneys, Appellate Staff
Civil Division, Room 7513
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530
(202) 532-0211
maxwell.baldi@usdoj.gov

Of Counsel:
ROBERT FOX FOSTER
Acting General Counsel
ELIZABETH C. KELLEY
Acting General Counsel
JOCELYN S. BEER
Acting Deputy Associate General Counsel for Litigation
KENNETH R. WHITLEY
ANANT KUMAR
Attorneys
U.S. Department of Health and Human Services

SEPTEMBER 2025

[*] The Assistant Attorney General is recused in this matter.

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 12,967 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Word for Microsoft 365 in Garamond 14-point font, a proportionally spaced typeface.

/s/ Maxwell A. Baldi
MAXWELL A. BALDI

United States Court of Appeals

FIFTH CIRCUIT
OFFICE OF THE CLERK

LYLE W. CAYCE
CLERK

TEL. 504-310-7700
600 S. MAESTRI PLACE,
Suite 115
NEW ORLEANS, LA 70130

September 19, 2025

Mr. Maxwell A. Baldi
U.S. Department of Justice
Civil Division, Appellate Section
950 Pennsylvania Avenue, N.W.
Washington, DC 20530

No. 25-50661 Natl Infusion Center v. Kennedy
USDC No. 1:23-CV-707

Dear Mr. Baldi,

You must submit the 6 paper copies of your brief required by 5th Cir. R. 31.1 within 5 days of the date of this notice pursuant to 5th Cir. ECF Filing Standard E.1. Failure to timely provide the appropriate number of copies may result in the dismissal of your appeal pursuant to 5th Cir. R. 42.3.

Sincerely,

LYLE W. CAYCE, Clerk

By: _____
Casey A. Sullivan, Deputy Clerk
504-310-7642

cc:
Mr. Timothy A. Cleveland
Mr. John Patrick Elwood
Mr. Jeffrey Handwerker
Mr. Allon Kedem
Mr. Michael Strauss Kolber
Mr. Austin Krist
Mr. William Perdue
Mr. Stephen Michael Pezzi
Ms. Allissa Aileen Rose Pollard

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 United States District Court
for the Western District of Texas

STATUTORY ADDENDUM

Of Counsel:

ROBERT FOX FOSTER
Acting General Counsel

ELIZABETH C. KELLEY
Acting Deputy General Counsel

JOCELYN S. BEER
Acting Deputy Associate General Counsel for Litigation

KENNETH R. WHITLEY
ANANT KUMAR
Attorneys
U.S. Department of Health and Human Services

ERIC J. HAMILTON
Deputy Assistant Attorney General

JUSTIN R. SIMMONS
United States Attorney

MICHAEL S. RAAB
MAXWELL A. BALDI
Attorneys, Appellate Staff
Civil Division, Room 7513
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530
(202) 532-0211

TABLE OF CONTENTS

42 U.S.C. § 1320f

§ 1320f. Establishment of program

(a) In general

The Secretary shall establish a Drug Price Negotiation Program (in this part referred to as the "program"). Under the program, with respect to each price applicability period, the Secretary shall—

(1) publish a list of selected drugs in accordance with section 1320f–1 of this title;

(2) enter into agreements with manufacturers of selected drugs with respect to such period, in accordance with section 1320f–2 of this title;

(3) negotiate and, if applicable, renegotiate maximum fair prices for such selected drugs, in accordance with section 1320f–3 of this title;[*]

(4) carry out the publication and administrative duties and compliance monitoring in accordance with sections 1320f–4 and 1320f–5 of this title.

(b) Definitions relating to timing

For purposes of this part:

(1) Initial price applicability year

The term "initial price applicability year" means a year (beginning with 2026).

(2) Price applicability period

The term "price applicability period" means, with respect to a qualifying single source drug, the period beginning with the first initial price applicability year with respect to which such drug is a selected drug and ending with the last year during which the drug is a selected drug.

(3) Selected drug publication date

The term "selected drug publication date" means, with respect to each initial price applicability year, February 1 of the year that begins 2 years prior to such year.[†]

---

[*] So in original. Probably should be followed by "and".

[†] So in original. Probably should read as follows: "during the most recent 12-month period for which data are available prior to such selected drug publication date (but ending no later than October 31 of the year prior to the year of such drug publication date)".

(4) Negotiation period

The term "negotiation period" means, with respect to an initial price applicability year with respect to a selected drug, the period—

(A) beginning on the sooner of—

(i) the date on which the manufacturer of the drug and the Secretary enter into an agreement under section 1320f–2 of this title with respect to such drug; or

(ii) February 28 following the selected drug publication date with respect to such selected drug; and

(B) ending on November 1 of the year that begins 2 years prior to the initial price applicability year.

(c) Other definitions

For purposes of this part:

(1) Manufacturer

The term "manufacturer" has the meaning given that term in section 1395w–3a(c)(6)(A) of this title.

(2) Maximum fair price eligible individual

The term "maximum fair price eligible individual" means, with respect to a selected drug—

(A) in the case such drug is dispensed to the individual at a pharmacy, by a mail order service, or by another dispenser, an individual who is enrolled in a prescription drug plan under part D of subchapter XVIII or an MA–PD plan under part C of such subchapter if coverage is provided under such plan for such selected drug; and

(B) in the case such drug is furnished or administered to the individual by a hospital, physician, or other provider of services or supplier, an individual who is enrolled under part B of subchapter XVIII, including an individual who is enrolled in an MA plan under part C of such subchapter, if payment may be made under part B for such selected drug.

(3) Maximum fair price

The term "maximum fair price" means, with respect to a year during a price applicability period and with respect to a selected drug (as defined in section 1320f–1(c) of this title) with respect to such period, the price negotiated pursuant

to section 1320f–3 of this title, and updated pursuant to section 1320f–4(b) of this title, as applicable, for such drug and year.

(4) Reference product

The term "reference product" has the meaning given such term in section 262(i) of this title.

(5) Total expenditures

The term "total expenditures" includes, in the case of expenditures with respect to part D of subchapter XVIII, the total gross covered prescription drug costs (as defined in section 1395w–115(b)(3) of this title). The term "total expenditures" excludes, in the case of expenditures with respect to part B of such subchapter, expenditures for a drug or biological product that are bundled or packaged into the payment for another service.

(6) Unit

The term "unit" means, with respect to a drug or biological product, the lowest identifiable amount (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological product that is dispensed or furnished.

(d) Timing for initial price applicability year 2026

Notwithstanding the provisions of this part, in the case of initial price applicability year 2026, the following rules shall apply for purposes of implementing the program:

(1) Subsection (b)(3) shall be applied by substituting "September 1, 2023" for ", with respect to each initial price applicability year, February 1 of the year that begins 2 years prior to such year".

(2) Subsection (b)(4) shall be applied—

(A) in subparagraph (A)(ii), by substituting "October 1, 2023" for "February 28 following the selected drug publication date with respect to such selected drug"; and

(B) in subparagraph (B), by substituting "August 1, 2024" for "November 1 of the year that begins 2 years prior to the initial price applicability year".

(3) Section 1320f–1 of this title shall be applied—

(A) in subsection (b)(1)(A), by substituting "during the period beginning on June 1, 2022, and ending on May 31, 2023" for "during the most recent period of 12 months prior to the selected drug publication date (but ending not later than October 31 of the year prior to the year of such drug publication date), with respect to such year, for which data are available"; and

(B) in subsection (d)(1)(A), by substituting "during the period beginning on June 1, 2022, and ending on May 31, 2023" for "during the most recent period for which data are available of at least 12 months prior to the selected drug publication date (but ending no later than October 31 of the year prior to the year of such drug publication date), with respect to such year".[2]

(4) Section 1320f–2(a) of this title shall be applied by substituting "October 1, 2023" for "February 28 following the selected drug publication date with respect to such selected drug".

