No. _____

In the Supreme Court of the United States

NOVARTIS PHARMACEUTICALS CORP.,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

The Drug Price Negotiation Program (Program) threatens enterprise-destroying fines unless a drug manufacturer both provides its products at government-dictated prices and publicly declares that those coerced prices are "fair." The fines at the root of the law are unprecedented in scope—for petitioner Novartis, they would swiftly escalate to $93.1 billion annually. The Third Circuit declined even to address whether this extraordinary penalty was excessive under the Eighth Amendment, because it found that the Anti-Injunction Act (AIA) divests federal court jurisdiction over any challenge to a civil penalty unconnected to criminal conduct so long as Congress labels it a tax. The court then concluded that the coerced transfers did not reflect an unconstitutional taking because they were "voluntary," and that the compelled speech at issue did not implicate the First Amendment because it was merely "incidental" to the regulation of conduct. Each holding involves constitutional questions of first-order importance.

The questions presented are:

1. Whether the AIA bars review of any challenge under the Excessive Fines Clause of a civil penalty unconnected to criminal conduct whenever Congress labels it a tax, even when it is effectively unpayable.

2. Whether the Program violates the Fifth Amendment by forcing manufacturers to transfer drugs to third parties at government-dictated prices.

3. Whether the Program violates the First Amendment by coercing manufacturers into expressing the government's preferred viewpoints on matters of public concern with which the manufacturers disagree.

RULE 29.6 STATEMENT

Pursuant to Supreme Court Rule 29.6, petitioner Novartis Pharmaceuticals Corporation (Novartis) makes the following disclosures: Novartis is a direct, wholly owned subsidiary of Novartis Finance Corporation, a New York corporation; and Novartis is an indirect, wholly owned subsidiary of Novartis AG, a Swiss company. No other publicly held corporation owns 10% or more of Novartis's stock.

PARTIES TO THE PROCEEDINGS BELOW

Petitioner Novartis was the plaintiff in the district court and the appellant in the court of appeals.

Respondents the Secretary of the United States Department of Health and Human Services; Administrator of the Centers for Medicare & Medicaid Services; the United States Department of Health and Human Services; and Centers for Medicare & Medicaid Services were the defendants in the district court and the appellees in the court of appeals. Respondents the Secretary United States Department of the Treasury; the United States Department of the Treasury; the Commissioner Internal Revenue Service; and the Internal Revenue Service were added as defendants to this action in the court of appeals.

RELATED PROCEEDINGS

There are no proceedings directly related to this case within the meaning of Rule 14.1(b)(iii).

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PETITION FOR A WRIT OF CERTIORARI

Novartis respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Third Circuit in this case.

OPINIONS BELOW

The court of appeals' opinion (App.1a-17a) is available at 155 F.4th 223. The district court's opinion (App.18a-29a) is available at 2024 WL 4524357.

JURISDICTION

The court of appeals entered judgment on September 11, 2025 (App.1a-17a). On November 20, 2025, Justice Alito extended the date to file a petition for a writ of certiorari to January 9, 2026. On December 11, 2025, Justice Alito further extended the date to file a petition to January 23, 2026. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Relevant provisions are reproduced in the Appendix. App.111a-42a.

INTRODUCTION

This case involves a challenge to Congress's unprecedented attempt to radically reshape the Nation's $600-billion prescription-drug market by forcing pharmaceutical companies to turn over their drugs at prices far below market levels on threat of enterprise-crippling fines labeled as a "tax" that raise no revenue at all. No one questions Congress's authority to address the cost of prescription drugs. But as with any subject, the Constitution places important limits on the means Congress can use. Here, Congress's program not only crosses numerous

constitutional red lines, but also, if allowed to stand, will adversely affect the health of tens of millions of Americans by impacting the healthcare available to them. This Court's immediate intervention is needed.

In August 2022, Congress enacted the "Drug Price Negotiation Program" (Program), as part of the Inflation Reduction Act (IRA). Contrary to its Orwellian name, the "Negotiation Program" does not involve any true negotiation. Rather, it operates as a sledgehammer. It threatens manufacturers with seismic fines unless they submit to a performative process in which they first publicly state that the government-dictated prices are the "maximum fair price" for their drugs—essentially forcing the companies to denounce their own earlier prices as unfair—and then hand over their most innovative and widely used products at prices far beneath market values. 42 U.S.C. § 1320f-2(a)(1). The penalties underlying the Program run up to *nineteen times* a manufacturer's total nationwide revenues from the sale of the drug—representing dollar fines that are, by design, unpayable.

Congress branded this extraordinary penalty as a "tax" in a brazen attempt to insulate this penalty scheme from judicial review under the Anti-Injunction Act (AIA), which bars suits brought "for the purpose of restraining the assessment or collection of any tax." 26 U.S.C. § 7421(a). But the Congressional Budget Office has estimated this "tax" would, in fact, raise zero revenue—even though revenue collection is the principal if not defining feature of a true tax. Rather, in the words of the statute itself, the penalty is designed to force manufacturers' "[]compliance" with the Program's requirements. 26 U.S.C. § 5000D.

Novartis is one of several manufacturers that have challenged the Program's constitutionality. After its innovative drug ENTRESTO® was selected for inclusion in the Program, Novartis was forced to perform sham "negotiations" over a purported "maximum fair price" for its drug, execute a series of "agreements" misrepresenting that process to the public, and then transfer its products to third parties at government-dictated prices far below market values. As Judge Hardiman explained in dissent in a related challenge, this "byzantine scheme" of forced transfers and compelled speech on pain of "extraordinary" penalties blatantly violates the Fifth and First Amendments of the Constitution. App.76a, App.110a. The Program also violates the Eighth Amendment's Excessive Fines Clause, which prohibits the government from punishing parties with monetary penalties that are disproportionate to the proscribed conduct. *See Austin v. United States*, 509 U.S. 602, 621 (1993). A fine that would effectively bankrupt a business simply because it refused to negotiate is an obvious and undeniable violation of the Eighth Amendment.

Yet the court of appeals upheld the Program. In doing so, it resolved three questions of first-order constitutional importance, each of which independently warrants this Court's review.

First, the Third Circuit wrongly declined even to address the merits of Novartis's Eighth Amendment claim on the ground that the AIA divested it of jurisdiction to review this undeniably unconstitutional exaction simply because Congress labeled it a "tax." That holding creates a roadmap for the government to violate the Eighth Amendment with impunity: create a sanction so exorbitant that no

party could ever pay it and therefore force them to comply, negating their ability ever to challenge the sanction post-payment. But label the sanction a "tax," precluding pre-payment review, and thereby insulate it from judicial review altogether. If allowed to stand, the Third Circuit's decision will render the Excessive Fines Clause a dead letter in the context of civil penalties. Moreover, a core premise of the Third Circuit's decision—that it is doubtful whether the Excessive Fines Clause applies to civil fines unconnected to criminal conduct *at all*—is the subject of a circuit conflict that it is imperative the Court resolve. This case provides the opportunity to do so, in the context of national legislation of far-reaching importance. The Eighth Amendment question alone warrants review.

Second, the panel held that the Program's mandates are "voluntary"—and thus do not violate the Takings Clause or the First Amendment—because manufacturers may purportedly withdraw all their drugs from Medicare and Medicaid to avoid them. In other words, the panel held that the ability to avoid a penalty via withdrawing entirely from a government-stabilized market gives the government carte blanche to commit constitutional violations against participants. Under the panel's logic, a constitutional violation is deemed consented to, even when, as here, it is *impossible* for a manufacturer to exit the market. So the government could, for example, force manufacturers to surrender their factories as a "condition" of remaining in Medicare, or compel universities to endorse the President's economic agenda as the price of federal funding. The Third Circuit's reasoning is plainly wrong, and

sharply undercuts this Court's recent Takings jurisprudence.

Third, the panel held that the Program imposes only an "incidental effect on speech"—and thus does not violate the First Amendment—because it *primarily* regulates conduct, or the prices manufacturers may charge. But as Judge Hardiman explained, if Congress had wished to impose a straightforward price regulation, it could have simply "capped what [manufacturers] may charge or what CMS will pay for selected drugs." App.98a (Hardiman, J., dissenting). Instead, "in Orwellian fashion," App.103a (Hardiman, J., dissenting), the Program goes much further by compelling manufacturers to affirm government-dictated views on a highly contentious political issue on which they have long disagreed—the "fairness" of their prices. The panel's reasoning would allow the government to compel regulated entities to characterize any regulation in the government's preferred terms, with no limiting principle. The First Amendment does not permit that result.

The panel's reasoning on all three issues squarely conflicts with this Court's precedents, and has profound consequences for bedrock constitutional limits on government power. This Court's review is imperative now, before any further damage is inflicted. As Judge Hardiman emphasized, the constitutionality of the Program "is of great importance to consumers of pharmaceutical drugs, the companies that provide them, and the public at large." App.110a. The Program affects millions of patients; reshapes an entire industry; and is altering research and development decisions, steering

investment away from certain drugs likely to become subject to the Program's mandates.

Furthermore, the longer the Program stays in place, the more extensive and severe its consequences. The Program is designed to expand radically—adding 15 new drugs next month and 20 additional drugs every year thereafter. Each successive expansion pulls additional manufacturers into the Program's regime of compelled speech, forced transfers, and punitive enforcement. And the injuries inflicted by the Program are irreparable. Compelled statements by manufacturers about the unfairness of their market-based prices reshape public and market perceptions in ways no later ruling can reverse. And once research and development programs are abandoned or never pursued, the lost innovation will be hard to recover. Review of this unprecedented federal program is needed now.

STATEMENT OF THE CASE

A. Legal Background

1. Medicare is a federal program that provides health-insurance coverage for those over the age of 65 and individuals with certain disabilities and medical conditions. The Medicare program includes two parts relevant here. Medicare Part B insures Medicare beneficiaries for outpatient healthcare services, including physician-administered drugs. *See* 42 U.S.C. §§ 1395k(a), 1395x(s)(2)(A). Medicare Part D permits beneficiaries to choose from a variety of insurance plans offered by private insurers under contracts with the government, which provide coverage for self-administered drugs. Together, Medicare Parts B and D dominate the U.S. prescription drug market, accounting "'for almost half

the annual nationwide spending on prescription drugs.'" App.32a.

Until Congress's passage of the IRA, both parts of the Medicare program guaranteed manufacturers market-based pricing for all of their drugs, in order to incentivize investment and innovation in new products. Medicare Part B reimbursement is based on a drug's average sales price, which ensures that reimbursement tracks market prices. 42 U.S.C. § 1395w-3a. And Medicare Part D expressly prohibits HHS from "interfer[ing] with the negotiations between drug manufacturers[,] . . . pharmacies[,] and [private health plans]" regarding the price of Part D drugs in order to ensure that market forces drive pricing. *Id.* § 1395w-111(i). Historically, private plans "can and do negotiate prices with prescription drug manufacturers," and have market incentives to secure lower pharmaceutical prices. C.A. App. 212-56.

Under these programs, the government "does not directly purchase drugs" for its own use; rather, it acts as a sovereign, using tax revenue to "subsidize[] a portion of the costs of providing prescription drugs to Medicare beneficiaries." *United States ex rel. Behnke v. CVS Caremark Corp.*, No. 14-cv-824, 2024 WL 1416499, at *4 (E.D. Pa. Apr. 2, 2024). These subsidies, though complex in structure, essentially function as reimbursements from the government to beneficiaries (often through private insurers) to offset a portion of the costs beneficiaries incur purchasing prescription drugs.

2. The Program upends the traditional market-driven approach by (1) allowing government agencies to unilaterally set the price for certain drugs, (2) compelling those drugs' manufacturers to sell

their products at that price, and (3) forcing the manufacturers to publicly endorse those prices as "maximum fair prices" arrived at via "negotiations."

CMS first identifies the drugs that account for the highest Medicare Part D expenditures and selects a subset of those drugs for negotiation. 42 U.S.C. § 1320f-1(b)(1)(A). Each year, starting in 2023, at least ten Part D drugs are selected, with Part B drugs added to the selection process beginning in 2026. *Id.* § 1320f-1(a)(1), (4). Within 10 years, as many as 180 drugs will be covered by the Program.

After a drug is chosen, the manufacturer has only 30 days to enter into an initial "agreement[]" with CMS to participate in the Program's "negotiation" process. *Id.* §§ 1320f(d)(2)(A), 1320f-2(a). That "agreement" commits the manufacturer to publicly "agree[ing]" that the price CMS eventually chooses—no matter how low—is the "maximum fair price" for the drug. C.A. App. 259-62.

If a manufacturer refuses to sign the initial agreement by the statutory deadline, the statute imposes a swiftly increasing penalty based on all United States sales of the listed drug (not just Medicare), which the Program terms an "excise tax." *See* 26 U.S.C. § 5000D(a). The penalty "begins at 185.71 percent and rises to 1,900 percent of the selected drug's total daily revenues from all domestic sales." App.72a (Hardiman, J., dissenting). For Novartis, this would mean that the penalty for not reaching an agreement to "negotiat[e]" over the "maximum fair price" for its groundbreaking drug ENTRESTO® would quickly rise to an annual rate of *$93.1 billion*—almost double Novartis's total global annual net revenue. C.A. App. 91-92. It is undisputed that this is not a penalty that Novartis—

or any other manufacturer—could ever afford to incur. *See id.*

The only statutory mechanism to avoid these penalties is for a manufacturer to "opt out of Medicare [and Medicaid] . . . *entirely*"—not merely for the selected drug, but for all of its drugs—"meaning [CMS] will not reimburse patients or providers for any of the drugs that the manufacturer sells (whether or not those drugs are part of the [Program])." *Nat'l Infusion Ctr. Ass'n v. Becerra* (*NICA*), 116 F.4th 488, 495 (5th Cir. 2024). But manufacturers cannot opt out immediately. Under the IRA, a manufacturer that gives notice to terminate its Medicare agreements must wait between 11 and 23 months before that termination takes effect. *See* 42 U.S.C. §§ 1395w-114a(b)(4)(B)(ii), 1395w-114c(b)(4)(B)(ii). So to avoid penalties for refusing to sign an agreement by October 1, 2023, a manufacturer would have needed to act by January 2022—months before the IRA was passed in August 2022. App.74a (Hardiman, J., dissenting).

Once a manufacturer has entered into the initial "agreement," CMS makes the first "offer." 42 U.S.C. § 1320f-3(b)(2). Although the manufacturer is allowed to provide a "counteroffer," CMS is under no obligation to consider it. *Id.* § 1320f-3(b)(2)(C)(ii), (e).

At the end of this process, CMS has the unfettered discretion, unchecked by any processes of administrative or judicial review, to unilaterally set a "maximum fair price." *Id.* § 1320f-7. The Program provides no floor below which CMS may not set the price. *Id.* § 1320f-3(c), (b)(2)(F)(ii). The law does however impose a ceiling on how *high* a price CMS can set. Specifically, CMS is directed to use as the ceiling price the lowest number produced by two

specified statutory methods. *Id.* § 1320f-3(c)(1)(A), (b)(2)(F). "These methods are expressly designed to yield prices that are well below market value." C.A. App. 51-52. Moreover, Congress specifically directed CMS to "aim[] to achieve the lowest maximum fair price for each selected drug." 42 U.S.C. § 1320f-3(b)(1).

The Program next imposes a date by which manufacturers must "agree" that CMS's demand is the "maximum fair price" for their drugs. For drugs subject to price caps in 2026, that date was August 1, 2024. *See* 42 U.S.C. §§ 1320f(d)(5)(C), 1320f-3(b)(2)(E). While CMS claims that manufacturers are bound to respond to CMS's "final offer by either accepting or rejecting [it]," C.A. App. 421, manufacturers cannot in reality "reject" CMS's offer and walk away as in a normal negotiation. If a manufacturer rejects CMS's final "maximum fair price" demand, "the consequences . . . are severe": it is subjected to the previously discussed excise "tax" that runs up to 1900% (nineteen times) of the total revenue derived from sales of that drug in the United States. *NICA*, 116 F.4th at 495, 500; 42 U.S.C. § 1320f-2(a)(1). Congress was well aware that no manufacturer could afford to incur such a "tax"; the Congressional Budget Office (CBO) projected that this "tax" would raise zero dollars. CBO, *Cost Estimate, Estimated Budgetary Effects of Public Law 117-169, to Provide for Reconciliation Pursuant to Title II of S. Con. Res. 14*, at 4-5 (Sept. 7, 2022).[1]

The Program then requires manufacturers to provide "access" to their drugs at the "maximum fair

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[1] https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf.

price" to a wide array of individuals and entities, including all eligible individuals dispensed drugs under Medicare Parts B and D. 42 U.S.C. §§ 1320f-2(a)(1), 1320f(c)(2). If a manufacturer does not do so, it is subject to a different but equally harsh sanction—civil monetary penalties at the extraordinary rate of ten times the alleged overcharge. *Id.* §§ 1320f-2(a)(1), 1320f-6(a)-(b).

B. Factual And Procedural Background

1. Novartis is one of the world's leading pharmaceutical companies. It deploys cutting-edge research to address some of society's most challenging healthcare problems and has developed a number of groundbreaking pharmaceutical drugs. One such drug is ENTRESTO®, a lifesaving medication that treats heart failure. ENTRESTO® has helped more than 2 million United States heart failure patients.

On August 29, 2023, Novartis's ENTRESTO® was selected for "negotiation" by CMS. Novartis signed the "agreement" with the Secretary on September 28, 2023, and entered into the "negotiation" process established by the statute to avoid the ruinous penalties described above. App.7a. At the close of the "negotiation" process, Novartis acceded to the government's "maximum fair price" for ENTRESTO® to avoid the Program's catastrophic fines. That price took effect on January 1, 2026. 42 U.S.C. §§ 1320f(b), (d); *see id.* §§ 1320f-2(a), 1320f-3(b).

2. Novartis filed suit in September 2023, seeking declaratory and injunctive relief. Novartis alleged the Program violates (1) the Eighth Amendment by using the threat of excessive fines to coerce Novartis into complying with the Program; (2) the Fifth Amendment by appropriating Novartis's property

rights in ENTRESTO®; and (3) the First Amendment by compelling Novartis's speech about the Program.

The district court heard oral argument in Novartis's case at the same time as three other challenges to the Program: *Janssen Pharmaceuticals, Inc. v. Becerra*, No. 3:23-cv-3818; *Bristol Myers Squibb Co. v. Becerra* (*BMS*), No. 3:23-cv-3335; and *Novo Nordisk Inc. v. Becerra*, No. 3:23-cv-20814. *Janssen* and *BMS* involve overlapping First and Fifth Amendment claims, while *Novo Nordisk* involves an overlapping First Amendment claim. None of the other three cases includes an Eighth Amendment claim. The district court reached decisions in each case at different times, granting summary judgment to the government in all four.

As to Novartis's Eighth Amendment challenge, the court concluded that the AIA divested it of jurisdiction to adjudicate the merits because "Congress labeled the excise tax a 'tax.'" App.26a. The district court also rejected Novartis's claims under the First and Fifth Amendments because Novartis purportedly is not "legally compelled" to participate in Medicare. App.23a.

3a. The four manufacturers appealed. The court of appeals addressed BMS and Janssen's challenges first and, in a split decision, affirmed the district court. App.30a-110a. As to their Fifth Amendment challenges, the panel held that no physical taking occurred because manufacturers were not "legally compelled" to participate in Medicare and Medicaid—rendering any transfer of their property "voluntary." App.39a-54a. In the majority's view, the fact that manufacturers could legally "stop doing business with the government" meant there could be no "physical taking" as a matter of law. App.38a. The panel

dismissed as irrelevant "basic economic rationality dictat[ing]" participation in Medicare and Medicaid given the government's dominance of the prescription-drug market. App.41a.

As to the First Amendment, the panel acknowledged that the mandated "agreements" carry "expressive component[s]," but nonetheless concluded that any compelled speech is solely "incidental" to the Program's regulation of "conduct." App.58a. In the panel's view, compelled statements about the "negotiation" process and manufacturers' prices simply "effectuate the Program" and therefore do not trigger First Amendment scrutiny. App.60a. The panel also relied on the premise that manufacturers "voluntarily chose to participate in the Program," despite the ruinous penalties threatened. App.63a.

Judge Hardiman dissented in full. He argued that the Program effects a "clear physical taking by forcing [manufacturers] to turn over physical doses" of their drugs at government-dictated prices. App.76a. And he rejected the manufacturers' theoretical ability to withdraw from Medicare and Medicaid in time to avoid this taking as illusory, because under the statute's timing requirements, manufacturers could not have withdrawn from Medicare and Medicaid in time to avoid the Program at all. App.81a-92a.

Judge Hardiman likewise concluded that the Program violates the First Amendment by, in "Orwellian fashion," forcing manufacturers to "convey the Government's message about a subject of great political significance and debate: whether the Program is a voluntary negotiation or a forced sale at prices set by CMS." App.103a. He rejected the panel's characterization of this speech burden as merely "incidental to regulated conduct," emphasizing that

Congress could have "regulate[d] conduct" by capping prices directly and simply requiring manufacturers to sign onto those prices. App.99a-100a. Instead, he explained, the Program "does much more than that" by requiring manufacturers to make representations about the negotiation "process" and resulting prices that "they have abjured from the start." App.98a, App.103a.

b. One week later, the panel affirmed the district court's dismissal of Novartis's challenge as well. It rejected Novartis's First and Fifth Amendment challenges "[f]or the reasons" set forth in its earlier opinion rejecting BMS and Janssen's challenges. App.16a. And it concluded that the AIA barred review of Novartis's Eighth Amendment Excessive Fines Clause claim. App.11a-16a. In the panel's view, Congress's decision to label the Program's ruinous penalties as "taxes" triggered the AIA's judicial-review bar, even though these penalties were never intended to raise revenue, were designed solely to coerce compliance, and will never be "assess[ed] or collect[ed]" with or without Novartis's suit. App.12a-15a.

The panel further declined to apply the *Enochs v. Williams Packing & Navigation Co.*, 370 U.S. 1 (1962), exception to the AIA, which applies when a plaintiff would suffer irreparable injury if it had to wait to challenge a tax until after paying it and it is clear the plaintiff will prevail on the merits. App.15a. The panel did not dispute that Novartis would face irreparable harm absent a pre-enforcement challenge, given that no rational entity would ever pay this exorbitant penalty to challenge it after-the-fact. Instead, the panel concluded that it was not "certain" that the Excessive Fines Clause can *ever*

apply to civil penalties imposed on non-criminal conduct, such that it is clear Novartis would win on the merits. App.15a-16a. In other words, the panel reasoned that the very fact that the government chose to punish *innocent* conduct—here, declining to agree to transfer a product at prices far beneath market values—placed an indisputably punitive and disproportionate sanction beyond constitutional scrutiny altogether.

