United States Court of Appeals for the Fifth Circuit

United States Court of Appeals
Fifth Circuit
FILED
August 26, 2026
Lyle W. Cayce
Clerk

No. 25-50661

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,

versus

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.

Appeal from the United States District Court
for the Western District of Texas
USDC No. 1:23-CV-707

Before SOUTHWICK, HIGGINSON, and WILSON, *Circuit Judges*.

LESLIE H. SOUTHWICK, *Circuit Judge*:

The Plaintiffs challenge the constitutionality of the Drug Pricing Program created by the Inflation Reduction Act of 2022. They claim violations of the nondelegation doctrine, the Eighth Amendment's Excessive

Fines Clause, and the Fifth Amendment's Due Process Clause. The district court granted the Government's motion for summary judgment. We AFFIRM.

FACTUAL AND PROCEDURAL BACKGROUND

The Medicare program reimburses patients and providers for certain healthcare costs. *See* 42 U.S.C. § 1395 *et seq*. The Centers for Medicare and Medicaid Services ("CMS") administers Medicare on behalf of the Secretary of Health and Human Services (the official, the "Secretary," and the agency, "HHS"). *See* 42 U.S.C. § 1395 *et seq*; Health Care Financing Administration Et Al., 42 Fed. Reg. 13262 (Mar. 9, 1977) (effective Mar. 8, 1977); 42 C.F.R. § 1000.10 (2025). Medicare covers prescription drugs through two programs: Part B and Part D. Part B provides reimbursements for drugs administered incident to a physician's services, based on the "average sales price" of a drug plus a specified percentage (generally 6%). *See id.* §§ 1395k(a)(1), 1395x(s)(2)(A), 1395w-3a(b)(1). Part D provides reimbursements for a portion of the cost of outpatient drugs, based on market prices agreed to between private plan sponsors and manufacturers. *See id.* § 1395w-101(a)(1). When Congress enacted Part D, it forbade the Secretary from interfering in commercial negotiations between private plans and manufacturers. *See id.* § 1395w-111(i). This was despite the fact that those negotiations would produce agreements about drug prices that Medicare would ultimately pay.

When Congress passed the Inflation Reduction Act ("IRA") in 2022, it created an exception to that directive. *See id.* §§ 1320f–1320f-7; 26 U.S.C. § 5000D. The IRA instructs the Secretary to create a "Drug Price Negotiation Program" ("Program") aimed at controlling drug costs under Medicare Parts B and D. *See* 42 U.S.C. § 1320f. The statute instructs the

Secretary to negotiate prices for certain drugs accounting for high costs to Medicare, and the Secretary has delegated this power to CMS. *Id.*

To bring drugs within the ambit of the Program, HHS must first rank the drugs with the highest Medicare expenditures using data "aggregated across dosage forms and strengths of the drug . . . and not based on the specific formulation or package size or package type of the drug." *Id.* § 1320f-1(d)(3)(B). To be "negotiation-eligible" and thus eligible for selection, a drug must be among the top fifty by Medicare expenditures under a given Part, have no generic competitors, and have been on the market for over seven years. *See id.* § 1320f-1(d)–(e). HHS then selects drugs for negotiations for that drug-pricing year, *id.* § 1320f-1(a), prioritizing those representing the greatest Medicare expenditures. *See id.* § 1320f-1(b)(1)(B). The number of selected drugs increases over time, from ten for 2026, to fifteen for 2027 and 2028, and finally to twenty for 2029 and all subsequent years. *See id.* § 1320f-1(a). Selected drugs remain in the Program until a generic or other similar version becomes approved and marketed. *See id.* §§ 1320f-1(c)(1), 1320f-2(b).

After making selections, HHS enters into agreements with manufacturers under which the parties negotiate prices. *See id.* § 1320f-2(a)(1). Congress has instructed HHS "to achieve the lowest maximum fair price for each selected drug" through a negotiation process that begins with an initial offer by HHS. *Id.* § 1320f-3(b)(1)–(2). The IRA does not limit how low HHS's offer may be but provides a ceiling that is a percentage of a baseline price (generally the average manufacturer price in a recent year); the ceiling is 40% of that baseline for drugs approved for over 16 years, 65% for drugs approved for between 12 and 16 years, and 75% for all other drugs. *Id.* § 1320f-3(b)(2)(F), (c)(1)(C), (c)(3)–(5). When formulating its initial offer, HHS also must consider the following factors: the drug's research and development costs and the extent to which they have been recovered,

production and distribution costs, federal funding for the drug's development, patent rights and statutory exclusivities, product approvals from the Food and Drug Administration, sales data, and alternative treatments. *Id.* § 1320f-3(e).

Next, the manufacturer can provide a counteroffer, to which HHS responds. *Id.* § 1320f-3(b)(2). Negotiations must conclude by November 1 of the year two years prior to the effective year of the price at issue. *Id.* § 1320f(b)(3), 1320f-3(b)(2)(E). If negotiations prove successful, the agreed maximum fair price is recorded in an addendum to the agreement with the manufacturer and published by HHS by November 30. *Id.* §§ 1320f-4(a)(1). By March 1 of the following year, HHS must publish an explanation of that price's consonance with the statutory factors. *Id.* § 1320f-4(a)(2).

A manufacturer that does not enter into an agreement to negotiate is subject to an excise tax accruing during the period of noncompliance on a drug's sales that are reimbursed by Medicare.[1] *See* 26 U.S.C. § 5000D.

---

[1] The statute states that the tax applies to "the sale by the manufacturer, producer, or importer of any designated drug." 26 U.S.C. § 5000D(a). The Plaintiffs contend that the tax applies to all domestic sales of a designated drug. The Government responds that the Internal Revenue Service ("IRS"), which Congress has charged with enforcing the statute, *see id.* § 5000D(h), has issued a notice, effective immediately and upon which taxpayers may rely, stating that the tax will be imposed only on "taxpayer sales of designated drugs dispensed, furnished, or administered to individuals under the terms of Medicare." I.R.S. Notice 2023-52, 2023-35 I.R.B. 650 (Aug. 4, 2023), perma.cc/FN3F-HGSU ("*IRS Notice*"). The IRS has also proposed a rule adopting the same interpretation. *See* Excise Tax on Designated Drugs, 90 Fed. Reg. 31, 32–34 (proposed on Jan. 2, 2025) (to be codified at 26 C.F.R. pt. 47).