(5) Section 1320f–3(b)(2) of this title shall be applied—

(A) in subparagraph (A), by substituting "October 2, 2023" for "March 1 of the year of the selected drug publication date, with respect to the selected drug";

(B) in subparagraph (B), by substituting "February 1, 2024" for "the June 1 following the selected drug publication date"; and

(C) in subparagraph (E), by substituting "August 1, 2024" for "the first day of November following the selected drug publication date, with respect to the initial price applicability year".

(6) Section 1320f–4(a)(1) of this title shall be applied by substituting "September 1, 2024" for "November 30 of the year that is 2 years prior to such initial price applicability year".

42 U.S.C. § 1320f-1

§ 1320f-1. Selection of negotiation-eligible drugs as selected drugs

(a) In general

Not later than the selected drug publication date with respect to an initial price applicability year, in accordance with subsection (b), the Secretary shall select and publish a list of—

(1) with respect to the initial price applicability year 2026, 10 negotiation-eligible drugs described in subparagraph (A) of subsection (d)(1), but not subparagraph (B) of such subsection, with respect to such year (or, all (if such number is less than 10) such negotiation-eligible drugs with respect to such year);

(2) with respect to the initial price applicability year 2027, 15 negotiation-eligible drugs described in subparagraph (A) of subsection (d)(1), but not subparagraph (B) of such subsection, with respect to such year (or, all (if such number is less than 15) such negotiation-eligible drugs with respect to such year);

(3) with respect to the initial price applicability year 2028, 15 negotiation-eligible drugs described in subparagraph (A) or (B) of subsection (d)(1) with respect to such year (or, all (if such number is less than 15) such negotiation-eligible drugs with respect to such year); and

(4) with respect to the initial price applicability year 2029 or a subsequent year, 20 negotiation-eligible drugs described in subparagraph (A) or (B) of subsection (d)(1), with respect to such year (or, all (if such number is less than 20) such negotiation-eligible drugs with respect to such year).

Subject to subsection (c)(2) and section 1320f–3(f)(5) of this title, each drug published on the list pursuant to the previous sentence and subsection (b)(3) shall be subject to the negotiation process under section 1320f–3 of this title for the negotiation period with respect to such initial price applicability year (and the renegotiation process under such section as applicable for any subsequent year during the applicable price applicability period).

(b) Selection of drugs

(1) In general

In carrying out subsection (a), subject to paragraph (2), the Secretary shall, with respect to an initial price applicability year, do the following:

(A) Rank negotiation-eligible drugs described in subsection (d)(1) according to the total expenditures for such drugs under parts B and D of subchapter XVIII, as determined by the Secretary, during the most recent period of 12

months prior to the selected drug publication date (but ending not later than October 31 of the year prior to the year of such drug publication date), with respect to such year, for which data are available, with the negotiation-eligible drugs with the highest total expenditures being ranked the highest.

(B) Select from such ranked drugs with respect to such year the negotiation-eligible drugs with the highest such rankings.

(C) In the case of a biological product for which the inclusion of the biological product as a selected drug on a list published under subsection (a) has been delayed under subsection (f)(2), remove such biological product from the rankings under subparagraph (A) before making the selections under subparagraph (B).

(2) High spend part D drugs for 2026 and 2027

With respect to the initial price applicability year 2026 and with respect to the initial price applicability year 2027, the Secretary shall apply paragraph (1) as if the reference to "negotiation-eligible drugs described in subsection (d)(1)" were a reference to "negotiation-eligible drugs described in subsection (d)(1)(A)" and as if the reference to "total expenditures for such drugs under parts B and D of subchapter XVIII" were a reference to "total expenditures for such drugs under part D of subchapter XVIII".

(3) Inclusion of delayed biological products

Pursuant to subparagraphs (B)(ii)(I) and (C)(i) of subsection (f)(2), the Secretary shall select and include on the list published under subsection (a) the biological products described in such subparagraphs. Such biological products shall count towards the required number of drugs to be selected under subsection (a)(1).

(c) Selected drug

(1) In general

For purposes of this part, in accordance with subsection (e)(2) and subject to paragraph (2), each negotiation-eligible drug included on the list published under subsection (a) with respect to an initial price applicability year shall be referred to as a "selected drug" with respect to such year and each subsequent year beginning before the first year that begins at least 9 months after the date on which the Secretary determines at least one drug or biological product—

(A) is approved or licensed (as applicable)—

(i) under section 355(j) of title 21 using such drug as the listed drug; or

(ii) under section 262(k) of this title using such drug as the reference product; and

(B) is marketed pursuant to such approval or licensure.

(2) Clarification

A negotiation-eligible drug—

(A) that is included on the list published under subsection (a) with respect to an initial price applicability year; and

(B) for which the Secretary makes a determination described in paragraph (1) before or during the negotiation period with respect to such initial price applicability year;

shall not be subject to the negotiation process under section 1320f–3 of this title with respect to such negotiation period and shall continue to be considered a selected drug under this part with respect to the number of negotiation-eligible drugs published on the list under subsection (a) with respect to such initial price applicability year.

(d) Negotiation-eligible drug

(1) In general

For purposes of this part, subject to paragraph (2), the term "negotiation-eligible drug" means, with respect to the selected drug publication date with respect to an initial price applicability year, a qualifying single source drug, as defined in subsection (e), that is described in either of the following subparagraphs (or, with respect to the initial price applicability year 2026 or 2027, that is described in subparagraph (A)):

(A) Part D high spend drugs

The qualifying single source drug is, determined in accordance with subsection (e)(2), among the 50 qualifying single source drugs with the highest total expenditures under part D of subchapter XVIII, as determined by the Secretary in accordance with paragraph (3), during the most recent 12-month period for which data are available prior to such selected drug publication date (but ending no later than October 31 of the year prior to the year of such drug publication date).

(B) Part B high spend drugs

The qualifying single source drug is, determined in accordance with subsection (e)(2), among the 50 qualifying single source drugs with the highest total expenditures under part B of subchapter XVIII, as determined by the

Secretary in accordance with paragraph (3), during such most recent 12-month period, as described in subparagraph (A).

(2) Exception for small biotech drugs

(A) In general

Subject to subparagraph (C), the term "negotiation-eligible drug" shall not include, with respect to the initial price applicability years 2026, 2027, and 2028, a qualifying single source drug that meets either of the following:

(i) Part D drugs

The total expenditures for the qualifying single source drug under part D of subchapter XVIII, as determined by the Secretary in accordance with paragraph (3)(B), during 2021—

(I) are equal to or less than 1 percent of the total expenditures under such part D, as so determined, for all covered part D drugs (as defined in section 1395w–102(e) of this title) during such year; and

(II) are equal to at least 80 percent of the total expenditures under such part D, as so determined, for all covered part D drugs for which the manufacturer of the drug has an agreement in effect under section 1395w–114a of this title during such year.

(ii) Part B drugs

The total expenditures for the qualifying single source drug under part B of subchapter XVIII, as determined by the Secretary in accordance with paragraph (3)(B), during 2021—

(I) are equal to or less than 1 percent of the total expenditures under such part B, as so determined, for all qualifying single source drugs for which payment may be made under such part B during such year; and

(II) are equal to at least 80 percent of the total expenditures under such part B, as so determined, for all qualifying single source drugs of the manufacturer for which payment may be made under such part B during such year.

(B) Clarifications relating to manufacturers

(i) Aggregation rule

All persons treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 shall be treated as one manufacturer for purposes of this paragraph.

(ii) Limitation

A drug shall not be considered to be a qualifying single source drug described in clause (i) or (ii) of subparagraph (A) if the manufacturer of such drug is acquired after 2021 by another manufacturer that does not meet the definition of a specified manufacturer under section 1395w–114c(g)(4)(B)(ii) of this title, effective at the beginning of the plan year immediately following such acquisition or, in the case of an acquisition before 2025, effective January 1, 2025.

