

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**NOVARTIS PHARMACEUTICALS
CORPORATION,**

Plaintiff,

v.

XAVIER BECERRA, *et al.*,

Defendants.

Civil Action No. 23-14221 (ZNQ) (JBD)

OPINION

QURAIISHI, District Judge

THIS MATTER comes before the Court upon Cross-Motions for Summary Judgment. Plaintiff Novartis Pharmaceuticals Corporation (“Plaintiff”) filed a Motion for Summary Judgment. (“Plf.’s Motion”, ECF No. 18.) Plaintiff filed a brief in support of its Motion. (“Plf.’s Moving Br.”, ECF No. 18.) Defendants Xavier Becerra, Chiquita Brooks-Lasure, U.S. Department of Health & Human Services (“HHS”), and Centers for Medicare & Medicaid Services (“CMS”) (collectively, “Defendants”) filed a Cross-Motion for Summary Judgment. (“Defs.’ Cross-Motion”, ECF No. 24.) Defendants filed a combined brief in support of their Cross-Motion and in opposition to Plaintiff’s Motion. (“Defs.’ Cross-Br.”, ECF No. 24.) Plaintiff then filed a combined brief in opposition to Defendants’ Cross-Motion and reply in support of its Motion. (“Plf.’s Reply Br.”, ECF No. 57.)

The Court held oral argument on March 7, 2024. (“Oral Arg. Tr.”, ECF No. 71.)¹ The Court has carefully considered the parties’ submissions and oral argument.² For the reasons set forth below, the Court will **GRANT** Defendants’ Cross-Motion and **DENY** Plaintiff’s Motion as to all claims.

I. BACKGROUND AND PROCEDURAL HISTORY

This is the last of four cases before the undersigned challenging the Drug Price Negotiation Program (“Program”) created by the Inflation Reduction Act of 2022, Pub. L. No. 117-169 (“IRA”). See *Bristol Myers Squibb Co. v. Becerra*, Civ. No. 23-3335 (D.N.J.); *Janssen Pharms., Inc. v. Becerra*, Civ. No. 23-3818 (D.N.J.); *Novo Nordisk Inc. v. Becerra*, Civ. No. 23-20814 (D.N.J.). Briefly, the Program directs the Secretary of HHS to negotiate with pharmaceutical manufacturers the prices Medicare pays for certain covered drugs. See *AstraZeneca Pharms. LP v. Becerra*, Civ. No. 23-931, 2024 WL 895036, at *1–5 (D. Del. Mar. 1, 2024) (providing a meticulous general background and recitation of the Program).

On April 29, 2024, the Court issued a single Opinion granting summary judgment in favor of Defendants against constitutional challenges raised by both Bristol Myers Squibb Co. and Janssen Pharmaceuticals, Inc., including Fifth Amendment Takings Clause and First Amendment Compelled Speech claims. *Bristol Myers Squibb Co. v. Becerra*, Civ. No. 23-3335 and *Janssen Pharm. Inc. v. Becerra*, Civ. No. 23-3818, 2024 WL 1855054 (D.N.J. Apr. 29, 2024) [hereinafter

¹ Given the significant overlap between the present case and the three other cases challenging the Program before the undersigned, Defendants extensively briefed their arguments across submissions made in this case, in the three other cases, and at oral argument. During oral argument, Defendants waived their right to file a reply in further support of their Cross-Motion in this case.

² Several amicus briefs have also been filed. The amici include: Intellectual Property Law and Health Law Scholars, Center for American Progress, UnidosUS Action Fund, The Century Foundation, AARP, AARP Foundation, Public Citizen, Patients for Affordable Drugs Now, Doctors for America, Protect Our Care, Families USA, American Public Health Association, American College of Physicians, Society of General Internal Medicine, American Geriatrics Society, American Society of Hematology, Nationally Recognized Healthcare and Medicare Experts, Economists and Scholars of Health Policy, Abrams Institute for Freedom of Expression, and Alliance for Aging Research.

