PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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No. 24-2968

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NOVARTIS PHARMACEUTICALS CORP.,
Appellant

v.

SECRETARY UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ADMINISTRATOR CENTERS FOR MEDICARE & MEDICAID SERVICES; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; CENTERS FOR MEDICARE & MEDICAID SERVICES; SECRETARY UNITED STATES DEPARTMENT OF THE TREASURY; UNITED STATES DEPARTMENT OF THE TREASURY; COMMISSIONER INTERNAL REVENUE SERVICE; INTERNAL REVENUE SERVICE

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On Appeal from the United States District Court
for the District of New Jersey
(D.C. No. 3:23-cv-14221)
District Judge: Honorable Zahid N. Quraishi

_____

Argued on April 8, 2025

Before: HARDIMAN, PHIPPS, and FREEMAN, *Circuit Judges*.

(Filed: September 11, 2025)

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OPINION OF THE COURT

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HARDIMAN, *Circuit Judge*.

Novartis appeals a summary judgment rejecting its constitutional challenge to portions of the Inflation Reduction Act of 2022 (the Act). As relevant here, the Act was passed to

slow the rapid growth of federal outlays for prescription drugs. To that end, the Act established what it called the "Drug Price Negotiation Program" (the Program). The Program directs the Department of Health and Human Services (HHS)—through the Centers for Medicare and Medicaid Services (CMS)—to "negotiate" prices with drug manufacturers. *See* 42 U.S.C. § 1320f(a)(3).

Novartis contends that the Program (1) threatens it with an excessive fine in violation of the Eighth Amendment; (2) takes its property without just compensation in violation of the Fifth Amendment; and (3) compels it to speak in violation of the First Amendment. Perceiving no error in the District Court's judgment, we will affirm.

I

"Medicare is a federal medical insurance program for people ages sixty-five and older and for younger people with certain disabilities." *AstraZeneca Pharms. LP v. Sec'y U.S. Dep't of HHS*, 137 F.4th 116, 119 (3d Cir. 2025). "Medicaid is a joint federal and state program that provides medical coverage for people with limited incomes." *Id.*

The Program at issue in this appeal targets Medicare Parts B and D. *See id.* at 120. Part B is a "supplemental insurance program that covers outpatient care, including certain prescription drugs that are typically administered by a physician." *Id.* Part D is a "prescription drug benefit program that subsidizes the cost of prescription drugs and prescription

drug insurance premiums for Medicare enrollees." *Id.* (citation omitted).

Part D is administered through prescription drug plans operated by private insurers called "sponsors." *Id.* Sponsors bid to be accepted into Medicare Part D and contract with CMS for reimbursement. *See* 42 U.S.C. §§ 1395w-111–1395w-112; *see also* 42 C.F.R. § 423.301 *et seq.* (setting forth rules for reimbursing sponsors). Sponsors, in turn, work with subcontractors, such as pharmacy benefit managers, who process claims and perform other administrative tasks. *See AstraZeneca*, 137 F.4th at 120. Those subcontractors then work with the pharmacies that dispense prescription drugs to Medicare Part D beneficiaries. *See id.*

When Congress enacted Part D in 2003, it prohibited CMS from "interfer[ing] with the negotiations between drug manufacturers and pharmacies and . . . sponsors" and from "institut[ing] a price structure for the reimbursement of covered part D drugs." 42 U.S.C. § 1395w-111(i)(1), (3) (2003). Almost twenty years later, however, the Act created an exception, directing CMS to "negotiate . . . maximum fair prices" for certain drugs, *id.* § 1320f(a)(3), subject to price ceilings derived from a benchmark market-based price, *id.* § 1320f-3(c). A "selected drug's 'maximum fair price' applies beginning in a given drug-pricing period (a period of one calendar year), the first of which is 2026, until the drug is no longer eligible for negotiation or the price is renegotiated." *AstraZeneca*, 137 F.4th at 120 (citing 42 U.S.C. §§ 1320f(b)(1)–(2), 1320f–1(c), 1320f–3(f)).

