

Nos. 24-1820 & 24-1821

**IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT**

BRISTOL MYERS SQUIBB Co.,

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; AND ANANDA V. BURRA,

Appellees,

JANSSEN PHARMACEUTICALS, INC.,

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; AND ANANDA V. BURRA,

Appellees.

On Appeal from the United States District Court for the District of New Jersey,
Hon. Zahid N. Quraishi, Nos. 3-23-cv-3335 & 3-23-cv-3818

***AMICUS CURIAE* BRIEF OF
NATIONAL TAXPAYERS UNION FOUNDATION
IN SUPPORT OF APPELLANTS AND REVERSAL**

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July 19, 2024

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and Third Circuit Local Appellate Rule 26.1.1, counsel for *Amicus Curiae* certifies that the National Taxpayers Union Foundation is a nonprofit, tax-exempt organization under Internal Revenue Code §501(c)(3) and is incorporated in the District of Columbia. *Amicus* further states that it has no parent companies, subsidiaries, or affiliates that have issued shares to the public.

s/ Tyler Martinez

Tyler Martinez

Dated: July 19, 2024

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Pete Sepp, *Prescription Drug Market Needs Thoughtful Reform For Taxpayer Interests*, NTU (May 22, 2024)3

INTEREST OF *AMICUS CURIAE*

Founded in 1973, the National Taxpayers Union Foundation (“NTUF”) is a non-partisan research and educational organization dedicated to showing Americans how taxes, government spending, and regulations affect everyday life. NTUF advances principles of limited government, simple taxation, and transparency on both the state and federal level. NTUF’s Taxpayer Defense Center advocates for taxpayers in the courts, produces scholarly analyses, and engages in direct litigation and *amicus curiae* briefs upholding taxpayers’ rights and challenging administrative overreach by tax authorities. Accordingly, *Amicus* has an institutional interest in this case. All parties consented to the filing of this brief.¹

SUMMARY OF ARGUMENT

The Inflation Reduction Act’s Medicare Drug Price Negotiation Program aims to control rising medical costs—a laudable goal—but employs excessive measures that violate constitutional principles. The 95% excise tax on non-compliant pharmaceutical companies is not a legitimate tax but rather a coercive penalty, violating the Eighth Amendment’s prohibition of excessive fines and potentially amounting to a regulatory taking under the Fifth Amendment.

¹ *Amicus Curiae* confirms that this brief was not authored in whole or in part by counsel for any party, and no person or entity other than *Amicus* and its counsel made a monetary contribution to the preparation or submission of this brief.

Determining if the exaction here is a “tax” or “fine” is paramount because of the danger of Congress misapplying its powers can have dire consequences. Regulation of commerce, for example, can prohibit activity all together, but need to be pursuant to the limits imposed by the Constitution. In contrast, Congress’ taxing power is broader in what can be taxed, but cannot be used to directly regulate activity. The Supreme Court mandates a functional approach to distinguish between taxes and penalties. The Program’s heavy excise tax, akin to past rejected penalties, serves as a regulatory punishment of commercial activity rather than a tax.

But no matter a tax or a fine, the Bill of Rights constrains the government here. High punitive exactions, particularly those designed to enforce compliance with government pricing, create an Excessive Fines problem under the Eighth Amendment. In conventional negotiations, parties can reject unfavorable terms without severe repercussions. However, under the Program, refusal to comply results in punitive fines levied as “taxes,” stripping companies of their negotiation rights and imposing disproportionate financial burdens. The penalty’s severity makes failure to comply ruinous.

Additionally, the Program’s penalties undermine companies’ investment-backed expectations and control over their products, constituting a regulatory taking in violation of the Fifth Amendment. This is different than merely regulating the drugs based on safety or some other objective measure. Instead, the excessive

exaction and the resulting threat of economic devastation for non-compliance breach constitutional protections and set a dangerous precedent for regulatory overreach.

Therefore, this Court should recognize the unconstitutional nature of the Program’s penalties, ruling that the 95% excise tax violates the Eighth Amendment and the Fifth Amendment. Upholding constitutional limits ensures that cost-saving measures do not come at the expense of fundamental rights and fair market practices.

ARGUMENT

The National Taxpayers Union Foundation, and its sister organization the National Taxpayers Union, have long followed proposals for reining in medical costs under Medicare, Medicaid, Veterans Affairs, and for current government employees. *See, e.g.,* Andrew Lautz, *Analyzing the New Prescription Drug Pricing Proposal For Reconciliation*, NTU (Nov. 5, 2021).² Taxpayers certainly have a “deep and direct interest” because “[n]o bigger challenge exists to the federal government’s financial stability, and for that matter most states’ financial stability, than getting ahead of the health care cost spiral.” Pete Sepp, *Prescription Drug Market Needs Thoughtful Reform For Taxpayer Interests*, NTU (May 22, 2024).³ Drug pricing

² Available at: <https://www.ntu.org/publications/detail/analyzing-the-new-prescription-drug-pricing-proposal-for-reconciliation>.