We conclude that the "best reading" of the statute interprets "sale" to apply to sales of a designated drug reimbursed by Medicare. *See Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 400 (2024). This interpretation reads the statute in a manner consistent with the statutory scheme of the IRA, whose text is concerned with drug costs in sales under Medicare rather than in all sales. *See, e.g.*, 42 U.S.C. § 1320f. Aside from fitting well within the context of the IRA, this reading also avoids unnecessary conflict with the Constitution

The statute expresses the tax rate as a percentage of the total sale price, including the tax amount. *See id.* § 5000D(a). That rate begins at 65% and, after 271 days, reaches 95%. *See id.* § 5000D(d). Expressed as a percentage of the post-tax amount retained by the manufacturer, the tax begins at 186% and, after 271 days, reaches 1,900%.[2] *See National Infusion Ctr. Ass'n v. Becerra* ("*NICA I*"), 116 F.4th 488, 495 (5th Cir. 2024). The IRA tasks the Treasury Department, which includes the Internal Revenue Service ("IRS"), with enforcing the tax. *See* 26 U.S.C. § 5000D(h).

A manufacturer that signs an agreement but then refuses to provide access to the agreed maximum fair price to Medicare-participating entities becomes subject to a civil monetary penalty, which consists of ten times the difference between the price charged and the maximum fair price for every unit sold to such entities. *See* 42 U.S.C. § 1320f-6(a)(2). The manufacturer will also be liable for a civil monetary penalty of $1,000,000 for each day it stands in violation. *See id.* § 1320f-6(c). The manufacturer may avoid liability for these penalties and the excise tax (and exit the Program altogether) by transferring its interest in the drug to another entity or withdrawing from Medicare and Medicaid altogether.[3] *See* 26 U.S.C.

---

that could arise if the statute were applied to all domestic sales of a designated drug. "Statutes . . . should be read, if possible, to comport with the Constitution, not to contradict it." *FCC v. Consumers' Rsch.*, 606 U.S. 656, 691 (2025); *see also United States v. Hansen*, 599 U.S. 762, 781 (2023) ("When legislation and the Constitution brush up against each other, our task is to seek harmony, not to manufacture conflict.").

[2] The IRS provides an illustrative example: "[I]f a manufacturer charges a purchaser $100 for a designated drug during the first 90 days in a statutory period . . . $65 is allocated to the § 5000D tax and $35 is allocated to the price of the designated drug." *IRS Notice* at 650. The tax ($65) would therefore be 186% of the price exclusive of the tax ($35).

[3] The Plaintiffs argue they cannot avoid liability by withdrawing from Medicare and Medicaid because the statute states that once a manufacturer provides HHS with notice of its intent to withdraw, it must wait 11 to 23 months for its termination to become

§ 5000D(c)(1); CMS, MEDICARE DRUG PRICE NEGOTIATION PROGRAM: REVISED GUIDANCE 33–34, 120–21, 129–31 (June 30, 2023), perma.cc/K6QB-C3MM ("*2023 Revised Guidance*").

The Program includes notable procedural features. The IRA states that there shall be no administrative or judicial review of drug selection or the determination of a maximum fair price. *See* 42 U.S.C. § 1320f-7(2)–(3). Furthermore, the IRA provides that HHS will implement the Program by "program guidance" for the first three negotiation cycles, *i.e.*, the negotiations producing prices effective in 2026, 2027, and 2028. *Id.* § 1320f note. CMS has read this language to exempt the Program from the Administrative Procedure Act's notice-and-comment requirements for those

---

effective. *See* 42 U.S.C. §§ 1395w-114a(b)(4)(B)(ii), 1395w-114c(b)(4)(B)(ii). They contend the excise tax would accrue during this period absent compliance by the manufacturer. The statute also provides, however, that HHS may terminate its agreement with a manufacturer on only 30 days' notice "for a knowing and willful violation of the requirements of the agreement or other good cause shown." *Id.* §§ 1395w-114a(b)(4)(B)(i), 1395w-114c(b)(4)(B)(i).

We conclude that the "best reading" of the IRA interprets "other good cause" to include a manufacturer's intent, communicated to HHS, to withdraw from Medicare, Medicaid, and the Program. *Loper Bright*, 603 U.S. at 400. CMS has issued guidance that it will find "good cause" to trigger the 30-day termination and "facilitate an expeditious termination of" a manufacturer's Medicare agreement whenever a manufacturer notifies CMS that it wishes to withdraw from Medicare, Medicaid, and the Program. CMS, MEDICARE DRUG PRICE NEGOTIATION PROGRAM: REVISED GUIDANCE 33, 121 (June 30, 2023), perma.cc/K6QB-C3MM ("*2023 Revised Guidance*"). Thus, a manufacturer can avoid incurring excise tax liability by submitting such notice 30 days before excise tax liability would otherwise begin accruing. *Id.* at 33–34. The IRA makes this guidance binding. *See* 42 U.S.C. § 1320f note (permitting CMS to implement the Program using "program guidance" for drug-pricing years 2026 through 2028); *see also 2023 Revised Guidance* at 92–93 (announcing that it is being promulgated as final, without notice and comment). In addition to being the best reading for the reasons just discussed, this interpretation also avoids unnecessary conflict with the Constitution. *See Consumers' Rsch.*, 606 U.S. at 691 ("Statutes . . . should be read, if possible, to comport with the Constitution, not to contradict it.").

years. *See* CMS, MEDICARE DRUG PRICE NEGOTIATION PROGRAM: INITIAL MEMORANDUM 2 (Mar. 15, 2023), perma.cc/8S5P-Q7Y4; CMS, MEDICARE DRUG PRICE NEGOTIATION PROGRAM: FINAL GUIDANCE 160–62 (Oct. 2, 2024), https://perma.cc/P8D5-3MYN.