(C) Drugs not included as small biotech drugs

A new formulation, such as an extended release formulation, of a qualifying single source drug shall not be considered a qualifying single source drug described in subparagraph (A).

(3) Clarifications and determinations

(A) Previously selected drugs and small biotech drugs excluded

In applying subparagraphs (A) and (B) of paragraph (1), the Secretary shall not consider or count—

(i) drugs that are already selected drugs; and

(ii) for initial price applicability years 2026, 2027, and 2028, qualifying single source drugs described in paragraph (2)(A).

(B) Use of data

In determining whether a qualifying single source drug satisfies any of the criteria described in paragraph (1) or (2), the Secretary shall use data that is aggregated across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation, and not based on the specific formulation or package size or package type of the drug.

(e) Qualifying single source drug

(1) In general

For purposes of this part, the term "qualifying single source drug" means, with respect to an initial price applicability year, subject to paragraphs (2) and (3), a covered part D drug (as defined in section 1395w–102(e) of this title) that is described in any of the following or a drug or biological product for which payment may be made under part B of subchapter XVIII that is described in any of the following:

(A) Drug products

A drug—

(i) that is approved under section 355(c) of title 21 and is marketed pursuant to such approval;

(ii) for which, as of the selected drug publication date with respect to such initial price applicability year, at least 7 years will have elapsed since the date of such approval; and

(iii) that is not the listed drug for any drug that is approved and marketed under section 355(j) of such title.

(B) Biological products

A biological product—

(i) that is licensed under section 262(a) of this title and is marketed under section 262 of this title;

(ii) for which, as of the selected drug publication date with respect to such initial price applicability year, at least 11 years will have elapsed since the date of such licensure; and

(iii) that is not the reference product for any biological product that is licensed and marketed under section 262(k) of this title.

(2) Treatment of authorized generic drugs

(A) In general

In the case of a qualifying single source drug described in subparagraph (A) or (B) of paragraph (1) that is the listed drug (as such term is used in section 355(j) of title 21) or a product described in clause (ii) of subparagraph (B), with respect to an authorized generic drug, in applying the provisions of this part, such authorized generic drug and such listed drug or such product shall be treated as the same qualifying single source drug.

(B) Authorized generic drug defined

For purposes of this paragraph, the term "authorized generic drug" means—

(i) in the case of a drug, an authorized generic drug (as such term is defined in section 355(t)(3) of title 21); and

(ii) in the case of a biological product, a product that—

(I) has been licensed under section 262(a) of this title; and

(II) is marketed, sold, or distributed directly or indirectly to retail class of trade under a different labeling, packaging (other than repackaging as the reference product in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trade mark than the reference product.

(3) Exclusions

In this part, the term "qualifying single source drug" does not include any of the following:

(A) Certain orphan drugs

A drug that is designated as a drug for only one rare disease or condition under section 360bb of title 21 and for which the only approved indication (or indications) is for such disease or condition.

(B) Low spend medicare drugs

A drug or biological product with respect to which the total expenditures under parts B and D of subchapter XVIII, as determined by the Secretary in accordance with subsection (d)(3)(B)—

(i) with respect to initial price applicability year 2026, is less than, during the period beginning on June 1, 2022, and ending on May 31, 2023, $200,000,000;

(ii) with respect to initial price applicability year 2027, is less than, during the most recent 12-month period applicable under subparagraphs (A) and (B) of subsection (d)(1) for such year, the dollar amount specified in clause (i) increased by the annual percentage increase in the consumer price index for all urban consumers (all items; United States city average) for the period beginning on June 1, 2023, and ending on September 30, 2024; or

(iii) with respect to a subsequent initial price applicability year, is less than, during the most recent 12-month period applicable under subparagraphs (A) and (B) of subsection (d)(1) for such year, the dollar amount specified in this subparagraph for the previous initial price applicability year increased by the annual percentage increase in such consumer price index for the 12-month period ending on September 30 of the year prior to the year of the selected drug publication date with respect to such subsequent initial price applicability year.

(C) Plasma-derived products

A biological product that is derived from human whole blood or plasma.

(f) Special rule to delay selection and negotiation of biologics for biosimilar market entry

(1) Application

(A) In general

Subject to subparagraph (B), in the case of a biological product that would (but for this subsection) be an extended-monopoly drug (as defined in section 1320f–3(c)(4) of this title) included as a selected drug on the list published under subsection (a) with respect to an initial price applicability year, the rules described in paragraph (2) shall apply if the Secretary determines that there is a high likelihood (as described in paragraph (3)) that a biosimilar biological product (for which such biological product will be the reference product) will be licensed and marketed under section 262(k) of this title before the date that is 2 years after the selected drug publication date with respect to such initial price applicability year.

(B) Request required

(i) In general

The Secretary shall not provide for a delay under—

(I) paragraph (2)(A) unless a request is made for such a delay by a manufacturer of a biosimilar biological product prior to the selected drug publication date for the list published under subsection (a) with respect to the initial price applicability year for which the biological product may have been included as a selected drug on such list but for subparagraph (2)(A); or

(II) paragraph (2)(B)(iii) unless a request is made for such a delay by such a manufacturer prior to the selected drug publication date for the list published under subsection (a) with respect to the initial price applicability year that is 1 year after the initial price applicability year for which the biological product described in subsection (a) would have been included as a selected drug on such list but for paragraph (2)(A).

(ii) Information and documents

(I) In general

A request made under clause (i) shall be submitted to the Secretary by such manufacturer at a time and in a form and manner specified by the Secretary, and contain—

(aa) information and documents necessary for the Secretary to make determinations under this subsection, as specified by the Secretary and including, to the extent available, items described in subclause (III); and

(bb) all agreements related to the biosimilar biological product filed with the Federal Trade Commission or the Assistant Attorney General pursuant to subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

(II) Additional information and documents

After the Secretary has reviewed the request and materials submitted under subclause (I), the manufacturer shall submit any additional information and documents requested by the Secretary necessary to make determinations under this subsection.

(III) Items described

The items described in this clause are the following:

(aa) The manufacturing schedule for such biosimilar biological product submitted to the Food and Drug Administration during its review of the application under such section 262(k) of this title.

(bb) Disclosures (in filings by the manufacturer of such biosimilar biological product with the Securities and Exchange Commission required under section 78l(b), 78l(g), 78m(a), or 78o(d) of title 15 about capital investment, revenue expectations, and actions taken by the manufacturer that are typical of the normal course of business in the year (or the 2 years, as applicable) before marketing of a biosimilar biological product) that pertain to the marketing of such biosimilar biological product, or comparable documentation that is distributed to the shareholders of privately held companies.

(C) Aggregation rule

(i) In general

All persons treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986, or in a partnership, shall be treated as one manufacturer for purposes of paragraph (2)(D)(iv).

(ii) Partnership defined

In clause (i), the term "partnership" means a syndicate, group, pool, joint venture, or other organization through or by means of which any business, financial operation, or venture is carried on by the manufacturer of the biological product and the manufacturer of the biosimilar biological product.

(2) Rules described

The rules described in this paragraph are the following:

(A) Delayed selection and negotiation for 1 year

If a determination of high likelihood is made under paragraph (3), the Secretary shall delay the inclusion of the biological product as a selected drug on the list published under subsection (a) until such list is published with respect to the initial price applicability year that is 1 year after the initial price applicability year for which the biological product would have been included as a selected drug on such list.