BMS-Janssen]. On July 31, 2024, the Court issued a second Opinion, again granting summary judgment in favor of Defendants, this time against plaintiffs Novo Nordisk, Inc. and Novo Nordisk Pharma, Inc.’s Separation of Powers and Fifth Amendment Due Process Clause claims and statutory challenges under the Administrative Procedure Act and the Social Security Act. *Novo Nordisk Inc. v. Becerra*, Civ. No. 23-20814, 2024 WL 3594413 (D.N.J. July 31, 2024).

Given the parties’ familiarity with the IRA and the Program, the Court incorporates by reference the background of this dispute as set forth in *BMS-Janssen* and provides the relevant procedural history for this matter as follows. *See* 2024 WL 1855054, at * 1–2.

Plaintiff initiated this action by filing a Complaint on September 1, 2023. (“Compl.,” ECF No. 1.) Plaintiff is a pharmaceutical company that developed, and now manufactures and sells, ENTRESTO®. (*Id.* ¶ 13.) ENTRESTO is a heart failure medication that “reduce[s] the risk of cardiovascular death and hospitalization . . . in adult patients with chronic heart failure,” and treats “symptomatic heart failure . . . in pediatric patients aged one year and older.” (*Id.*) CMS selected ENTRESTO for the Program on August 29, 2023. (*Id.* ¶ 20.)

Plaintiff alleges three claims in its Complaint. (*Id.* ¶¶ 100–18.) First, Plaintiff alleges that the Program effects a *per se* taking of private property for public use without just compensation, in violation of the Fifth Amendment’s Takings Clause (“Takings Clause claim”). (*Id.* ¶¶ 100–07.) Next, Plaintiff alleges that the Program compels its speech in violation of the First Amendment (“Compelled Speech claim”). (*Id.* ¶ 113–18.) Finally, Plaintiff alleges that the Program’s “excise tax” is an excessive fine in violation of the Eighth Amendment’s Excessive Fines Clause (“Excessive Fines claim”). (*Id.* ¶¶ 108–12.)

II. JURISDICTION

The Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331.

III. LEGAL STANDARD

A motion for summary judgment may be granted when “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). If there is “no genuine dispute over material facts,” then courts “will order judgment to be entered in favor of the party deserving judgment in light of the law and undisputed facts.” *Iberia Foods Corp. v. Romeo*, 150 F.3d 298 (3d Cir. 1998).

IV. DISCUSSION

A. FIFTH AND FIRST AMENDMENT CLAIMS

Plaintiff argues that the Program (1) deprives it of its right to control its personal property and compels sales on the government’s terms, and cannot be upheld as part of a voluntary exchange, (Plf.’s Moving Br. at 11–26); and (2) compels Plaintiff to sign agreements which “promote the government’s preferred narrative” that it is engaged in a “negotiation” which results in the “maximum fair price” for the product, (*id.* at 27–35.).

In both *BMS-Janssen* and *Novo Nordisk*, the Court addressed nearly identical constitutional challenges to the Program. That is, the Court considered whether the Program effects a taking in violation of the Fifth Amendment’s Takings Clause and whether the Program compels speech in violation of the First Amendment. *BMS-Janssen*, 2024 WL 1855054, at *2–12; *Novo Nordisk*, 2024 WL 3594413, at *5–6.

i. Takings Clause

First, in *BMS-Janssen*, the Court found that participation in the Program is voluntary. 2024 WL 1855054, at * 6–7 (noting that other district courts that have considered the same challenge to the Program have found that a manufacturer's participation in the Program is voluntary). As such, the Court further held that the Program is not a classic, *per se* physical taking of a manufacturer's drugs.³ *Id.* at * 4–7. The Court reasoned that “there is no physical appropriation taking place, and . . . Plaintiffs fail to show how they are being legally compelled to participate in the Program.” *Id.* at * 5. Distinguishing the case before it from the Supreme Court's decision in *Horne v. Department of Agriculture*,⁴ the Court explained that “[t]here is no statutory provision that imposes a requirement that pharmaceutical manufacturers must set aside, keep, or otherwise reserve any of their drugs for the government's use, for the use of Medicare beneficiaries, or any other entity's use.” *Id.* at * 6. Further, the Program does not require “a manufacturer to physically transmit or transport drugs at the agreed price.” *Id.* As Defendants highlight here, “[u]nlike the Department of Agriculture in *Horne*, CMS will not ‘send[d] trucks to [Plaintiff's] facility at eight o'clock one morning’ to haul away pills.” (Defs.' Cross-Br. at 29 (quoting 576 U.S. at 356).)