The Plaintiffs filed a facial constitutional challenge to relevant portions of the IRA. The Plaintiffs contended those provisions violate the nondelegation doctrine, the Eighth Amendment's Excessive Fines Clause, and the Fifth Amendment's Due Process Clause. The district court dismissed the case, determining that it lacked subject-matter jurisdiction over the National Infusion Center Association's (NICA) claims because the Medicare statute required channeling claims through HHS, and that the remaining Plaintiffs could not proceed because, without NICA, venue was improper in the Western District of Texas. On appeal, this court reversed, holding that NICA was not required to channel its claims and that it had established Article III standing. *NICA I*, 116 F.4th at 501–02, 509.

On remand, the parties cross-moved for summary judgment. The district court granted the Government's motion, holding that the IRA does not violate the nondelegation doctrine because it "provides sufficient guidance to the HHS and CMS" to satisfy the "intelligible principle" standard. The court did not reach the merits of the Plaintiffs' Excessive Fines claim, concluding that the excise tax is a tax for Anti-Injunction Act ("AIA") purposes and that neither of the AIA's exceptions applies. The court also rejected the Plaintiffs' due process claim, holding that the Plaintiffs lacked a protected interest implicated by the Program. The court reasoned that providers have no protected interest in being reimbursed at their preferred levels, manufacturers participate in the Program voluntarily and are not entitled to sell their drugs to the Government at a preferred price,

and patients lack a right of perpetual access to all current Medicare and Medicaid products. The Plaintiffs timely appealed.

DISCUSSION

"The standard of review on summary judgment is *de novo*." *Miller v. Michaels Stores, Inc.*, 98 F.4th 211, 215 (5th Cir. 2024). Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a).

I. The Nondelegation Doctrine

The Plaintiffs argue the Program violates the Constitution's separation-of-powers principles as embodied in the nondelegation doctrine because the IRA does not provide sufficient guidance to administrative agencies regarding implementation. They also contend the IRA's bar against judicial review and notice-and-comment rulemaking compounds the nondelegation violation. Thus, the Plaintiffs reason that even if the Program's guidance does not fail the intelligible principle test, this combination of factors causes the IRA to run afoul of the nondelegation doctrine.

A. Intelligible Principle

Article I of the Constitution provides: "All legislative Powers herein granted shall be vested in a Congress of the United States." U.S. CONST. art. I, § 1. "Accompanying that assignment of power to Congress is a bar on its further delegation: Legislative power . . . belongs to the legislative branch, and to no other." *Consumers' Rsch.*, 606 U.S. at 672. Nonetheless, the nondelegation doctrine still allows Congress to "seek "assistance from its coordinate branches to secure the effect intended by its acts of legislation." *Id.* (quotation omitted and alteration adopted). "Congress does not violate

the Constitution merely because it legislates in broad terms, leaving a certain degree of discretion to executive or judicial actors." *Touby v. United States*, 500 U.S. 160, 165 (1991). Indeed, "Congress may 'vest[] discretion' in executive agencies to implement and apply the laws it has enacted — for example, by deciding on 'the details of [their] execution.'" *Consumers' Rsch.*, 606 U.S. at 672 (alterations in original) (quoting *J.W. Hampton, Jr., & Co. v. United States*, 276 U.S. 394, 406 (1928)).

When Congress charges an agency with implementation of a statute, the nondelegation doctrine requires that Congress supply an "intelligible principle," making "clear both the general policy that the agency must pursue and the boundaries of [its] delegated authority." *Id.* at 673 (alteration in original) (quotation omitted). These requirements are "not demanding." *Gundy v. United States*, 588 U.S. 128, 146 (2019) (plurality opinion). The Supreme Court has "almost never felt qualified to second-guess Congress regarding the permissible degree of policy judgment that can be left to those executing or applying the law." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 474–75 (2001) (quotation omitted).

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.'" *Id.* at 474 (first citing *Panama Refin. Co. v. Ryan*, 293 U.S. 388 (1935); and then quoting *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 531 (1935)). On the other hand, the Court has "upheld as providing sufficient guidance 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,'" among others. *Touby*, 500 U.S. at 165 (first quoting *Lichter v. United States*, 334 U.S. 742, 778–86 (1948); then quoting *Yakus v. United States*, 321 U.S. 414, 426–27 (1944); and then quoting *National Broad. Co. v. United States*, 319 U.S. 190, 225–26 (1943)).

We examine whether the statute before us contains an intelligible principle. Although it directs HHS to "consider" certain factors when formulating offers to manufacturers, the Plaintiffs submit that the statute fails to guide or limit in any meaningful way HHS's discretion and that it broadly instructs HHS to "achieve the lowest maximum fair price." *See* 42 U.S.C. § 1320f-3(b)(1), (c), (e).

As discussed above, the statute is considerably more detailed than the Plaintiffs' reading suggests. Congress defined the Program's chief terminology. *See id.* § 1320f(b), (c). It established a framework for the timing and terms of agreements with manufacturers. *See id.* § 1320f-2. It provided procedures for negotiations and formulae for determining ceiling prices. *See id.* § 1320f-3. In sum, Congress supplied an intelligible principle by defining the general policy HHS must pursue (as well as the way HHS must pursue it) and the boundaries of HHS's delegated authority. *See Consumers' Rsch.*, 606 U.S. at 673.

Moreover, precedent belies the Plaintiffs' contention that directing HHS to "consider" certain factors is insufficiently constraining for nondelegation purposes. In *Hampton*, the Supreme Court rejected a nondelegation challenge to a statute providing that "the President, in so far as he finds it practicable, shall take into consideration" four factors in setting customs duties. *Hampton*, 276 U.S. at 401, 409. By comparison, the IRA contains no qualification similar to practicability. Instead, it states that HHS "shall consider" nine factors, thus making the IRA's compliance with

nondelegation rules even clearer than the statute in *Hampton*. *See* 42 U.S.C. § 1320f-3(e).