(B) If not licensed and marketed during the initial delay

(i) In general

If, during the time period between the selected drug publication date on which the biological product would have been included on the list as a selected drug pursuant to subsection (a) but for subparagraph (A) and the selected drug publication date with respect to the initial price applicability year that is 1 year after the initial price applicability year for which such biological product would have been included as a selected drug on such list, the Secretary determines that the biosimilar biological product for which the manufacturer submitted the request under paragraph (1)(B)(i)(II) (and for which the Secretary previously made a high likelihood determination under paragraph (3)) has not been licensed and marketed under section 262(k) of this title, the Secretary shall, at the request of such manufacturer—

(I) reevaluate whether there is a high likelihood (as described in paragraph (3)) that such biosimilar biological product will be licensed and marketed under such section 262(k) before the date that is 2 years after the selected drug publication date for which such biological product would have been included as a selected drug on such list published but for subparagraph (A); and

(II) evaluate whether, on the basis of clear and convincing evidence, the manufacturer of such biosimilar biological product has made a significant amount of progress (as determined by the Secretary) towards both such licensure and the marketing of such biosimilar biological product (based on information from items described in subclauses (I)(bb) and (II) of paragraph (1)(B)(ii)) since the receipt by the Secretary of the request made by such manufacturer under paragraph (1)(B)(i)(I).

(ii) Selection and negotiation

If the Secretary determines that there is not a high likelihood that such biosimilar biological product will be licensed and marketed as described in clause (i)(I) or there has not been a significant amount of progress as described in clause (i)(II)—

(I) the Secretary shall include the biological product as a selected drug on the list published under subsection (a) with respect to the initial price applicability year that is 1 year after the initial price applicability year for which such biological product would have been included as a selected drug on such list but for subparagraph (A); and

(II) the manufacturer of such biological product shall pay a rebate under paragraph (4) with respect to the year for which such manufacturer would have provided access to a maximum fair price for such biological product but for subparagraph (A).

(iii) Second 1-year delay

If the Secretary determines that there is a high likelihood that such biosimilar biological product will be licensed and marketed (as described in clause (i)(I)) and a significant amount of progress has been made by the manufacturer of such biosimilar biological product towards such licensure and marketing (as described in clause (i)(II)), the Secretary shall delay the inclusion of the biological product as a selected drug on the list published under subsection (a) until the selected drug publication date of such list with respect to the initial price applicability year that is 2 years after the initial price applicability year for which such biological product would have been included as a selected drug on such list but for this subsection.

(C) If not licensed and marketed during the year two delay

If, during the time period between the selected drug publication date of the list for which the biological product would have been included as a selected drug but for subparagraph (B)(iii) and the selected drug publication date with

respect to the initial price applicability year that is 2 years after the initial price applicability year for which such biological product would have been included as a selected drug on such list but for this subsection, the Secretary determines that such biosimilar biological product has not been licensed and marketed—

(i) the Secretary shall include such biological product as a selected drug on such list with respect to the initial price applicability year that is 2 years after the initial price applicability year for which such biological product would have been included as a selected drug on such list; and

(ii) the manufacturer of such biological product shall pay a rebate under paragraph (4) with respect to the years for which such manufacturer would have provided access to a maximum fair price for such biological product but for this subsection.

(D) Limitations on delays

(i) Limited to 2 years

In no case shall the Secretary delay the inclusion of a biological product on the list published under subsection (a) for more than 2 years.

(ii) Exclusion of biological products that transitioned to a long-monopoly drug during the delay

In the case of a biological product for which the inclusion on the list published pursuant to subsection (a) was delayed by 1 year under subparagraph (A) and for which there would have been a change in status to a long-monopoly drug (as defined in section 1320f–3(c)(5) of this title) if such biological product had been a selected drug, in no case may the Secretary provide for a second 1-year delay under subparagraph (B)(iii).

(iii) Exclusion of biological products if more than 1 year since licensure

In no case shall the Secretary delay the inclusion of a biological product on the list published under subsection (a) if more than 1 year has elapsed since the biosimilar biological product has been licensed under section 262(k) of this title and marketing has not commenced for such biosimilar biological product.

(iv) Certain manufacturers of biosimilar biological products excluded

In no case shall the Secretary delay the inclusion of a biological product as a selected drug on the list published under subsection (a) if Secretary

determined that the manufacturer of the biosimilar biological product described in paragraph (1)(A)—

(I) is the same as the manufacturer of the reference product described in such paragraph or is treated as being the same pursuant to paragraph (1)(C); or

(II) has, based on information from items described in paragraph (1)(B)(ii)(I)(bb), entered into any agreement described in such paragraph with the manufacturer of the reference product described in paragraph (1)(A) that—

(aa) requires or incentivizes the manufacturer of the biosimilar biological product to submit a request described in paragraph (1)(B); or

(bb) restricts the quantity (either directly or indirectly) of the biosimilar biological product that may be sold in the United States over a specified period of time.

(3) High likelihood

For purposes of this subsection, there is a high likelihood described in paragraph (1) or paragraph (2), as applicable, if the Secretary finds that—

(A) an application for licensure under section 262(k) of this title for the biosimilar biological product has been accepted for review or approved by the Food and Drug Administration; and

(B) information from items described in sub clauses* (I)(bb) and (III) of paragraph (1)(B)(ii) submitted to the Secretary by the manufacturer requesting a delay under such paragraph provides clear and convincing evidence that such biosimilar biological product will, within the time period specified under paragraph (1)(A) or (2)(B)(i)(I), be marketed.

(4) Rebate

(A) In general

For purposes of subparagraphs (B)(ii)(II) and (C)(ii) of paragraph (2), in the case of a biological product for which the inclusion on the list under subsection (a) was delayed under this subsection and for which the Secretary has negotiated and entered into an agreement under section 1320f–2 of this title with respect to such biological product, the manufacturer shall be

* So in original.

required to pay a rebate to the Secretary at such time and in such manner as determined by the Secretary.

(B) Amount

Subject to subparagraph (C), the amount of the rebate under subparagraph (A) with respect to a biological product shall be equal to the estimated amount—

(i) in the case of a biological product that is a covered part D drug (as defined in section 1395w–102(e) of this title), that is the sum of the products of—

(I) 75 percent of the amount by which—

(aa) the average manufacturer price, as reported by the manufacturer of such covered part D drug under section 1396r–8 of this title (or, if not reported by such manufacturer under section 1396r–8 of this title, as reported by such manufacturer to the Secretary pursuant to the agreement under section 1320f–2(a) of this title) for such biological product, with respect to each of the calendar quarters of the price applicability period that would have applied but for this subsection; exceeds

(bb) in the initial price applicability year that would have applied but for a delay under—

(AA) paragraph (2)(A), the maximum fair price negotiated under section 1320f–3 of this title for such biological product under such agreement; or

(BB) paragraph (2)(B)(iii), such maximum fair price, increased as described in section 1320f–4(b)(1)(A) of this title; and

(II) the number of units dispensed under part D of subchapter XVIII for such covered part D drug during each such calendar quarter of such price applicability period; and

(ii) in the case of a biological product for which payment may be made under part B of subchapter XVIII, that is the sum of the products of—

(I) 80 percent of the amount by which—

(aa) the payment amount for such biological product under section 1395w–3a(b) of this title, with respect to each of the

calendar quarters of the price applicability period that would have applied but for this subsection; exceeds

(bb) in the initial price applicability year that would have applied but for a delay under—

(AA) paragraph (2)(A), the maximum fair price negotiated under section 1320f–3 of this title for such biological product under such agreement; or

(BB) paragraph (2)(B)(iii), such maximum fair price, increased as described in section 1320f–4(b)(1)(A) of this title; and

(II) the number of units (excluding units that are packaged into the payment amount for an item or service and are not separately payable under such part B) of the billing and payment code of such biological product administered or furnished under such part B during each such calendar quarter of such price applicability period.

(C) Special rule for delayed biological products that are long-monopoly drugs

(i) In general

In the case of a biological product with respect to which a rebate is required to be paid under this paragraph, if such biological product qualifies as a long-monopoly drug (as defined in section 1320f–3(c)(5) of this title) at the time of its inclusion on the list published under subsection (a), in determining the amount of the rebate for such biological product under subparagraph (B), the amount described in clause (ii) shall be substituted for the maximum fair price described in clause (i)(I) or (ii)(I) of such subparagraph (B), as applicable.