³ Available at: <https://www.ntu.org/publications/detail/prescription-drug-market-needs-thoughtful-reform-for-taxpayer-interests>.

negotiations are therefore a good idea in the abstract. But the means of achieving these goals is just as important as the eventual savings to taxpayers.

The Inflation Reduction Act of 2022 created the Medicare Drug Price Negotiation Program (“Program”). Pub. L. 117–169 § 11001, 136 Stat. 1818, 1833 (Aug. 16, 2022) (“IRA”). As is relevant here, the Program made the classic errors associated with price controls and added a coercive new enforcement weapon to the government’s arsenal: up to a 95 percent “excise tax” on the Medicare sales of companies that do not accede to Washington’s pricing demands. 26 U.S.C. § 5000D. This “tax” is not aimed at generating revenue, but is instead a penalty for refusing to do as the government wishes—and thus implicates the Eighth Amendment as an excessive fine. In the alternative, this scheme is also functionally a regulatory taking of the value of prescription drugs, violating the Fifth Amendment. Either way, the Program’s framework, while laudable, is unconstitutional and the lower court should be reversed.

I. THE PROGRAM’S PENALTIES ARE EXCESSIVE, VIOLATING THE EIGHTH AMENDMENT.

In a normal arms-length negotiation, if a party does not like the payment offered, the seller of a product can refuse to sell. But under the Program, refusal to sell is risking a 95% “excise tax” on all Medicare sales. As appellant Bristol Meyers Squibb describes it, “the Program involves no real negotiations and no genuine agreements.” Br. of Bristol Meyers Squibb at 13. The penalties for not agreeing to

the government’s price structure is housed in the tax code at 26 U.S.C. § 5000D. But this is not really a tax aimed at garnering revenue, and is instead an excessive fine for not doing as the government demands.

A. Section 5000D is Not a Tax, it is Fine.

The Program’s “excise tax” is misnamed—really the Program creates a structure for civil fines to be applied to non-compliant companies. Policing the line between “tax” and “fines” is important because revenue generation is a distinct power than regulating commerce and this rule is clearly aimed at punishing those who do not agree to contract with the government at its preferred price point. *See, e.g., Nat’l Fed’n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 573 (2012) (“*NFIB*”) (“[A]lthough the breadth of Congress’s power to tax is greater than its power to regulate commerce, the taxing power does not give Congress the same degree of control over individual behavior.”) Therefore “Congress cannot change whether an exaction is a tax or a penalty for *constitutional* purposes simply by describing it as one or the other.” *Id.* at 544 (emphasis in original). Because the scope of power is different for taxes than other regulations, locking down whether § 5000D is a tax or a fine is essential to this Court’s analysis.

The Supreme Court commands that we take a “functional approach” to understanding if a provision is a “tax” or a penalty for failure to abide by some other regulatory scheme. *Id.* at 565; *see also id.* at 564–66 (applying functional approach

analysis). First and foremost, if the “tax” imposed is an “exceedingly heavy burden,” then it is susceptible to be considered a penalty, not a tax. *Id.* at 565. In *Bailey v. Drexel Furniture Co.*, 259 U.S. 20, 34, 36 (1922), for example, the Supreme Court rejected a 10% excise tax as on business income because it held the exaction was not a tax, but a penalty for employing child labor. While not dispositive, high taxes for specific acts “are at least consistent with a punitive character.” *Dep’t of Rev. of Mont. v. Kurth Ranch*, 511 U.S. 767, 780 (1994). While the Supreme Court in recent years has been less aggressive in policing this line, “there comes a time in the extension of the penalizing features of the so-called tax when it loses its character as such and becomes a mere penalty with the characteristics of regulation and punishment.” *NFIB*, 567 U.S. at 573 (internal quotation marks and citations omitted).

Such is the situation here: the Program’s 95% tax is really a penalty for not negotiating a price at the government’s preferred rate. It is true that some regulatory schemes have been upheld as a constitutional use of Congress’ taxing power—*NFIB* itself upheld such a tax for not buying health insurance. *See, e.g., id.* at 566. But the tax under the Affordable Care Act is different in kind and scope: for at most the tax paid was a few hundred dollars, not the near-total confiscation of an individual’s whole income. *See, e.g., id.* at 566, n.8 (“Someone with an annual income of \$100,000 a year would likely owe about \$200. The price of a qualifying insurance policy is projected to be around \$400 per month.”). Payment of the tax in *NFIB* was

a voluntary and relatively minimal intrusion to an individual's activity. The Program here, in contrast, takes years' worth of sales at 95% rate in more of a punitive fashion. It should therefore be held to be a fine, and an excessive one at that.