The Plaintiffs also assert that HHS has boundless discretion to slash prices because, while the IRA provides formulae for calculating ceiling prices and requires that HHS achieve a "fair" price, it does not contain a price floor. The district court concluded that term adequately limits HHS by imposing strictures similar to those created by the word "sufficient," at issue in a precedent we will now discuss. *See Consumers' Rsch.*, 606 U.S. at 681.

Consumers' Research concerned the Telecommunications Act, which directs the Federal Communications Commission ("FCC") to collect an amount that is "sufficient" to support communications access programs Congress has tasked it with implementing. *Id.* The Supreme Court held that term satisfies the nondelegation doctrine's requirements because it "sets a floor and a ceiling alike," even if it does not transform budgeting into an "exact science." *Id.* at 681–82. The Court explained that "sufficient" meant that the FCC "cannot raise *less* than is adequate or necessary to finance the universal-service programs Congress wants." *Id.* at 681. Importantly, it also meant "that the FCC cannot raise *more* than that amount. Were the FCC to raise, say, twice as much as needed, the revenue would not be 'sufficient' but instead excessive." *Id.* at 681–82. Using a hypothetical scenario, the Court illustrated that the statute did not give the FCC overly broad discretion to raise as much revenue as it saw fit: "If you told a friend to order a 'sufficient' amount of food for five people and 500 boxes of pizza showed up at your house, you would not think he had followed instructions." *Id.* at 682. The Court reasoned that, although "sufficient" alone would not provide guidance adequate to satisfy doctrinal demands, the statute supplies an intelligible principle because "sufficient" is combined with "determinate standards for operating" the program and "specific criteria" regarding services rendered thereunder. *Id.* at 684.

Here, too, the statute provides a ceiling and a floor alike. As previously stated, the IRA explicitly sets a ceiling by providing a figure between 40% and 75% of the average manufacturer price in a recent year. *See* 42 U.S.C. § 1320f-3(b)(2)(F), (c)(1)(C), (c)(3)–(5). Congress's directive to HHS to achieve a fair price also sets a floor. The term "fair" is given meaning in the IRA. Congress essentially defined it by providing that HHS cannot reach a price less than is fair in light of the drug's research and development costs and the extent to which they have been recovered, production and distribution costs, and several other considerations previously discussed. *See id.* § 1320f-3(e). The Plaintiffs assert that HHS could set a price of zero for a given drug, but such pricing would violate the IRA; "they read [the IRA] extravagantly, the better to create a constitutional problem." *Consumers' Rsch.*, 606 U.S. at 690. HHS could not set a price of zero because doing so would not be fair in light of a manufacturer's presumably significant costs in developing and distributing such a drug, just as the FCC could not raise twice as much as needed for universal-service programs because such an amount is not necessary. *See id.* at 681–82. This conclusion accords with the Third Circuit's assessment of the same issue. *See Novo Nordisk Inc. v. Sec'y U.S. Dep't of Health & Hum. Servs.*, 154 F.4th 105, 113–14 (3d Cir. 2025) (reasoning that the IRA provides a ceiling of "75 to 40 percent of a benchmark" and a floor in the requirement that a price be "justified" based on the statutory factors).

It is not a problem for nondelegation purposes that the IRA's guidance regarding negotiations gives HHS some discretion in executing Congress's commands; after all, such guidance need not be the equivalent of an "exact science." *Consumers' Rsch.*, 606 U.S. at 682. The IRA supplies an intelligible principle in its directive to achieve a maximum fair price in conjunction with the "determinate standards" and several "specific criteria" HHS must consider. *Id.* at 684. The level of guidance the IRA

provides HHS is also significantly greater than that provided in other statutes that the Supreme Court has held satisfy nondelegation requirements. *See, e.g.*, *Yakus*, 321 U.S. at 427 (upholding authority to determine "fair and equitable" commodity prices); *Lichter*, 334 U.S. at 792–93 (upholding authority to recover "excessive profits" on military contracts); *American Trucking Ass'ns*, 531 U.S. at 472 (upholding authority to set air quality standards at a level "requisite to protect the public health").

Furthermore, Congress's grant of latitude to an agency to implement statutory goals through price negotiations is not a novel approach. Federal agencies commonly enjoy discretion over hundreds of billions of dollars each year, often with little guidance from Congress regarding spending. Examples stretch back to the nation's early days. *See, e.g.*, Act to establish the Office of Purveyor of Public Supplies, ch. 27, 3 Stat. 419, 419 (1795) (creating the office of Purveyor of Public Supplies to "conduct the 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"), *repealed by*, Act of Mar. 28, 1812, 2 Stat. 696, 697; *United States v. Tingey*, 30 U.S. (5 Pet.) 115, 126 (1831) ("There is no statute of the United States expressly defining the duties of pursers in the navy."). Given the extensive purchasing activities of the federal government, it would be impractical to require Congress to specify a floor price before the government could make any such purchases, which underscores the unlikelihood that the Constitution demands such specification.

B. Combination Theory

The Plaintiffs next contend that even if the Program's guidance does not by itself fail the intelligible principle test, the IRA violates the nondelegation doctrine because of the Program's exemptions from judicial review and notice-and-comment rulemaking. They assert that these

elements exacerbate the IRA's guidance deficiencies and "push[] the combination over a constitutional line." The district court rejected this argument because it resembled the combination theory the Supreme Court declined to adopt in *Consumers' Research*. The statute at issue there (1) empowered the FCC to operate the universal-service program, including by mandating contributions from carriers, and (2) allowed the FCC to appoint a private entity to perform calculations and financial projections for the FCC's use in determining those contributions. *See Consumers' Rsch.*, 606 U.S. at 666–69. The Court held that this combination did not create a constitutional violation because the first element implicated the traditional, public nondelegation doctrine and the second implicated the private nondelegation doctrine. *Id.* at 697.