(ii) Amount described

The amount described in this clause is an amount equal to 65 percent of the average non-Federal average manufacturer price for the biological product for 2021 (or, in the case that there is not an average non-Federal average manufacturer price available for such biological product for 2021, for the first full year following the market entry for such biological product), increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year prior to the selected drug publication date with respect to the initial price applicability year that would have applied but for this subsection.

(D) Rebate deposits

Amounts paid as rebates under this paragraph shall be deposited into—

(i) in the case payment is made for such biological product under part B of subchapter XVIII, the Federal Supplementary Medical Insurance Trust Fund established under section 1395t of this title; and

(ii) in the case such biological product is a covered part D drug (as defined in section 1395w–102(e) of this title), the Medicare Prescription Drug Account under section 1395w–116 of this title in such Trust Fund.

(5) Definitions of biosimilar biological product

In this subsection, the term "biosimilar biological product" has the meaning given such term in section 1395w–3a(c)(6) of this title.

42 U.S.C. § 1320f-2

§ 1320f-2. Manufacturer agreements

(a) In general

For purposes of section 1320f(a)(2) of this title, the Secretary shall enter into agreements with manufacturers of selected drugs with respect to a price applicability period, by not later than February 28 following the selected drug publication date with respect to such selected drug, under which—

(1) during the negotiation period for the initial price applicability year for the selected drug, the Secretary and the manufacturer, in accordance with section 1320f–3 of this title, negotiate to determine (and, by not later than the last date of such period, agree to) a maximum fair price for such selected drug of the manufacturer in order for the manufacturer to provide access to such price—

(A) to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (A) of section 1320f(c)(2) of this title and are dispensed such drug (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed such drugs) during, subject to paragraph (2), the price applicability period; and

(B) to hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (B) of such section and are furnished or administered such drug during, subject to paragraph (2), the price applicability period;

(2) the Secretary and the manufacturer shall, in accordance with section 1320f–3 of this title, renegotiate (and, by not later than the last date of the period of renegotiation, agree to) the maximum fair price for such drug, in order for the manufacturer to provide access to such maximum fair price (as so renegotiated)—

(A) to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (A) of section 1320f(c)(2) of this title and are dispensed such drug (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed such drugs) during any year during the price applicability period (beginning after such renegotiation) with respect to such selected drug; and

(B) to hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (B) of such section and are furnished or administered such drug during any year described in subparagraph (A);

(3) subject to subsection (d), access to the maximum fair price (including as renegotiated pursuant to paragraph (2)), with respect to such a selected drug, shall be provided by the manufacturer to—

(A) maximum fair price eligible individuals, who with respect to such drug are described in subparagraph (A) of section 1320f(c)(2) of this title, at the pharmacy, mail order service, or other dispenser at the point-of-sale of such drug (and shall be provided by the manufacturer to the pharmacy, mail order service, or other dispenser, with respect to such maximum fair price eligible individuals who are dispensed such drugs), as described in paragraph (1)(A) or (2)(A), as applicable; and

(B) hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (B) of such section and are furnished or administered such drug, as described in paragraph (1)(B) or (2)(B), as applicable;

(4) the manufacturer submits to the Secretary, in a form and manner specified by the Secretary, for the negotiation period for the price applicability period (and, if applicable, before any period of renegotiation pursuant to section 1320f–3(f) of this title), and for section 1320f–1(f) of this title, with respect to such drug—

(A) information on the non-Federal average manufacturer price (as defined in section 8126(h)(5) of title 38) for the drug for the applicable year or period;

(B) information that the Secretary requires to carry out the negotiation (or renegotiation process) under this part; and

(C) information that the Secretary requires to carry out section 1320f–1(f) of this title, including rebates under paragraph (4) of such section; and

(5) the manufacturer complies with requirements determined by the Secretary to be necessary for purposes of administering the program and monitoring compliance with the program.

(b) Agreement in effect until drug is no longer a selected drug

An agreement entered into under this section shall be effective, with respect to a selected drug, until such drug is no longer considered a selected drug under section 1320f–1(c) of this title.

(c) Confidentiality of information

Information submitted to the Secretary under this part by a manufacturer of a selected drug that is proprietary information of such manufacturer (as determined by the

Secretary) shall be used only by the Secretary or disclosed to and used by the Comptroller General of the United States for purposes of carrying out this part.

(d) Nonduplication with 340B ceiling price

Under an agreement entered into under this section, the manufacturer of a selected drug—

(1) shall not be required to provide access to the maximum fair price under subsection (a)(3), with respect to such selected drug and maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed such selected drug at a covered entity described in section 340B(a)(4) of the Public Health Service Act [42 U.S.C. 256b(a)(4)], to such covered entity if such selected drug is subject to an agreement described in section 340B(a)(1) of such Act [42 U.S.C. 256b(a)(1)] and the ceiling price (defined in section 340B(a)(1) of such Act [42 U.S.C. 256b(a)(1)]) is lower than the maximum fair price for such selected drug; and

(2) shall be required to provide access to the maximum fair price to such covered entity with respect to maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed such selected drug at such entity at such ceiling price in a nonduplicated amount to the ceiling price if such maximum fair price is below the ceiling price for such selected drug.

42 U.S.C. § 1320f-3

§ 1320f-3. Negotiation and renegotiation process

(a) In general

For purposes of this part, under an agreement under section 1320f–2 of this title between the Secretary and a manufacturer of a selected drug (or selected drugs), with respect to the period for which such agreement is in effect and in accordance with subsections (b), (c), and (d), the Secretary and the manufacturer—

(1) shall during the negotiation period with respect to such drug, in accordance with this section, negotiate a maximum fair price for such drug for the purpose described in section 1320f–2(a)(1) of this title; and

(2) renegotiate, in accordance with the process specified pursuant to subsection (f), such maximum fair price for such drug for the purpose described in section 1320f–2(a)(2) of this title if such drug is a renegotiation-eligible drug under such subsection.

(b) Negotiation process requirements

(1) Methodology and process

The Secretary shall develop and use a consistent methodology and process, in accordance with paragraph (2), for negotiations under subsection (a) that aims to achieve the lowest maximum fair price for each selected drug.

(2) Specific elements of negotiation process

As part of the negotiation process under this section, with respect to a selected drug and the negotiation period with respect to the initial price applicability year with respect to such drug, the following shall apply:

(A) Submission of information

Not later than March 1 of the year of the selected drug publication date, with respect to the selected drug, the manufacturer of the drug shall submit to the Secretary, in accordance with section 1320f–2(a)(4) of this title, the information described in such section.

(B) Initial offer by Secretary

Not later than the June 1 following the selected drug publication date, the Secretary shall provide the manufacturer of the selected drug with a written initial offer that contains the Secretary's proposal for the maximum fair price of the drug and a concise justification based on the factors described in subsection (e) that were used in developing such offer.

(C) Response to initial offer

(i) In general

Not later than 30 days after the date of receipt of an initial offer under subparagraph (B), the manufacturer shall either accept such offer or propose a counteroffer to such offer.

(ii) Counteroffer requirements

If a manufacturer proposes a counteroffer, such counteroffer—

(I) shall be in writing; and

(II) shall be justified based on the factors described in subsection (e).

(D) Response to counteroffer

After receiving a counteroffer under subparagraph (C), the Secretary shall respond in writing to such counteroffer.

(E) Deadline

All negotiations between the Secretary and the manufacturer of the selected drug shall end prior to the first day of November following the selected drug publication date, with respect to the initial price applicability year.