REASONS FOR GRANTING THE WRIT

This case presents a challenge to a novel regulatory regime of extraordinary breadth and consequence. The Program compels manufacturers to transfer their most valuable drugs to third parties at prices far below market values while publicly endorsing that government-dictated process and the resulting prices—all under threat of ruinous financial penalties unprecedented in American history. In doing so, it crosses multiple constitutional red lines. The court of appeals' decision nevertheless allowing this Program to stand grants Congress sweeping power to evade constitutional limits, deepens an existing division in the court of appeals, and conflicts with this Court's precedents. Review is needed now to limit the potentially irreversible damage this Program is already inflicting, and this case is an ideal vehicle to resolve the important questions presented.

I. THE DECISION BELOW WRONGLY EXCUSES CONSTITUTIONAL VIOLATIONS OF AN EXTRAORDINARY MAGNITUDE

The decision below sanctions three distinct constitutional violations. The reasoning supporting each one is not only wrong but highly consequential,

materially expanding the government's ability to evade constitutional scrutiny of its actions.

A. The Anti-Injunction Act Holding Warrants This Court's Review

The court of appeals' ruling expanding the AIA's judicial-review bar deepens a circuit conflict, is wrong, and warrants review. The Third Circuit below held that the AIA insulates from judicial review *any* penalty Congress labels a "tax" that is unconnected to criminal conduct—even if that penalty is coercive, non-revenue-raising, and ruinous in amount, and regardless of how disproportionate it is to any alleged wrongdoing. That conclusion is irreconcilable with this Court's precedents as well as the precedent of other circuits. And it cannot be right. If allowed, it would grant governments the unchecked power to shield from judicial review any penalty imposed on entirely innocent conduct, no matter how exorbitant or unreasonable, simply by labeling it a "tax." In fact, a penalty's very excessiveness is what would insulate it from Eighth Amendment review. That untenable result demands this Court's intervention.

1. The Third Circuit's interpretation of the AIA and refusal to apply the *Williams Packing* exception have severe ramifications. Together, they foreclose judicial review of *any* civil penalty unconnected to criminal conduct labeled a "tax."

According to the panel, Congress's statutory labeling is decisive in determining whether the AIA applies to bar pre-enforcement review of a penalty. If Congress labels an exaction a "fine" or a "penalty," the AIA does not apply, and a federal court may assess whether the fine is excessive under the Eighth Amendment. But once "Congress label[s] [a]n

exaction a 'tax,'" any pre-enforcement lawsuit arguing that the "tax violates the Excessive Fines Clause" falls within the AIA's scope, and is therefore barred. App.12a-14a. The panel acknowledged that this holds true even when "Congress expects to raise no revenue from [the tax]," even when the tax is set at a level so astronomically high that it could never be paid, and even when no refund action could ever realistically be brought. App.14a.

The panel then compounded its error by essentially removing, in the context of civil penalties, the core safety valve of the *Williams Packing* exception to the AIA. That exception permits injunctions against the enforcement of "taxes" when the plaintiff will otherwise suffer "irreparable injury" and can demonstrate a "certainty of success on the merits." *Bob Jones Univ. v. Simon*, 416 U.S. 725, 737 (1974) (citing *Enochs v. Williams Packing & Navigation Co.*, 370 U.S. 1, 6-7 (1962)). The panel did not dispute the profound irreparable injury Novartis would suffer by being forced either to engage in speech with which it disagrees or pay ruinous penalties. Nor did it dispute that imposing a *$93 billion* penalty on wholly innocent conduct is grossly disproportionate under the Eighth Amendment. Yet the court held that the *Williams Packing* exception was unavailable because Novartis's right to relief was not "certain" due to the absence of a precedent from this Court establishing that "the Excessive Fines Clause applies to civil penalties imposed without any connection to criminal conduct." App.15a-16a. In other words, the panel held that there is no exception under *Williams Packing* for civil fines unconnected to criminal conduct. That holding leads to the astonishing result that such a civil penalty escapes

constitutional scrutiny altogether, whenever it is labeled a tax.

This reasoning paves the way for unchecked governmental overreach masquerading as "taxation." Under the panel's logic, Congress could punish even the most innocent conduct with enterprise-destroying fines, and block any judicial review by channeling lawsuits into "refund" actions that, by definition, will never occur. That is exactly what happened in this case: Congress imposed a *$93 billion* penalty on the completely innocent conduct of declining to sign an agreement to negotiate, and then insulated that sanction from judicial review by calling it a "tax"—knowing full well no one would ever pay this "tax" to unlock a refund suit.

The implications of that reasoning extend far beyond drug pricing. The government could, for example, levy a trillion-dollar "tax" on individuals who choose not to recycle. Under the Third Circuit's logic, affected individuals would first have to pay that tax in order to initiate a refund suit, because (1) the AIA would bar pre-enforcement review and (2) the *Williams Packing* exception would be unavailable because the penalty is civil, not criminal. And if those individuals simply complied with the law (as anyone surely would), they would lose the ability to challenge it post-enforcement—meaning they could not challenge it at all. The upshot is that the *more* excessive a fine is, the *less* able a court is to review it. Such an illogical and sweeping rule cannot be correct, and demands this Court's review.

2. The Third Circuit's AIA holding is not just consequential—it conflicts with this Court's precedents, while deepening a circuit conflict.

For starters, the premise underlying the Third Circuit's refusal to apply the *Williams Packing* exception—that this Court has "reserved" the question whether civil penalties can qualify as "fines"—is simply incorrect. App.15a. *Austin v. United States* squarely answered that question. 509 U.S. 602 (1993).

In *Austin*, the government argued—just as it does here—that the Excessive Fines Clause reaches only those sanctions that resemble traditional "criminal" punishment. *Id.* at 607. This Court unanimously and emphatically rejected that theory, explaining that the question for Excessive Fines Clause purposes "is not, as the United States would have it, whether [a penalty] is civil or criminal, but rather whether it is punishment." *Id.* at 610. The Court underscored that the Eighth Amendment serves "to limit the government's power to punish," a power that "'cuts across the division between the civil and criminal law.'" *Id.* at 609-10. And it explained that a fine has the hallmark of punishment when it "cannot fairly be said solely to serve a remedial purpose, but rather can only be explained as also serving either retributive or deterrent purposes." *Id.* at 610. *Austin* is fatal to the Third Circuit's *Williams Packing* analysis.

The Third Circuit's *Williams Packing* analysis also deepens an entrenched and severely lopsided circuit split. The Fourth, Seventh, Eighth, Ninth, and Eleventh Circuits have all correctly read *Austin* as holding that the Excessive Fines Clause applies to civil monetary penalties that are at least partly punitive or deterrent, even when they are not

connected to criminal conduct.[2] Meantime, the First Circuit has continued to treat civil penalties as categorically outside the Clause absent a "criminal" nexus, notwithstanding *Austin*. *United States v. Toth*, 33 F.4th 1, 16 (1st Cir. 2022). The Third Circuit's decision here aligns with the First Circuit's outlier view; although the court stopped short of expressly adopting the civil-criminal limitation, it treated the question as unresolved even though *Austin* firmly settles it. App.15a.

Scholars and jurists alike have recognized this lingering "split as to whether the Excessive Fines Clause extends to civil fines and forfeitures unconnected to a criminal proceeding." Jessica L. Asbridge, *Fines, Forfeitures, and Federalism*, 111 Va. L. Rev. 67, 76 (2025); *see, e.g.*, *Schwarzbaum*, 127 F.4th at 275 ("declin[ing] to 'repeat [the First Circuit's] mistakes'" and instead following *Austin*). And members of this Court have urged resolution of

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[2] *See, e.g.*, *United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 387 (4th Cir. 2015) ("[W]here 'a civil sanction "can only be explained as serving in part to punish," then the fine is subject to the Eighth Amendment.'"); *Grashoff v. Adams*, 65 F.4th 910, 916 (7th Cir. 2023) ("The inquiry does not depend on whether the sanction arises in the civil or criminal context."); *Grant ex rel. United States v. Zorn*, 107 F.4th 782, 797 (8th Cir. 2024) ("The FCA's combination of treble damages with per-claim penalties constitutes a punitive sanction that falls within the reach of the Excessive Fines Clause."); *United States v. Mackby*, 261 F.3d 821, 829 (9th Cir. 2001) ("[T]he Supreme Court [has] held that civil fines fall within the scope of the Eighth Amendment."); *United States v. Schwarzbaum*, 127 F.4th 259, 270, 274-75 (11th Cir. 2025) (noting that "[t]he question of whether the Excessive Fines Clause applies to civil cases was squarely presented to the Court . . . in *Austin*" and holding that the Clause applied to a civil penalty imposed by the IRS).

this lopsided divide once and for all. *See Toth v. United States*, 143 S. Ct. 552, 553 (2023) (Gorsuch, J., dissenting from denial of certiorari) (identifying "reasons to worry about the First Circuit's decision," including that it "incentivizes governments to impose exorbitant civil penalties" and "clashes with the approach many other courts have taken").[3]

This case underscores why clarification from this Court on the scope of the Excessive Fines Clause is urgently needed. The government here exploited this perceived doctrinal uncertainty to insulate massive, coercive financial exactions from constitutional scrutiny, notwithstanding their blatant unconstitutionality and the severe and irreparable harm they impose on manufacturers like Novartis. This case provides the ideal vehicle to both correct that error, and resolve the underlying circuit conflict.

Separate from its *Austin* error, the Third Circuit also misread the text of the AIA to find it applicable in the first place. The AIA only bars suits that are brought "*for the purpose of* restraining the assessment or collection of any tax." 26 U.S.C. § 7421(a) (emphasis added). As this Court has explained, the

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[3] The Court has granted certiorari in *Pung v. Isabella County*, No. 25-95 (scheduled for argument Feb. 25, 2026), which presents the question whether the civil penalty imposed in that case—unconnected to any criminal conduct—constitutes an excessive fine under the Eighth Amendment. But there is a substantial prospect that the Court will not reach that question, because the case also presents an alternative challenge under the Fifth Amendment's Takings Clause. At a minimum, this case should be held for *Pung*, because if this Court were to find that the Eighth Amendment applies to civil fines unconnected to criminal conduct, vacatur would be required as to the panel's *Williams Packing* holding.

AIA's language thus directs courts to look past any "tax" label to the actual "injuries alleged"—analyzing whether the plaintiff faces an "impending or eventual tax obligation"—to determine whether a suit has the "purpose of" restraining tax collection and will "disrupt[] the flow of revenue to the Federal Government." *CIC Servs., LLC v. IRS*, 593 U.S. 209, 212, 218-19 (2021). The whole point of the AIA is to "'protect[] the [Federal] Government's ability to collect a consistent stream of revenue.'" *Id.* at 212.

Here, Novartis's alleged injury does not stem from a tax being "assessed or collected" because, with or without its requested injunction, no tax will ever be levied or paid, which Congress knew when it passed the IRA. *Supra* 10. Rather, Novartis's injury arises from CMS's use of an exorbitantly high "tax" as a sledgehammer during negotiations.

No case has ever held that the AIA bars a suit implicating a "tax" that is neither expected nor intended to generate *a single penny* of revenue. The reason is evident: the AIA's "familiar pay-now-sue-later procedure," *CIC Servs.*, 593 U.S. at 222, makes no sense in the context of an unpayable fine. Such fines, by their very nature, cannot raise revenue or be subject to refund actions. In these circumstances, the AIA serves no function other than to permanently bar judicial review of allegedly unconstitutional fines.

B. The Fifth Amendment Holding Warrants This Court's Review

The Program also effects a physical taking by requiring manufacturers to transfer their drugs to third parties at below-market, government-dictated prices. The panel did not meaningfully dispute that reality. Instead, it excused the taking on the theory

that these compelled transfers are "voluntary" because manufacturers may purportedly avoid them by withdrawing *all* their medicines from the Medicare and Medicaid programs. App.38a-54a. That reasoning—endorsing what the panel itself described as the government's "unrestricted power" over participants in government-subsidized markets—has sweeping implications and squarely conflicts with this Court's Takings Clause precedents. App.39a. The Third Circuit's Fifth Amendment holding independently warrants review.

1. The consequences of the Third Circuit's "voluntariness" holding are profound. The panel reasoned that because manufacturers are purportedly "free to stop doing business with the government," any physical taking of their property is categorically immune from constitutional scrutiny. App.38a. That is so even though the government is not a purchaser within those markets, but rather subsidizes private purchases made by program-beneficiaries. In other words, the theoretical ability of a seller to withdraw from a market where the government chooses to subsidize purchases gives the government carte blanche to commit constitutional violations against that seller.

That result has alarming and far-reaching implications. Under the Third Circuit's reasoning, a rent-assistance program would permit the government to seize landlords' property simply because participants have the "option" to stop renting their property to people who receive government subsidies. Similarly, the government could force drug manufacturers to surrender their raw materials or manufacturing plants without compensation, provided they have the "option" of leaving Medicare.

The panel's reasoning effectively suspends constitutional protections for participants in government-stabilized markets. A rule of such breadth and consequence should not take hold without this Court's review.

2. The court of appeals' "voluntariness" holding also squarely conflicts with this Court's decision in *Horne v. Department of Agriculture*, 576 U.S. 351 (2015). Indeed, *Horne* rejected the precise theory on which the court below relied: that the theoretical "option" to stop selling to people who receive subsidies from the government excuses constitutional violations against market participants.

In *Horne*, a federal statute required farmers to "turn over a percentage of their raisin crop" under pain of penalties, subject to the right to recover some proceeds if the government resold the raisins. *Id.* at 362. When farmers declined to comply, "[t]he Government sent trucks . . . to pick up the raisins"; and when the farmers "refused [the government] entry," the government imposed fines for "disobeying." *Id.* at 356. Even though the government never physically seized the raisins, the Court held that the statute effected a "clear physical taking" because the farmers lost their "right to control their [raisins'] disposition." *Id.* at 358, 361, 364. As Judge Hardiman explained, that reasoning applies *a fortiori* here: "Like th[e] reserve requirement [in *Horne*]," the Program "imposes a clear physical taking by forcing the Companies to turn over physical doses of [their drugs] to Medicare beneficiaries at certain prices." App.76a.

Critically, the government argued in *Horne*—just as it does here—that there could be no physical taking because the farmers "voluntarily enter[ed] the

commercial market for raisins." *Horne* Respondent's Br. 28-29 (No. 14-275), 2015 WL 1478016. But the Court emphatically rejected that argument, holding that the government may *never* take physical property as a "condition" for market participation—regardless whether property owners "voluntarily cho[se] to participate in [that] market" and irrespective of how regulated that market may be. *Horne*, 576 U.S. at 364-67. That holding is fatal to the Program. If a "government mandate" were a precondition to a *per se* takings claim (as the panel here concluded), *Horne* would have come out the opposite way.

The panel's attempts to distinguish *Horne* do not withstand scrutiny. The panel reasoned that whereas the farmers in *Horne* would have had "to exit the raisin market entirely" to avoid a taking, Novartis need only "withdraw from [Medicare and Medicaid]" while continuing to participate "in the pharmaceutical market—including by selling . . . to private parties." App.44a.

But the growers in *Horne* were not "manufacturers" of raisins—they grew grapes, and sought to sell those grapes into the federally supported raisins market. So they *could* sell the same grapes to other buyers in alternative markets, such "'as table grapes or for use in juice or wine'"—just as Novartis can (by the panel's telling) sell the same products outside the federally regulated market. *Horne*, 576 U.S. at 365. But *Horne* rejected this "'[l]et them sell wine'" defense as "wrong as a matter of law." *Id.* If anything, the cost of withdrawal here is even more onerous than in *Horne*, because a manufacturer must, by the panel's telling, withdraw "*all its products"* from the relevant market, rather than just

the one subject to the taking. App.73a (Hardiman, J., dissenting).

Regardless, as Judge Hardiman explained, manufacturers in fact had no "option" to exit Medicare and Medicaid in time to avoid the Program. *See* App.81a-92a. Congress expressly *blocked* manufacturers from withdrawing from those programs without providing up to 23 months' notice. *See* 42 U.S.C. §§ 1395w-114a(b)(4)(B)(ii), 1395w-114c(b)(4)(B)(ii). So to avoid penalties for refusing to sign the initial agreement by October 1, 2023, Novartis would have had "to accomplish the impossible": provide notices of termination by January 31, 2022—before the IRA even "became law." App.74a (Hardiman, J., dissenting) (emphasis omitted). "The upshot is that the Companies could not have declined to participate in the first year of the program." App.82a (Hardiman, J., dissenting). And "[o]nce a manufacturer . . . signed [the initial] [a]greement, it [became] bound by it, full stop"—meaning CMS is required to "impose civil monetary penalties each time [a manufacturer] violates an Agreement," including by failing to provide Medicare beneficiaries "access" to selected drugs at below-market prices. App.90a (Hardiman, J., dissenting).

The panel focused on CMS's "promise" in a non-binding guidance document to offer manufacturers an expedited 30-day exit from Medicare and Medicaid. *See* App.7a. But as Judge Hardiman explained in *BMS*, that "expedited exit option conflicts with the Act," which sets forth only two exit options: (1) a manufacturer can voluntarily withdraw and wait 11 to 23 months; or (2) *CMS* can remove a manufacturer with 30-days' notice if the manufacturer engaged in "knowing and willful violations" of the program

agreements or "similar misconduct." App.81a-88a. The statute does not give CMS the authority to create an additional exit pathway. If the government may defeat constitutional scrutiny by pointing to an exit that exists in name only—or worse, does not exist at all—there would be no limiting principle. Such a rule warrants this Court's review, too.

C. The First Amendment Holding Warrants This Court's Review

Finally, the Third Circuit's First Amendment holding also independently merits review. On its face, the Program directly compels speech. Rather than simply capping the prices of manufacturers' drugs, it orders that manufacturers *speak* about those prices, attesting that government-dictated prices were obtained through a "negotiation" and are the "*maximum* fair prices"—which means that manufacturers' higher market-set prices are *unfair*. Yet the panel held that the Program imposes only an "incidental effect on speech" or, in the alternative, does not compel *any* speech because participation in the Program is "voluntary." App.54a. That reasoning conflicts with this Court's precedents and opens the door to sweeping government regulations forcing private entities to speak the government's preferred messages.

1. As Judge Hardiman explained, the Program violates the First Amendment by compelling manufacturers to speak under threat of ruinous penalties.

For example, it forces manufacturers to represent to the public that they voluntarily engaged in a "negotiation" over the "maximum fair price," when, in reality, the government unilaterally sets the price.

App.102a-03a (Hardiman, J., dissenting). And it compels manufacturers to sign documents stating that they "agree" to the "maximum fair price" CMS sets after those pretend "negotiation[s]" conclude. 42 U.S.C. §§ 1320f-2(a)(1), 1320f(c)(2). Signing those documents conveys clear political messages to the public: that these are genuine, good-faith negotiations; that this voluntary give-and-take culminated in a true "agreement"; that the "agreed-on" price reflects the selected drug's value; and that manufacturers' previous and current market prices, even those resulting from genuine negotiations, are "unfair prices." App.101.a (Hardiman, J., dissenting).

Of course, Novartis does not genuinely "agree" with any of this. It has been coerced into signing these "agreements" because, otherwise, it would be deemed in "noncompliance" with the Program, facing untenable penalties that would quickly balloon to *$93.1 billion*.

The Program also compels speech through performative conduct. Manufacturers are forced to participate in a sham "negotiation" process that is designed to create the appearance to the public of voluntary give-and-take when no such flexibility exists. By compelling Novartis to express "support for views [it] find[s] objectionable"—both through its statements in the agreements and its participation in the performative "negotiation" process—the Program violates the First Amendment. *Janus v. American Fed'n of State, Cnty., & Mun. Emps., Council 31*, 585 U.S. 878, 892 (2018).

2. The Third Circuit's contrary holding does not comport with this Court's compelled-speech precedents. It also carries serious consequences for federal regulation going forward.

a. The panel first reasoned that the Program "permissibly regulates conduct"—the prices manufacturers charge—and thus carries "only an incidental effect on speech." App.54a. But that directly conflicts with this Court's decision in *Expressions Hair Design v. Schneiderman*, 581 U.S. 37 (2017).

In *Expressions*, the Court drew a critical distinction between laws that merely set prices—which impose lawful, incidental restrictions on speech—and laws that control "how sellers may *communicate* their prices," which impose non-incidental restrictions on speech. *Id.* at 47-48 (emphasis added). A law that simply requires sellers to charge a particular amount—such as a rule "requiring all New York delis to charge $10 for their sandwiches"—regulates conduct, and any effects on the sellers' speech, such as updating menus to include "$10," would be incidental. *Id.* at 47. The statute in *Expressions* crossed the constitutional line because it dictated how merchants could "convey" their prices, prohibiting them from framing charges as a cash price plus a credit-card "surcharge." *Id.* In other words, the law compelled a particular way of communicating price information.

The Program falls squarely on the forbidden side of that line. It is not a "typical price regulation," *id.* at 47, as it mandates communications "characteriz[ing]" "product price[s]," *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 292 (D.C. Cir. 2019), including statements about the nature of the process used to adopt those prices and their perceived fairness—statements with which Novartis profoundly disagrees.

As Judge Hardiman explained, if Congress truly wished to impose a price regulation, it could have simply "capped what [manufacturers] may charge or what CMS will pay for selected drugs," App.98a. Alternatively, Congress could have employed neutral, purely descriptive terms such as "maximum allowable price." Instead, in "Orwellian fashion." App.103a (Hardiman, J., dissenting), the Program requires that manufacturers "convey" the government's preferred message on a highly contentious political issue on which manufacturers have disagreed from the outset, *Expressions*, 581 U.S. at 47-48. That is direct regulation of speech.

The panel's contrary reasoning, once again, carries startling consequences. By the panel's telling, any price regulation permits the government to simultaneously compel market participants to *characterize* the regulation in a certain (government-favorable) way as "incidental" to that regulation. App.55a-61a. So the government could require banks to state that prior interest rates were "exploitative," or force landlords subject to rent control to state that previous rents were "unjust." Under that rationale, "there would be no end to the government's ability to skew public debate by forcing companies to use the government's preferred language." *National Ass'n of Mfrs. v. SEC*, 800 F.3d 518, 530 (D.C. Cir. 2015). A ruling that grants such power warrants this Court's review.

b. The Third Circuit alternatively held that manufacturers "voluntarily chose to participate in the Program" and "[a]ny ancillary speech component inherent in Program participation was therefore not compelled." App.63a-64a. That argument is wrong—and carries dire consequences—for all the same

reasons discussed in the Fifth Amendment context. *Supra* 10. Indeed, the notion that voluntary participation in a program can excuse a constitutional violation carries even *less* force in the First Amendment context.