Another precedent did conclude that the combination of statutory provisions, namely, a statutory grant of two layers of tenure protection to certain executive officers, was unconstitutional. *See Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 492 (2010). The *Consumers' Research* Court distinguished *Free Enterprise Fund* because there, "each of the two layers of for-cause protection limited the same thing — the President's power to remove executive officers. And when combined, each compounded the other's effect, so that the President was left with no real authority." *Consumers' Rsch.*, 606 U.S. at 696–97. This meant that "the two layers of restrictions operated on a single axis," with one exacerbating the other. *Id.* at 697. By contrast, the public nondelegation and private nondelegation "doctrines do not operate on the same axis (save if it is defined impossibly broadly)," so "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.*

Having identified what *Consumers' Research* held to be relevant, we conclude that precedent does not squarely foreclose the Plaintiffs' claim

here. Unlike in that case, the statutory features the Plaintiffs challenge do not operate on different axes but are part of a single grant of authority from Congress to HHS. Nevertheless, we need not decide whether *Consumers' Research* allows the Plaintiffs' use of a combination theory to prove a constitutional violation in this context. Even if the combination is to be considered, the Plaintiffs have not proven a violation. The Plaintiffs submit that the IRA's preclusion of judicial review and notice-and-comment rulemaking, when combined with the broad discretion the IRA grants HHS (even if cabined by an intelligible principle), creates such a violation. Those features, however, do not present nondelegation problems, let alone problems serious enough to transform the constitutionally valid discretion that the IRA provides to HHS into an unconstitutional delegation. We explain.

First, the IRA provides that there shall be no administrative or judicial review of HHS's selection of drugs or determination of negotiation-eligible drugs, qualifying single-source drugs, maximum fair price, or renegotiation-eligible drugs. 42 U.S.C. § 1320f-7. The Plaintiffs do not argue this preclusion alone renders the IRA unconstitutional under the nondelegation doctrine, but they do contend it militates in favor of such a finding by rendering the powers delegated to HHS that much stronger and more insulated from constraints.

The availability of judicial review weighs in favor of rejecting a nondelegation challenge because such review "safeguards against statutory or constitutional excesses." *American Power & Light Co. v. SEC*, 329 U.S. 90, 106 (1946). Nonetheless, the Plaintiffs cite no precedent, and we are aware of none, holding that the *preclusion* of judicial review causes a nondelegation problem. Even if such preclusion should be considered as a factor, the constitutionality of the IRA's delegation is not so close that such preclusion would change the outcome, transforming a constitutionally valid

grant of authority to HHS into an unconstitutional delegation. We have already explained that Congress's guidance to HHS is sufficiently constraining, both when examined individually and when compared to prior delegations upheld by the Supreme Court. We decide today only that the absence of judicial review may be relevant in the analysis of nondelegation claims, but it is neither dispositive nor, in this case, sufficient in combination with other features of the statutory scheme to make the IRA unconstitutional.

Next, the Plaintiffs assert that the lack of notice-and-comment rulemaking also broadens the delegation to HHS and exacerbates the constitutional problem. Of course, the Constitution does not require that agencies give the public an opportunity to be heard, such as through notice-and-comment procedures, before instituting broadly applicable policies. *See Minnesota State Bd. for Cmty. Colls. v. Knight*, 465 U.S. 271, 283 (1984). Additionally, a statutory requirement that an agency follow notice-and-comment procedures does not substantively limit the authority granted to that agency by Congress. *Cf. Vermont Yankee Nuclear Power Corp. v. Nat'l Res. Def. Council, Inc.*, 435 U.S. 519, 558 (1978) (noting the difference between substantive and procedural statutory requirements).

The absence of notice-and-comment rulemaking with respect to the IRA therefore has little relevance to "the constitutional question" at the heart of a delegation challenge, which "is whether the statute has delegated legislative power to the agency." *American Trucking Ass'ns*, 531 U.S. at 472. Courts answer that question by analyzing whether the statute contains an intelligible principle to guide the agency. *See Consumers' Rsch.*, 606 U.S. at 673. "[T]he intelligible-principle standard has focused our nondelegation doctrine for a century." *Id.* The Plaintiffs unconvincingly attempt to reorient that doctrine through undue emphasis on the preclusion of judicial review and lack of notice-and-comment procedures. The IRA complies with

the nondelegation doctrine because it contains an intelligible principle to guide HHS.

II. Excessive Fines Clause Claim

The Plaintiffs contend the IRA's excise tax constitutes an excessive fine in violation of the Eighth Amendment. The Government submits that the Plaintiffs lack standing. The district court dismissed the Plaintiffs' claim on the sole ground that the Anti-Injunction Act applied. We begin with standing.

A. Standing

According to the Government, the Plaintiffs lack standing for this claim because a judgment against HHS and CMS would not redress the Plaintiffs' injury. The Government asserts that the Treasury Department and IRS are indispensable parties, as the IRA's tax provisions are codified in the Internal Revenue Code at 26 U.S.C. § 5000D, the Treasury Department is charged with enforcing Section 5000D, and the IRS has published notices and regulations implementing the excise tax.

To establish standing, "a plaintiff must demonstrate (i) that she has suffered or likely will suffer an injury in fact, (ii) that the injury likely was caused or will be caused by the defendant, and (iii) that the injury likely would be redressed by the requested judicial relief." *FDA. v. All. for Hippocratic Med.*, 602 U.S. 367, 380 (2024). "The second and third standing requirements — causation and redressability — are often flip sides of the same coin" because "[i]f a defendant's action causes an injury, enjoining the action or awarding damages for the action will typically redress that injury." *Id.* at 380–81 (quotation omitted). When establishing redressability, a plaintiff "need only show that a favorable ruling could potentially lessen its injury; it need not definitively demonstrate that a victory would completely

remedy the harm." *Sanchez v. R.G.L.*, 761 F.3d 495, 506 (5th Cir. 2014) (quotation omitted).

Here, the injury-in-fact requirement is satisfied because the Plaintiffs will suffer an economic injury if required to pay the excise tax. The Plaintiffs have also established causation and redressability; a favorable ruling could inhibit enforcement of the tax and thus potentially lessen the Plaintiffs' injury by prohibiting the Defendants from fulfilling their obligation to provide the Treasury Secretary "such information as is necessary to determine the tax imposed by section 5000D." 42 U.S.C. § 1320f-5(a)(6); *cf. Novartis Pharms. Corp. v. Sec'y United States Dep't of Health & Hum. Servs.*, 155 F.4th 223, 231 (3d Cir. 2025), *cert. denied*, 224 L. Ed. 2d 832 (May 18, 2026) (holding a manufacturer had standing to challenge the IRA because CMS contributed to the manufacturer's injury, which was redressable by a ruling against CMS).