Because the Program seeks to establish the prices at which sales may be made and does not tax Plaintiff for not selling the drugs in the first place, the Court reaches the same conclusion here.

³ The government commits a physical taking when it “physically takes possession of property without acquiring title to it.” *Cedar Point Nursery v. Hasid*, 594 U.S. 139, 148 (2021). And, “[w]henever a regulation results in a physical appropriation of property, a *per se* taking has occurred” *Id.* at 149.

⁴ 56 U.S. 350 (2015). In *Horne*, the Supreme Court weighed a Takings Clause challenge to a Department of Agriculture market order requiring raisin growers to reserve a portion of their crop for the government's use. *Id.* The government argued that “the reserve requirement [was] not a taking because raisin growers voluntarily choose to participate in the raisin market,” and had the option to “sell their raisin-variety grapes as table grapes or for use in juice or wine.” *Id.* at 365. The Court disagreed, holding that “a governmental mandate to relinquish specific, identifiable property as a ‘condition’ on permission to engage in commerce effects a *per se* taking.” *Id.* at 364–65.

ii. Compelled Speech

In its prior decision, the Court also concluded that the Program does not compel speech in violation of the First Amendment.⁵ *BMS-Janssen*, 2024 WL 1855054, at *9–12. Given that the “primary purpose of the Program is to determine the price manufacturers may charge for those specific drugs they choose to sell to Medicare,” the Court reasoned that the Program regulates commercial conduct, not speech. *Id.* at *10–11. “Any ‘speech’ aspects of the Program, such as the agreements and negotiations, are merely incidental mechanisms used during the price-setting process.” *Novo Nordisk*, 2024 WL 3594413, at *5. The Court determined, therefore, that the pharmaceutical manufacturer plaintiffs are not compelled to speak by virtue of participating in the Program or by signing the agreements and accordingly did not conduct a strict scrutiny analysis. *BMS-Janssen*, 2024 WL 1855054, at *12.

As in *Novo Nordisk*, the Court again declines to disturb its prior holdings and applies its reasoning and conclusions here. *See* 2024 WL 3594413, at *5. The Court holds that the Program does not constitute a taking of Plaintiff’s property and does not compel Plaintiff’s speech. The Court therefore concludes that the Plaintiff’s Fifth and First Amendment claims fail. As such, that leaves one constitutional challenge remaining: whether the Program’s “excise tax” violates the Excessive Fines Clause of the Eighth Amendment.

B. EIGHTH AMENDMENT

Plaintiff challenges the Program’s excise tax as a fine under the Eighth Amendment’s Excessive Fines Clause. (Plf.’s Moving Br. at 36–37.) Defendants contend that the Court lacks

⁵ The First Amendment prohibits the government from “telling people what they must say.” *Rumsfeld v. Forum for Acad. & Institutional Rts., Inc.*, 547 U.S. 47, 61 (2006) [hereinafter “*FAIR*”]. But “[t]he government . . . does not necessarily run afoul of the First Amendment when it regulates conduct in a manner that incidentally burdens one’s speech.” *Moore v. Hadestown Broadway Ltd. Liab. Co.*, Civ. No. 23-04837, 2024 WL 989843, at *17 (S.D.N.Y. Mar. 7, 2024); *see FAIR*, 547 U.S. at 62 (holding that compelling speech that “is plainly incidental to [a statute’s] regulation of conduct” does not violate the First Amendment).

subject-matter jurisdiction over this claim because (1) the claim is not redressable and Plaintiff therefore does not have standing; and (2) the claim is barred by the Anti-Injunction Act (AIA), 26 U.S.C. § 7421(a), and the tax exception to the Declaratory Judgment Act (DJA), 28 U.S.C. § 2201(a). (Defs.’ Moving Br. at 37–47.) The Court concludes that it lacks jurisdiction to resolve this claim under the AIA.