The Act required CMS to select ten drugs for the first drug-pricing period. *See* 42 U.S.C. §§ 1320f(d) and 1320f–1(a). As the Program ramps up, CMS must select 15 more

drugs per year for the 2027 and 2028 drug-pricing periods and up to 20 more drugs per year for 2029 and subsequent drug-pricing periods. *See id.* § 1320f–1(a). The selected drugs must have accounted for the largest costs for Medicare that prior year. *See id.* § 1320f–1(b)(1)(A). A selected drug remains in the Program until CMS determines that a generic or biosimilar version of the drug has been approved and is being marketed. *See id.* §§ 1320f–1(c)(1), 1320f–2(b).

When CMS selects a drug for the Program, the drug's manufacturer must "enter into [an] agreement[]" to "negotiate . . . a maximum fair price for such selected drug." *Id.* § 1320f–2(a)(1). For the first round of selections, the manufacturer of a selected drug had until October 1, 2023, to enter an agreement obligating it to "negotiate" a "maximum fair price" for the drug. *See id.* § 1320f(b)(4), (d)(2)(A).

CMS drafted a template agreement that manufacturers must sign to comply with this "negotiation" obligation. *See* CMS, *Medicare Drug Price Negotiation Program Agreement*, https://perma.cc/ZC3E-XCQ5 (last visited June 20, 2025), at 1–6 (hereinafter Agreement). The Agreement states that "CMS and the Manufacturer agree" that they "shall negotiate to determine (and, by not later than the last date of [the negotiation] period, agree to) a maximum fair price for the Selected Drug." Agreement at 2; *see also* 42 U.S.C. § 1320f–2(a)(1).

Once a manufacturer signs the Agreement, the agency makes a "written initial offer." 42 U.S.C. § 1320f–3(b)(2)(B). The agency must issue the offer by a statutory deadline, propose a "maximum fair price," and include a concise justification for the offer based on statutory criteria. *Id.* The manufacturer then has 30 days to accept the offer or make a

counteroffer. *See id.* § 1320f–3(b)(2)(C). CMS must respond in writing to any counteroffer. *See id.* § 1320f–3(b)(2)(D).

Negotiations for the first round of selections were to end by August 1, 2024. *See id.* §§ 1320f(b)(4), (d)(2)(B), (d)(5)(C), 1320f–3(b)(2)(E). Before that deadline, the manufacturer had to "respond in writing" to the agency "by either accepting or rejecting the final offer." 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 158 (June 30, 2023) (2023 Revised Guidance), https://perma.cc/AV2Z-4F9U. The agency and manufacturers must follow a similar process for future drug-pricing periods, except the deadlines will be set for different times of the calendar year. *See id.* § 1320f–3(b)(2).

The Act sets a price ceiling for selected drugs that CMS cannot exceed when it makes a manufacturer an offer. *Id.* § 1320f–3(c)(1)(A). And it requires CMS to "aim[] to achieve the lowest maximum fair price for each selected drug," *id.* § 1320f–3(b)(1), not to exceed 75 percent of a benchmark based on private market prices for the drug, *id.* § 1320f–3(b)(2)(F), (c)(1)(C), (c)(3). Lower price ceilings (65 or 40 percent) apply to drugs that have been approved for a longer time (at least 12 or 16 years, respectively). *Id.* There is no price floor, but the offer must be "justified" based on certain factors identified in the statute. *Id.* § 1320f–3(b)(2)(B), (b)(2)(C)(ii), (e). The Act forecloses judicial review of, among other things, CMS's pricing decisions, selection of drugs, and determinations about which drugs are eligible for selection. *See id.* § 1320f–7.

In addition to the Agreement, CMS created a template addendum a manufacturer must sign to formalize a price for its

selected drug. *See* Agreement at 7–9. The addendum states that "[t]he parties agree to a price of [$]," which the addendum's recitals note is referred to as a "maximum fair price" in the statute. Agreement at 7. Once the process is completed, the Act directs CMS to publish the "maximum fair price" that it "negotiated with the manufacturer" and its "explanation" for the price. 42 U.S.C. § 1320f–4(a).