The Court's decision in *Agency for International Development v. Alliance for Open Society International, Inc.* (*USAID*), controls. *See* 570 U.S. 205 (2013). There, the Court explained that "the relevant distinction" in assessing speech conditions on federal programs is between conditions that "specify the activities Congress wants to subsidize" and conditions that "seek to leverage funding to regulate speech." *Id.* at 214-15. Applying that distinction, the Court invalidated a requirement that federal funds not "be used by an organization 'that does not have a policy explicitly opposing prostitution and sex trafficking.'" *Id.* at 208, 221.

Here, the Program's compelled-speech provisions do not merely "specify" what Congress wishes to subsidize; they leverage the threat of exorbitant fines to force manufacturers to engage in government-mandated performative speech. Those mandates operate "on the *recipient* of the [government's benefits] rather than on a particular program or service," and are therefore unlawful. *Rust v. Sullivan*, 500 U.S. 173, 197 (1991); *see USAID*, 570 U.S. at 218-19.

To try to sidestep *USAID*, the panel reasoned that any "compelled" speech is "within the scope of the Program because the contracts at issue effectuate the drug price negotiation process established by Congress." App.66a. But that reasoning is entirely circular—the government cannot avoid First Amendment scrutiny simply by defining its program

to include compelled speech. *See USAID*, 570 U.S. at 214-15. As Judge Hardiman explained, the Program does not need loaded language conveying value judgments about its results to function. App.102a-03a. The sole purpose of this compelled speech is to mislead the public.

The upshot of the decision below is that the government may force participants in federal programs to say virtually anything so long as the mandate is packaged as part of the program's implementation. That is a positively Orwellian result.

D. The Combination Of These Three Constitutional Violations Makes This Case Uniquely Important

It is uncommon for a federal statute to raise even a single serious constitutional question. It is rarer still for a single regulatory scheme to implicate multiple constitutional limits at once. The Program's "byzantine scheme" of compelled speech, mandated transfers of property, and grossly disproportionate fines forms a coercive regulatory model unprecedented in federal economic regulation. App.110a (Hardiman, J., dissenting).

Allowing that model to stand will simply invite replication across other sectors. Congress now has a ready-made template for committing constitutional violations with impunity: provide subsidies for the purchase of goods in a market, claim that this subsidy makes participation in the market voluntary, and enforce surrender of constitutional rights through boundless civil penalties—which escape judicial review altogether because they are labeled "taxes." That is a serious threat to the rule of law, and its

implications for future federal regulation are too significant to be left to percolate without this Court's review.

II. THE COURT'S REVIEW IS NEEDED NOW

The constitutionality of the Program is, as Judge Hardiman explained, "of great importance to consumers of pharmaceutical drugs, the companies that provide them, and the public at large." App.110a. The Program affects millions of patients, reshapes an entire industry, and radically redefines limits of regulatory power. Questions of that magnitude call out for this Court's review, and review should come now—before further irreversible harm takes hold.

The federal government dominates the Nation's healthcare market, "account[ing] for almost half of all spending on prescription drugs—some $200 billion per year." App.68a (Hardiman, J., dissenting). The Program is poised to radically transform that market: The CBO estimates that the Program will redirect about "*$100 billion*" in healthcare payments in just its first decade. CBO, *Prescription Drug Pricing Reduction Act of 2019* (July 24, 2019) (emphasis added).[4]

But the importance of this case extends well beyond its implications for our economy. Although the Program remains in its early stages, it has already inflicted profound and irreparable harm on regulated entities. The first "cycle" of the Program is now complete, with ten manufacturers each forced into a series of "agreements" misrepresenting that

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[4] https://www.cbo.gov/system/files/2019-07/PDPRA_preliminary_estimate.pdf.

they endorse government-dictated prices for their drugs and engaged in real "negotiations" over those prices. Those prices took effect this month and reflect dramatic departures from prior market levels—reductions ranging from 40% to 80% off of list prices. Press Release, CMS, *HHS Announces 15 Additional Drugs Selected for Medicare Drug Price Negotiations in Continued Effort to Lower Prescription Drug Costs for Seniors* (Jan. 17, 2025).[5] The result is billions of dollars of threatened exactions against manufacturers, which will fundamentally and irretrievably alter investment decisions. For example, a CBO report indicates that the Program will result in thirteen fewer potentially life-saving drugs coming to market over the next three decades. *See* CBO, *Cost Estimate, supra*, at 15.

And that is only the beginning. By design, the Program will scale rapidly—pulling additional manufacturers and drugs into its coercive regime. The Program's second "cycle" is already underway; CMS has forced the manufacturers of 15 additional drugs into sham "negotiations" and "agreements," which culminated in government-dictated prices set to take effect January 2027. CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2027* (Nov. 2025).[6] And CMS will select 15 additional drugs for inclusion in the Program in February 2026, including (for the first time) drugs covered under Part B as well as Part

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[5] https://www.cms.gov/newsroom/press-releases/hhs-announces-15-additional-drugs-selected-medicare-drug-price-negotiations-continued-effort-lower.

[6] https://www.cms.gov/files/document/fact-sheet-negotiated-prices-ipay-2027.pdf.

D—bringing the number of total drugs subject to sham negotiations and forced agreements and transfers to 40. 42 U.S.C. § 1320f-1(a). And the statute then accelerates further—sweeping in *20* additional drugs per year from 2027 onward—so the number of drugs and manufacturers subject to the Program's regime of forced misrepresentations and transfers of property accumulates year after year. *Id.*

If the Court has any doubt about the constitutionality of the program, it should intervene now. Waiting comes at a steep and unnecessary cost; each successive cycle of the Program layers new compelled speech, forced transfers, and punitive threats on top of those already in place. And those effects cannot later be undone. Compelled declarations by manufacturers that government-dictated prices are "fair" obviously reshape political debate on issues of the utmost importance, altering how both voters and lawmakers will perceive the issues. The longer those misrepresentations stay in place, the harder the resulting reputational damage becomes to overcome.

Nor can manufacturers later undo the strategic decisions forced by this sustained, below-market pricing—including dramatic, forward-looking reductions to their research and development budgets to operate under prices set far beneath market levels. The Program "reduce[s] investments that [would] produce new drugs and new applications of existing drugs—side effects that are already being felt." Erica York, *Inflation Reduction Act's Price Controls Are Deterring New Drug Development*, Tax Foundation

(Apr. 26, 2023).[7] And it has shifted research priorities away from certain products that "would likely be subject to [the Program]," including therapies for "conditions that disproportionally affect older adults." Greg Licholai, *Inflation Reduction Act Unintended Consequences For Medical Innovation*, Forbes (Feb. 3, 2025).[8] This reallocation of innovation capital will have "profound" impacts on the "future of drug innovation—and ultimately [on] patients." *Id.* The longer the Program remains in force, the deeper and more irreversible those effects become, even if the Court later strikes down the statute.

This case is an ideal vehicle for reviewing the Program's constitutionality. It squarely presents the three most important issues raised by the Program. The court of appeals resolved each of these issues on purely legal grounds. App.11a-16a. And no other pending petition presents an Eighth Amendment challenge to the Program. Resolution of the AIA question is crucial to ensuring that this challenge can be resolved by the courts. In an era of "more and more civil laws bearing more and more extravagant punishments," *Sessions v. Dimaya*, 584 U.S. 148, 184 (2018) (Gorsuch, J., concurring in part and concurring in the judgment), the Program at issue in this case breaks new barriers when it comes to imposing fines. Review is urgently needed on this question.

This case accordingly offers an ideal vehicle to review this immensely consequential federal program

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[7] https://taxfoundation.org/blog/inflation-reduction-act-medicare-prescription-drug-price-controls/.

[8] https://www.forbes.com/sites/greglicholai/2025/02/03/inflation-reduction-act-unintended-consequences-for-medical-innovation/.

at a time when such review will be most effective and meaningful. Review is warranted now.

CONCLUSION

The petition should be granted.

Respectfully submitted,

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January 23, 2026

APPENDIX

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[155 F.4th 223]

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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

No. 24-2968

Argued on April 8, 2025

(Filed: September 11, 2025

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

OPINION OF THE COURT

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*, 155 F.4th 245, 254–55 (3d Cir. 2025).

Novartis claims that this exit option is illusory, but this Court recently held otherwise. *See Bristol Myers Squibb*, 155 F.4th at 257–58. 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*, 155 F.4th at 260.

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 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,

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[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).

291–92, 143 S.Ct. 1609, 216 L.Ed.2d 254 (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, 144 S.Ct. 1540, 219 L.Ed.2d 121 (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, 127 S.Ct. 1438, 167 L.Ed.2d 248 (2007); *see also Diamond Alternative Energy, LLC v. EPA*, 606 U.S. 100, 145 S. Ct. 2121, 2135, 222 L.Ed.2d 370 (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, 94 S.Ct. 2038, 40 L.Ed.2d 496 (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

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[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.

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, 132 S.Ct. 2566, 183 L.Ed.2d 450 (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, 42 S.Ct. 419, 66 L.Ed. 816 (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, 42 S.Ct. 449, 66 L.Ed. 817 (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 Congress's intent is the statutory text." *NFIB*, 567 U.S. at 544, 132 S.Ct. 2566. 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, 141 S.Ct. 1582, 209 L.Ed.2d 615 (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, 141 S.Ct. 1582. 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, 141 S.Ct. 1582. The advisor asked the court to set aside the notice, enjoin its enforcement, and declare it unlawful. *Id.* at 215, 141 S.Ct. 1582.

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, 141 S.Ct. 1582. 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, 141 S.Ct. 1582.

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, 141 S.Ct. 1582.

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, 141 S.Ct. 1582. 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, 94 S.Ct. 2038 (citing *Enochs v. Williams Packing & Nav. Co.*, 370 U.S. 1, 6–7, 82 S.Ct. 1125, 8 L.Ed.2d 292 (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, 82 S.Ct. 1125. 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, 82 S.Ct. 1125. "[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, 109 S.Ct. 2909, 106 L.Ed.2d 219 (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, 94 S.Ct. 2038; *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* 155 F.4th at 254–63. For the reasons we explained there, we hold that the Program does not violate the Takings Clause. *See* 155 F.4th at 262–63. 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* 155 F.4th at 263–70. For the reasons we explained there, we hold that the Program does not violate the First Amendment. *See id.* at 263–64. 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.

[2024 WL 4524357]

NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. **XAVIER BECERRA, *et al.***, Respondent.	Civil Action No. 23-14221 (ZNQ) (JBD) **OPINION**

QURAISHI, 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

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[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.

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 *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

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[3] The government commits a physical taking when it "physically takes possession of property without acquiring title

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).)

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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.

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.

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.

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[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).

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 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) (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).

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[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.

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

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[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.)

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.")

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 reparable.

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

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[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).

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 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

[155 F.4th 245]

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 *

(Amended as per the Clerk's 09/13/2024 Order)

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

No. 24-1820, No. 24-1821

Argued on October 30, 2024

(Opinion filed: September 4, 2025)

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

OPINION OF THE COURT

FREEMAN, Circuit Judge.

Medicare Part D is a voluntary prescription drug benefit program for Medicare beneficiaries. When Congress first created Part D in 2003, it barred the Centers for Medicare and Medicaid Services ("CMS") from using its market share to negotiate lower prices for the drugs it covers. But Congress changed course when it enacted the Inflation Reduction Act of 2022 (the "IRA"). The IRA includes a Drug Price Negotiation Program (the "Program") that directs CMS to negotiate prices over a subset of covered drugs that lack a generic competitor and represent the highest expenditures to the government.

In these cases, Bristol Myers Squibb Company ("BMS") and Janssen Pharmaceuticals Incorporated ("Janssen") (together, "the Companies") challenge the Program on constitutional grounds. They contend that the Program (1) effects an uncompensated taking of their property, (2) compels speech in violation of the First Amendment, and (3) imposes unconstitutional conditions on participation.

The District Court determined that these claims fail as a matter of law and entered judgments in favor of the government. For the following reasons, we will affirm the District Court's orders.

I

A

"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 Health & Hum.*

Servs., 137 F.4th 116, 119 (3d Cir. 2025).[1] Medicare is divided into Parts, one of which is Part D: "a voluntary prescription drug benefit program that subsidizes the cost of prescription drugs and prescription drug insurance premiums for Medicare enrollees." *United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 749 (3d Cir. 2017). Part D reimburses private insurance companies called "sponsors," who work with pharmacy benefit managers and other subcontractors, who in turn contract with pharmacies that provide drugs to Medicare beneficiaries. *AstraZeneca*, 137 F.4th at 120. "Through Medicare and Medicaid, the federal government pays for almost half the annual nationwide spending on prescription drugs." *Id.* at 119 (cleaned up).[2]

When Congress created Part D, it included a provision that barred 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) (2003). But Congress created an exception to that non-interference provision when it enacted the Program. The Program directs CMS to "negotiate . . . maximum fair prices" for certain drugs. *Id.* § 1320f(a)(3). The drugs subject to negotiation are those that have been approved by the Food and Drug Administration for at

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[1] Our opinion in *AstraZeneca* provides more detail on Medicare Part D, the Program, and CMS's implementation of the IRA's directives. *See* 137 F.4th at 119–21.

[2] "Medicaid is a joint federal and state program that provides medical coverage for people with limited incomes." *AstraZeneca*, 137 F.4th at 119.

least seven years, lack a generic competitor, and represent the highest expenditures under Medicare Part B or D. *AstraZeneca*, 137 F.4th at 120.[3]

Once CMS selects and announces which drugs are subject to negotiation, a pharmaceutical manufacturer that holds regulatory approval for a selected drug must choose whether to participate in the Program. If the manufacturer chooses to participate, it executes a Medicare Drug Price Negotiation Program Agreement ("Agreement") with CMS. In 2023, CMS provided a template Agreement on its website. CMS, *Medicare Drug Price Negotiation Program Agreement*, https://www.cms.gov/files/document/inflation-reduction-act-manufacturer-agreement-template.pdf [https://perma.cc/ZC3E-XCQ5]. In an introductory paragraph, the Agreement states:

> CMS is responsible for the administration of the Medicare Drug Price Negotiation Program . . . , which sets forth a framework under which manufacturers and CMS may negotiate to determine a price (referred to as "maximum fair price" in the Act) for selected drugs in order for manufacturers to provide access to such price to maximum fair price eligible individuals . . . .

Id. at 1. The Agreement goes on to summarize the statutory process for the exchange of offers and counteroffers, stating that the parties agree to "negotiate to determine . . . a maximum fair price," in

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[3] Medicare Part B is a voluntary insurance program covering outpatient care, including prescription drugs typically administered by a physician, while Part D covers self-administered drugs. *See AstraZeneca*, 137 F.4th at 120.

accordance with the statutory scheme.[4] *Id.* at 2. It also specifies that the "[u]se of the term 'maximum fair price' and other statutory terms throughout this Agreement reflects the parties' intention that such terms be given the meaning specified in the statute and does not reflect any party's views regarding the colloquial meaning of those terms." *Id.* at 4. (The statute defines "maximum fair price" to mean "with respect to a year during a price applicability period and with respect to a selected drug . . . with respect to such period, the price negotiated pursuant to section 1320f-3 of this title, and updated pursuant to section 1320f-4(b) of this title, as applicable, for such drug and year." 42 U.S.C. § 1320f(c)(3).)

If the parties agree to a "maximum fair price," they memorialize it in a Negotiated Maximum Fair Price Addendum ("Addendum") to the Agreement. *See* Agreement at 7–9 (template Addendum). The manufacturer then must provide Medicare beneficiaries "access to such price" for the drug until CMS determines that a generic competitor is on the market. 42 U.S.C. § 1320f-2(a)(1), (b).

If a manufacturer's drug is selected for negotiation and the parties fail to reach agreement on a price, the manufacturer becomes subject to steep daily excise taxes delineated in the IRA. *See* 26 U.S.C. § 5000D. Those excise taxes apply to sales of selected drugs during "noncompliance periods" that begin a few

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[4] When CMS negotiates a price for a selected drug, it must consider several factors, including the drug's production and development costs and federal involvement in its development. *See AstraZeneca*, 137 F.4th at 121 (summarizing factors). It also must adhere to a statutory price cap based on the drug's price on the private market and number of years on the market. *See id.* at 120–21.

months after CMS selects the drug and last until the parties reach an agreement on a price or until a generic competitor is marketed. *Id.* § 5000D(b)(1), (b)(3).[5] The excise taxes escalate during a noncompliance period. *Id.* § 5000D(d). The daily excise tax begins at 185.71% of a selected drug's sale price on the first day of noncompliance and reaches 1,900% of the sale price after 270 days. *Id.* § 5000D(a), (d). And these excise taxes apply to all sales of the drug made during a noncompliance period, including sales outside of the Medicare system. *Id.* § 5000D(a).

A manufacturer can avoid the excise taxes if it withdraws all of its drugs (not just those selected for negotiation) from coverage in two programs: (1) Medicare Part D's Manufacturer Discount Program or its predecessor, the Coverage Gap Discount Program,[6] and (2) the Medicaid Drug Rebate Program (together, "the Opt-Out Programs"). 26 U.S.C. § 5000D(c)(1)(A), (2).[7] Any terminations from

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5 For the first year of the Program, the noncompliance period would have begun on October 2, 2023. 26 U.S.C. § 5000D(b)(1). For subsequent years, the noncompliance period begins on the March 1st following the selection of a drug for price negotiation. *Id.*

6 The IRA replaced the Coverage Gap Discount Program with the Manufacturer Discount Program, effective January 1, 2025. *See* 42 U.S.C. § 1395w-114c. Because a manufacturer will have agreements under only one of these programs at any given time, the IRA only requires a manufacturer to terminate its participation in one of those programs.

7 Although the parties and the dissent contend that a manufacturer only avoids excise taxes by withdrawing its drugs from Medicare and Medicaid entirely, the statute specifies the two programs from which a manufacturer must withdraw to

the Manufacturer Discount Program or the Coverage Gap Discount Program must go into effect before the excise taxes are suspended. *Id.* § 5000D(c)(1)(A)(ii). For the Medicaid Rebate Program, notice of termination is sufficient to suspend the excise taxes. *Id.* §§ 5000D(c)(1)(A)(i), (2). If a manufacturer reenters either of the Opt-Out Programs, the taxes will go back into effect the next March 1st. *Id.* § 5000D(c)(1)(B).

B

In June 2023, BMS challenged the Program by suing the Secretary of the Department of Health and Human Services and the Administrator of CMS. In July 2023, Janssen did the same. Both Companies sought declaratory and injunctive relief, claiming violations of the Fifth Amendment's Takings Clause, the First Amendment, and the unconstitutional conditions doctrine.

In August 2023, CMS published the list of ten drugs selected for negotiation for 2026. BMS and Janssen each had a drug on the list: for BMS, Eliquis, and for Janssen, Xarelto. Each company agreed to participate in the Program and, while these cases were pending, agreed to a price for its respective drug.

In the District Court, these cases proceeded in tandem. The parties agreed that the District Court could resolve the constitutional claims on cross-motions for summary judgment, without the need for discovery. The District Court did so in April 2024, denying the Companies' motions for summary judgment and granting the government's. The

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avoid those excise taxes. References to the loss of all Medicare and Medicaid funding are therefore misplaced.

Companies timely appealed, and we consolidated the appeals for purposes of briefing and disposition.

II[8]

We exercise plenary review of orders resolving cross-motions for summary judgment, applying the same standard used by district courts. *Spivack v. City of Philadelphia*, 109 F.4th 158, 165 (3d Cir. 2024). Summary judgment is appropriate only "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). The parties have stipulated that no material facts are in dispute and that their motions present only questions of law.

III

"The Fifth Amendment's Takings Clause prohibits the government from taking private property for public use without providing just compensation." *Newark Cab Ass'n v. City of Newark*, 901 F.3d 146, 151 (3d Cir. 2018) (internal quotation marks omitted). Physical takings—i.e., appropriating or occupying private property—are "the clearest sort of taking[s]." *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 148, 141 S.Ct. 2063, 210 L.Ed.2d 369 (2021) (cleaned up). Here, the Companies argue that Program effects a physical taking because it permits the government to physically appropriate their drugs without paying just compensation.

The Companies are incorrect. The Program permits the government to acquire the Companies' drugs only when it pays prices the Companies have

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8 The District Court had jurisdiction under 28 U.S.C. § 1331. We have jurisdiction under 28 U.S.C. § 1291.

agreed to. If the Companies dislike the prices the government is willing to pay, they are free to stop doing business with the government. So the Companies' participation in the Program is voluntary, and there is no physical taking. We also decline to apply a version of the unconstitutional conditions doctrine used to assess conditions on land-use permitting to the Program (and, in any event, the Program withstands scrutiny under the test the Companies suggest).

A

To establish a physical taking, a party must show that "the government has physically taken property for itself or someone else—by whatever means." *Id.* at 149, 141 S.Ct. 2063.[9] For example, the government commits a physical taking "when it uses its power of eminent domain to formally condemn property[,] . . . physically takes possession of property without acquiring title to it[,] . . . [or] occupies property—say, by recurring flooding as a result of building a dam." *Id.* at 147–48, 141 S.Ct. 2063 (citations omitted). A physical taking may involve real property or personal property. *Id.* at 152, 141 S.Ct. 2063. Either way, when the government effects this type of physical appropriation, it "must pay for what it takes." *Id.* at 148, 141 S.Ct. 2063 (citation omitted).

The various means of committing a physical taking share one feature: a government mandate. Absent a government mandate to relinquish the use of private property, there is no physical taking. Thus,

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[9] The Companies do not argue that the Program constitutes a regulatory taking. *See Cedar Point Nursery*, 594 U.S. at 148–49, 141 S.Ct. 2063 (distinguishing physical from regulatory takings).

there is no physical taking when a party gives up private property as part of a voluntary exchange with the government. *See Valancourt Books, LLC v. Garland*, 82 F.4th 1222, 1232 (D.C. Cir. 2023).

The government is a major purchaser in our Nation's economy. When it acts as a purchaser, "the Government enjoys the unrestricted power . . . to fix the terms and conditions upon which it will make needed purchases," just as private individuals and businesses do. *Perkins v. Lukens Steel Co.*, 310 U.S. 113, 127, 60 S.Ct. 869, 84 L.Ed. 1108 (1940). Because contracts delineate the terms of many government purchases, items subject to government contracts rarely give rise to takings claims. *See Hughes Commc'ns Galaxy, Inc. v. United States*, 271 F.3d 1060, 1070 (Fed. Cir. 2001).