That the Treasury Department's and IRS's roles in enforcing the tax also contribute to the Plaintiffs' injury does not destroy standing for their Eighth Amendment claim, given that a favorable ruling need not completely remedy the harm. *See Sanchez*, 761 F.3d at 506. Therefore, the Plaintiffs have standing.

B. The Anti-Injunction Act

The Plaintiffs challenge the district court's conclusion that it lacked jurisdiction because the Anti-Injunction Act applies to the Plaintiffs' claim. Under the AIA, "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 AIA applies." *Hotze v. Burwell*, 784 F.3d 984, 996 (5th Cir. 2015).

To determine whether the AIA bars a claim, we must consider whether (1) the exaction in question is a "tax" and (2) the purpose of the claim is to "restrain[] the assessment or collection of [that] tax." 26 U.S.C. § 7421(a). Courts defer to Congress on the first question because a challenged federal statute and the "Anti-Injunction Act . . . are creatures of Congress's own creation," so their relation "to each other is up to Congress, and the best evidence of Congress's intent is the statutory text." *National Fed'n of Indep. Bus. v. Sebelius* ("*NFIB*"), 567 U.S. 519, 544 (2012).

Here, Congress described the exaction as a "tax." 26 U.S.C. § 5000D(a). That makes it a tax for AIA purposes. *See NFIB*, 567 U.S. at 544. The Plaintiffs contend "applying the AIA here would make no sense" because the IRA's exaction "does not seek to collect revenue." This argument fails given that the AIA "draws no distinction between regulatory and revenue-raising tax rules. It applies whenever a suit calls for enjoining the IRS's assessment and collection of taxes — of whatever kind." *CIC Servs., LLC v. IRS*, 593 U.S. 209, 225 (2021). As to the AIA inquiry's second step, the purpose of the Plaintiffs' claim is to restrain assessment or collection because they have requested that this court "[e]njoin HHS from enforcing the IRA excise tax."

The Plaintiffs argue that even if the AIA appears applicable, the excise tax satisfies an exception to the AIA that applies when "Congress has not provided the plaintiff with an alternative legal way to challenge the validity of a tax," aside from a prepayment suit. *South Carolina v. Regan*, 465 U.S. 367, 373 (1984). "In a typical tax case, that other avenue is a postpayment refund suit." *In re Westmoreland Coal Co.*, 968 F.3d 526, 535 (5th Cir. 2020) (citing *NFIB*, 567 U.S. at 543). The Plaintiffs contend the latter route is unavailable here. They reason that no manufacturer could afford the excise tax liability that would accrue during the pendency of a refund suit if the manufacturer continued selling the drug at a price not agreed to by the Government.

The Government maintains that the district court correctly concluded a refund suit is an alternative and therefore the *Regan* exception does not apply. That conclusion is based on the proposition that a manufacturer would need to pay the tax on only a single drug sale before suing and would not have to make any other payments during the suit's pendency. The Government relies on the Supreme Court's statement that "excise tax deficiencies may be divisible into a tax on each transaction or event." *Flora v. United States*, 362 U.S. 145, 171 n.37 (1960). It also cites a nonbinding IRS policy statement that, while a refund suit for a divisible tax is ongoing, the IRS generally does not collect the remainder of the tax that would otherwise be due. *See* IRS Policy Statement 5-16, IRM § 1.2.1.6.4(6), 2007 WL 9790655 (Mar. 1, 1984).

Nonetheless, a tentatively phrased footnote that excise taxes *may* be divisible and a nonbinding policy that the IRS will generally forbear from collection do not provide sufficient certainty to make a refund suit an alternative here. The excise tax liability that would accrue during a refund suit could well be staggering, potentially reaching 95% of the amount of the manufacturer's sales to Medicare during that time for the drug at issue and dwarfing the post-tax amount retained by the manufacturer. For instance, if a manufacturer had monthly sales to Medicare of $1 million for a drug, its excise tax liability would begin at $650,000 per month and, after 271 days, reach $950,000 per month. In fact, the unaffordability of this tax is why the Congressional Budget Office predicted that the tax would raise no revenue — because all manufacturers of selected drugs would comply with the negotiation process. *See* CONG. BUDGET OFF., ESTIMATED BUDGETARY EFFECTS OF PUBLIC LAW 117-169, 5 (Sept. 7, 2022), cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf ("*Estimated Budgetary Effects*"); CONG. BUDGET OFF., ALTERNATIVE APPROACHES TO REDUCING PRESCRIPTION DRUG PRICES, 20

(Oct. 2024), cbo.gov/system/files/2024-10/58793-rx-drug-prices.pdf ("*Alternative Approaches*").

That prediction has proven accurate thus far. *See* The White House, *Biden-Harris Administration Takes Major Step Forward in Lowering Health Care Costs; Announces Manufacturers Participating in Drug Price Negotiation Program* (Oct. 3, 2023), perma.cc/XT84-HRU6; CMS, CMS Announces Manufacturer Participation in Second Cycle of Medicare Drug Price Negotiation (Mar. 14, 2025), perma.cc/XS8B-86JT; CMS, CMS Announces Manufacturer Participation in Third Cycle of Medicare Drug Price Negotiation (Mar. 13, 2026), perma.cc/QB5E-36JB.

It is true that the hardship of a taxpayer in paying a challenged tax generally does not justify equitable relief preventing enforcement. *See Flora*, 362 U.S. at 175. The present situation, however, differs from the typical circumstances. Here, it is not merely the specific taxpayers in this litigation who likely cannot afford to incur the tax liability that would accrue during the challenge; rather, any taxpayer subject to the tax would find it extraordinarily difficult to pay.