Once signed, the Agreement obliges the manufacturer to "provide access to such price" for its selected drug to Medicare beneficiaries beginning in 2026. Agreement at 2; 42 U.S.C. § 1320f–2(a)(1). Failure to do so triggers a civil monetary penalty of ten times the difference between the price charged and the maximum fair price for every unit sold. 42 U.S.C. § 1320f–6(a). An offending manufacturer also will be subject to a civil monetary penalty of $1,000,000 for each day the Agreement was violated. *Id.* § 1320f–6(c).

After CMS includes a drug in the Program, the manufacturer can walk away and choose not to do business with the government. But if a manufacturer continues to fully participate in Medicare and Medicaid without signing an agreement under the Program, it must pay a daily excise tax that begins at 185.71 percent and rises to 1,900 percent of the selected drug's total daily revenues from all domestic sales. *See* 26 U.S.C. § 5000D.

We have held that the Act provides an escape hatch for a company that declines to participate in the Program. A manufacturer can cause the excise tax to be "[s]uspen[ded]" by terminating its extant Medicare and Medicaid agreements (under the Medicare Coverage Gap Discount Program, the Manufacturer Discount Program, and the Medicaid Drug Rebate Program). 26 U.S.C. § 5000D(c); *Bristol Myers Squibb*

v. Sec'y U.S. Dep't of HHS, ___ F.4th ____, ____, 2025 WL 2537005, at *3 (3d Cir. Sept. 4, 2025).

Novartis claims that this exit option is illusory, but this Court recently held otherwise. *See Bristol Myers Squibb*, ___ F.4th at ____, 2025 WL 2537005, at *5. CMS may terminate a manufacturer's extant Medicare agreements under the Coverage Gap Discount and Manufacturer Discount Programs for "good cause" effective upon 30 days' notice. 42 U.S.C. §§ 1395w-114a(b)(4)(B)(i), 1395w-114c(b)(4)(B)(i). Relying on that authority, CMS promised to offer manufacturers a 30-day exit from the Coverage Gap Discount and Manufacturer Discount Programs upon request, which it said would enable a manufacturer to avoid excise tax liability. 2023 Revised Guidance at 33–34, 120–21. We have held that CMS has statutory authority to do so and that participation in the Program is therefore voluntary. *See Bristol Myers Squibb*, ___ F.4th at ____, 2025 WL 2537005, at *8.

II

In the first round of selections, CMS selected Novartis's drug Entresto for inclusion in the Program. Novartis signed an Agreement to participate in the Program by the October 1, 2023, deadline and an addendum setting a "maximum fair price" by the August 1, 2024, deadline.

In September 2023, Novartis sued HHS and its Secretary along with CMS and its Administrator. It alleged that the Program violated the Eighth Amendment's Excessive Fines Clause, the Fifth Amendment's Takings Clause, and the First Amendment's Free Speech Clause.

The parties filed cross-motions for summary judgment.

The District Court denied Novartis's motion, granted the Government's motion, and entered judgment in favor of the Government. *See Novartis Pharms. Corp. v. Becerra*, 2024 WL 4524357, at *1 (D.N.J. Oct. 18, 2024). It rejected Novartis's Fifth and First Amendment claims by reasoning, among other things, that participation in the Program is voluntary and that the Program primarily regulates conduct. As for the Eighth Amendment argument, the Court concluded that the Tax Anti-Injunction Act and Declaratory Judgment Act divested it of jurisdiction. Novartis appealed.[1]

III

A

Novartis argues that the Act's excise tax threatens it with an excessive fine in violation of the Eighth Amendment. But before we can reach that contention, we must first decide (1) whether Novartis has standing to raise it and (2) whether

[1] The District Court had jurisdiction under 28 U.S.C. § 1331, and we have jurisdiction under 28 U.S.C. § 1291. Our review of the District Court's summary judgment is de novo. *See Canada v. Samuel Grossi & Sons, Inc.*, 49 F.4th 340, 345 (3d Cir. 2022). 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).

our review of the claim is barred by the Tax Anti-Injunction Act and the Declaratory Judgment Act.