I

The Companies have signed contracts specifying the prices at which they will provide their drugs to Medicare beneficiaries. Despite those contracts, the Companies raise Takings Clause challenges, asserting that the contracts they signed were not voluntary. But the Companies acknowledge (as they must) that they are not legally compelled to participate in Medicare. *See* 42 U.S.C. § 1395cc (allowing providers to elect to enter into agreements under Medicare); *see also United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 749 (3d Cir. 2017) (describing Medicare Part D as "voluntary"). So if the companies opt not to participate in Medicare, they need not sign any contracts regarding drug sales to Medicare beneficiaries. This opt-out option defeats the Companies' argument that they were forced to sign contracts under the Program.

This logic underlies the decisions of our sister Courts of Appeals in analogous cases. Medical providers who have brought takings claims about Medicare or Medicaid have uniformly lost due to their ability to stop participating in those programs.[10]

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[10] *See Franklin Mem'l Hosp. v. Harvey*, 575 F.3d 121, 129–30 (1st Cir. 2009) (holding that a hospital voluntarily participated in Medicaid, precluding takings liability, because it had the alternative of pursuing Medicaid-eligible patients directly for the amount that Medicaid would otherwise reimburse); *Garelick v. Sullivan*, 987 F.2d 913, 916–17 (2d Cir. 1993) (holding that limits on what physicians could charge Medicare Part B beneficiaries effected no taking, because the physicians "voluntarily choose to provide services in the price-regulated Part B program" and "retain the right to provide medical services to non-Medicare patients"); *id.* at 917 ("All court decisions of which we are aware that have considered takings challenges by physicians to Medicare price regulations have rejected them in the recognition that participation in Medicare is voluntary."); *Burditt v. U.S. Dep't of Health & Hum. Servs.*, 934 F.2d 1362, 1376 (5th Cir. 1991) (holding that a federal law requiring hospitals that participate in Medicare to treat emergency patients was not a taking of their physicians' services because hospitals voluntarily participated in the program); *St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875–76 (7th Cir. 1983) (holding that hospitals did not suffer a taking when they were not reimbursed by Medicare for certain capital expenditures, because "provider participation is voluntary"); *Key Med. Supply, Inc. v. Burwell*, 764 F.3d 955, 965–66 (8th Cir. 2014) (concluding that a medical equipment provider's takings claim against a competitive-bidding system for Medicare pricing was "patently meritless" under Circuit precedent finding Medicaid participation voluntary); *Baker Cnty. Med. Servs., Inc. v. Att'y Gen.*, 763 F.3d 1274, 1279–80 (11th Cir. 2014) (holding that a mandate that hospitals participating in Medicare treat federal detainees was not a taking); *see also Livingston Care Ctr., Inc. v. United States*, 934 F.2d 719, 720 (6th Cir. 1991) (observing, in the context of a due process challenge, that

Recently, the Second Circuit applied these cases to reject a functionally identical takings challenge to the Program. *See Boehringer Ingelheim Pharms., Inc. v. HHS*, 150 F.4th 76, 91 (2d Cir. Aug. 7, 2025) ("[B]ecause Boehringer voluntarily chose to participate in the . . . Program, no taking has occurred.").

Despite the Companies' ability to withdraw from the Opt-Out Programs, they argue that their participation is not "voluntary" because of their dependence on Medicare and Medicaid reimbursements and the size of the government's market share. In their view, basic economic rationality dictates participation in those federal programs, making the exit option illusory.[11] But, as our sister courts have recognized, "economic hardship is not equivalent to legal compulsion for purposes of takings analysis." *Baker Cnty. Med. Servs., Inc. v. Att'y Gen.*, 763 F.3d 1274, 1280 (11th Cir. 2014) ("Although the Hospital contends that opting out of Medicare would amount to a grave financial setback, economic hardship is not equivalent to legal compulsion for purposes of takings analysis." (internal quotation marks omitted)); *accord*

"participation in the Medicare program is a voluntary undertaking").

[11] The Companies also note that the Congressional Research Service anticipated the Program's excise tax provisions—applicable to manufacturers who remain participants in the Opt-Out Programs and fail to reach a price agreement—would raise zero revenue. This forecast reflects the strong incentive to reach agreement with CMS if a manufacturer chooses to participate in the Program. But it does not reflect the additional way for a manufacturer to avoid being assessed excise taxes: by choosing not to participate in the Program and withdrawing from the Opt-Out Programs.

Boehringer, 150 F.4th at 90 ("[T]he choice to participate in a voluntary government program does not become involuntary simply because the alternatives to participation appear to entail worse, even substantially worse, economic outcomes."); *Garelick v. Sullivan*, 987 F.2d 913, 917 (2d Cir. 1993) (rejecting an argument that non-participation in Medicare "is not an economically viable option," because "economic hardship is not equivalent to legal compulsion for purposes of takings analysis"); *Minn. Ass'n of Health Care Facilities, Inc. v. Minn. Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984) ("Despite the strong financial inducement to participate in Medicaid, a nursing home's decision to do so is nonetheless voluntary."); *St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875 (7th Cir. 1983) ("[T]he fact that practicalities may in some cases dictate participation does not make participation involuntary.").

Those courts' reasoning makes sense. The federal government, by virtue of its size, possesses a sizable market share in many of the markets it enters. In certain markets—for example, for military hardware that is unlawful for civilians to own—the government may be the only purchaser. Economic factors may have a strong influence on a company's choice to do business with the government, but a company that chooses to do so still acts voluntarily.

II

The Companies resist the withdrawal option's dispositive effect on their takings claim. They make arguments based on two Supreme Court decisions, and they raise one practical objection. None is availing.

First, the Companies invoke the Supreme Court's Takings Clause decision in *Horne v. Department of Agriculture*, 576 U.S. 350, 135 S.Ct. 2419, 192 L.Ed.2d 388 (2015). *Horne* involved a federal government mandate that raisin growers reserve a percentage of their crop for the government, free of charge. *Id.* at 354–55, 135 S.Ct. 2419. When a family of raisin growers refused to comply with the reserve requirement, the government sent trucks to the family's raisin-handling facility to collect the reserve raisins, and when the family refused entry to the trucks the government assessed a fine and civil penalty. *Id.* at 356, 135 S.Ct. 2419. The Court held that the government's reserve requirement was "a clear physical taking" because it caused "[a]ctual raisins [to be] transferred from the growers to the Government." *Id.* at 361, 135 S.Ct. 2419.

In defending the reserve requirement, the government argued that raisin growers "voluntarily choose to participate in the raisin market" and could avoid the reserve requirement by "plant[ing] different crops" or by selling their "raisin-variety grapes as table grapes or for use in juice or wine." *Id.* at 365, 135 S.Ct. 2419 (citation omitted). It likened the case to *Ruckelshaus v. Monsanto Company*, 467 U.S. 986, 104 S.Ct. 2862, 81 L.Ed.2d 815 (1984), where the Court held that the Environmental Protection Agency could require companies to disclose health, safety, and environmental information about the hazardous pesticides they sell as a condition of receiving permits to sell those products. *Horne*, 576 U.S. at 365–66, 135 S.Ct. 2419. The Court rejected the government's attempt to extend *Monsanto* by characterizing participation in interstate raisin markets as a special governmental benefit, akin to a permit to sell

dangerous chemicals. *Id.* at 366, 135 S.Ct. 2419. Because selling raisins was a "basic and familiar use[ ] of property," not part of a voluntary exchange with the government, the Court held that the government's taking required just compensation. *Id.* at 366–67, 135 S.Ct. 2419.

The Companies argue that *Horne* controls this case. Not so. To avoid the reserve requirement in *Horne*, the raisin growers would have had to exit the raisin market entirely. *See id.* at 364–65, 135 S.Ct. 2419 (characterizing the reserve requirement as "a condition on permission to engage in commerce" of raisins (internal quotation marks omitted)). Here, if the Companies wish to avoid the excise taxes, they can withdraw from the Opt-Out Programs and remain free to participate in the pharmaceutical market—including by selling Xarelto and Eliquis to private parties.[12] Thus, *Horne* does not disturb our conclusion that the voluntary nature of Medicare participation precludes takings liability.[13]

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[12] Janssen attempts to reframe the relevant market in *Horne* as one for grapes, rather than raisins, arguing that the growers could sell their products to other buyers just as Janssen could sell Xarelto to private parties. But the Court made clear in *Horne* that raisin growers' theoretical ability to sell "raisin-variety grapes" for non-raisin uses was no real alternative. *See* 576 U.S. at 365, 135 S.Ct. 2419 (citation omitted). Instead, the government's argument failed because it would have forced raisin growers to cease doing business as raisin growers. *Id.* Here, losing Medicare reimbursement would not preclude Janssen from selling its drugs to private parties.

[13] Other courts have reached the same conclusion. *See, e.g., Se. Ark. Hospice, Inc. v. Burwell*, 815 F.3d 448, 450 (8th Cir. 2016) (citing *Horne* for the proposition that because participation in a hospice program run through Medicare is a "voluntary exchange," it cannot create takings liability); *Va. Hosp. &*

The Companies also rely on *National Federation of Independent Business v. Sebelius*, 567 U.S. 519, 132 S.Ct. 2566, 183 L.Ed.2d 450 (2012) ("*NFIB*"). *NFIB* struck down a provision of the Patient Protection and Affordable Care Act ("PPACA") that conditioned all of a State's Medicaid funds on the State's expanding of Medicaid eligibility. *Id.* at 585, 132 S.Ct. 2566. The Court applied the anti-commandeering doctrine, which bars the federal government from "commandeer[ing] a State's legislative or administrative apparatus for federal purposes." *Id.* at 577, 132 S.Ct. 2566. Because the challenged PPACA provision "threatened loss of over 10 percent of a State's overall budget," the Court concluded that it was "economic dragooning that le[ft] the States with no real option but to acquiesce in the Medicaid expansion." *Id.* at 582, 132 S.Ct. 2566.

The Companies characterize the Program as economic dragooning, just like in *NFIB*. But the Companies ignore *NFIB*'s explicit and repeated focus on federalism and the States' role as distinct sovereigns.[14] Federalism prohibits the federal

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Healthcare Ass'n v. Roberts, 671 F. Supp. 3d 633, 666–67 (E.D. Va. 2023) (distinguishing *Horne*); *see also, e.g., Eli Lilly & Co. v. U.S. Dep't of Health & Hum. Servs.*, No. 1:21-cv-00081-SEB-MJD, 2021 WL 5039566, at *21 (S.D. Ind. Oct. 29, 2021); *Kaiser Found. Health Plan, Inc. v. Burwell*, 147 F. Supp. 3d 897 (N.D. Cal. 2015).

[14] *See, e.g.*, 567 U.S. at 577, 132 S.Ct. 2566 ("Spending Clause legislation [may] not undermine the status of the States as independent sovereigns in our federal system."); *id.* at 577–78, 132 S.Ct. 2566 ("[W]hen pressure turns into compulsion, the legislation runs contrary to our system of federalism. The Constitution simply does not give Congress the authority to . . . directly command[ ] a State to regulate or indirectly coerce[ ] a State to adopt a federal regulatory system as its own." (cleaned

government from trampling on a State's prerogatives under the Tenth Amendment. *See id.* at 577–78, 132 S.Ct. 2566; *Printz v. United States*, 521 U.S. 898, 918–22, 117 S.Ct. 2365, 138 L.Ed.2d 914 (1997) ("[O]ur citizens . . . have two political capacities, one state and one federal, each protected from incursion by the other . . . ." (cleaned up)); *New York v. United States*, 505 U.S. 144, 156–57, 112 S.Ct. 2408, 120 L.Ed.2d 120 (1992) ("[T]he Tenth Amendment confirms that the power of the Federal Government is subject to limits that may, in a given instance, reserve power to the States."). These Tenth Amendment concerns are simply not present here, where the federal government contracts with private parties, rather than dealing with separate sovereigns.[15]

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up)); *id.* at 578, 132 S.Ct. 2566 ("Permitting the Federal Government to force the States to implement a federal program would threaten the political accountability key to our federal system. . . . [W]hen a State has a legitimate choice whether to accept the federal conditions in exchange for federal funds[,] . . . state officials can fairly be held politically accountable for choosing to accept or refuse the federal offer."); *id.* at 579, 132 S.Ct. 2566 ("In the typical case we look to the States to defend their prerogatives by adopting the simple expedient of not yielding to federal blandishments when they do not want to embrace the federal policies as their own." (internal quotation marks omitted)); *id.* at 580, 132 S.Ct. 2566 ("When . . . conditions take the form of threats to terminate other significant independent grants, the conditions are properly viewed as a means of pressuring the States to accept policy changes.").

[15] Moreover, the Companies' reading of *NFIB* would effectively bless all existing federal funding streams with constitutional protection in perpetuity. If *NFIB* applies to the government's dealings with private parties, it is hard to see how the government could ever renegotiate or discontinue contracts. In the absence of any indication that the Court intended to sweep

Finally, we reach the Companies' practical objection to withdrawal. They argue that even if withdrawing from the Opt-Out Programs precludes takings liability, the Program does not permit the Companies to withdraw in time to suspend the excise taxes.

Because CMS announced its selection of the Companies' drugs in August 2023, the excise taxes would have kicked in on October 2, 2023, unless the Companies agreed to participate in the Program or withdrew from the Opt-Out Programs. 26 U.S.C. § 5000D(b)(1), (c)(1)(A).[16] According to the Companies, to avoid any excise taxes beginning to accrue in October 2023, the statute required them to terminate their agreements in the Opt-Out Programs before the IRA was even enacted. But the statute, as clarified by regulatory guidance with the force of law, says otherwise.

Congress created two paths to effectuate termination of a manufacturer's agreements and suspend the excise taxes.[17] The first path is

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so broadly, *NFIB* cannot support the weight the Companies seek to put on it.

[16] In 2023, the Coverage Gap Discount Program had not yet been replaced by the Manufacturer Discount Program. *See supra* n.6. Thus, to avoid excise taxes in October 2023, the Companies needed to ensure that the termination of their agreements under the Coverage Gap Discount Program had taken effect and give notice terminating their agreements under the Medicaid Rebate Program. *Id.* § 5000D(c)(1)(A).

[17] As discussed above, excise taxes are suspended when the termination of a manufacturer's agreements under one of the Opt-Out Programs (the Coverage Gap Discount Program or its replacement the Manufacturer Discount Program) has taken effect. *See supra* Section I.A. A manufacturer need only give notice of termination from its agreements under the Medicaid

manufacturer-initiated and requires a lengthy period of notice: A manufacturer may terminate its agreements with CMS "for any reason"—even over CMS's objection—upon providing 11 to 23 months' notice. 42 U.S.C. §§ 1395w-114a(b)(4)(B)(ii) (Coverage Gap Discount Program), 1395w-114c(b)(4)(B)(ii) (Manufacturer Discount Program). The second path is CMS-initiated and is much speedier: CMS may terminate its agreements with a manufacturer "for a knowing and willful violation of the requirements of the agreement or other good cause shown" with only 30 days' notice. *Id.* §§ 1395w-114a(b)(4)(B)(i), 1395w-114c(b)(4)(B)(i). And CMS announced in a regulatory guidance—one that has the force of law—that it will find "good cause" to use the speedier path to termination whenever a manufacturer submits notice of its decision not to participate in the Drug Price Negotiation Program. CMS, *Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2026*, at 120–21 (June 30, 2023) ("2023 Revised Guidance"), https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf [https://perma.cc/AV2Z-4F9U].[18]

Rebate Program to avoid excise taxes. 26 U.S.C. § 5000D(c)(1)(A), (2).

[18] *See* 42 U.S.C. § 1320f note (allowing CMS to implement the Program by issuing program guidance for program years 2026 through 2028); 2023 Revised Guidance at 92–93 (stating that the 2023 Revised Guidance is being promulgated without notice and comment as final). The dissent contends that the IRA does not authorize CMS to promulgate the 2023 Revised Guidance without notice and comment. Dissent at 277 n.6; *see* 5

CMS issued the 2023 Revised Guidance two months before it announced the drugs selected for the first round of price negotiations. So before the Companies' drugs were selected for negotiation on August 29, 2023, the Companies had been apprised of their ability to expedite withdrawal from Medicare if they decided not to participate in the Program. Had the Companies exercised that option promptly, they could have avoided any excise tax liability.

The dissent sees the 30-day expedited withdrawal as stretching the meaning of "other good cause" beyond what the statutes can bear. *See* Dissent at 277–79. Because the phrase "other good cause" appears following a specific ground upon which CMS may terminate an agreement—"a knowing and willful

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U.S.C. § 559 (contemplating that a statute may displace the requirements of the Administrative Procedure Act "to the extent that it does so expressly"). To determine if a statute displaces the procedural requirements of the APA, we look for "express language exempting agencies" or "alternative procedures that could reasonably be understood as departing from the APA." *California v. Azar*, 911 F.3d 558, 579 (9th Cir. 2018); *accord Mann Constr., Inc. v. United States*, 27 F.4th 1138, 1145 (6th Cir. 2022) (similar). Language that is "permissive, wide-ranging, . . . and does not contain any specific deadlines for agency action" suggests that Congress did not mean to do away with APA requirements. *Pennsylvania v. Pres. United States*, 930 F.3d 543, 566 (3d Cir. 2019) (cleaned up), *rev'd on other grounds sub nom. Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 591 U.S. 657, 140 S.Ct. 2367, 207 L.Ed.2d 819 (2020). Here, the statute provides an alternative procedure (issue program instruction or other forms of program guidance) in mandatory terms (CMS "shall," rather than may, do so). 42 U.S.C. § 1320f note. That Congress limited CMS's authority to only the first three program years supports this reading: "that Congress made a deliberate decision to authorize an exemption (albeit temporary) from the APA's requirements." *Boehringer*, 150 F.4th at 99.

violation" of the agreement's requirements—the dissent would limit "good cause" to other forms of misconduct. But good cause is "a uniquely flexible and capacious concept, meaning simply a legally sufficient reason." *Polansky v. Exec. Health Res. Inc.*, 17 F.4th 376, 387 (3d Cir. 2021) (internal quotation marks omitted), *affirmed sub nom. United States ex rel. Polansky v. Exec. Health Res., Inc.*, 599 U.S. 419, 143 S.Ct. 1720, 216 L.Ed.2d 370 (2023). Congress chose to include that flexible and capacious phrase alongside just one example of a legally sufficient reason for CMS to terminate an agreement with a manufacturer. And it makes sense that Congress would permit CMS to use the speedier path to termination when CMS consents to a manufacturer's withdrawal, rather than when a manufacturer acts unilaterally.

Moreover, the Companies entered into their Coverage Gap Discount Program agreements before Congress enacted the IRA. At that time, the Companies could not have known that a future statute would condition excise taxes on the continued existence of their Coverage Gap agreements. Later, when CMS selected the Companies' drugs for negotiation in August 2023, the Companies had to decide whether to participate in the Program or withdraw from their Coverage Gap agreements in order to suspend the IRA's excise taxes. The unforeseeable legal and economic significance of the Companies' Coverage Gap agreements supports CMS's conclusion that a manufacturer's decision not to participate in the Program constitutes "other good

cause" supporting an expedited withdrawal from those agreements.[19]

If Congress wished to limit CMS's termination authority to instances of manufacturer misconduct, it knew how to do so. *See Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 394–95, 144 S.Ct. 2244, 219 L.Ed.2d 832 (2024). We see no conflict between the expedited withdrawal that the 2023 Revised Guidance permits and the intent of Congress, as expressed in the Medicare statutes.[20]

B

The Companies argue that even if the Program does not directly seize their property, it still violates the Takings Clause because it amounts to extortion. They ask us to apply the *Nollan-Dolan* test—a test the Supreme Court has applied only to takings claims involving land-use permits—to this case. *See Koontz*

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[19] The dissent also sees tension between a CMS-initiated termination of a manufacturer's agreement (which requires CMS to send notice to the manufacturer) and the excise tax statute (which says taxes are suspended when CMS receives notice of terminations, 26 U.S.C. § 5000D(c)(1)(A)(i)). *See* Dissent at 278–79. But all agree that CMS may remove a malfeasant manufacturer unilaterally for a willful violation of an agreement. And, post-termination, the malfeasant manufacturer would avoid excise taxes even though CMS never received any notice from the manufacturer. Thus, "notice of terminations" must be read to include all notices, whether initiated by a manufacturer or CMS.

[20] Of course, if CMS were to retract its assurance in the 2023 Revised Guidance that it will find good cause to terminate a manufacturer's agreements whenever a manufacturer submits notice of its decision not to participate in the Drug Price Negotiation Program, that reversal could be deemed arbitrary and capricious. *See Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221–22, 136 S.Ct. 2117, 195 L.Ed.2d 382 (2016).

v. St. Johns River Water Mgmt. Dist., 570 U.S. 595, 604, 133 S.Ct. 2586, 186 L.Ed.2d 697 (2013) ("*Nollan* and *Dolan* involve a special application of th[e] [unconstitutional conditions] doctrine that protects the Fifth Amendment right to just compensation for property the government takes when owners apply for land-use permits." (internal quotation marks omitted)).