Other non-revenue generating focus of "taxes" also counsel for treating them as fines. For example, in *Drexel Furniture*, the "taxes" were paid only by those who knowingly used child labor. *Drexel Furniture*, 259 U.S. at 35. And the Secretary of Labor oversaw enforcement. *Id.* Similarly Montana's marijuana tax in *Kurth Ranch* was paid when the offender was no longer in possession of the drug, but instead had been long destroyed by the police. *See Kurth Ranch*, 511 U.S. at 783.

Again, such is the case here. The Program is overseen by the Secretary of Health and Human Services as part of its engagement in the drug marketplace. Payment of the "tax" under § 5000D only kicks in if the government and a manufacturer cannot come to an agreement on drug pricing. In this way, § 5000D is not designed to generate revenue or even "nudge" behavior (like sin taxes on cigarettes), but to force compliance with the wishes of a department that is not the Treasury or the Internal Revenue Service. Furthermore, the "tax" is not on the items sold (or, rather offered but ultimately not sold) at the bargaining table, but instead a retroactive look back to the whole economic activity of the pharmaceutical company.

These are all the hallmarks of a fine, not a tax, in both its purpose and effect. But even if, *arguendo*, this Court disagrees, and holds § 5000D is a classic excise

tax, that still does not resolve the question of constitutionality of the exaction. For “[e]ven if the taxing power enables Congress to impose a tax” in this situation, “any tax must still comply with other requirements in the Constitution.” *NFIB*, 567 U.S. at 570. Therefore, whether a tax or penalty, the next question is if § 5000D comports with the Excessive Fines clause of the Eighth Amendment.

B. Section 5000D’s Extraction is Excessive.

All citizens possess is the liberty to be free from excessive, punitive government penalties. *See, e.g.*, U.S. CONST. amend. VIII. These protections are “fundamental to our scheme of ordered liberty, with deep roots in our history and tradition.” *Timbs v. Indiana*, 586 U.S. 146, 149–50 (2019) (cleaned up, quoting *McDonald v. Chicago*, 561 U.S. 742, 767 (2010)).

Starting with the Magna Carta, these rights continued at the Founding. For example, the Northwest Ordinance provided that “[a]ll fines shall be moderate; and no cruel or unusual punishments inflicted.” Ordinance of 1787, § 14, art. 2 (1787). Several state Constitutions also protected this right at the dawn of the United States. *See, e.g.*, DEL. CONST., art. I, § 11 (1792); MD. CONST., Decl. of Rights, art. XXII (1776); MASS. CONST., pt. 1, art. XXVI (1780); N.H. CONST., pt. 1, art. 1, § XXXIII (1784); N.C. CONST., Decl. of Rights, art. X (1776); PA. CONST., art. IX, § 13 (1790); S.C. CONST., art. IX, § 4 (1790); VA. CONST., Bill of Rights, § 9 (1776). Vermont specified that “all fines shall be proportionate to the offences.” VT. CONST., ch. II, §

XXIX (1786). (Georgia’s 1777 Constitution had an excessive fines clause, GA. CONST., art. LIX (1777), but its 1789 Constitution did not.). Later the Bill of Rights codified the protections against excessive fines under the Eighth Amendment. U.S. CONST. amend. VIII.

Under the Supreme Court’s precedents, an excessive fine cannot be “grossly disproportional” to the offense and the government action must be “remedial.” *See, e.g., United States v. Bajakajian*, 524 U.S. 321, 334 (1998); *Austin v. United States*, 509 U.S. 602, 610 (1993). This is a straightforward test that needs to be applied to §5000D. And a fine cannot “be so large as to deprive [an offender] of his livelihood.” *Timbs*, 586 U.S. at 151 (quoting *Browning-Ferris Indus. of Vt., Inc. v. Kelco Disposal, Inc.*, 492 U.S. 257, 271 (1989), brackets in *Timbs*).