1

Novartis has standing to bring its Eighth Amendment claim. To establish standing, Novartis must show that it "has suffered an injury in fact that is fairly traceable to the defendant's allegedly unlawful conduct and likely to be redressed by the requested relief." *Haaland v. Brackeen*, 599 U.S. 255, 291–92 (2023) (citation modified).

The Government focuses on redressability. It argues that Novartis's requested relief is unlikely to redress its injuries because the entity it sued, CMS, is not responsible for them. Novartis should have sued the IRS or the Treasury, the Government explains, because its alleged injury stems from a tax that is assessed, collected, and enforced by those entities. Because "the IRS can collect on that tax regardless of anything CMS does," the Government argues that an injunction against CMS will not remedy Novartis's injury. Gov't Br. 34. We disagree.

CMS is, at least in part, responsible for Novartis's alleged injuries. The Act obliges CMS to collect the information necessary for determining whether a manufacturer is subject to the excise tax. And it instructs CMS to "shar[e] with the Secretary of the Treasury . . . such information as is necessary to determine the tax imposed by section 5000D." 42 U.S.C. § 1320f–5(a)(6). That "includ[es] the application of such tax to a manufacturer, producer, or importer or the

determination of any date described in section 5000D(c)(1)." *Id.* It also includes:

> (A) the date on which the Secretary receives notification of any termination of an agreement under the Medicare coverage gap discount program . . . 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 . . . 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.

Id. This information is necessary to determine whether a manufacturer is subject to the excise tax. *See* 26 U.S.C. § 5000D(b), (c). In guidance, CMS has also stated that "[m]anufacturers of selected drugs without an Agreement in place are referred to IRS." App. 354. So contrary to the Government's assertion, CMS does contribute to Novartis's alleged injury.

That injury "likely would be redressed" by injunctive and declaratory relief issued against CMS. *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 380 (2024). Novartis's

requested injunctive and declaratory relief would prohibit CMS from following its statutory obligation to provide the information the IRS would need to calculate excise tax liability. So the relief Novartis requested would reduce its "risk of [future] harm . . . . to some extent." *Massachusetts v. EPA*, 549 U.S. 497, 526 (2007); *see also Diamond Alternative Energy, LLC v. EPA*, 145 S. Ct. 2121, 2135 (2025).

After Novartis filed its complaint, the IRS issued regulations requiring manufacturers to self-report excise tax liability. Excise Tax on Designated Drugs; Procedural Requirements, 89 Fed. Reg. 55507 (July 5, 2024). To avoid any doubt about redressability, we will add the Treasury and IRS as parties. Fed. R. Civ. P. 21; *Balgowan v. State of N.J.*, 115 F.3d 214, 216–17 (3d Cir. 1997). We exercise our discretion to do so because the IRS issued its regulations well into the litigation of this case and the circumstances indicate that the joined parties and their counsel have been on notice of Novartis's claim. *See Silbaugh v. Chao*, 942 F.3d 911, 913–14 (9th Cir. 2019); *see also Swan v. Clinton*, 100 F.3d 973, 980 n.3 (D.C. Cir. 1996).

2

Although Novartis has standing to bring its Eighth Amendment challenge, the Tax Anti-Injunction Act and the Declaratory Judgment Act preclude our review. The Tax Anti-Injunction Act provides that, with certain enumerated exceptions, "no suit for the purpose of restraining the assessment or collection of any tax shall be maintained in any

court by any person." 26 U.S.C. § 7421(a).[2] Similarly, the Declaratory Judgment Act, with certain exceptions, precludes courts from issuing declaratory judgments "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 Univ. v. Simon*, 416 U.S. 725, 732 n.7 (1974).

A claim is barred by the Anti-Injunction Act if (1) the exaction at issue 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). Novartis's suit satisfies these preconditions.