Interpreting the AIA as broadly and the *Regan* exception as narrowly as the Government does would effectively insulate the IRA from judicial scrutiny of its potential unconstitutionality. We decline to adopt such an interpretation because "where Congress intends to preclude judicial review of constitutional claims its intent to do so must be clear." *Webster v. Doe*, 486 U.S. 592, 603 (1988) (explaining a "serious constitutional question" would "arise if a federal statute were construed to deny any judicial forum for a colorable constitutional claim"). Indeed, "Congress did not intend the [AIA] to apply to actions brought by aggrieved parties for whom it has not provided an alternative remedy." *Regan*, 465 U.S. at 378. With respect to

the IRA's excise tax, a postpayment refund suit is not an alternative remedy because no taxpayer subject to the tax could afford such a suit if the suit proceeded as the Plaintiffs contend it could. Therefore, the AIA does not bar the Plaintiffs' claim, so we have jurisdiction to consider that claim.[4]

C. Merits

The Excessive Fines Clause provides: "Excessive bail shall not be required, nor excessive fines imposed." U.S. CONST. amend. VIII. This "limits the government's power to extract payments . . . as punishment for some offense." *United States v. Bajakajian*, 524 U.S. 321, 328 (1998) (quotation omitted). It applies to criminal fines as well as civil fines designed "in part to punish." *Austin v. United States*, 509 U.S. 602, 610 (1993).

Caselaw demonstrates that a connection to criminality is central to the question whether an exaction is punitive and thus a "fine" within the Clause's meaning. The Supreme Court has never applied the Clause outside the criminal or quasi-criminal context and has only found it implicated in two categories of cases. The first is those involving forfeiture imposed as a sanction for a defendant's criminal conduct after a conviction for such conduct. *See Bajakajian*, 524 U.S. at 325–26, 328; *Alexander v. United States*, 509 U.S. 544, 547–48, 558–59 (1993). The second is civil suits regarding forfeiture of property used in the commission of a crime for which the owner was already convicted. *See Timbs v. Indiana*, 586 U.S. 146, 148–49 (2019); *Austin*, 509 U.S. at 604–05, 622.

---

[4] The Third Circuit held in another IRA case that the AIA precluded review; however, there the Third Circuit only examined the *Williams Packing* exception to the AIA, and we examine the *Regan* exception. *See Novartis Pharms. Corp.*, 155 F.4th 223, 233 (3d Cir. 2025), *cert. denied*, 224 L. Ed. 2d 832 (May 18, 2026).

By contrast, the IRA's excise tax lacks any connection to criminal conduct. Manufacturers become subject to the tax through their lawful choices concerning sales reimbursed by Medicare. The Plaintiffs cite the tax's high rates, a Congressional Research Service summary of predecessor legislation describing the tax as a "steep, escalating penalty," the relevant section of the tax code referring to "noncompliance," and the Congressional Budget Office's prediction that the tax would raise no revenue because no manufacturer would want to trigger it. *H.R. 3 Title Summary*, POLITICO, 2021, at 1, perma.cc/GHT9-6TZL; 26 U.S.C. § 5000D; *see Estimated Budgetary Effects* at 5; *Alternative Approaches* at 20. These indicia, however, fail to demonstrate any connection to criminality. That means the excise tax is not "punishment for some offense," *i.e.*, a criminal offense. *Bajakajian*, 524 U.S. at 328 (quotation omitted). We acknowledge the Plaintiffs' insistence that the tax would be punishment for not agreeing to accept the pricing set by the government, but that form of governmental pressure does not make the Excessive Fines Clause applicable. We uphold the district court's dismissal of the Plaintiffs' claim, not because the AIA bars that claim but because it fails on the merits.

III. Fifth Amendment Due Process Clause Claim

Finally, the Plaintiffs contend the Program deprives manufacturers, providers, and patients of constitutionally protected interests without due process. The Fifth Amendment provides that no person shall "be deprived of life, liberty, or property, without due process of law." U.S. CONST. amend. V. Property interests are created by "existing rules or understandings that stem from an independent source such as state law." *Board of Regents of State Colls. v. Roth*, 408 U.S. 564, 577 (1972). Such an interest must be "a legitimate claim of entitlement" that is "more than a unilateral expectation." *Id.*

A. Manufacturers' Property Interests

The Plaintiffs submit that the Program deprives manufacturers of the right to offer their products at market prices to the private individuals involved in the sales at issue. To remind, the prices negotiated through the Program apply only to drugs purchased through Medicare. *See* 42 U.S.C. §§ 1395w-111–112 (providing that sponsors bid for acceptance into Medicare Part D and enter contracts with HHS and CMS for reimbursement). In another case challenging the IRA on due process grounds, the Third Circuit accurately observed that "the Negotiation Program only sets prices for drugs *that CMS pays for* when it reimburses sponsors." *AstraZeneca Pharms. LP v. Sec'y U.S. Dep't of Health & Hum. Servs.*, 137 F.4th 116, 126 (3d Cir. 2025), *cert. denied*, 224 L. Ed. 2d 830 (May 18, 2026); *see also Novo Nordisk*, 154 F.4th at 114 (applying this reasoning in another IRA challenge).

"Like private individuals and businesses, the Government enjoys the unrestricted power . . . to fix the terms and conditions upon which it will make needed purchases." *Perkins v. Lukens Steel Co.*, 310 U.S. 113, 127 (1940). Accordingly, we agree with the Third Circuit that there "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.[5]

---

[5] This court's decision in *NICA I* does not control our result here. There, we held that NICA had standing because it possesses "a concrete interest in not seeing its members' revenue decrease as a result of allegedly unconstitutional government action." *NICA I*, 116 F.4th 488, 503 (5th Cir. 2024). That analysis performed for jurisdictional purposes does not resolve the question on the merits here. We agree with the Second Circuit that "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 Ingelheim Pharms., Inc. v. U.S. Dep't of Health & Hum. Servs.*, 150 F.4th 76, 94

Furthermore, pursuant to the federal government's power to determine the prices it pays for goods and services, agencies have for decades negotiated with manufacturers and entered into agreements for drugs subject to statutory price ceilings. *See, e.g.*, 38 U.S.C. § 8126 (price ceilings for drugs procured by various federal agencies); 42 U.S.C. § 256b (price ceilings for drug sales to specified healthcare facilities, as condition of manufacturers' Medicaid participation); 48 C.F.R. pt. 15 (negotiation process for goods and services procurement); *id.* pt. 215 (same for defense procurement).