The Excessive Fines Clause applies to both civil and criminal law: “[t]he notion of punishment, as we commonly understand it, cuts across the division between the civil and the criminal law.” *Austin*, 509 U.S. at 610 (quoting *United States v. Halper*, 490 U.S. 435, 447–48 (1989)). This Court recognizes as such. *See, e.g., Myrie v. Comm’r, N.J. Dep’t of Corr.*, 267 F.3d 251, 262 (3d Cir. 2001) (the Excessive Fines clause “is not confined to exactions imposed as an aspect of the criminal law enforcement process”); *id.* (“A civil imposition, such as a civil forfeiture, which is adjudged ‘excessive,’ would fall within the purview of the constitutional bar.”). Other circuits have held that civil penalties are subject to the

Excessive Fines Clause, applying the Supreme Court’s holding in *Austin*. See, e.g., *Yates v. Pinellas Hematology & Oncology P.A.*, 21 F.4th 1288, 1308 (11th Cir. 2021) (holding that civil penalties under the False Claims Act were fines under the Excessive Fines Clause); *United States v. Mackby*, 261 F.3d 821, 830 (9th Cir. 2001) (finding that “the civil sanctions provided by the False Claims Act are subject to analysis under the Excessive Fines Clause because the sanctions represent a payment to the government, at least in part, as punishment.”). There should therefore be no doubt that this is so even in the tax context. As Justices Gorsuch and Jackson recently observed, “[e]conomic penalties imposed to deter willful noncompliance with the law are fines by any other name. And the Constitution has something to say about them: They cannot be excessive.” *Tyler v. Hennepin Cnty., Minnesota*, 598 U.S. 631, 649–50 (2023) (Gorsuch, J. concurring).

Applied here, § 5000D has more in common with a mob-style protection racket—accede to our discounted price demands or be taxed to the point of near-complete confiscation of most of a company’s revenues. A 95% extraction for the value of the items sold in the past to the biggest single insurer in the nation is a heavy burden. The traditional solution always has been that if a buyer—even the government—does not like a sale price, then it should not buy or look to a competitor. Here the Program goes a step further and strong-arms compliance by threatening 95% of revenues of a business for failing to agree to the government’s

terms. This penalty for not agreeing to sell goods to the government violates the Eighth Amendment.

Whether characterized as a massive tax with little precedent in U.S. experience, or a punitive artifice crafted to achieve price controls on prescription drugs, § 5000D risks further damaging the integrity of the U.S. tax system if it is left to stand. This court should apply the Eighth Amendment's excessive fines clause to reign in the protection racket created by the IRA.

II. THE PROGRAM CREATES A REGULATORY TAKING.

The Constitution makes clear private property cannot “be taken for public use, without just compensation.” U.S. CONST. amend. V. The pharmaceutical companies argue that the Program in this case constitutes a physical taking. *See, e.g.*, Br. for Bristol Myers Squibb at 10, 15; Br. for Janssen Pharmaceuticals, Inc., at 23, n. 14. *Amicus* suggests that, even if the Court finds there was no physical taking in this case, the Program creates a regulatory taking.⁴

Beginning with *Pennsylvania Coal Company v. Mahon*, 260 U.S. 393, 415 (1922), the United States Supreme Court recognized “[t]he general rule” that “while property may be regulated to a certain extent, if regulation goes too far it will be recognized as a taking.” This rule is reaffirmed as recently as 2005, where the Court

⁴ Physical takings analysis is distinct from regulatory takings analysis. *See Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg'l Plan. Agency*, 535 U.S. 302, 323 (2002). This Court should consider both paths to find the Program unconstitutional.

recognized a regulatory taking when a program creates a situation “so onerous that its effect is tantamount to a direct appropriation or ouster.” *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 537 (2005). In a regulatory taking analysis, the aim is to “identify regulatory actions that are functionally equivalent to the classic taking in which government directly appropriates private property or ousts the owner from his domain.” *Id.* at 539.

Lingle establishes two categorial regulations which are considered *per se* takings under the Fifth Amendment. *See id.* at 538 First, when a government “requires an owner to suffer a permanent physical invasion of her property” and second, when a governmental regulation “completely deprives an owner of ‘all economically beneficial use’ of her property.” *Id.* (quoting *Lucas v. S.C. Coastal Council*, 505 U.S. 1003, 1019 (1998) (emphasis and internal brackets omitted)). To be sure, the Supreme Court has hinted regulatory takings of personal property may not subject to the same protection under Fifth Amendment as other types of takings. *See Lucas*, 505 U.S. at 1027–28 (“And in the case of personal property, by reason of the State’s traditionally high degree of control commercial dealings, he ought to be aware of the possibility that new regulation might even render his property economically worthless (at least if the property's only economically productive use is sale or manufacture for sale).”). The case here is different in kind and scope. The government is mandating for the pharmaceutical companies to make a deal with it

under the Program or face severe fines levied as “taxes.” Unlike *Lucas*, Appellants’ property is not worthless by traditional regulation, *e.g.*, a change in U.S. Federal Drug Administration approval for the drugs based on new science, but by forced sale of their goods at the government’s preferred price as outlined in a regulatory scheme.