(F) Limitations on offer amount

In negotiating the maximum fair price of a selected drug, with respect to the initial price applicability year for the selected drug, and, as applicable, in renegotiating the maximum fair price for such drug, with respect to a subsequent year during the price applicability period for such drug, the Secretary shall not offer (or agree to a counteroffer for) a maximum fair price for the selected drug that—

(i) exceeds the ceiling determined under subsection (c) for the selected drug and year; or

(ii) as applicable, is less than the floor determined under subsection (d) for the selected drug and year.

(c) Ceiling for maximum fair price

(1) General ceiling

(A) In general

The maximum fair price negotiated under this section for a selected drug, with respect to the first initial price applicability year of the price applicability

period with respect to such drug, shall not exceed the lower of the amount under subparagraph (B) or the amount under subparagraph (C).

(B) Subparagraph (B) amount

An amount equal to the following:

(i) Covered part D drug

In the case of a covered part D drug (as defined in section 1395w–102(e) of this title), the sum of the plan specific enrollment weighted amounts for each prescription drug plan or MA–PD plan (as determined under paragraph (2)).

(ii) Part B drug or biological

In the case of a drug or biological product for which payment may be made under part B of subchapter XVIII, the payment amount under section 1395w–3a(b)(4) of this title for the drug or biological product for the year prior to the year of the selected drug publication date with respect to the initial price applicability year for the drug or biological product.

(C) Subparagraph (C) amount

An amount equal to the applicable percent described in paragraph (3), with respect to such drug, of the following:

(i) Initial price applicability year 2026

In the case of a selected drug with respect to which such initial price applicability year is 2026, the average non-Federal average manufacturer price for such drug for 2021 (or, in the case that there is not an average non-Federal average manufacturer price available for such drug for 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year prior to the year of the selected drug publication date with respect to such initial price applicability year.

(ii) Initial price applicability year 2027 and subsequent years

In the case of a selected drug with respect to which such initial price applicability year is 2027 or a subsequent year, the lower of—

(I) the average non-Federal average manufacturer price for such drug for 2021 (or, in the case that there is not an average non-Federal

average manufacturer price available for such drug for 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year prior to the year of the selected drug publication date with respect to such initial price applicability year; or

(II) the average non-Federal average manufacturer price for such drug for the year prior to the selected drug publication date with respect to such initial price applicability year.

(2) Plan specific enrollment weighted amount

For purposes of paragraph (1)(B)(i), the plan specific enrollment weighted amount for a prescription drug plan or an MA–PD plan with respect to a covered Part D drug is an amount equal to the product of—

(A) the negotiated price of the drug under such plan under part D of subchapter XVIII, net of all price concessions received by such plan or pharmacy benefit managers on behalf of such plan, for the most recent year for which data is available; and

(B) a fraction—

(i) the numerator of which is the total number of individuals enrolled in such plan in such year; and

(ii) the denominator of which is the total number of individuals enrolled in a prescription drug plan or an MA–PD plan in such year.

(3) Applicable percent described

For purposes of this subsection, the applicable percent described in this paragraph is the following:

(A) Short-monopoly drugs and vaccines

With respect to a selected drug (other than an extended-monopoly drug and a long-monopoly drug), 75 percent.

(B) Extended-monopoly drugs

With respect to an extended-monopoly drug, 65 percent.

(C) Long-monopoly drugs

With respect to a long-monopoly drug, 40 percent.

(4) Extended-monopoly drug defined

(A) In general

In this part, subject to subparagraph (B), the term "extended-monopoly drug" means, with respect to an initial price applicability year, a selected drug for which at least 12 years, but fewer than 16 years, have elapsed since the date of approval of such drug under section 355(c) of title 21 or since the date of licensure of such drug under section 262(a) of this title, as applicable.

(B) Exclusions

The term "extended-monopoly drug" shall not include any of the following:

(i) A vaccine that is licensed under section 262 of this title and marketed pursuant to such section.

(ii) A selected drug for which a manufacturer had an agreement under this part with the Secretary with respect to an initial price applicability year that is before 2030.

(C) Clarification

Nothing in subparagraph (B)(ii) shall limit the transition of a selected drug described in paragraph (3)(A) to a long-monopoly drug if the selected drug meets the definition of a long-monopoly drug.

(5) Long-monopoly drug defined

(A) In general

In this part, subject to subparagraph (B), the term "long-monopoly drug" means, with respect to an initial price applicability year, a selected drug for which at least 16 years have elapsed since the date of approval of such drug under section 355(c) of title 21 or since the date of licensure of such drug under section 262(a) of this title, as applicable.

(B) Exclusion

The term "long-monopoly drug" shall not include a vaccine that is licensed under section 262 of this title and marketed pursuant to such section.

(6) Average non-Federal average manufacturer price

In this part, the term "average non-Federal average manufacturer price" means the average of the non-Federal average manufacturer price (as defined in section 8126(h)(5) of title 38) for the 4 calendar quarters of the year involved.

(d) Temporary floor for small biotech drugs

In the case of a selected drug that is a qualifying single source drug described in section 1320f–1(d)(2) of this title and with respect to which the first initial price applicability year of the price applicability period with respect to such drug is 2029 or 2030, the maximum fair price negotiated under this section for such drug for such initial price applicability year may not be less than 66 percent of the average non-Federal average manufacturer price for such drug (as defined in subsection (c)(6)) for 2021 (or, in the case that there is not an average non-Federal average manufacturer price available for such drug for 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year prior to the selected drug publication date with respect to the initial price applicability year.

(e) Factors

For purposes of negotiating the maximum fair price of a selected drug under this part with the manufacturer of the drug, the Secretary shall consider the following factors, as applicable to the drug, as the basis for determining the offers and counteroffers under subsection (b) for the drug:

(1) Manufacturer-specific data

The following data, with respect to such selected drug, as submitted by the manufacturer:

(A) Research and development costs of the manufacturer for the drug and the extent to which the manufacturer has recouped research and development costs.

(B) Current unit costs of production and distribution of the drug.

(C) Prior Federal financial support for novel therapeutic discovery and development with respect to the drug.

(D) Data on pending and approved patent applications, exclusivities recognized by the Food and Drug Administration, and applications and approvals under section 355(c) of title 21 or section 262(a) of this title for the drug.

(E) Market data and revenue and sales volume data for the drug in the United States.

(2) Evidence about alternative treatments

The following evidence, as available, with respect to such selected drug and therapeutic alternatives to such drug:

(A) The extent to which such drug represents a therapeutic advance as compared to existing therapeutic alternatives and the costs of such existing therapeutic alternatives.

(B) Prescribing information approved by the Food and Drug Administration for such drug and therapeutic alternatives to such drug.

(C) Comparative effectiveness of such drug and therapeutic alternatives to such drug, taking into consideration the effects of such drug and therapeutic alternatives to such drug on specific populations, such as individuals with disabilities, the elderly, the terminally ill, children, and other patient populations.

(D) The extent to which such drug and therapeutic alternatives to such drug address unmet medical needs for a condition for which treatment or diagnosis is not addressed adequately by available therapy.

In using evidence described in subparagraph (C), the Secretary shall not use evidence from comparative clinical effectiveness research in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.

(f) Renegotiation process

(1) In general

In the case of a renegotiation-eligible drug (as defined in paragraph (2)) that is selected under paragraph (3), the Secretary shall provide for a process of renegotiation (for years (beginning with 2028) during the price applicability period, with respect to such drug) of the maximum fair price for such drug consistent with paragraph (4).

(2) Renegotiation-eligible drug defined

In this section, the term "renegotiation-eligible drug" means a selected drug that is any of the following:

(A) Addition of new indication

A selected drug for which a new indication is added to the drug.

(B) Change of status to an extended-monopoly drug

A selected drug that—

(i) is not an extended-monopoly or a long-monopoly drug; and

(ii) for which there is a change in status to that of an extended-monopoly drug.