First, the excise tax is a "tax" within the meaning of the Anti-Injunction Act. Congress has wide latitude to label an exaction a "tax." *See Nat'l Fed'n of Indep. Bus. v. Sebelius (NFIB)*, 567 U.S. 519, 544 (2012). That is because the Anti–Injunction Act is a "creature[] of Congress's own creation." *Id.* Because of this discretion, the Supreme Court has applied the Anti-Injunction Act bar to exactions Congress labeled as taxes even where that label was inaccurate for constitutional purposes. *Compare Bailey v. George*, 259 U.S. 16, 20 (1922) (holding that a suit seeking to enjoin a child labor tax was barred), *with Child Labor Tax Case (Bailey v. Drexel Furniture Co.)*, 259 U.S. 20, 36–37, 44 (1922) (striking down a child labor tax because it exceeded Congress's taxing power). How the Inflation Reduction Act and the Anti-Injunction Act "relate to each other is up to Congress, and the best evidence of

[2] We refer to 26 U.S.C. § 7421(a) as the Tax Anti-Injunction Act to distinguish it from an unrelated statute called the Anti-Injunction Act: 28 U.S.C. § 2283, which restricts a federal court's authority to enjoin state court proceedings, subject to certain exceptions.

Congress's intent is the statutory text." *NFIB*, 567 U.S. at 544. Because Congress labeled the exaction a "tax," it is a tax within the meaning of the Anti-Injunction Act. 26 U.S.C. § 5000D(a), (c), (f)(2).

Second, the purpose of Novartis's Eighth Amendment claim is to "restrain[] the assessment or collection of [the] tax." 26 U.S.C. § 7421(a). To determine the purpose of a suit, "we inquire not into a taxpayer's subjective motive, but into the action's objective aim—essentially, the relief the suit requests." *CIC Servs., LLC v. IRS*, 593 U.S. 209, 217 (2021).

The Supreme Court's decision in *CIC Services* is illustrative. There, a material advisor to taxpayers brought a pre-enforcement challenge to an IRS notice imposing a new self-reporting requirement on parties that engage in certain potentially taxable transactions. *Id.* at 213–15. If a taxpayer or advisor failed to comply with the notice, he could be subject to civil monetary penalties (deemed by Congress to be "taxes" for purposes of the Anti-Injunction Act) and criminal prosecution. *Id.* at 214. The advisor asked the court to set aside the notice, enjoin its enforcement, and declare it unlawful. *Id.* at 215.

The Court held that the advisor's suit was not barred by the Anti-Injunction Act because it targeted the notice, not the taxes that backed the notice. *Id.* at 223. Three aspects of the regulatory scheme supported the Court's conclusion: (1) the notice imposed affirmative reporting obligations, which inflicted costs separate and apart from the tax penalty for noncompliance; (2) the statutory tax penalty for noncompliance was several steps removed from the notice's reporting rule; and (3) noncompliance could be punished by

separate criminal penalties, which "practically necessitate[d] a pre-enforcement, rather than a refund, suit." *Id.* at 220–22.

This case is different. Unlike the advisor in *CIC Services*, Novartis sought declaratory and injunctive relief that would run against the assessment and collection of the excise tax *itself*. True, it did not specifically request an injunction with respect to the tax. But it asked the District Court to "[d]eclare that the Program's 'excise tax' violates the Excessive Fines Clause." App. 86. It also asked the Court to "[d]eclare void any agreement that Novartis may be unconstitutionally coerced into entering before this case is adjudicated" and to "[e]njoin Defendants from forcing Novartis to sign an initial 'manufacturer agreement' or to 'agree' to prices set by the Program." *Id.* By seeking to enjoin CMS from "forcing" it to participate in the Program, Novartis effectively sought to enjoin CMS from collecting information about excise tax liability and sharing it with the IRS for collection.

Novartis disputes this characterization of its complaint. It argues that it seeks "invalidation of" and "an injunction against the enforcement of" the "entire statute" on Eighth Amendment grounds, "not just the fine." Reply Br. 2, 15. But at bottom, its claim is that the excise tax violates the Excessive Fines Clause—not that some other part of the statute does so. That is the inverse of *CIC Services*, where the plaintiff targeted the IRS notice (rather than the taxes for noncompliance). 593 U.S. at 214–15, 219.