The *Nollan-Dolan* test is "modeled on the unconstitutional conditions doctrine" and is designed to "address th[e] potential abuse of the permitting process." *Sheetz v. Cnty. of El Dorado, Cal.*, 601 U.S. 267, 275, 144 S.Ct. 893, 218 L.Ed.2d 224 (2024). Under the test, "permit conditions must have an 'essential nexus' to the government's land-use interest, . . . [and] have 'rough proportionality' to the development's impact on the land-use interest." *Id.* at 275–76, 144 S.Ct. 893 (first citing *Nollan v. Cal. Coastal Comm'n*, 483 U.S. 825, 107 S.Ct. 3141, 97 L.Ed.2d 677 (1987); and then citing *Dolan v. City of Tigard*, 512 U.S. 374, 114 S.Ct. 2309, 129 L.Ed.2d 304 (1994)). For example, if a development were expected to increase traffic, the government might condition approval on the developer turning over land needed to widen a public road. *Koontz*, 570 U.S. at 605, 133 S.Ct. 2586. Such a condition would be related to the government's interest in protecting traffic-flows, though it would still need to be proportional to the development's impact on traffic. *Id.*

For over thirty years, the Supreme Court has not expanded the *Nollan-Dolan* test beyond conditions on land-use permitting. Instead, it has emphasized how that specific context drives its reasoning. A special test for challenges to land-use permitting is necessary because of "two realities of the permitting process": (1)

"the government often has broad discretion to deny a permit that is worth far more than property it would like to take," making "land-use permit applicants . . . especially vulnerable to the type of coercion that the unconstitutional conditions doctrine prohibits," and (2) "many proposed land uses threaten to impose costs on the public that dedications of property can offset." *Koontz*, 570 U.S. at 604–5, 133 S.Ct. 2586. Plainly, the realities of land-use permitting have no bearing on Medicare contracts. We therefore decline the Companies' invitation to subject the Program to scrutiny under *Nollan-Dolan*.[21]

* * *

In effect, the Companies argue that they have a constitutionally protected right to be reimbursed for their products at price levels they have historically enjoyed. From the creation of Part D until the creation of the Program, those prices were set by a market in which the government (far and away the largest buyer) did not use its purchasing power to negotiate. In *AstraZeneca*, we noted that, for

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[21] Even if an adaptation of the *Nollan-Dolan* test applied here, the Program would withstand scrutiny. In the Companies' view, a condition on a voluntary government benefit that takes property from the recipient must (1) have a nexus to the government program, and (2) be proportional to the benefit conferred. Here, the Program has the required nexus to Medicare. Requiring the Companies to make selected drugs available to Medicare beneficiaries at negotiated prices supports the government's aim to provide greater access to affordable prescription drugs. And the Program's putative taking of property is proportional to the benefit conferred. In exchange for reduced profits from selected drugs, each company is able to obtain Medicare reimbursements for numerous products that it manufactures.

purposes of the Fifth Amendment's guarantee of procedural due process, "[t]here is no protected property interest in selling goods to Medicare beneficiaries (through sponsors or pharmacy benefit plans) at a price higher than what the government is willing to pay when it reimburses those costs." 137 F.4th at 125–26. This logic applies with equal force in the context of the Fifth Amendment's Takings Clause. The Companies face a choice: forgo participation in certain Medicare and Medicaid programs or accept federal reimbursements for selected drugs on less lucrative terms. Economic realities may provide a strong incentive for a manufacturer to choose the latter. But this choice is not a taking.

IV

The Companies next claim that CMS's form Agreement and Addendum compel speech in violation of the First Amendment. They object to these documents' use of the term "maximum fair price," arguing that the phrase suggests that the Companies previously were not charging fair prices for their drugs. They also object to these documents' use of the terms "agree" and "negotiate" to describe their participation in the Program. The Companies argue that these terms mask that they are acting under duress.

The First Amendment claim fails for two independent reasons: (1) The Program permissibly regulates conduct, with only an incidental effect on speech, and (2) participation in the Program is voluntary, so the Companies are not compelled to speak at all. The Program also does not place unconstitutional conditions on participation because

it does not regulate or compel speech outside of the contracts needed to effectuate the Program itself.

A

I

"The First Amendment does not prevent restrictions directed at commerce or conduct from imposing incidental burdens on speech." *Nat'l Inst. of Fam. & Life Advocs. v. Becerra*, 585 U.S. 755, 769, 138 S.Ct. 2361, 201 L.Ed.2d 835 (2018) ("*NIFLA*") (alteration omitted) (quoting *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 567, 131 S.Ct. 2653, 180 L.Ed.2d 544 (2011)). In other words, a law may permissibly restrict or compel speech if the "effect on speech [is] only incidental to its primary effect on conduct." *Expressions Hair Design v. Schneiderman*, 581 U.S. 37, 47, 137 S.Ct. 1144, 197 L.Ed.2d 442 (2017).

"While drawing the line between speech and conduct can be difficult, [courts] have long drawn it . . . ." *NIFLA*, 585 U.S. at 769, 138 S.Ct. 2361. We must do so because many government actions impose some ancillary burden on speech that is unrelated to any suppression of ideas or creation of a government-approved orthodoxy, thus posing no First Amendment problems. *See Sorrell*, 564 U.S. at 567, 131 S.Ct. 2653 (noting that, e.g., "a ban on race-based hiring may require employers to remove 'White Applicants Only' signs, . . . an ordinance against outdoor fires might forbid burning a flag, and . . . antitrust laws can prohibit agreements in restraint of trade" because these government actions have only incidental effects on speech (cleaned up)); *see also, e.g., Zauderer v. Off. of Disciplinary Couns. of Sup. Ct. of Ohio*, 471 U.S. 626, 651, 105 S.Ct. 2265, 85 L.Ed.2d 652 (1985) (allowing states to mandate that professionals make

specific disclosures so long as they are not "unjustified or unduly burdensome"); *United States v. O'Brien*, 391 U.S. 367, 382, 88 S.Ct. 1673, 20 L.Ed.2d 672 (1968) (holding that, despite the communicative aspect of burning a draft card, a conviction based on the "noncommunicative impact of [the defendant's] conduct" was permissible).

For example, in *Rumsfeld v. Forum for Academic & Institutional Rights, Inc.*, 547 U.S. 47, 126 S.Ct. 1297, 164 L.Ed.2d 156 (2006) ("*FAIR*"), the Supreme Court rejected a First Amendment challenge to the Solomon Amendment—a statute that required schools receiving certain federal grants to host military recruiters on the same terms as other employers. A group of law schools opposed to a military policy argued that the Solomon Amendment compelled them to speak by requiring them to accommodate the military recruiters' messages and distribute notices on the recruiters' behalf. *Id.* at 53, 61–62, 126 S.Ct. 1297. The compelled messages were statements of fact such as "The U.S. Army recruiter will meet interested students in Room 123 at 11 a.m." *Id.* at 61–62, 126 S.Ct. 1297. The Court held that the compelled speech the schools complained of was subject to First Amendment scrutiny but was "plainly incidental to the Solomon Amendment's regulation of conduct"—i.e., the hosting of military recruiters on campus. *Id.* at 62, 126 S.Ct. 1297. It explained that compelling schools to send scheduling emails and post notices on behalf of military recruiters is a far cry from "a Government-mandated pledge or motto that the school must endorse." *Id.*[22] And it reiterated that

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[22] The Court also noted that the Solomon Amendment only compels speech "if, and to the extent, the school provides such

"it has never been deemed an abridgment of freedom of speech or press to make a course of conduct illegal merely because the conduct was in part initiated, evidenced, or carried out by means of language, either spoken, written, or printed." *Id.* (quoting *Giboney v. Empire Storage & Ice Co.*, 336 U.S. 490, 502, 69 S.Ct. 684, 93 L.Ed. 834 (1949)).

By contrast, in *Expressions Hair Design*, the Supreme Court concluded that a state law related to credit card surcharges was a regulation of speech. 581 U.S. at 40, 47–48, 137 S.Ct. 1144. The law permitted merchants to charge customers using cash less than customers using credit cards, but it also regulated what a merchant could *call* this differential pricing: referring to it as a "cash discount" was permissible, while calling it a "credit card surcharge" was not. *See id.* at 44, 137 S.Ct. 1144. Therefore, the Court held that the law "regulat[ed] the communication of prices rather than prices themselves" making it subject to First Amendment scrutiny. *Id.* at 48, 137 S.Ct. 1144. Because the law allowed merchants to charge whatever they wanted, it regulated only speech, not conduct. *Id.* at 47, 137 S.Ct. 1144. Such a regulation could not be said to have an "incidental" effect on conduct.

II

Applying these principles to the Program, we have no trouble concluding that the Program is directed at conduct. When Congress enacted the IRA, it required CMS to negotiate the prices at which Medicare will reimburse manufacturers for selected drugs. To comply with this mandate, CMS must follow the

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speech for other recruiters." 547 U.S. at 62, 126 S.Ct. 1297. *See infra* Section IV.B.

statute's process for the exchange of offers and counteroffers with a manufacturer. That process is outlined in a contract governing the negotiation: the Agreement. And when the parties agree to a price, they memorialize it in a contract governing how much money CMS will tender and the manufacturer will accept as reimbursement for covered drugs: the Addendum.

When a manufacturer signs the Agreement or the Addendum, it engages in speech entitled to some form of constitutional scrutiny. After all, the legal effect of signing a contract does not deprive the signing of its expressive component. *Doe No. 1 v. Reed*, 561 U.S. 186, 195, 130 S.Ct. 2811, 177 L.Ed.2d 493 (2010); *see also Greater Phila. Chamber of Com. v. City of Philadelphia*, 949 F.3d 116, 135 (3d Cir. 2020) (noting "the well settled proposition" that negotiating contract terms "is speech subject to the protections of the First Amendment"). But any First Amendment speech contained in those contracts is incidental to the contracts' regulation of conduct.[23]

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[23] The dissent contends that *FAIR* establishes that, even if the Program primarily regulates conduct, we must ask whether any incidentally compelled speech is expressive. *See* Dissent at 273–77. But all speech is expressive. That is why the Supreme Court only discussed the "inherently expressive" nature of conduct (not speech) in *FAIR*. *See* 547 U.S. at 64–68, 126 S.Ct. 1297. In its separate assessment of whether the Solomon Amendment's compelled verbal statements were unconstitutional, the Court looked to whether the law compelled statements of opinion or of fact. *Id.* at 61–62, 126 S.Ct. 1297. And although First Amendment scrutiny applies to both, the factual statements about recruiting that the law schools were required to make were "a far cry" from the "Government-mandated pledge or motto" at issue in landmark compelled speech cases. *Id.* (citing *West Virginia Bd. of Educ. v. Barnette*,

Although the Companies view the contracts' use of the term "maximum fair price" as normative, the Agreement expressly states that the parties intend to give all statutorily-defined terms their statutory meaning, not their colloquial meaning. And the statutory meaning of "maximum fair price" is, in essence, the agreed-upon price for a selected drug during a specified pricing period. *See* 42 U.S.C. § 1320f(c)(3) (defining the term). We must construe the term as defined in the IRA, without reference to how "it might be read by a layman, or as it might be understood by someone who has not even read [the statute]." *Meese v. Keene*, 481 U.S. 465, 484–85, 107 S.Ct. 1862, 95 L.Ed.2d 415 (1987). When we do, the term loses the expressive weight the Companies place on it. *Cf. Engelhard Corp. v. NLRB*, 437 F.3d 374, 381

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319 U.S. 624, 63 S.Ct. 1178, 87 L.Ed. 1628 (1943), and *Wooley v. Maynard*, 430 U.S. 705, 97 S.Ct. 1428, 51 L.Ed.2d 752 (1977)). The lack of ideological weight supported the Court's conclusion that any speech compulsion was "plainly incidental" to the Solomon Amendment's regulation of conduct. *Id.* at 62, 126 S.Ct. 1297. The Court then independently considered whether the *conduct* of hosting recruiters had an inherently expressive quality and whether accommodating a military recruiter would interfere with the schools' speech. *Id.* at 64, 126 S.Ct. 1297. The answer to both questions was no, as "[n]othing about recruiting suggests that law schools agree with any speech by recruiters," military or otherwise, and the equal-access mandate did not restrict the law schools' speech. *Id.* at 65, 126 S.Ct. 1297.

Here, the Program regulates the price at which the companies will be reimbursed for their products. The challenged contracts are an ancillary part of a government reimbursement process and do nothing to limit the Companies' speech about the Program. More to the point, notwithstanding the Companies' subjective views of the contractual terms, nothing about signing the Agreement or Addendum suggests that the Companies hold any particular view.

(3d Cir. 2006) (citing the "well established principle[ ] of contract construction [ ] to read . . . all provisions of a contract together as a harmonious whole").

The Companies also argue that, because they have a strong economic incentive to participate in in the Program, they are not truly negotiating or freely agreeing to the process or a drug price. As with the term "maximum fair price," the IRA uses the terms "agree" and "negotiate" to describe the parties' dealings in the Program. *E.g.*, 42 U.S.C. §§ 1320f-2(a)(1), 1320f-3(a), 1320f-3(b)(2)(F). Indeed, it is difficult to imagine how any contract could effectuate the Program without using the terms "agree" or "negotiate," or equivalents that would draw the same objections from the Companies.[24] This is strong evidence that the objected-to terms regulate conduct, despite their presence in written instruments.

In essence, the Companies complain about contract terms they dislike but do not have the bargaining power to convince CMS to remove. But the terms of the contracts are meant to effectuate the Program, not to force the Companies to endorse a government-mandated message. *See FAIR*, 547 U.S. at 62, 126 S.Ct. 1297. Notably, the Companies also remain free to criticize the Program outside of the contracts used to effectuate it. *See id.* at 60, 126 S.Ct.

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[24] Although the Companies claim they were coerced into signing the contracts, agreements between parties with unequal bargaining power remain agreements. *Cf. AT&T Mobility LLC v. Concepcion*, 563 U.S. 333, 346 n.5, 131 S.Ct. 1740, 179 L.Ed.2d 742 (2011) (explaining that agreements to arbitrate made between parties with "unequal bargaining power" are enforceable). And it is common for purchasers to negotiate with a ceiling on what they are willing to pay, as CMS does here because of the statutory price cap. *See* 42 U.S.C. § 1320f-3(c).

1297 ("Law schools remain free under the statute to express whatever views they may have . . . all the while retaining eligibility for federal funds."); *id.* at 65, 126 S.Ct. 1297 ("[N]othing in the Solomon Amendment restricts what the law schools may say about the military's policies.").[25]

Because the Program regulates conduct, with only an incidental effect on speech, it withstands First Amendment scrutiny.[26]

B

The Companies' First Amendment challenge also fails because the Program only "compels" them to speak if they choose to participate. As with their takings claims, the economic hardship that would

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[25] Separately, Janssen argues that its "forced participation in the Program" is an independent First Amendment violation: compelled expressive conduct. Janssen Br. 44–46. It is not. As discussed throughout this opinion, Janssen is not forced to participate in the Program. Furthermore, Janssen has not shown that observers are likely to understand the company's participation in the Program communicates something about its beliefs. *See Tenafly Eruv Ass'n, Inc. v. Borough of Tenafly*, 309 F.3d 144, 161 (3d Cir. 2002).

[26] Arguably, the introductory paragraphs (i.e., the "recitals") to a contract do not directly regulate conduct in the way the operative terms of a contract do. Thus, when government contracts regulate conduct, the recitals and operative terms could have different First Amendment implications. However, the recitals to the Agreement merely provide factual context for the Program: They state that a manufacturer and CMS will "negotiate to determine a price (referred to as "maximum fair price" in the [IRA]) for selected drugs." Agreement at 1. Thus, like the operative terms of the Agreement, any burden on speech that the recitals impose is incidental to the Program's regulation of conduct.

result from declining to participate in the Program does not amount to unconstitutional compulsion. [27]

"A violation of the First Amendment right against compelled speech occurs only in the context of actual compulsion, although that compulsion need not be a direct threat." *Miller v. Mitchell*, 598 F.3d 139, 152 (3d Cir. 2010) (internal quotation marks omitted). "In order to compel the exercise of speech, the governmental measure must punish, or threaten to punish, protected speech by governmental action that is regulatory, proscriptive, or compulsory in nature." *C.N. v. Ridgewood Bd. of Educ.*, 430 F.3d 159, 189 (3d Cir. 2005) (cleaned up). For instance, a state government compels speech when a prosecutor promises to criminally charge high school students unless they write essays about how "sexting" is wrong. *Miller*, 598 F.3d at 143–44, 152. But a school district does not compel speech when it seeks to collect information from students without threatening punishment or discipline for failure to respond. *C.N.*, 430 F.3d at 189.[28]

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[27] As discussed above, we join our sister Circuits in holding that Medicare participation is voluntary for purposes of the Takings Clause. *See supra* Section III.A.I. It is unclear if the level of compulsion required to violate the First Amendment differs from the level of compulsion needed to violate other constitutional provisions and, if so, to what extent. *Cf. Newman v. Beard*, 617 F.3d 775, 780 (3d Cir. 2010). In the absence of clearer authority, our holding with respect to takings liability counsels against finding compulsion for purposes of the First Amendment.

[28] While the First Amendment "right to refrain from speaking at all . . . is necessarily different in the public school setting," it still includes the right not to "profess beliefs or views with which the student does not agree." *C.N.*, 430 F.3d at 186–87 (citation omitted).

Here, the government does not threaten to punish the Companies for declining to participate in the Program. Although the Companies will lose certain revenues from Medicare and Medicaid if they decide not to participate in the Program, Congress can permissibly leverage funding in this way.[29] In *FAIR*, the Solomon Amendment stated that that if any part of a university denied military recruiters access equal to that provided other recruiters, the entire university—not just the particular school that denied access—would lose federal funds from multiple government departments. 547 U.S. at 51, 54 n.3, 126 S.Ct. 1297. Despite these major funding consequences, universities who disagreed with the Solomon Amendment's condition remained "free to decline the federal funds" that subjected them to the condition. *Id.* at 59, 126 S.Ct. 1297; *cf. Wooley v. Maynard*, 430 U.S. 705, 715, 97 S.Ct. 1428, 51 L.Ed.2d 752 (1977) (finding a state "in effect require[d]" speech by mandating that drivers display a motto on their license plates, because driving is "a virtual necessity"). There was no unconstitutional compulsion. The same is true here.[30]

The Companies voluntarily chose to participate in the Program. Any ancillary speech component inherent in Program participation was therefore not

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[29] The Companies argue that the IRA improperly leverages Medicare funding for drugs covered by the Program. This framing artificially cleaves off drugs selected for negotiation from the rest of Medicare. There is one Medicare funding stream, and the Program sets conditions on a portion of it.

[30] The IRA's excise tax provisions do not change this conclusion, as they only apply after a manufacturer chooses to participate in the Program. *See supra* note 11.

compelled. For this additional reason, their First Amendment claims fail.

C

The Companies argue in the alternative that even if the Program does not directly violate the First Amendment, it imposes an unconstitutional condition on a voluntary government benefit. This argument fails, because any speech compulsion does not reach outside of the contours of the Program.

Generally, when a party complains that a government benefit comes on objectionable terms, the party's remedy is to forego the benefit. *See Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.*, 570 U.S. 205, 214, 133 S.Ct. 2321, 186 L.Ed.2d 398 (2013) ("*AID*") ("As a general matter, if a party objects to a condition on the receipt of federal funding, its recourse is to decline the funds . . . [even when] a condition may affect the recipient's exercise of its First Amendment rights."). That said, a funding condition that reaches beyond the scope of the program to compel or regulate a funding recipient's speech may violate the First Amendment. *Id.* at 215–16, 133 S.Ct. 2321.

In *AID*, the Supreme Court distinguished between two types of conditions of federal funding that burden First Amendment rights: (1) those "that define the limits of the government spending program . . . [by] specify[ing] the activities Congress wants to subsidize," and (2) those "that seek to leverage funding to regulate speech outside the contours of the program itself." *Id.* at 214–15, 133 S.Ct. 2321. The former conditions are permissible while the latter are not.

The condition at issue in *AID* required organizations receiving federal funds related to

HIV/AIDS prevention to certify in their award documents that they have policy of opposing prostitution and sex trafficking. *Id.* at 210, 133 S.Ct. 2321. The Court held that the certification requirement regulated speech outside of the HIV/AIDS prevention program for two reasons. First, it was unnecessary; a separate provision barred funds from being used to promote or advocate prostitution. *Id.* at 217–18, 133 S.Ct. 2321. Second, it was overbroad; it limited the organization's First Amendment activity conducted "on its own time and dime." *Id.* at 218, 133 S.Ct. 2321. Similarly, in *FCC v. League of Women Voters of California*, federal funding conditioned on television and radio stations not "engag[ing] in editorializing" violated the First Amendment because the stations were "barred absolutely from all editorializing," not just when using the federal funds. 468 U.S. 364, 366, 400, 104 S.Ct. 3106, 82 L.Ed.2d 278 (1984) (citation omitted). But there was no First Amendment violation in *Rust v. Sullivan*, where a condition barring federal funds from being used on family planning programs that included abortion "le[ft] the grantee unfettered in its . . . activities" outside of the funded program. 500 U.S. 173, 196, 111 S.Ct. 1759, 114 L.Ed.2d 233 (1991); *see also Speiser v. Randall*, 357 U.S. 513, 78 S.Ct. 1332, 2 L.Ed.2d 1460 (1958) (striking down requirement that applicants for a tax exemption attest that they do not seek to overthrow the United States government by unlawful means).

Finally, in *Regan v. Taxation With Representation of Washington*, 461 U.S. 540, 103 S.Ct. 1997, 76 L.Ed.2d 129 (1983), the Supreme Court held that a federal ban on lobbying by tax-exempt non-profit organizations was permissible under the First

Amendment. There, organizations with favorable treatment under 26 U.S.C. § 501(c)(3) received a government benefit—tax exemptions for the organization and tax deductions for contributors—on the condition that they forgo political advocacy. *Id.* at 542 & n.1, 103 S.Ct. 1997. This condition was permissible, in part because the organizations could organize a lobbying affiliate under 26 U.S.C. § 501(c)(4), which grants tax exemptions but not tax deductions for contributors. *Id.* at 544–45 & n.6, 103 S.Ct. 1997. In short, the restriction on funds, offered in the form of favorable tax treatment, survived First Amendment scrutiny because it reflected Congress' choice of what activities to subsidize and permitted participants to engage in protected activity on their own time and dime. *See id.* at 545, 103 S.Ct. 1997.

These cases establish that the Program does not impose an unconstitutional condition on participation. Any "compelled" speech is squarely within the scope of the Program because the contracts at issue effectuate the drug price negotiation process established by Congress. Any expressive content in the contracts—including statements that the parties are agreeing to negotiate a price, and that that price is referred to as the "maximum fair price" in the IRA—effectuates the government's policy choices, rather than "leverage[s] funding to regulate speech outside the contours of the program itself." *AID*, 570 U.S. at 214–15, 133 S.Ct. 2321; *cf. Sheetz*, 601 U.S. at 275–76, 144 S.Ct. 893.

Moreover, the Program does not limit or compel speech outside of the contractual documents any company must sign to participate in the Program. The Companies remain free to criticize the Program in any forum or instrument other than the contracts

needed to effectuate the Program. *See Rust*, 500 U.S. at 197, 111 S.Ct. 1759 ("[U]nconstitutional conditions . . . involve situations in which the Government has placed a condition on the *recipient* of the subsidy rather than on a particular program or service . . . ." (internal quotation marks omitted)).

* * *

For the foregoing reasons, we will affirm the District Court's orders granting summary judgment to the government.

HARDIMAN, Circuit Judge, dissenting.

These consolidated appeals pit two large pharmaceutical manufacturers—Bristol Myers Squibb (BMS) and Janssen Pharmaceuticals (collectively, the Companies)—against the federal government. The Companies appeal adverse summary judgments. They contend that the District Court erred when it rejected their constitutional challenges to the Inflation Reduction Act of 2022 (the Act). The Act established a "Drug Price Negotiation Program" (the Program) to reduce skyrocketing expenses. 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).