(C) Change of status to a long-monopoly drug

A selected drug that—

(i) is not a long-monopoly drug; and

(ii) for which there is a change in status to that of a long-monopoly drug.

(D) Material changes

A selected drug for which the Secretary determines there has been a material change of any of the factors described in paragraph (1) or (2) of subsection (e).

(3) Selection of drugs for renegotiation

For each year (beginning with 2028), the Secretary shall select among renegotiation-eligible drugs for renegotiation as follows:

(A) All extended-monopoly negotiation-eligible drugs

The Secretary shall select all renegotiation-eligible drugs described in paragraph (2)(B).

(B) All long-monopoly negotiation-eligible drugs

The Secretary shall select all renegotiation-eligible drugs described in paragraph (2)(C).

(C) Remaining drugs

Among the remaining renegotiation-eligible drugs described in subparagraphs (A) and (D) of paragraph (2), the Secretary shall select renegotiation-eligible drugs for which the Secretary expects renegotiation is likely to result in a significant change in the maximum fair price otherwise negotiated.

(4) Renegotiation process

(A) In general

The Secretary shall specify the process for renegotiation of maximum fair prices with the manufacturer of a renegotiation-eligible drug selected for renegotiation under this subsection.

(B) Consistent with negotiation process

The process specified under subparagraph (A) shall, to the extent practicable, be consistent with the methodology and process established under subsection

(b) and in accordance with subsections (c), (d), and (e), and for purposes of applying subsections (c)(1)(A) and (d), the reference to the first initial price applicability year of the price applicability period with respect to such drug shall be treated as the first initial price applicability year of such period for which the maximum fair price established pursuant to such renegotiation applies, including for applying subsection (c)(3)(B) in the case of renegotiation-eligible drugs described in paragraph (3)(A) of this subsection and subsection (c)(3)(C) in the case of renegotiation-eligible drugs described in paragraph (3)(B) of this subsection.

(5) Clarification

A renegotiation-eligible drug for which the Secretary makes a determination described in section 1320f–1(c)(1) of this title before or during the period of renegotiation shall not be subject to the renegotiation process under this section.

(g) Clarification

The maximum fair price for a selected drug described in subparagraph (A) or (B) of paragraph (1)[*] shall take effect no later than the first day of the first calendar quarter that begins after the date described in subparagraph[†] (A) or (B), as applicable.

[*] So in original. Probably means subparagraph (A) or (B) of paragraph (1) of section 1320f–1(e) of this title.

[†] So in original. Probably should be preceded by "such".

42 U.S.C. § 1320f–4

§1320f–4. Publication of maximum fair prices

(a) In general

With respect to an initial price applicability year and a selected drug with respect to such year—

(1) not later than November 30 of the year that is 2 years prior to such initial price applicability year, the Secretary shall publish the maximum fair price for such drug negotiated with the manufacturer of such drug under this part; and

(2) not later than March 1 of the year prior to such initial price applicability year, the Secretary shall publish, subject to section 1320f–2(c) of this title, the explanation for the maximum fair price with respect to the factors as applied under section 1320f–3(e) of this title for such drug described in paragraph (1).

(b) Updates

(1) Subsequent year maximum fair prices

For a selected drug, for each year subsequent to the first initial price applicability year of the price applicability period with respect to such drug, with respect to which an agreement for such drug is in effect under section 1320f–2 of this title, not later than November 30 of the year that is 2 years prior to such subsequent year, the Secretary shall publish the maximum fair price applicable to such drug and year, which shall be—

(A) subject to subparagraph (B), the amount equal to the maximum fair price published for such drug for the previous year, increased by the annual percentage increase in the consumer price index for all urban consumers (all items; United States city average) for the 12-month period ending with the July immediately preceding such November 30; or

(B) in the case the maximum fair price for such drug was renegotiated, for the first year for which such price as so renegotiated applies, such renegotiated maximum fair price.

(2) Prices negotiated after deadline

In the case of a selected drug with respect to an initial price applicability year for which the maximum fair price is determined under this part after the date of publication under this section, the Secretary shall publish such maximum fair price by not later than 30 days after the date such maximum price is so determined.

42 U.S.C. § 1320f–5

§1320f–5. Administrative duties and compliance monitoring

(a) Administrative duties

For purposes of section 1320f(a)(4) of this title, the administrative duties described in this section are the following:

(1) The establishment of procedures to ensure that the maximum fair price for a selected drug is applied before—

(A) any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of maximum fair price eligible individuals; and

(B) any other discounts.

(2) The establishment of procedures to compute and apply the maximum fair price across different strengths and dosage forms of a selected drug and not based on the specific formulation or package size or package type of such drug.

(3) The establishment of procedures to carry out the provisions of this part, as applicable, with respect to—

(A) maximum fair price eligible individuals who are enrolled in a prescription drug plan under part D of subchapter XVIII or an MA–PD plan under part C of such subchapter; and

(B) maximum fair price eligible individuals who are enrolled under part B of such subchapter, including who are enrolled in an MA plan under part C of such subchapter.

(4) The establishment of a negotiation process and renegotiation process in accordance with section 1320f–3 of this title.

(5) The establishment of a process for manufacturers to submit information described in section 1320f–3(b)(2)(A) of this title.

(6) The sharing with the Secretary of the Treasury of such information as is necessary to determine the tax imposed by section 5000D of the Internal Revenue Code of 1986, including the application of such tax to a manufacturer, producer, or importer or the determination of any date described in section 5000D(c)(1) of such Code. For purposes of the preceding sentence, such information shall include—

(A) the date on which the Secretary receives notification of any termination of an agreement under the Medicare coverage gap discount program under section 1395w–114a of this title and the date on which any subsequent agreement under such program is entered into;

(B) the date on which the Secretary receives notification of any termination of an agreement under the manufacturer discount program under section 1395w–114c of this title and the date on which any subsequent agreement under such program is entered into; and

(C) the date on which the Secretary receives notification of any termination of a rebate agreement described in section 1396r–8(b) of this title and the date on which any subsequent rebate agreement described in such section is entered into.

(7) The establishment of procedures for purposes of applying subsections (d)(2)(B) and (f)(1)(C) of section 1320f–1 of this title.

(b) Compliance monitoring

The Secretary shall monitor compliance by a manufacturer with the terms of an agreement under section 1320f–2 of this title and establish a mechanism through which violations of such terms shall be reported.

42 U.S.C. § 1320f–6

§1320f–6. Civil monetary penalties

(a) Violations relating to offering of maximum fair price

Any manufacturer of a selected drug that has entered into an agreement under section 1320f–2 of this title, with respect to a year during the price applicability period with respect to such drug, that does not provide access to a price that is equal to or less than the maximum fair price for such drug for such year—

(1) to a maximum fair price eligible individual who with respect to such drug is described in subparagraph (A) of section 1320f(c)(2) of this title and who is dispensed such drug during such year (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed such drugs); or

(2) to a hospital, physician, or other provider of services or supplier with respect to maximum fair price eligible individuals who with respect to such drug is described in subparagraph (B) of such section and is furnished or administered such drug by such hospital, physician, or provider or supplier during such year;

shall be subject to a civil monetary penalty equal to ten times the amount equal to the product of the number of units of such drug so furnished, dispensed, or administered during such year and the difference between the price for such drug made available for such year by such manufacturer with respect to such individual or hospital, physician, provider of services, or supplier and the maximum fair price for such drug for such year.

(b) Violations relating to providing rebates

Any manufacturer that fails to comply with the rebate requirements under section 1320f–1(f)(4) of this title shall be subject to a civil monetary penalty equal to 10 times the amount of the rebate the manufacturer failed to pay under such section.