Novartis insists that its suit cannot have the purpose of restraining the assessment or collection of the excise tax when Congress expects to raise no revenue from it. This purposive argument suggests that because the government's ability to collect revenue is not in danger, Congress could not possibly

have intended for the Anti-Injunction Act to bar this suit. We decline Novartis's invitation to elevate the statute's supposed purpose over its plain text. The Supreme Court has been clear that the Anti-Injunction Act "draws no distinction between regulatory and revenue-raising tax rules." *CIC Servs.*, 593 U.S. at 225. And Novartis points to no case in which the Court has drawn a distinction between regulatory taxes expected to raise revenue and those that are not.

Novartis finally argues that its suit fits within a narrow carveout to the Anti-Injunction Act: the *Williams Packing* exception. A plaintiff may obtain an injunction under that exception if it (1) will otherwise suffer "irreparable injury" and (2) can demonstrate "certainty of success on the merits." *Bob Jones*, 416 U.S. at 737 (citing *Enochs v. Williams Packing & Nav. Co.*, 370 U.S. 1, 6–7 (1962)).

We need not consider whether Novartis would suffer irreparable injury because it cannot demonstrate "certainty of success on the merits." *Id.* Novartis can evade the Anti-Injunction Act bar only if it is "apparent that, under the most liberal view of the law and the facts," its Eighth Amendment claim will succeed. *Williams Packing*, 370 U.S. at 7. The Supreme Court has warned that this deferential standard stems from the Anti-Injunction Act's "objective of . . . protect[ing] . . . the collector from litigation pending a suit for refund." *Id.* at 8. "[T]o permit even the maintenance of a suit in which an injunction could issue only after the taxpayer's nonliability had been conclusively established might in every practical sense operate to suspend collection of the taxes until the litigation is ended." *Id.* (citation modified).

The Supreme Court has reserved the question of whether the Excessive Fines Clause applies to civil penalties

imposed without any connection to criminal conduct. *See Browning-Ferris Indus. of Vermont, Inc. v. Kelco Disposal, Inc.*, 492 U.S. 257, 262–64 (1989). So it was far from certain that Novartis would win on the merits of its claim at the time the District Court considered its Eighth Amendment claim.

As for the Declaratory Judgment Act, Novartis plainly sought declaratory relief "with respect to Federal taxes." 28 U.S.C. § 2201(a); App. 86 (asking for the District Court to "[d]eclare that the Program's 'excise tax' violates the Excessive Fines Clause"). So the Declaratory Judgment Act bars the District Court from offering Novartis declaratory relief on its claim. *Bob Jones*, 416 U.S. at 732 n.7; *Rivero v. Fid. Invs., Inc.*, 1 F.4th 340, 344–46 (5th Cir. 2021). Accordingly, we cannot review Novartis's Eighth Amendment claim.

B

We now consider Novartis's claim that the Program takes its property without providing just compensation. We addressed this issue in *Bristol Myers Squibb*. *See* ___ F.4th at ____, 2025 WL 2537005, at *3–9. For the reasons we explained there, we hold that the Program does not violate the Takings Clause. *See* ___ F.4th at ____, 2025 WL 2537005, at *9. So we will affirm the District Court's summary judgment on Novartis's Fifth Amendment claim.

C

Finally, we turn to Novartis's claim that the Program compels it to speak in violation of the First Amendment. We addressed this issue too in *Bristol Myers Squibb*. *See* ___ F.4th at ____, 2025 WL 2537005, at *10–15. For the reasons we explained there, we hold that the Program does not violate the

First Amendment. *See id.* at ____, 2025 WL 2537005, at *10. So we will affirm the District Court's summary judgment on this claim.

* * *

Novartis seeks an injunction and declaratory relief with respect to a federal tax on its Eighth Amendment claim, so we cannot review its claim on the merits. And its Fifth and First Amendment claims are foreclosed by our precedent. Accordingly, we will affirm the District Court's judgment.