The Plaintiffs also assert that manufacturers' property interests are injured because the Program cheapens manufacturers' patent rights that entitle them to seek supracompetitive profits. Not so. The "federal patent laws do not create any affirmative right to make, use, or sell anything." *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1372 (Fed. Cir. 2007) (quotation omitted). *A fortiori*, "they do not confer a right to sell at a particular price." *AstraZeneca*, 137 F.4th at 125.

Moreover, we conclude that manufacturers lack a protected interest in selling to Medicare beneficiaries at a preferred price because participation in Medicare and Medicaid, and thus in the Program, is voluntary. We agree with the Second Circuit, which rejected another IRA due process challenge on the grounds that a "company suffers no deprivation of its property interests by voluntarily submitting to a price-regulated government program." *Boehringer Ingelheim Pharms., Inc. v. U.S. Dep't of Health & Hum. Servs.*, 150 F.4th 76, 94 (2d Cir. 2025); *see also Baptist Hosp. E. v. Sec'y U.S.*

---

n.12 (2d Cir. 2025) (quoting *Booker-El v. Superintendent, Ind. State Prison*, 668 F.3d 896, 899–901 (7th Cir. 2012) (holding that for standing purposes, plaintiff had adequately pled injury in fact based on "substantial risk [of] losing benefits" to which he was allegedly entitled, and then holding plaintiff actually lacked protected property interest in those same benefits)).

Dep't of Health & Hum. Servs., 802 F.2d 860, 869–70 (6th Cir. 1986) (rejecting due process claim by hospitals seeking Medicare reimbursement because "participation in the Medicare program is wholly voluntary"); *Teva Pharms. USA, Inc. v. Kennedy*, No. 25-5425, 2026 WL 2409591, at *18 (D.C. Cir. Aug. 18, 2026).

Of course, the financial importance to manufacturers of their drugs being available through the Medicare and Medicaid programs is clear. Even so, we agree with a sister circuit that Medicare participation should not be considered involuntary because of that importance, given that "economic hardship is not equivalent to legal compulsion for purposes of takings analysis." *Garelick v. Sullivan*, 987 F.2d 913, 917 (2d Cir. 1993). That reasoning, though done in a different context, applies equally here.

The Plaintiffs contend that withdrawing is not an economically viable option and that the Program is therefore unconstitutionally coercive. They cite a Supreme Court decision that held it was unconstitutional for the federal government to withhold all of a state's Medicaid funding if the state refused to expand Medicaid eligibility. *NFIB*, 567 U.S. at 585. The Court relied on the Tenth Amendment's principle against "commandeer[ing] a State's legislative or administrative apparatus for federal purposes." *Id.* at 577. That precept is rooted in respect for "the status of the States as independent sovereigns in our federal system." *Id.* Another circuit explained it well when stating: "These Tenth Amendment concerns are simply not present . . . where the federal government contracts with private parties, rather than dealing with separate sovereigns." *Bristol Myers Squibb Co. v. Sec'y U.S. Dep't of Health & Hum. Servs.*, 155 F.4th 245, 259 (3d Cir. 2025); *see also Teva Pharms. USA, Inc.*, 2026 WL 2409591, at *18 (explaining that *NFIB* fails to "rescue[] Teva's argument" because the Supreme Court's analysis rested on federalism concerns that "do not carry over to private businesses"). The *NFIB* opinion does not assist the private-party Plaintiffs.

B. Providers' Property Interests

The Plaintiffs next argue the Program deprives providers of their protected interests in reimbursement on a non-arbitrary basis at a lawful rate and in the resources they have invested in developing facilities and processes for administering Medicare-reimbursed drugs.

This court has held that "health care providers are not the intended beneficiaries of the federal health care programs[, and] they therefore do not have a property interest in continued participation or reimbursement." *Shah v. Azar*, 920 F.3d 987, 997–98 (5th Cir. 2019) (quotation omitted). That reasoning applies here. "While the physicians may be correct that they lost a considerable amount of money in reimbursable services because of their inability to participate in Medicare" on the terms they enjoyed before the Program's implementation, "the income losses do not rise to the level of a protected property interest because no clear promises have been made by the Government that would create a legitimate claim of entitlement." *Id.* (quotation omitted).

To the extent the Plaintiffs have a protected interest in reimbursements through Medicare, it is not so broad. They are entitled only to what the law provides. The Seventh Circuit concluded that "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." *Rock River Health Care, LLC v. Eagleson*, 14 F.4th 768, 774 (7th Cir. 2021). Similar analysis was performed by the Second Circuit when noting that "professionals 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." *Furlong v. Shalala*, 156 F.3d 384, 393 (2d Cir. 1998) (quotation omitted).

The statutory reimbursement formulas provided by Congress determine those rates. *See* 42 U.S.C. § 1395w-3a(b)(1)(A)–(B), (b)(3) (setting reimbursement at 106% of "the volume-weighted average of the average sales price[]" for non-negotiated drugs and 106% of the maximum fair price for Program drugs). Providers are not entitled to anything more.

Additionally, regarding the Plaintiffs' reference to the resources that providers have invested in developing facilities and processes for administering Medicare-reimbursed drugs, the Plaintiffs do not allege that the Program deprives providers of those facilities or processes, though we agree the economic return from those is affected. The Program does not implicate a protected interest of providers.

C. Patients' Liberty Interests

We conclude with the Plaintiffs' brief and unsupported contention that by reducing the availability of life-saving medicines, the Program infringes on Medicare and Medicaid patients' protected interest in those drugs. We find no basis to hold that the Plaintiffs have shown the Due Process Clause protects such a right of access to prescription drugs. *Cf. Abigail All. for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 711 (D.C. Cir. 2007) (*en banc*) (no fundamental right to experimental drugs).

CONCLUSION

The district court's grant of summary judgment to the Government is AFFIRMED.