(c) Violations of certain terms of agreement

Any manufacturer of a selected drug that has entered into an agreement under section 1320f–2 of this title, with respect to a year during the price applicability period with respect to such drug, that is in violation of a requirement imposed pursuant to section 1320f–2(a)(5) of this title, including the requirement to submit information pursuant to section 1320f–2(a)(4) of this title, shall be subject to a civil monetary penalty equal to $1,000,000 for each day of such violation.

(d) False information

Any manufacturer that knowingly provides false information pursuant to section 1320f–5(a)(7) of this title shall be subject to a civil monetary penalty equal to $100,000,000 for each item of such false information.

(e) Application

The provisions of section 1320a–7a of this title (other than subsections (a) and (b)) shall apply to a civil monetary penalty under this section in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a(a) of this title.

42 U.S.C. § 1320f–7

§1320f–7. Limitation on administrative and judicial review

There shall be no administrative or judicial review of any of the following:

(1) The determination of a unit, with respect to a drug or biological product, pursuant to section 1320f(c)(6) of this title.

(2) The selection of drugs under section 1320f–1(b) of this title, the determination of negotiation-eligible drugs under section 1320f–1(d) of this title, and* the determination of qualifying single source drugs under section 1320f–1(e) of this title the† application of section 1320f–1(f) of this title,.‡

(3) The determination of a maximum fair price under subsection (b) or (f) of section 1320f–3 of this title.

(4) The determination of renegotiation-eligible drugs under section 1320f–3(f)(2) of this title and the selection of renegotiation-eligible drugs under section 1320f–3(f)(3) of this title.

* So in original. The word "and" probably should not appear.
† So in original. Probably should be preceded by ", and".
‡ So in original.

26 U.S.C. § 5000D

§ 5000D. Designated drugs during noncompliance periods

(a) In general

There is hereby imposed on the sale by the manufacturer, producer, or importer of any designated drug during a day described in subsection (b) a tax in an amount such that the applicable percentage is equal to the ratio of—

(1) such tax, divided by

(2) the sum of such tax and the price for which so sold.

(b) Noncompliance periods

A day is described in this subsection with respect to a designated drug if it is a day during one of the following periods:

(1) The period beginning on the March 1st (or, in the case of initial price applicability year 2026, the October 2nd) immediately following the date on which such drug is included on the list published under section 1192(a) of the Social Security Act and ending on the earlier of—

(A) the first date on which the manufacturer of such designated drug has in place an agreement described in section 1193(a) of such Act with respect to such drug, or

(B) the date that the Secretary of Health and Human Services has made a determination described in section 1192(c)(1) of such Act with respect to such designated drug.

(2) The period beginning on the November 2nd immediately following the March 1st described in paragraph (1) (or, in the case of initial price applicability year 2026, the August 2nd immediately following the October 2nd described in such paragraph) and ending on the earlier of—

(A) the first date on which the manufacturer of such designated drug and the Secretary of Health and Human Services have agreed to a maximum fair price under an agreement described in section 1193(a) of the Social Security Act, or

(B) the date that the Secretary of Health and Human Services has made a determination described in section 1192(c)(1) of such Act with respect to such designated drug.

(3) In the case of any designated drug which is a selected drug (as defined in section 1192(c) of the Social Security Act) that the Secretary of Health and Human Services has selected for renegotiation under section 1194(f) of such Act,

the period beginning on the November 2nd of the year that begins 2 years prior to the first initial price applicability year of the price applicability period for which the maximum fair price established pursuant to such renegotiation applies and ending on the earlier of—

(A) the first date on which the manufacturer of such designated drug has agreed to a renegotiated maximum fair price under such agreement, or

(B) the date that the Secretary of Health and Human Services has made a determination described in section 1192(c)(1) of such Act with respect to such designated drug.

(4) With respect to information that is required to be submitted to the Secretary of Health and Human Services under an agreement described in section 1193(a) of the Social Security Act, the period beginning on the date on which such Secretary certifies that such information is overdue and ending on the date that such information is so submitted.

(c) Suspension of tax

(1) In general

A day shall not be taken into account as a day during a period described in subsection (b) if such day is also a day during the period—

(A) beginning on the first date on which—

(i) the notice of terminations of all applicable agreements of the manufacturer have been received by the Secretary of Health and Human Services, and

(ii) none of the drugs of the manufacturer of the designated drug are covered by an agreement under section 1860D–14A or 1860D–14C of the Social Security Act, and

(B) ending on the last day of February following the earlier of—

(i) the first day after the date described in subparagraph (A) on which the manufacturer enters into any subsequent applicable agreement, or

(ii) the first date any drug of the manufacturer of the designated drug is covered by an agreement under section 1860D–14A or 1860D–14C of the Social Security Act.

(2) Applicable agreement

For purposes of this subsection, the term "applicable agreement" means the following:

(A) An agreement under—

(i) the Medicare coverage gap discount program under section 1860D–14A of the Social Security Act, or

(ii) the manufacturer discount program under section 1860D–14C of such Act.

(B) A rebate agreement described in section 1927(b) of such Act.

(d) Applicable percentage

For purposes of this section, the term "applicable percentage" means—

(1) in the case of sales of a designated drug during the first 90 days described in subsection (b) with respect to such drug, 65 percent,

(2) in the case of sales of such drug during the 91st day through the 180th day described in subsection (b) with respect to such drug, 75 percent,

(3) in the case of sales of such drug during the 181st day through the 270th day described in subsection (b) with respect to such drug, 85 percent, and

(4) in the case of sales of such drug during any subsequent day, 95 percent.

(e) Definitions

For purposes of this section—

(1) Designated drug

The term "designated drug" means any negotiation-eligible drug (as defined in section 1192(d) of the Social Security Act) included on the list published under section 1192(a) of such Act which is manufactured or produced in the United States or entered into the United States for consumption, use, or warehousing.

(2) United States

The term "United States" has the meaning given such term by section 4612(a)(4).

(3) Other terms

The terms "initial price applicability year", "price applicability period", and "maximum fair price" have the meaning given such terms in section 1191 of the Social Security Act.

(f) Special rules

(1) Coordination with rules for possessions of the United States

Rules similar to the rules of paragraphs (2) and (4) of section 4132(c) shall apply for purposes of this section.

(2) Anti-abuse rule

In the case of a sale which was timed for the purpose of avoiding the tax imposed by this section, the Secretary may treat such sale as occurring during a day described in subsection (b).

(g) Exports

Rules similar to the rules of section 4662(e) (other than section 4662(e)(2)(A)(ii)(II)) shall apply for purposes of this chapter.

(h) Regulations

The Secretary shall prescribe such regulations and other guidance as may be necessary to carry out this section.

United States Court of Appeals

FIFTH CIRCUIT
OFFICE OF THE CLERK

LYLE W. CAYCE
CLERK

TEL. 504-310-7700
600 S. MAESTRI PLACE,
Suite 115
NEW ORLEANS, LA 70130

September 19, 2025

Mr. Maxwell A. Baldi
U.S. Department of Justice
Civil Division, Appellate Section
950 Pennsylvania Avenue, N.W.
Washington, DC 20530

No. 25-50661 Natl Infusion Center v. Kennedy
USDC No. 1:23-CV-707

Dear Mr. Baldi,

You must submit the **4 paper copies of your Addendum** required by 5th Cir. R. 31.1 within 5 days of the date of this notice pursuant to 5th Cir. ECF Filing Standard E.1. Failure to timely provide the appropriate number of copies may result in the dismissal of your appeal pursuant to 5th Cir. R. 42.3.

Sincerely,

LYLE W. CAYCE, Clerk

By: _____
Casey A. Sullivan, Deputy Clerk
504-310-7642

cc:
Mr. Timothy A. Cleveland
Mr. John Patrick Elwood
Mr. Jeffrey Handwerker
Mr. Allon Kedem
Mr. Michael Strauss Kolber
Mr. Austin Krist
Mr. William Perdue
Mr. Stephen Michael Pezzi
Ms. Allissa Aileen Rose Pollard