The Companies contend that the Program takes their property without just compensation in violation of the Fifth Amendment and compels them to speak in violation of the First Amendment. This Court rejects these arguments and affirms the District Court. I see things differently. The Companies have persuasively argued that their constitutional rights

were violated and that they are entitled to invalidation of the Program as applied to them.

I

Begin with some general principles. The federal government now accounts for almost half of all spending on prescription drugs—some $200 billion per year. *See Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023); KFF, *10 Prescription Drugs Accounted for $48 Billion in Medicare Part D Spending in 2021, or More Than One-Fifth of Part D Spending That Year* (July 12, 2023), https://perma.cc/76RC-DDJR. As a dominant market participant, the United States can do business with whomever it wishes, and it may offer whatever prices it deems proper. So businesses—including pharmaceutical companies like BMS and Janssen—have no constitutional right to sell their wares to the federal government or its designated beneficiaries. And counsel for both sides agree that Congress could have sought to reduce federal outlays simply by passing a law setting prices for the costliest Medicare drugs.

Instead, the Act compelled the Companies to participate in the Program by threatening them with unavoidable, enterprise-crippling tax liabilities if they refused to sell drugs at prices set by CMS (an arm of the Executive Branch). Because the Companies could not avoid participating in the Program without paying those taxes, I would hold that the Act effects a taking of their property under the Fifth Amendment and compels them to speak in violation of the First Amendment. So I would reverse and remand.

II

The Program at issue targets Medicare Parts B and D. *See AstraZeneca Pharms. LP v. Sec'y U.S. Dep't of HHS*, 137 F.4th 116, 120 (3d Cir. 2025). 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, its 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 (hereinafter, the Agreement). *See id.* § 1320f(b)(4), (d)(2)(A).

CMS drafted the 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 (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) and 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)–(5). 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)(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 an addendum a manufacturer must sign to participate in the Program (hereinafter, the Addendum). *See* Agreement at 7–9. The Addendum states that "[t]he parties agree to a price of [$]," which the Addendum's recitals note is called 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).

The Agreement obliges the manufacturer to "provide access to such price" to Medicare beneficiaries beginning in 2026 for the first round of ten drugs. 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).

Once CMS includes a drug in the Program, the manufacturer can theoretically walk away and choose not to do business with the government. But a manufacturer that does so 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.[1] *See* 26 U.S.C. § 5000D. The

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[1] The Government downplays the excise tax rate, contending that it ranges from 65 to 95 percent. But those percentages refer to the tax-inclusive rate—what the Act calls the "applicable percentage," 26 U.S.C. § 5000D(a), (d)—instead of the tax-exclusive rate—the ordinary way to express an excise tax rate. *See, e.g., Imposition and Calculation of the Manufacturers Excise Tax on Sales of Designated Drugs*, [2025] Fed. Tax Coordinator 2d (RIA) ¶ W-6603, 2022 WL 10409574 (Mar. 12, 2025). A tax-inclusive rate calculates the tax as a percentage of the total sale price plus the tax, while the tax-exclusive rate calculates the tax as a percentage of the pre-tax price alone. The tax-exclusive rate is what matters to taxpayers because it reflects the actual burden of the tax relative to earnings per sale. There is no dispute that the tax-exclusive rate ranges from 185.71 to 1,900 percent. *See* 26 U.S.C. § 5000D(a),

Congressional Budget Office observed that "[t]he combination of that excise tax and corporate income taxes could exceed a manufacturer's profits from that product." Congressional Budget Office, *How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act*, at 9 (February 17, 2023), https://perma.cc/Y74A-ATLS and https://perma.cc/2WVR-47TS. Indeed, the excise tax would be so confiscatory that Congress's Joint Committee on Taxation projected that a nearly identical excise tax provision in a precursor bill would raise "no revenue." Joint Comm. on Tax'n, *Estimated Budget Effects of the Revenue Provisions of Title XIII—Committee On Ways And Means, of H.R. 5376, Fiscal Years 2022-2031*, at 8 (Nov. 19, 2021), https://perma.cc/SMC3-GZMF (calculating the excise tax in Build Back Better Act, H.R. 5376, 117th Cong. § 139002 (1st Sess. 2021) (as passed by the House of Representatives, Nov. 19, 2021)). To state the obvious, Congress knew that no manufacturer would ever be able to pay this tax.

But is there an escape hatch from this confiscatory tax? My colleagues think so, reasoning that a manufacturer can decline to participate in the Program by terminating Medicare and Medicaid coverage *of all its products*. *See* 26 U.S.C. § 5000D(c). A manufacturer can cause the excise tax to be "suspend[ed]" by terminating its extant Medicare and Medicaid agreements (under the Medicare Coverage Gap Discount Program, the Manufacturer Discount

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(d); Molly F. Sherlock et al., Cong. Rsch. Serv., R47202, Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376) 4 (2022), https://perma.cc/2XPR-G7NL.

Program, and the Medicaid Drug Rebate Program). *See id.*

There is a practical problem that made this exit option illusory, however. Because nearly all large manufacturers (including BMS and Janssen) once participated in the Coverage Gap Discount Program and now participate in the Manufacturer Discount Program, they will be subject to the excise tax if they refuse to participate in the Program. A manufacturer that terminates its Medicare Coverage Gap and Discount Program agreements must wait between 11 and 23 months, depending on when the notice is given in a calendar year, before the termination becomes effective. *See* 42 U.S.C. §§ 1395w-114a(b)(4)(B)(ii), 1395w-114c(b)(4)(B)(ii). Thus, to avoid being subject to the Program's excise tax for refusing to sign an Agreement by October 1, 2023, *a manufacturer would have had to accomplish the impossible*: provide notices of termination by January 29, 2022, *before the Act became law.*

III

BMS's drug Eliquis and Janssen's drug Xarelto were among the first ten drugs selected for the Program by CMS. Both manufacturers signed the necessary Agreements by the October 1, 2023, deadline. And both signed the Addendum setting a "maximum fair price" by the August 1, 2024, deadline.[2]

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[2] According to CMS, the list price for a 30-day supply of Eliquis was $521.00 in 2023. *See* CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026* (Aug. 15, 2024), https://www.cms.gov/newsroom/fact-sheets/medicare-drug-price-negotiation-program-negotiated-prices-initial-price-

BMS submitted evidence to the District Court that if it had refused to sign the Agreement, the excise tax on sales of Eliquis would have been hundreds of millions of dollars on the first day after the deadline and would have soon exceeded one billion dollars per day. App. 87. Janssen likewise submitted evidence that the excise tax on sales of Xarelto would have started at over $50 million per day and escalated to more than $600 million per day, likely exceeding $90 billion in the first year. App. 795–96. The Government has not disputed these calculations.

IV

Having described the complexities of the Program, I turn to the Companies' constitutional arguments.

A

Consider first the Takings Clause argument. The Fifth Amendment provides: "nor shall private property be taken for public use, without just compensation." U.S. Const. amend. V. "[A] physical *appropriation* of property [gives] rise to a *per se* taking, without regard to other factors." *Horne v. Dep't of Agric.*, 576 U.S. 350, 360, 135 S.Ct. 2419, 192 L.Ed.2d 388 (2015). That is true for physical appropriations of real and personal property. *Id.* An owner of personal property has the "rights to possess, use, and dispose of" it. *Id.* at 361–62, 135 S.Ct. 2419 (citation omitted). So the Companies have a right to decline to sell the doses of their drugs that sit in warehouses to Medicare beneficiaries.

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applicability-year-2026. The price set by the Program is $231.00, which represents a 56 percent discount. *Id.* The list price for a 30-day supply of Xarelto was $517.00 in 2023. *Id.* The price set by the Program is $197.00, which represents a 62 percent discount. *Id.*

In *Horne*, the Supreme Court recognized that a reserve requirement for raisin growers imposed "a clear physical taking" because it forced them to turn over possession of a percentage of their raisin crop to the government. *Id.* at 361, 135 S.Ct. 2419. Like that reserve requirement, here the Act imposes a clear physical taking by forcing the Companies to turn over physical doses of Eliquis and Xarelto to Medicare beneficiaries at certain prices.

The Act forces the Companies to turn over their property to Medicare beneficiaries by threatening them with ruinous excise tax liability. Although participation in Medicare and Medicaid is voluntary, participation in the Program is not. If a Medicare provider declines to participate in the Program, the Act imposes an unavoidable tax on all sales of its selected drug, including sales outside the Medicare system. *See* 26 U.S.C. § 5000D(a). That extraordinary threat compels manufacturers to turn over their drugs at prices set by CMS. *See Horne v. Dep't of Agric.*, 569 U.S. 513, 523–24 & n.4, 133 S.Ct. 2053, 186 L.Ed.2d 69 (2013) (*Horne I*); *cf. E. Enters. v. Apfel*, 524 U.S. 498, 529, 118 S.Ct. 2131, 141 L.Ed.2d 451 (1998) (plurality opinion). The Act's threat of excise taxes and civil penalties looms like a sword of Damocles, creating a de facto mandate to participate.[3]

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[3] The majority cites cases rejecting the argument that participation in Medicare is involuntary because foregoing participation would hurt providers' profits. *See* Majority Op. Section III-A-I & n.10. I agree that declining profitability does not raise a constitutional problem, but in none of those cases did the government threaten to impose major financial penalties on providers if they declined to participate in Medicare. So their reasoning has little bearing on the key issue here, which is

As it did in *Horne*, the Government identifies theoretical options a manufacturer has to avoid the taking of property. For example, the Government suggests that manufacturers can divest their interests in selected drugs. But the Court's decision in *Horne* forecloses that argument because the growers there could have divested their property interests as well. *See* 576 U.S. at 365, 135 S.Ct. 2419. The Government also contends that the Companies have the "option" to refuse to participate in the Program, continue selling their drugs to Medicare beneficiaries, and pay the excise tax. Once again, *Horne* rejected the argument that a property owner's "option" to pay a major financial penalty is relevant to determine whether the government has taken property under the Fifth Amendment.[4] *See Horne I*, 569 U.S. at 523–24 & n.4, 133 S.Ct. 2053; *cf. Cedar Point Nursery v. Hassid*, 594 U.S. 139, 144, 141 S.Ct. 2063, 210 L.Ed.2d 369 (2021).

1

The Government offers several reasons why the excise tax did not compel the Companies to participate in the Program. Those arguments are unavailing because they are based on efforts by CMS and the IRS to rewrite the statute, as the majority

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whether manufacturers can avoid the excise tax if they decline to participate in the Program.

[4] While the Government does not advance it as an "option," a manufacturer could avoid incurring excise tax liability by ceasing to sell its drug *entirely*, so that it never enters the stream of commerce. But *Horne* rejected the argument that the growers had the "option" to stop selling their product, explaining that a property owner's right to sell his goods to private market participants is a "basic and familiar use[ ] of property." 576 U.S. at 366, 135 S.Ct. 2419.

does in its opinion. But administrative agencies (and courts) lack the power to amend laws enacted by Congress. *See Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 412–13, 144 S.Ct. 2244, 219 L.Ed.2d 832 (2024).

The Act directs CMS to implement the Program "for 2026, 2027, and 2028 by program instruction or other forms of program guidance." 42 U.S.C. § 1320f note. CMS interpreted this language to absolve it of the duty to provide notice and an opportunity to comment to interested parties before it promulgates legislative rules. *See* 2023 Revised Guidance at 8–11. Consistent with that interpretation, CMS issued extensive guidance documents for the 2026, 2027, and 2028 drug-pricing periods. *See id.*; CMS, *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027* (Oct. 2, 2024), https://perma.cc/M59V-V2A9; CMS, *Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028* (May 12, 2025), https://perma.cc/G4CW-VANR.

Citing these guidance documents, the Government has adopted at least three new positions since the Act became law. First, it suggests the excise tax applies to sales of a selected drug only to Medicare beneficiaries. *See BMS* Dist. Ct. Dkt. No. 38-1 at 8 (citing IRS Notice No. 2023-52, 2023-35 I.R.B. 650 (Aug. 4, 2023), https://perma.cc/A5KB-Y48X); Excise Tax on Designated Drugs, 90 Fed. Reg. 31, 32–34

(Jan. 2, 2025). Second, the Government contends that the statutorily prescribed exit period of 11 to 23 months is no longer effective because CMS will allow a manufacturer to stop its sales to Medicare and Medicaid upon just 30 days' notice. *See* 2023 Revised Guidance at 120–21. Third, the Government argues a manufacturer can avoid the excise tax simply by ceasing to sell its selected drug to Medicare beneficiaries; it need not terminate all sales to Medicare and Medicaid. As I shall explain, none of these attempts to save the Act works.

a

The Government asserts that the excise tax applies when a manufacturer sells a selected drug only to a Medicare beneficiary. Not so. The excise tax applies to *all domestic sales* of a selected drug. Here's what the statute provides:

> There is hereby imposed on *the sale* by the manufacturer, producer, or importer of *any designated drug* during a day described in subsection (b) a tax in an amount such that the applicable percentage is equal to the ratio of—(1) such tax, divided by (2) the sum of such tax and *the price* for which so sold.

26 U.S.C. § 5000D(a) (emphasis added). Rather than limiting the tax to sales to Medicare beneficiaries, it refers only to "the sale . . . of any designated drug" and "the price" at which those sales occur. *Id.* Nor does it grant the IRS discretion to interpret the tax as applying to sales to Medicare beneficiaries alone, especially since that would conflict with the statutory text. *See Loper Bright*, 603 U.S. at 412–13, 144 S.Ct. 2244.

Adopting the Government's reading is inappropriate for another reason: it would render two parts of the law superfluous. *See Duncan v. Walker*, 533 U.S. 167, 174, 121 S.Ct. 2120, 150 L.Ed.2d 251 (2001) ("It is our duty to give effect, if possible, to every clause and word of a statute." (citation modified)). The tax is "suspend[ed]" once a manufacturer has completely exited the Medicare and Medicaid markets. 26 U.S.C. § 5000D(c). If, as the Government suggests, the tax applied to Medicare sales alone, there would be no need to suspend the tax once a manufacturer stopped all sales to Medicare beneficiaries. Similarly, the tax does not apply to exports. *Id.* § 5000D(g). Because Medicare is a domestic program, there would be no need to exclude exports if the tax applied only to Medicare sales.

The IRS has proposed the same interpretation of the excise tax as the one proffered here by the Government. But the IRS notice, issued on August 4, 2023, has no relevant analysis. *See* IRS Notice No. 2023-52, at 3. In January 2025, the IRS published a notice of proposed rulemaking announcing that it will promulgate a rule adopting the same interpretation. *See* Excise Tax on Designated Drugs, 90 Fed. Reg. 31, 32–34 (Jan. 2, 2025).

But the notice of proposed rulemaking conflicts with the statutory text and merely emphasizes "the broader statutory context of the Program." *Id.* at 33. It suggests that "[b]ecause the . . . tax depends substantively on, and operates only in relation to, the Program, the scope of the Program—which provides access to selected drugs at the negotiated prices only to Medicare beneficiaries and their pharmacies . . .—is reflected in the scope of the tax." *Id.* at 34. The IRS's attempt to rewrite the statute through vague

references to statutory context is inappropriate and should have no legal effect. *See Loper Bright*, 603 U.S. at 412–13, 144 S.Ct. 2244. By its terms, the excise tax applies to all domestic sales of a selected drug, including private market sales. It's as simple as that.

b

CMS has attempted to rewrite the statute in a different way from the IRS. Tacitly acknowledging the confiscatory penalties of the 11 to 23-month delay in withdrawal, CMS promises in a guidance document that it will offer manufacturers an expedited 30-day exit from the Program, the Coverage Gap Discount Program, and the Manufacturer Discount Program. CMS assures the manufacturers that this will allow them to avoid incurring excise taxes and civil monetary penalties. *See* 2023 Revised Guidance at 33–34. But here again, the expedited exit option conflicts with the Act. However vast the powers of CMS may be, it cannot vitiate the requirements of a law passed by Congress.

Recall that a manufacturer could have avoided excise tax liability only by terminating Medicare and Medicaid coverage for all its products. The tax is "suspend[ed]" when the manufacturer has terminated its extant Medicare or Medicaid agreements. *See* 26 U.S.C. § 5000D(c). Historically, manufacturers signed agreements to sell drugs to Medicare under the Medicare Coverage Gap Discount Program. *See* 42 U.S.C. § 1395w-114a. The Act phased out that program; since January 1, 2025, manufacturers have signed such agreements as part of the Medicare Manufacturer Discount Program. *See* 42 U.S.C. § 1395w-114c. Like the Coverage Gap Discount

Program, the Manufacturer Discount Program allows a manufacturer to unilaterally terminate an agreement for Medicare coverage of its drug. But the manufacturer must wait between 11 and 23 months, depending on when the notice is given in a calendar year, before the termination becomes effective. *See* 42 U.S.C. §§ 1395w-114a(b)(4)(B)(ii) and 1395w-114c(b)(4)(B)(ii).

The upshot is that the Companies could not have declined to participate in the first year of the Program. To avoid being subject to the excise tax on October 2, 2023, they had to do the impossible: terminate their Medicare agreements by January 29, 2022, months before the Act became law. And if they had provided such notice when Eliquis and Xarelto were selected on August 29, 2023, they would have incurred excise tax liability for the 15 months between October 2, 2023, and December 31, 2024.

Apparently recognizing this Catch-22, CMS purports to offer the Companies a solution based on its own statutory authority to terminate such agreements. *See* 2023 Revised Guidance at 120–21. CMS is correct that Congress granted CMS the power to unilaterally terminate Coverage Gap and Discount Program agreements at times. The two relevant statutory provisions state that:

> The Secretary may provide for termination of an agreement under this section *for a knowing and willful violation* of the requirements of the agreement or *other good cause shown.* Such termination shall not be effective earlier than 30 days after the date of notice to the manufacturer of such termination. The Secretary shall provide, upon request, a

> manufacturer with a hearing concerning such a termination, and such hearing shall take place prior to the effective date of the termination with sufficient time for such effective date to be repealed if the Secretary determines appropriate.

42 U.S.C. §§ 1395w-114a(b)(4)(B)(i) and 1395w-114c(b)(4)(B)(i) (same language except stating "[t]he Secretary *shall* provide for termination . . . ." (emphases added)) (emphasis added).

Citing these provisions, CMS promised in a guidance document for 2026 that, if a manufacturer "decide[d] not to participate in the [ ] Program," it would "facilitate an expeditious termination of" the manufacturer's Medicare Coverage Gap Discount Program and Manufacturer Discount Program agreements. 2023 Revised Guidance at 33. According to CMS, that would mean that the Companies could have "avoid[ed] incurring excise tax liability" by submitting notice and termination requests 30 days before liability would otherwise have begun to accrue. *Id.* at 33–34.

CMS purports to offer the Companies this offramp based on its statutory authority to terminate agreements for "other good cause shown." 42 U.S.C. §§ 1395w-114a(b)(4)(B)(i) and 1395w-114c(b)(4)(B)(i). It promises to "find good cause to terminate . . . [the Companies'] agreement(s)" if they submit to CMS: "(1) a notice of decision not to participate in the [ ] Program; and (2) a request for termination of . . . [their] applicable agreements under the Medicaid Drug Rebate Program, the Medicare Coverage Gap Discount Program, and the Manufacturer Discount Program." 2023 Revised Guidance at 120–21.

In other words, as the Government said at oral argument in a related case, CMS has promised to help manufacturers avoid the excise tax whenever they claim the Program is unconstitutional.[5] All the manufacturers need to do is formally cease doing business with Medicare and Medicaid while trusting the federal government to follow through on CMS's promise. Cold comfort, indeed.

CMS also says it is offering an exit option to manufacturers even if they have signed Program Agreements. *See id.* at 34 ("[A]ny manufacturer that has entered into an Agreement will retain the ability to promptly withdraw from the program prior to the imposition of civil monetary penalties or excise tax liability."). To take this exit option, a manufacturer must take the steps it would have had to take under the expedited exit option just mentioned. *See id.* at 130.

CMS's efforts to rewrite the statutory scheme by making promises in nonbinding guidance documents should fail for several reasons.[6] *First*, CMS lacks

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[5] *See Novartis Pharms. Corp. v. Sec'y U.S. Dep't of HHS*, No. 24-2968, Oral Arg. at 37:15–26 ("CMS has said that your constitutional objections to this program, we will determine that that is good cause for you to withdraw from the statute. That is a reasonable interpretation of the statutory phrase 'good cause.' "); *see also id.* at 37:00–39:20. *But see id.* at 41:10–41:35 ("I apologize for saying that it had to be for a specific constitutional reason . . . . All you have to do is ask.").

[6] CMS and the majority suggest that CMS's guidance implementing the Program has the force of law. Majority Op. Section III-A-II & n.18. I disagree. A statutory note to the Act provides that HHS "shall implement [the Program] . . . for 2026, 2027, and 2028 by program instruction or other forms of program guidance." 42 U.S.C. § 1320f (note). CMS claims this note

authority to offer this expedited exit option. The statutory provisions governing the Medicare Coverage Gap Discount Program and Manufacturer Discount Program describe two ways a manufacturer may exit those programs. A manufacturer may voluntarily withdraw by providing notice and waiting 11 to 23 months for its terminations to become effective. *See* 42 U.S.C. §§ 1395w-114a(b)(4)(B)(ii) and 1395w-114c(b)(4)(B)(ii). Or CMS may remove a manufacturer for engaging in misconduct. *See*

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authorizes it to issue binding guidance without following notice and comment procedures.

It is true that Congress may "expressly" authorize an agency to conduct rulemaking without following those procedures. 5 U.S.C. § 559; *see also* 42 U.S.C. § 1395hh(b)(2)(A) (similar). But Congress did not do so here. The question is "whether Congress has established procedures so clearly different from those required by the APA that it must have intended to displace" notice-and-comment rulemaking. *Asiana Airlines v. FAA*, 134 F.3d 393, 397 (D.C. Cir. 1998).

The statutory note fails that test. The terms "guidance" and "program instruction" refer to nonbinding interpretive rules and policy statements. *See, e.g.*, Admin. Conf. of the U.S., Recommendation 2017-5, Agency Guidance Through Policy Statements, 82 Fed. Reg. 61728, 61734 (Dec. 29, 2017); *see also Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96–97, 135 S.Ct. 1199, 191 L.Ed.2d 186 (2015). And CMS can promulgate interpretive rules and policy statements without following notice and comment procedures. 5 U.S.C. § 553(b)(A). So the statutory note's instruction that CMS must "implement" the Program through guidance and program instruction does not direct CMS to take any action that would conflict with the APA's notice and comment requirements. After all, it would be oxymoronic to say an agency may promulgate legislative rules by issuing "guidance."