Therefore, when a regulatory takings challenge does not fall into the two *per se* categories outlined in *Lingle*, the standards in *Penn Central Transportation Company v. City of New York*, 438 U.S. 104, 124 (1978), control. The *Penn Central* Court “identified several factors that have particular significance” for a regulatory takings challenge. *Id.* These factors include “[t]he economic impact of the regulation on the claimant and, particularly, the extent to which the regulation has interfered with distinct investment-backed expectations are, of course, relevant considerations.” *Id.* The “character of the governmental action” is also considered such that a taking more likely exists when governmental interference with property is more akin to a physical invasion “than when interference arises from some public program adjusting the benefits and burdens of economic life to promote the common good.” *Id.*

First, the Program clearly causes economic harm to and severely interferes with investment-backed expectations of Plaintiffs. As pharmaceutical companies explained in their briefs, manufacturers are forced under the Program to enter into a contractual agreement with the government to sell their products at the deeply

discounted rate ranging from 40% to 75% of the market-based price. *See* Br. for Bristol Myers Squibb at 6. Failure to enter into contractual agreements medicine triggers penalties up to \$1 billion a day for Bristol Myers Squibb. *See id.* at 7. Even if manufacturers opt out of the program, they are still economically penalized as they must then end Medicare and Medicaid coverage of all of their products, thereby losing access to nearly half of the U.S. prescription drug market. *See id.* at 8. Any of these situations severely burdens private property rights as each virtually eliminates their ability to sell and garner income from the property. *See Lingle*, 544 U.S. at 539 (explaining a regulatory takings examination “focus directly upon the severity of the burden that the government imposes upon private property rights”).

Under *Penn Central*'s second factor, the Program's interference with Plaintiffs' personal property more akin to a “physical invasion by the government than... interference aris[ing] from some public program adjusting the benefits and burdens of economic life to promote the common good.” *Penn Central*, 438 U.S. at 124. The Program mandates that companies reduce their prices or either face astronomical penalties. It is not enough that there is no deal in the classic business sense, the government gets the extra advantage of penalizing the pharmaceutical companies for not taking its deal.

Simply put, the Program “goes too far” such that is more properly “recognized as a taking.” *Penn. Coal Co. v. Mahon*, 260 U.S. 393, 415 (1922). Under the

Program, these pharmaceutical companies face catastrophic economic burdens and losses to their overall revenue, control of their product, and distinct investment-backed expectations. This is a regulatory taking in violation of the Fifth Amendment.

The Constitution limits what means the government can do to negotiate prices for products, and as Justice Holmes warned, “[w]e are in danger of forgetting that a strong public desire to improve the public condition is not enough to warrant achieving the desire by a shorter cut than the constitutional way of paying for the change.” *Id.* at 416. A 95% penalty stylized as a “tax” is both an excessive fine under the Eighth Amendment and a regulatory taking under the Fifth Amendment.

CONCLUSION

Amicus respectfully requests that this Court reverse the decision below and hold § 5000D to be unconstitutional.

Respectfully submitted,

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CERTIFICATE OF BAR MEMBERSHIP

Pursuant to 3d Cir. L.A.R. 28.3(d) and 3d Cir. L.A.R. 46.1(e), I certify that I am a member of the bar of this Court.

s/ Tyler Martinez
Tyler Martinez
NATIONAL TAXPAYERS UNION FOUNDATION

Dated: July 19, 2024

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CERTIFICATES OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rules of Appellate Procedure 32(a)(7)(B) and 29(a)(5) because this brief contains 3,596 words, as counted by Microsoft Word, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and 3d Cir. L.A.R. 29.1(b).

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Pursuant to 3d Cir. L.A.R. 31.1(c), I certify that the text of the electronic brief is identical to the text in the paper copies.

Pursuant to 3d Cir. L.A.R. 31.1(c), I certify that this brief was scanned for viruses by Microsoft Defender Antivirus (Version 1.415.186.0), last updated July 19, 2024, and is virus free.

s/ Tyler Martinez
Tyler Martinez
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Dated: July 19, 2024

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing *Amicus Curiae* Brief of National Taxpayers Union Foundation in Support of Appellants and Reversal using the court's CM/ECF system. A Notice of Docket Activity will be emailed to all registered attorneys currently participating in this case, constituting service on those attorneys:

s/ Tyler Martinez
Tyler Martinez
NATIONAL TAXPAYERS UNION FOUNDATION

Dated: July 19, 2024

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