The AIA provides that “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). In other words, the AIA “deprives federal courts of jurisdiction to entertain an action to enjoin the IRS from assessing or collecting taxes.” *Beale v. IRS*, 256 F. App’x 550, 551 (3d Cir. 2007). As a result, “a person can typically challenge a federal tax only after he pays it, by suing for a refund.” *CIC Services, LLC v. IRS*, 593 U.S. 209, 211 (2021); *Flynn v. U.S. ex rel. Eggers*, 786 F.2d 586, 588 (3d Cir. 1986) (AIA requires tax challenges “be determined in a suit for refund”). The Supreme Court further explained that the AIA “draws no distinction between regulatory and revenue-raising tax rules.” *CIC Services, LLC*, 593 U.S. at 225. That is, a so-called regulatory tax—“a tax designed mainly to influence private conduct, rather than to raise revenue” —does not have a special pass from the AIA. *Id.* at 224.

In the face of the AIA’s express prohibition, Plaintiff argues that the *Williams Packing* exception applies.⁶ (Plf.’s Reply Br. at 57.) *Williams Packing* requires “proof of the presence of two factors” to avoid “the literal terms of” the AIA: “first, irreparable injury, . . . and second, certainty of success on the merits.” *Bob Jones Univ. v. Simon*, 416 U.S. 725, 737 (1974)

⁶ Plaintiff first argues that the AIA does not bar this suit because the challenge here “does not seek to restrain the assessment or collection of any tax that could ever realistically be paid.” (Pl.’s Moving Br. at 56.) As such, Plaintiff contends that because its “claim has no implications for tax assessment or collection, the AIA does not apply.” (*Id.* (quoting *Z St. v. Koskinen*, 791 F.3d 24, 30 (D.C. Cir. 2015))). Insofar as Congress labeled the excise tax a “tax” within Section 5000D, *see* 26 U.S.C. § 5000D(a) (“There is hereby imposed on the sale by the manufacturer . . . of any designated drug . . . a tax . . .”), the Court rejects this argument.

(discussing *Enochs v. Williams Packing & Nav. Co.*, 370 U.S. 1, 6 (1962)). “Unless both conditions are met, a suit for preventive injunctive relief must be dismissed.” *Alexander v. Ams. United*, 416 U.S. 752, 758 (1974). As set forth below, the Court joins its sister court in the District of Connecticut in concluding that neither condition is met here. *See Boehringer Ingelheim Pharms., Inc. v. HHS*, Civ No. 23-01103, 2024 WL 3292657 (D. Conn. July 3, 2024).

i. Irreparable Injury

Plaintiff claims that it would suffer irreparable injury by being forced to pay “ruinous penalties.” (Pl.’s Reply Br. at 57 (estimating that it would owe “over 90 billion in penalties each year, which is nearly double [its] Fiscal Year 2022 net sales of 50.5 billion.”).⁷ But as Defendants contend, a refund suit is an adequate remedy. Under the Program, the excise tax is imposed on each “sale” of a designated drug, 26 U.S.C. § 5000D(a), and is thus a “divisible tax,” or “one that represents the aggregate of taxes due on multiple transactions, *Rocovish v. United States*, 933 F.2d 991, 995 (Fed. Cir. 1991). A taxpayer challenging a divisible tax need only pay “the excise tax on a single transaction [to] satisfy” the rule that it must fully pay the tax before seeking a refund. *Id.* And, pursuant to an IRS Policy, while a refund suit is pending on a divisible tax assessment, the IRS will typically “exercise forbearance with respect to collection.” IRS Policy Statement 5–16, IRM § 1.2.1.6.4(6) (“When a refund suit is pending on a divisible assessment, the Service will exercise forbearance with respect to collection provided that the interests of the government are adequately protected, and the revenue is not in jeopardy.”)