Regardless of whether CMS's guidance is binding, it is also inconsistent with the Act and the Medicare Act for the reasons I explain.

42 U.S.C. §§ 1395w-114a(b)(4)(B)(i) and 1395w-114c(b)(4)(B)(i).

As for misconduct, CMS can terminate an agreement "for a knowing and willful violation of the requirements of the agreement or other good cause shown." *Id.* But contrary to CMS's (and the majority's) reading, "other good cause shown" does not include *a manufacturer's request* for termination. That reading would require us to disregard the phrase "a knowing and willful violation of the requirements of the agreement," which provides important context for the meaning of "other good cause shown."[7] *See McDonnell v. United States*, 579 U.S. 550, 568–69, 136 S.Ct. 2355, 195 L.Ed.2d 639 (2016) ("Under the familiar interpretive canon *noscitur a sociis*, a word is known by the company it keeps." (citation modified)). In sum, the language that appears right before "good cause" makes clear that it refers to other forms of misconduct, not whatever CMS wishes it to mean.[8]

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[7] The majority reasons that "a knowing and willful violation of the requirements of the agreement" is "just one example of a legally sufficient reason for CMS to terminate an agreement." Majority Op. Section III-A-II. But Congress knows how to indicate when a concept is but one example of many. *See, e.g.*, 42 U.S.C. § 1320f–1(d)(3)(B) (instructing CMS to aggregate data "across dosage forms and strengths of the drug, *including* new formulations of the drug, *such as* an extended release formulation" (emphasis added)). Here, the statutory text primarily targets knowing and willful violations, while including a catchall for similar conduct that does not quite meet that high bar.

[8] The majority contends that "good cause" is "a uniquely flexible and capacious concept, meaning simply a legally sufficient reason." Majority Op. Section III-A-II (citation omitted). But the ultimate source for that gloss is simply the definition of "good cause" as "[a] legally sufficient reason."

A contrary interpretation also would render the voluntary termination provisions "insignificant, if not wholly superfluous," *Walker*, 533 U.S. at 174, 121 S.Ct. 2120, which is particularly inappropriate here as they are "another part of the same statutory scheme." *Marx v. Gen. Revenue Corp.*, 568 U.S. 371, 386, 133 S.Ct. 1166, 185 L.Ed.2d 242 (2013). Congress required manufacturers that provide notice of termination of their extant Medicare and Medicaid agreements to wait 11 to 23 months before the terminations are effective.[9] Automatically deeming such requests "good cause" for CMS to terminate those agreements effective upon just 30 days' notice would negate the option Congress enacted. Indeed, at oral argument in a related case, the Government

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Cause, Black's Law Dictionary (12th ed. 2024). Indeed, "good cause" is often a "burden placed on a litigant . . . to show why a request should be granted or an action excused." *Id.* While that standard leaves courts with some discretion, it cannot bear the extraordinary weight the majority and the Government place on it.

[9] The majority also argues that "[t]he unforeseeable legal and economic significance" placed by the Program on the Companies' extant Medicare agreements "supports CMS's conclusion" that it has "good cause" to terminate those agreements to facilitate its exit option. Majority Op. Section III-A-II. But as the majority observes, Congress passed the Act into law *after* the Medicare Coverage Gap Discount Program statute was enacted, and it replaced the termination language for that program with nearly identical language in the Manufacturer Discount Program statute. So although this outcome was "unforeseeable" to the Companies, it was precisely the scheme Congress chose to enact. The design of its statutory scheme, standing alone, cannot constitute "good cause" to avoid complying with the scheme.

struggled to explain how its reading of "good cause" would not mean anything and everything.[10]

In sum, CMS may terminate extant Medicare agreements only for knowing and willful violations or similar misconduct. CMS lacks authority to terminate those agreements to facilitate an expedited exit option that contravenes the exit option already provided in the statute. *See* 26 U.S.C. § 5000D(c)(1)(A)(ii) (providing that the excise tax is suspended once a manufacturer's extant Medicare agreements are no longer effective).

Second, even if CMS could terminate a manufacturer's extant Medicare agreements upon request for "good cause," its expedited exit option still would not allow a manufacturer to avoid the excise tax. The Act "suspend[s]" the tax when, among other things, "the notice of terminations of all applicable agreements of the manufacturer have been received by the Secretary of Health and Human Services." 26 U.S.C. § 5000D(c)(1)(A)(i), (2). When a manufacturer terminates its extant agreements, it must send a termination notice to CMS. *See* 42 U.S.C. §§ 1395w-114a(b)(4)(B)(ii) and 1395w-114c(b)(4)(B)(ii). The tax

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[10] *See Novartis Pharms. Corp. v. Sec'y U.S. Dep't of HHS*, No. 24-2968, Oral Arg. at 37:00–42:15. At one point, the Government said CMS would find any constitutional objection to the Program to be good cause. *Id.* at 37:15–26. At another point, it clarified that CMS would find any objection to the Program to be good cause and that "[a]ll [a manufacturer] ha[s] to do is ask" for the exit option. *Id.* at 41:10–41:35. Yet incongruously, "if [a manufacturer] want[s] to [exit] for other reasons, then [it] ha[s] to follow the normal process." *Id.* at 41:39–41:44. CMS apparently trusts that manufacturers will not "be lying" when they explain why they have asked to take the exit option or will attempt to discern when manufacturers do so. *Id.* at 41:52–41:57.

is suspended once the termination notice has been received by the agency and has become effective. *See* 26 U.S.C. § 5000D(c)(1)(A)(i)–(ii).

But if a manufacturer declines to participate in the Program by taking CMS's supposed expedited exit option, it has to send a written request to CMS asking the agency to terminate its agreements. CMS must then send the manufacturer a termination notice that has legal effect under its authority to terminate for "other good cause shown." 42 U.S.C. §§ 1395w-114a(b)(4)(B)(i) and 1395w-114c(b)(4)(B)(i). So the Secretary would not have "received" any "notice of termination" under the statute (because the termination notice would emanate from the agency) and the excise tax would not be suspended. 26 U.S.C. § 5000D(c)(1)(A)(i) (linking suspension of the excise tax to notices of termination sent with legal effect pursuant to 42 U.S.C. §§ 1395w-114a(b)(4)(B)(i) and 1395w-114c(b)(4)(B)(i)); *see also* 42 U.S.C. § 1320f–5(a)(6) (instructing CMS to share "the date on which [it] receives" such notices with the Treasury so that tax liability can be determined). Further, although CMS may promise not to collect excise taxes accrued by a manufacturer that has taken its supposed expedited exit option, it concedes that it has no control over whether the IRS collects the tax. *See Novartis Pharms. Corp. v. Sec'y U.S. Dep't of HHS*, No. 24-2968, ECF No. 25, Government Br. 34 ("If [a manufacturer] chooses to sell the selected drug to Medicare beneficiaries at non-negotiated prices, [it] will incur tax liability, and the IRS can collect on that tax regardless of anything CMS does.").

Third, CMS lacks the statutory authority to offer an expedited exit option to a manufacturer after it has signed a Program Agreement. For the same reasons

it lacked the statutory authority to offer the expedited exit option to avoid the October 1, 2023, deadline, CMS lacked statutory authority to offer the expedited exit option to avoid the August 1, 2024, deadline. And CMS's promise to grant an expedited exit to manufacturers after they have signed Agreements conflicts with a separate part of the Act: once a drug is selected, it must remain in the Program until generic competition is approved and marketed. *See* 42 U.S.C. §§ 1320f–1(c) and 1320f–2(b) (providing that a selected drug "shall" remain in the Program until CMS determined that a generic or biosimilar version of the drug has been approved and is marketed). Once a manufacturer has signed an Agreement, it is bound by it, full stop. And after a manufacturer has done so, CMS "shall" impose civil monetary penalties each time it violates an Agreement. *Id.* § 1320f–6.

Fourth, the Government contends that, even under the Companies' reading of the statute, they could have avoided the excise tax by sending termination notices to CMS by January 30, 2025.[11] Not so. That contention conflates a manufacturer's ability to terminate its extant Medicare agreements with its ability to terminate its Agreements under the Program. The Act would have imposed excise taxes on the Companies beginning on October 2, 2023, if they did not sign Program Agreements. *See* 26 U.S.C.

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[11] The Manufacturer Discount Program changed the termination deadline from January 29 to January 30 in 2024 for Coverage Gap and Discount Program agreements set to take effect in 2025. *See* 42 U.S.C. §§ 1395w-114a(b)(4)(B)(ii) and 1395w-114c(b)(4)(B)(ii). So my analysis discusses the January 29 deadline on a backward-looking basis and the January 30 deadline on a forward-looking basis.

§ 5000D(b)(1). Likewise, it would have imposed the excise tax beginning on August 2, 2024, if they did not sign Agreement Addendums. *See id.* § 5000D(b)(2).

If the Companies refused to sign on the dotted line, the Act purported to offer them one way to avoid the excise tax: by providing notice that they were terminating all their extant Medicaid agreements and no longer had Medicare agreements in effect. *See id.* § 5000D(c)(1)(A). But the Companies could terminate their Medicare agreements only by providing 11 to 23 months' notice, which prevented them from taking this illusory option to avoid the excise tax before the October 2023 and August 2024 deadlines. *See* 42 U.S.C. §§ 1395w-114a(b)(4)(B)(ii) and 1395w-114c(b)(4)(B)(ii).

Under the threat of the excise tax, the Companies signed Agreements and Addendums. Once they did so, they had to participate in the Program. And the Act neither offers them a way to terminate their Agreements, nor grants CMS unfettered discretion to terminate them to facilitate an early exit. *See* 42 U.S.C. §§ 1320f–1(c) and 1320f–2(b). So the Companies must abide by the terms of their Agreements, or they will be subject to civil penalties. *See id.* § 1320f–6.

To sum up: once the Companies signed the Agreements by the October 1, 2023 deadline, their prior ability to terminate their extant Medicare agreements upon 11 to 23 months' notice became irrelevant. They were bound by the Agreements to participate in the Program even if they ceased all other business with Medicare and Medicaid.

* * *

The majority errs fundamentally when it concludes that the Companies voluntarily joined the Program. The Companies could not have refused to participate in the Program without incurring enterprise-crippling excise taxes, even if they had stopped doing business with Medicare and Medicaid. To avoid the excise taxes, they could have notified CMS that they wished to terminate their extant Medicare and Medicaid agreements. *See* 26 U.S.C. § 5000D(c). But the excise tax would not have been suspended until the terminations of their Medicare agreements became effective, which would have taken 11 to 23 months. *See id.* § 5000D(c)(1)(A)(ii); 42 U.S.C. §§ 1395w-114a(b)(4)(B)(ii), 1395w-114c(b)(4)(B)(ii). During that period, the tax would have been imposed on the sales of Eliquis and Xarelto. *See* 26 U.S.C. § 5000D(b), (c)(1)(A)(ii). And if they signed a Program Agreement and then violated it, the Act would have subjected them to civil monetary penalties. 42 U.S.C. § 1320f–6(a)–(c). CMS, like Don Corleone in *The Godfather*, made the Companies "an offer [they] [couldn't] refuse." (Paramount Pictures 1972).

2

Having concluded that the Companies were compelled to participate in the Program, I now consider whether the Program forces them to turn over physical doses of their drugs to Medicare beneficiaries. It does.

The Government argues that the manufacturers have one other "option" to avoid a taking. It contends that the Program merely sets a price cap on drugs, providing only that if a manufacturer sells a dose of a

selected drug to a Medicare beneficiary, then it must do so at the "maximum fair price" set by CMS. In other words, the Government suggests that manufacturers participating in the Program can refuse to sell doses of their selected drugs to Medicare beneficiaries while continuing to sell other drugs to Medicare and Medicaid beneficiaries. Here again, the text and structure of the Program and the Agreement show otherwise.

Compelling a property owner to turn over his personal property effects a per se taking. *Horne*, 576 U.S. at 362, 135 S.Ct. 2419. That is true even though setting a price limit on sales does not. *Id.* "[T]hat distinction flows naturally from the settled difference . . . between appropriation and regulation" because "[t]he Constitution [ ] is concerned with means as well as ends." *Id.*

The Act requires the Secretary of HHS to sign Agreements with manufacturers that require them to provide "access to the maximum fair price . . . with respect to . . . a selected drug . . . to . . . maximum fair price eligible individuals." 42 U.S.C. § 1320f-2(a), (a)(3). Likewise, the Agreement requires a manufacturer to "provide access to [the maximum fair] price . . . to maximum fair price eligible individuals." Agreement at 2. So the statute and Agreement require participating manufacturers to offer their drugs to Medicare beneficiaries at the price set by CMS.

The Government reads the statute and Agreement differently. It contends that the scheme allows a manufacturer to refuse to sell a selected drug without withdrawing from Medicare and Medicaid or paying civil penalties. On that view, the scheme does not

compel the manufacturers to provide access to physical doses of its products.

But the Government's interpretation clashes with the Act's exit option, which allows a manufacturer to decline to participate in the Program only if it stops selling to Medicare and Medicaid beneficiaries (and pays the excise tax during the 11-to-23-month termination period). *See* 26 U.S.C. § 5000D(c). On the Government's reading of the Act, two exit options exist: an explicit one that requires a manufacturer to abandon roughly half the U.S. pharmaceutical market (*i.e.*, ceasing all Medicare and Medicaid sales) and an implicit one that allows a manufacturer to avoid most of those consequences (*i.e.*, refusing to sell a single selected drug to Medicare purchasers). Its interpretation has two vices: it both invents a second exit option that is not in the statute and negates the statute's explicit exit option. *See Marx*, 568 U.S. at 386, 133 S.Ct. 1166 ("[T]he canon against surplusage is strongest when an interpretation would render superfluous another part of the same statutory scheme.").

An adjacent provision the Act added to the Social Security Act highlights the flaw in the Government's proposed interpretation. *See* 42 U.S.C. § 1395w-104(b)(3)(I)(i). Section 1395w-104(b)(3)(I)(i), which guarantees "[a]ccess to covered Part D drugs," provides that private plan sponsors "shall include each covered part D drug that is a selected drug under section 1320f-1 of this title for which a maximum fair price (as defined in section 1320f(c)(3) of this title) is in effect with respect to the year." *Id.* In other words, sponsors *must* include drugs selected for the Program in the prescription drug plans they offer to Medicare

beneficiaries. There is no option to provide only some selected drugs.

The Government noted in a related case that this provision binds only plan sponsors, not manufacturers. True enough. But that does not cure the disharmony between the Government's interpretation of the Act's mandate to provide "access to the maximum fair price" and the "beneficiary protection[ ]" guaranteed by this provision. 42 U.S.C. §§ 1320f-2(a), (a)(3) and 1395w-104(b)(3)(I)(i). That protection would be illusory if a manufacturer could refuse to sell its selected drug to a Medicare beneficiary who is guaranteed "access" under the Program. *See Romero v. SmithKline Beecham*, 309 F.3d 113, 119 (3d Cir. 2002) (Alito, J.) (explaining interpretations that would "frustrate the evident purposes of [a] provision" are disfavored). So the Program forces the manufacturers to turn over physical doses of their drugs to Medicare beneficiaries.

* * *

For the reasons stated, the Program violates the Companies' right to refuse to sell doses of their drugs to Medicare beneficiaries and dispensers. None of the illusory alternative "options" proposed by the Government negates that fact. Because the Program forces the Companies to turn over their drugs to Medicare beneficiaries, it effects a per se taking. *See Horne*, 576 U.S. at 361–62. So the Companies cannot be compelled to participate in the Program unless they are provided with just compensation in return. U.S. Const. amend. V; *Horne*, 576 U.S. at 367, 135 S.Ct. 2419.

B

I next consider the Companies' argument that the Act violates their First Amendment rights because it compels them to engage in expressive speech.

Under threat of the excise tax, the Act orders the Companies to participate in "negotiations." *See* 42 U.S.C. §§ 1320f–2(a) and 1320f–3(a). As part of that process, they must sign an Agreement stating that they "agree" to "negotiate" a "maximum fair price" for their selected drugs. *See id.* § 1320f–2(a)(1). After the process is completed, they must sign an Addendum stating "[t]he parties agree to a price of [$]," which the statute calls the "maximum fair price." Agreement at 7. Thus, the Act compels the Companies to attest that they agreed to negotiate a "maximum fair price" for their drugs even though they were compelled to participate in the Program for the reasons I have explained.

1

The First Amendment states: "Congress shall make no law . . . abridging the freedom of speech." U.S. Const. amend. I. The Government cannot "compel a person to speak its own preferred messages." *303 Creative LLC v. Elenis*, 600 U.S. 570, 586, 143 S.Ct. 2298, 216 L.Ed.2d 1131 (2023). Nor may it "compel affirmance of a belief with which the speaker disagrees." *Hurley v. Irish-Am. Gay, Lesbian & Bisexual Grp. of Bos.*, 515 U.S. 557, 573, 115 S.Ct. 2338, 132 L.Ed.2d 487 (1995). And the "freedom of speech 'includes . . . the right to refrain from speaking at all.' " *Janus v. Am. Fed'n of State, Cnty. & Mun. Emps. Council 31*, 585 U.S. 878, 892, 138 S.Ct. 2448, 201 L.Ed.2d 924 (2018) (citation omitted).

Compelled speech violates the First Amendment "only in the context of actual compulsion." *C.N. v. Ridgewood Bd. of Educ.*, 430 F.3d 159, 189 (3d Cir. 2005). Yet compulsion "need not take the form of a direct threat or a gun to the head. " *Id.* (citation modified). According to one of our sister courts, "[t]he consequence may be an indirect discouragement, rather than a direct punishment, such as imprisonment, fines, injunctions or taxes." *Axson-Flynn v. Johnson*, 356 F.3d 1277, 1290 (10th Cir. 2004) (citation modified). In this case, the Companies are compelled to speak by the threat of "a direct punishment": an enterprise-crippling tax.[12] *Id.*

2

The Government (and the majority) contend that the Program regulates conduct, not speech, reasoning that its purpose is to "determine the price manufacturers may charge" and "[t]he agreements are ordinary commercial contracts that the government is using to set agreed-upon prices." Government Br. 46–47 (citation modified). On its

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[12] The majority holds that the Companies were not compelled to speak. Majority Op. Section IV-B & n.30. I disagree because the Companies could not have avoided the excise tax if they declined to participate in the Program. *See supra* Section IV-A-1. And the majority's statement that "[t]he IRA's excise tax provisions . . . only apply after a manufacturer chooses to participate in the Program," Majority Op. Section IV-B n.30, can be true only if one concludes that CMS's expedited exit option is lawful. But because it is unlawful, the excise tax would have applied to any manufacturer that participated in the Medicare Coverage Gap Discount Program before the Act was signed into law, even if the manufacturer did not want to participate in the Program from day one. *See supra* Section IV-A-1.

view, because the Program primarily regulates non-expressive, commercial conduct, it affects speech only incidentally. I disagree.

The Government inverts the distinction between regulations of conduct and speech. Conduct regulations can burden speech indirectly without offending the First Amendment. For example, bans on "outdoor fires" incidentally forbid flag burning. *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 567, 131 S.Ct. 2653, 180 L.Ed.2d 544 (2011) (citation modified). Likewise, a "typical price regulation" regulates a "seller's conduct" by prohibiting him from charging certain prices, which affects speech "indirectly" by forbidding him from advertising prices above the limit. *Expressions Hair Design v. Schneiderman*, 581 U.S. 37, 47, 137 S.Ct. 1144, 197 L.Ed.2d 442 (2017).

The Program does the opposite: it compels speech as a means to regulate conduct. It orders the Companies to sign a document stating that they "agree" to "negotiate" a "maximum fair price" for their selected drugs. *See* 42 U.S.C. § 1320f–2(a)(1). By doing so, it forces the Companies to convey the government's message about the Program—that it is a voluntary "negotiation" that resulted in an agreement on a "maximum fair price"—to incidentally set prices. To primarily regulate conduct, the Program could have capped what the Companies may charge or what CMS will pay for selected drugs. That would, in turn, incidentally require the Companies to sign agreements containing certain words and numbers—prices—for drugs they sell to Medicare and Medicaid. But the Act does much more than that.

To support its position, the Government analogizes to *Rumsfeld v. Forum for Academic &*

Institutional Rights, Inc., 547 U.S. 47, 62, 126 S.Ct. 1297, 164 L.Ed.2d 156 (2006) (*FAIR*). But its reliance on *FAIR* is misplaced. There, the plaintiffs challenged a law that, as a condition on federal funding, required universities to give military recruiters and non-military recruiters equal access to their campuses. 547 U.S. at 51–52, 126 S.Ct. 1297. The Supreme Court held that the law did not violate the First Amendment because its equal access mandate regulated conduct, not speech. *Id.* at 60, 126 S.Ct. 1297. Any speech was "plainly incidental." *Id.* at 62, 126 S.Ct. 1297. For example, if a school offered to send emails or post notices on an employer's behalf, it was also required to do so on behalf of the military. *Id.* at 61–62, 126 S.Ct. 1297.

The Court recognized that such "compelled statements of fact ('The U.S. Army recruiter will meet interested students in Room 123 at 11 a.m.'), like compelled statements of opinion, are subject to First Amendment scrutiny." *Id.* at 62, 126 S.Ct. 1297. Nonetheless, the mandate did not violate the First Amendment because the compelled speech was "not inherently expressive." *Id.* at 64, 126 S.Ct. 1297. The Court reasoned that "[n]othing about recruiting suggests that law schools agree with any speech by recruiters." *Id.* at 65, 126 S.Ct. 1297.

Here, by contrast, the Act's burdens on speech are not incidental to regulated conduct. The Act orders the Companies to speak meaningfully and substantively—by forcing them to sign the Agreements and Addenda in which they must "agree" to "negotiate" a "maximum fair price." *See* 42 U.S.C. §§ 1320f–2(a)(1); Agreement at 2, 7. Had the law challenged in *FAIR* required universities to send emails expressing certain opinions or representations

on behalf of military recruiters, that case likely would have come out differently. So too here. The Act could have avoided First Amendment scrutiny simply by setting prices the United States would pay for the selected drugs or directing CMS to do likewise. *See Expressions Hair Design*, 581 U.S. at 47, 137 S.Ct. 1144. Instead, the Act directly compels speech—rather than regulate conduct—so it is subject to First Amendment scrutiny. *FAIR*, 547 U.S. at 62, 126 S.Ct. 1297.