⁷ Plaintiff’s estimate is premised on the excise tax being imposed on all sales of ENTRESTO, rather than only on its sales made through Medicare. (Pl.’s Reply Br. at 58.) As Plaintiff acknowledges, this assumption disregards an IRS Notice, which interprets the statute to apply only to sales made through Medicare. (Plf.’s Moving Br. at 38.) The statute states that the excise tax is “imposed on the sale by the manufacturer, producer, or importer of any designated drug,” 26 U.S.C. § 5000D(a), which is defined as “any negotiation-eligible drug . . . included on the list [of drugs selected under 42 U.S.C. § 1320f-1(a) for the Program] which is manufactured or produced in the United States or entered into the United States for consumption, use, or warehousing,” *id.* § 5000D(e)(1). Plaintiff argues that the IRS Notice is non-binding and runs contrary to the text of the statute. (Plf.’s Moving Br. at 38–40.)

For these reasons, the Court joins the Connecticut district court’s conclusion that the IRS would likely exercise forbearance during the period when Plaintiff’s refund suit is pending. *See Boehringer Ingelheim Pharms., Inc.*, 2024 WL 3292657, at *22. Accordingly, the concurrent harm on Plaintiff is minimal and repairable.

ii. Certainty of Success

Even if Plaintiff could show an irreparable harm, it must be “clear that under no circumstances could the government ultimately prevail” on its defense of the merits. *Williams Packing*, 370 U.S. at 7. The district court in Connecticut concluded, and this Court agrees, that Plaintiff cannot meet this demanding standard because this claim is novel, and Plaintiff has not identified a case that has ever held that a tax—lacking any connection to criminal conduct—was a fine for Excessive Fines Clause purposes.⁸ *See Boehringer Ingelheim Pharms., Inc.*, 2024 WL 3292657, at * 23. Plaintiff provides only a conclusory declaration that “the Program’s so-called ‘excise tax’ is a fine” and moves on to discuss the test for determining when a fine is unconstitutionally disproportionate to the offense in violation of the Eighth Amendment. *See* Plf.’s Moving Br. at 36. But each of the Excessive Fines Clause cases Plaintiff cites to involve a related criminal penalty or proceeding. *See id.* at 36–37 (citing *Dep’t of Revenue of Mont. V. Kurth Ranch*, 511 U.S. 767, 780 (1994) (tax conditioned on the commission of a crime); *Dye v. Frank*, 355 F.3d 1102, 1105 (7th Cir. 2004) (finding a civil drug penalty for possession of certain controlled substances constituted criminal punishment for double jeopardy purposes); *U.S. v. Bajakajian*, 524

⁸ In any event, the Supreme Court has rejected the argument that “the amount of the tax is so excessive that it will bring about the destruction of a . . . business” as a sufficient ground to strike down a taxing act. *See A. Magnano Co. v. Hamilton*, 292 U.S. 40, 45–47 (1934) (discussing cases and concluding that a statute under review is “plainly a taxing act” by its terms and rejecting the excessiveness of the tax as a ground to strike).

U.S. 321, 328 (1998) (holding full forfeiture of currency in a failure to report transport of currency would be grossly disproportionate to the gravity of offense).)

Because Plaintiff has not met its burden, the *Williams Packing* exception to the AIA does not apply here. The Court therefore concludes that the AIA divests it of jurisdiction to consider a pre-enforcement challenge to the excise tax provisions of the Program.

V. CONCLUSION

For the reasons stated above, the Court will **GRANT** Defendants' Cross-Motion for Summary Judgment (ECF No. 24) and **DENY** Plaintiff's Motion for Summary Judgment (ECF No. 18). An appropriate Order will follow.

Date: **October 18, 2024**

s/ Zahid N. Quraishi
ZAHID N. QURAISHI
UNITED STATES DISTRICT JUDGE