Put simply, because the Act directly compels the Companies to make "statements of fact," it is "subject to First Amendment scrutiny." *FAIR*, 547 U.S. at 62, 126 S.Ct. 1297. So I must determine whether that compelled speech is expressive. *See id.* at 61–68, 126 S.Ct. 1297. That determination would be required even if the majority were correct in asserting that the Program primarily regulates conduct. *See id.*

3

I conclude that the speech compelled by the Act is expressive. That is true whether the Program's mandate that the Companies sign Agreements and Addendums is framed as compelling pure speech (*i.e.*, utter these words) or expressive conduct (*i.e.*, sign this document). The Supreme Court has recognized that signing a document—including government funding agreements—can constitute expression, although it has not clarified whether doing so is pure speech or inherently expressive conduct. *See, e.g., John Doe No. 1 v. Reed*, 561 U.S. 186, 194–95, 130 S.Ct. 2811, 177 L.Ed.2d 493 (2010); *Agency for Int'l Dev. v. All. for Open Soc'y Int'l*, 570 U.S. 205, 210, 218, 133 S.Ct. 2321, 186 L.Ed.2d 398 (*AID*).

In any case, the First Amendment protects "conduct . . . inten[ded] to convey a particularized message" where "the likelihood was great that the message would be understood by those who viewed it." *Texas v. Johnson*, 491 U.S. 397, 404, 109 S.Ct. 2533, 105 L.Ed.2d 342 (1989) (citation modified). Here, the Act forced the Companies to sign an Agreement saying they "agree" to "negotiate" a "maximum fair price" for Eliquis and Xarelto. *See* 42 U.S.C. §§ 1320f–2(a)(1). It also forced them to sign an Addendum stating they "agree to a price of [$]." Agreement at 7. Both statements are expressive. By attesting that they "agree" to "negotiate," the Companies represented that their participation in the negotiation was voluntary. And by stating that they have "agree[d]" that the price is a "maximum fair price," they are confessing to having previously charged unfair prices.

The Agreements at issue are similar to the funding award agreement at issue in *AID*, although they are further from the heartland of the First Amendment than the referendum petition at issue in *Reed*. In any event, "[t]he expressive, overtly political nature of" forcing the Companies to sign the Agreements is "both intentional and overwhelmingly apparent."[13]

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[13] Although the statute defines "maximum fair price" and uses the terms "agree" and "negotiate," that does not render these terms non-expressive. After all, "if the law were otherwise, there would be no end to the government's ability to skew public debate by forcing companies to use the government's preferred language." *Nat'l Ass'n Mfrs. v. SEC*, 800 F.3d 518, 530 (D.C. Cir. 2015) (citation modified). The majority relies on *Meese v. Keene*, 481 U.S. 465, 467, 107 S.Ct. 1862, 95 L.Ed.2d 415 (1987), to hold otherwise, but it is telling that even the Government was unwilling to do so in its brief. In *Keene*, the challenged statutory

Johnson, 491 U.S. at 406, 109 S.Ct. 2533. For example, the President said in a State of the Union address that "Medicare is negotiating lower prices for some of the costliest drugs." The White House, *Remarks by President Biden in State of the Union Address* (Mar. 8, 2024), https://perma.cc/J67S-MVU4. The President also released a video "announc[ing] that the manufacturers of ten drugs are coming to the negotiating table to lower prices. They're taking steps to participate in the negotiating program so we can give seniors the best possible deal." 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), https://perma.cc/N23L-CWVK. The White House similarly "announced that all manufacturers of all ten drugs selected for negotiation have signed agreements to participate." *Id.* And despite the excise tax precluding exit, CMS claimed that "entering into an Agreement is voluntary." CMS, *Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments*, at 27 (Mar. 15, 2023), https://perma.cc/SRN2-FQHF; *see also* 2023 Revised Guidance at 120.

It bears repeating that the Act could have avoided First Amendment scrutiny simply by setting prices the United States would pay for the selected drugs or

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term—"political propaganda"—did not appear on the form that the regulated parties had to sign. *Id.* at 471, 107 S.Ct. 1862. But here, the Act forces the Companies to use certain terms by compelling them to sign Agreements "agreeing" to "negotiate" a "maximum fair price." *See* 42 U.S.C. § 1320f–2(a)(1).

directing CMS to do likewise. *See Expressions Hair Design*, 581 U.S. at 47, 137 S.Ct. 1144. Instead, in Orwellian fashion, the Act forced the Companies to sign Agreements that include representations they have abjured from the start. *See* 42 U.S.C. § 1320f–2(a)(1). Their consistent view has been that they "agree" only under protest and there is no true "negotiation" because they must participate in the Program.

As for "maximum fair price," the Companies reject both the concept and substance of that phrase. And with very good reason. A fair price, both in common parlance and as defined by the United States Treasury, is what a knowledgeable buyer would pay a knowledgeable seller, with neither compelled to act. *See, e.g.*, 26 C.F.R. § 1.170A-1(c)(2); *see also* 4 Nichols on Eminent Domain § 12.02 (Matthew Bender, 3rd ed. 2025) (same). Measured against those standards, the phrase "maximum fair price" is oxymoronic at best. And even if the phrase were intelligible, the Companies have rejected it because it suggests that the prices they had charged—which were substantially higher than the prices set by the Program—were strikingly "unfair."

In sum, the Act forced the Companies to convey the Government's message about a subject of great political significance and debate: whether the Program is a voluntary negotiation or a forced sale at prices set by CMS.[14] *See Reed*, 561 U.S. at 195, 130

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[14] At oral argument in related cases, the Government argued for the first time that the Program is consistent with the First Amendment because CMS will not release signed Agreements to the public. *See Novo Nordisk Inc. v. Sec'y U.S. Dep't of HHS*, No. 24-2510, Oral Arg. at 39:30–41:48; *Novartis*

S.Ct. 2811 ("[T]he expression of a political view implicates a First Amendment right.").

4

CMS has added a disclaimer to the Agreement, which states that its terms are statutory terms of art and do not hold their colloquial meaning. The disclaimer says:

> In signing this Agreement, the Manufacturer does not make any statement regarding or endorsement of CMS' views, and makes no representation or promise beyond its intention to comply with its obligations under the terms of this Agreement with respect to the Selected Drug. Use of the term "maximum fair price" and other statutory terms throughout this Agreement reflects the parties' intention that such terms be given the meaning specified in the statute and does not reflect any party's views regarding the colloquial meaning of those terms.

Pharms. Corp. v. Sec'y U.S. Dep't of HHS, No. 24-2968, Oral Arg. at 30:00–30, 33:00–45. But compelled speech is not rendered constitutional because it is made only to the government. *See Americans for Prosperity Found. v. Bonta*, 594 U.S. 595, 616, 141 S.Ct. 2373, 210 L.Ed.2d 716 (2021); *see also NetChoice, LLC v. Bonta*, 113 F.4th 1101, 1117–18 (9th Cir. 2024). And nothing prevents CMS from making the Agreements public if it changes its mind. Moreover, even if the Agreements remain private, the public can easily connect the dots: CMS has released the template Agreement and Addendum, the names of manufacturers that have signed Agreements, the drugs selected, and the prices it has set. So a manufacturer could disclaim its value-laden actions and statements "only at the price of evident hypocrisy." *AID*, 570 U.S. at 219, 133 S.Ct. 2321.

Agreement at 4. That effort falls short because "general disclaimer[s] . . . [do] not erase [ ] First Amendment infringement[s]." *Circle Schools v. Pappert*, 381 F.3d 172, 182 (3d Cir. 2004); *see also Pac. Gas & Elec. Co. v. Pub. Utilities Comm'n of California*, 475 U.S. 1, 15 n.11, 106 S.Ct. 903, 89 L.Ed.2d 1 (1986) (plurality opinion); *Hurley*, 515 U.S. at 576, 115 S.Ct. 2338. The Government cannot "require speakers to affirm in one breath that which they deny in the next." *Hurley*, 515 U.S. at 576, 115 S.Ct. 2338 (citation omitted). For the same reason, the Companies' ability to criticize the Program does not erase the First Amendment infringement. *See id.*; *AID*, 570 U.S. at 219, 133 S.Ct. 2321. While CMS couched the disclaimer's language in lawyerly terms, it is also telling that the Government recognized the public could "view[ ] . . . the colloquial meaning of those terms," Agreement at 4, as conveying a politically charged message.

5

Because the Program compels expressive, content-based speech, it triggers strict scrutiny. *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 653–55, 114 S.Ct. 2445, 129 L.Ed.2d 497 (1994). To survive, "it must be narrowly tailored to promote a compelling Government interest." *United States v. Playboy Ent. Grp., Inc.*, 529 U.S. 803, 813, 120 S.Ct. 1878, 146 L.Ed.2d 865 (2000). And the Government must "choose[ ] the least restrictive means to further the articulated interest." *Sable Commc'ns of California, Inc. v. FCC*, 492 U.S. 115, 126, 109 S.Ct. 2829, 106 L.Ed.2d 93 (1989).

The speech mandate fails strict scrutiny. The Government does not have a compelling interest in

requiring the Companies to sign Agreements misrepresenting that they "agree[d]" to "negotiate" a "maximum fair price" for their drugs when they could not decline to do so without incurring enterprise-crippling tax liabilities. And while the Government surely has a legitimate interest in reducing Medicare expenditures, the Program is not narrowly tailored to further that interest. The Government often sets limits on what it will pay for drugs, including through voluntary negotiations, without requiring counterparties to sign Agreements attesting that they "agree" to "negotiate" the "maximum fair" terms. *See, e.g.*, 38 U.S.C. § 8126(a)–(h) (setting price limits on what the Departments of Defense and Veterans Affairs will pay for prescription drugs and enabling them to negotiate lower prices). So the Program quite gratuitously compels speech in violation of the First Amendment.

V

Because I would find several provisions of the Act unconstitutional, I must consider whether they are severable. I apply a "well established" two-part test. *Alaska Airlines, Inc. v. Brock*, 480 U.S. 678, 684, 107 S.Ct. 1476, 94 L.Ed.2d 661 (1987). First, I must determine whether the rest of the statute will operate as Congress intended. *Id.* at 685, 107 S.Ct. 1476. If not, I must conclude that the rest of the statute is invalid. *Id.* Second, even if the remaining provisions can operate as Congress intended, I must determine whether Congress would have enacted them standing alone. *Id.*

The provisions I would hold unconstitutional as applied to the Companies—26 U.S.C. § 5000D and 42 U.S.C. §§ 1320f–1, 1320f–2, 1320f–3, and 1320f–6—

are not severable from the rest of the Program. First, the rest of the statute would not operate as Congress intended if the unconstitutional provisions were severed. *See id.* As for the Companies' Fifth Amendment claims, the excise tax provision works together with the provisions governing the very heart of the Program—selections, negotiations, Agreements, and monetary penalties—to effect a taking. *See* 26 U.S.C. § 5000D; 42 U.S.C. §§ 1320f–1 (selections), 1320f–2 (Agreements), 1320f–3 (negotiations), and 1320f–6 (civil penalties). The Program would not work as Congress intended if manufacturers could decline to participate without incurring excise tax or civil penalty liability, particularly because that would allow manufacturers to continue to sell their selected drugs to Medicare beneficiaries at any price they chose without immediate consequences. 26 U.S.C. § 5000D(a)–(c); 42 U.S.C. § 1320f–6(a)–(c). Nor would the Program function as Congress intended without the clear rules Congress set about how long selected drugs must remain in the Program, 42 U.S.C. §§ 1320f–1(c) and 1320f–2(b), Congress's command that Agreements guarantee Medicare beneficiaries access to the "maximum fair price," *id.* § 1320f–2(a)(1), (3), and participating manufacturers' obligation to complete "negotiations," *id.* § 1320f–3(a).

As for the Companies' First Amendment claims, the excise tax provision works combined with another provision at the heart of the Program: the requirement for the Program to be implemented through Agreements signed by the manufacturer after "negotiat[ions]." *See* 26 U.S.C. § 5000D; 42 U.S.C. § 1320f–2(a). The Program cannot function at

all without such Agreements, much less operate as Congress intended.

The next question is whether the unconstitutional provisions of the Program are severable from the remaining portions of the Inflation Reduction Act. They are. The Act addressed a broad array of topics, including corporate taxes, stock repurchases, IRS funding, prescription drug inflation rebates, other amendments to Medicare Part D, energy production, carbon emissions, and more. *See* Inflation Reduction Act of 2022, Pub. L. No. 117–169, 136 Stat. 1818 (2022). The only significant relationship between the Program and the rest of the Act is that the Program's excise tax links liability to the withdrawal provisions of a separate program created by the Act: the Medicare Manufacturer Discount Program. *See* Inflation Reduction Act of 2022 § 11201(c)(1) (codified at 42 U.S.C. § 1395w–114c(b)(4)(B)(i)–(ii)).

First, the rest of the statute would operate as Congress intended standing alone. *See Alaska Airlines*, 480 U.S. at 685, 107 S.Ct. 1476. The Medicare Manufacturer Discount Program replaced the Coverage Gap Discount Program and governs how CMS normally enters agreements with manufacturers to cover prescription drugs. While the Drug Price Negotiation Program links liability to certain actions governed by the Manufacturer Discount Program, nothing in the operation of the Manufacturer Discount Program turns on a provision of the Drug Price Negotiation Program. So the rest of the Act remains "fully operative as a law." *Id.* at 684, 107 S.Ct. 1476 (citation omitted).

Second, there is no evidence that Congress would not have enacted the remaining provisions standing alone. *See id.* at 685, 107 S.Ct. 1476. And no party

suggests otherwise. The rest of the Act does not turn upon the legal mechanisms of the Program, and there is no sign that the policy goals of the remaining provisions will be so disrupted without the Program that Congress would not have enacted them standing alone. So my conclusion that the challenged statute cannot lawfully be enforced is limited to the Program. *See* Inflation Reduction Act of 2022 §§ 11001–03 (codified at 26 U.S.C. § 5000D and 42 U.S.C. §§ 1320f, 1320f–1, 1320f–2, 1320f–3, 1320f–4, 1320f–5, 1320f–6, and 1320f–7).

VI

Finally, I turn to the proper remedy. I would hold that the Program takes property from the Companies and compels them to speak. Still, the Government may take property so long as it provides just compensation in exchange. *See* U.S. Const. amend. V; *see also Horne*, 576 U.S. at 367, 135 S.Ct. 2419. But I need not reach whether the Program could provide the Companies with just compensation in certain circumstances because the Government cannot compel them to speak.

By its plain terms, the Act requires the Companies to sign Agreements in which they must attest that they "agree" to "negotiate" a "maximum fair price" for their drugs. *See* 42 U.S.C. § 1320f–2(a)(1). Because I would hold that this mandate compels speech in violation of the First Amendment, the constitutional infringement could not be remedied by removing certain terms from the Agreements. The Companies were forced to sign these Agreements under the threat of unavoidable, enterprise-crippling tax liability. So I would hold that they cannot be compelled to sign Agreements to participate in the

Program and that such Agreements obtained in violation of the Constitution cannot be enforced against them.

* * *

This appeal is of great importance to consumers of pharmaceutical drugs, the companies that provide them, and the public at large. The United States spends an estimated $200 billion per year on prescription drugs. *See* KFF, *supra.* As the dominant purchaser of those drugs, the federal government is in a strong position to negotiate, in arms-length transactions, favorable prices to benefit consumers and the public fisc alike. Or, as counsel for both sides and the Government agreed, Congress could simply pass a law setting drug prices.[15]

Instead of doing that, Congress compelled manufacturers to subject themselves to prices set by CMS. The byzantine scheme established by the Act forced BMS and Janssen to turn over Eliquis and Xarelto at prices set by CMS while requiring the Companies to misrepresent that they agreed to such prices. That scheme violates the Companies' First and Fifth Amendment rights. With respect, I dissent.

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[15] Oral Arg. at 3:00–4:05, 25:15–26:45.

26 U.S.C. § 5000D

§ 5000D. Designated drugs during noncompliance periods

(a) In general

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

(1) such tax, divided by

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

(b) Noncompliance periods

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

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

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

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

(2) The period beginning on the November 2nd immediately following the March 1st described in paragraph (1) (or, in the case of initial price

applicability year 2026, the August 2nd immediately following the October 2nd described in such paragraph) and ending on the earlier of—

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

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

(3) In the case of any designated drug which is a selected drug (as defined in section 1192(c) of the Social Security Act) that the Secretary of Health and Human Services has selected for renegotiation under section 1194(f) of such Act, the period beginning on the November 2nd of the year that begins 2 years prior to the first initial price applicability year of the price applicability period for which the maximum fair price established pursuant to such renegotiation applies and ending on the earlier of—

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

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

(4) With respect to information that is required to be submitted to the Secretary of Health and

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

(c) Suspension of tax

(1) In general

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

(A) beginning on the first date on which—

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

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

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

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

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

(2) Applicable agreement

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

(A) An agreement under—

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

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

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

(d) Applicable percentage

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

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

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

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

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

(e) Definitions

For purposes of this section—

(1) Designated drug

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

(2) United States

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

(3) Other terms

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

(f) Special rules

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

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

(2) Anti-abuse rule

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

(g) Exports

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

(h) Regulations

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

26 U.S.C. § 7421

§ 7421. Prohibition of suits to restrain assessment or collection

(a) Tax

Except as provided in sections 6015(e), 6212(a) and (c), 6213(a), 6232(c), 6330(e)(1), 6331(i), 6672(c), 6694(c), 7426(a) and (b)(1), 7429(b), and 7436, no suit for the purpose of restraining the assessment or collection of any tax shall be maintained in any court by any person, whether or not such person is the person against whom such tax was assessed.

(b) Liability of transferee or fiduciary

No suit shall be maintained in any court for the purpose of restraining the assessment or collection (pursuant to the provisions of chapter 71) of—

(1) the amount of the liability, at law or in equity, of a transferee of property of a taxpayer in respect of any internal revenue tax, or

(2) the amount of the liability of a fiduciary under section 3713(b) of title 31, United States Code, in respect of any such tax.

42 U.S.C. § 1320f

§ 1320f. Establishment of program

(a) In general

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

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

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

(3) negotiate and, if applicable, renegotiate maximum fair prices for such selected drugs, in accordance with section 1320f–3 of this title;[1]

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

(b) Definitions relating to timing

For purposes of this part:

(1) Initial price applicability year

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

(2) Price applicability period

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

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

(3) Selected drug publication date

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

(4) Negotiation period

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

(A) beginning on the sooner of—

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

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

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

(c) Other definitions

For purposes of this part:

(1) Manufacturer

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

(2) Maximum fair price eligible individual

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

(A) in the case such drug is dispensed to the individual at a pharmacy, by a mail order service, or by another dispenser, an individual

who is enrolled in a prescription drug plan under part D of subchapter XVIII or an MA–PD plan under part C of such subchapter if coverage is provided under such plan for such selected drug; and

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

(3) Maximum fair practice

The term "maximum fair price" means, with respect to a year during a price applicability period and with respect to a selected drug (as defined in section 1320f–1(c) of this title) with respect to such period, the price negotiated pursuant to section 1320f–3 of this title, and updated pursuant to section 1320f–4(b) of this title, as applicable, for such drug and year.

* * *

42 U.S.C. § 1320f-1

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

(a) In general

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

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

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

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

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

negotiation-eligible drugs with respect to such year).

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

(b) Selection of drugs

(1) In general

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

(A) Rank negotiation-eligible drugs described in subsection (d)(1) according to the total expenditures for such drugs under parts B and D of subchapter XVIII, as determined by the Secretary, during the most recent period of 12 months prior to the selected drug publication date (but ending not later than October 31 of the year prior to the year of such drug publication date), with respect to such year, for which data are available, with the negotiation-eligible drugs with the highest total expenditures being ranked the highest.

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

(C) In the case of a biological product for which the inclusion of the biological product as a selected drug on a list published under subsection (a) has

been delayed under subsection (f)(2), remove such biological product from the rankings under subparagraph (A) before making the selections under subparagraph (B).

* * *

42 U.S.C. § 1320f-2

§ 1320f-2. Manufacturer agreements

(a) In general

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

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

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

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

subject to paragraph (2), the price applicability period;

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

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

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

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

(A) maximum fair price eligible individuals, who with respect to such drug are described in

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

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

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

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

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

(C) information that the Secretary requires to carry out section 1320f–1(f) of this title,

including rebates under paragraph (4) of such section; and

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

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

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

* * *

42 U.S.C. § 1320f-3

§ 1320f-3. Negotiation and renegotiation process

(a) In general

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

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

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

(b) Negotiation process requirements

(1) Methodology and process

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

(2) Specific elements of negotiation process

As part of the negotiation process under this section, with respect to a selected drug and the negotiation period with respect to the initial price

applicability year with respect to such drug, the following shall apply:

(A) Submission of information

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

(B) Initial offer by Secretary

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

(C) Response to initial offer

(i) In general

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

(ii) Counteroffer requirements

If a manufacturer proposes a counteroffer, such counteroffer—

(I) shall be in writing; and

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

(D) Response to counteroffer

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

(E) Deadline

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

(F) Limitations on offer amount

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

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

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

(c) Ceiling for maximum fair price

(1) General ceiling

(A) In general

The maximum fair price negotiated under this section for a selected drug, with respect to the first initial price applicability year of the price applicability period with respect to such drug, shall not exceed the lower of the amount under subparagraph (B) or the amount under subparagraph (C).

(B) Subparagraph (B) amount

An amount equal to the following:

(i) Covered part D drug

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

(ii) Part B drug or biological

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

(C) Subparagraph (C) amount

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

(i) Initial price applicability year 2026

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

(ii) Initial price applicability year 2027 and subsequent years

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

(I) the average non-Federal average manufacturer price for such drug for 2021 (or, in the case that there is not an average non-Federal average manufacturer price available for such drug for 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the consumer price index for all urban

consumers (all items; United States city average) from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year prior to the year of the selected drug publication date with respect to such initial price applicability year; or

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

(2) Plan specific enrollment weighted amount

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

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

(B) a fraction—

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

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

(3) Applicable percent described

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

(A) Short-monopoly drugs and vaccines

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

(B) Extended-monopoly drugs

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

(C) Long-monopoly drugs

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

(4) Extended-monopoly drug defined

(A) In general

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

(B) Exclusions

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

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

(ii) A selected drug for which a manufacturer had an agreement under this part with the

Secretary with respect to an initial price applicability year that is before 2030.

(C) Clarification

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

(5) Long-monopoly drug defined

(A) In general

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

(B) Exclusion

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

(6) Average non-Federal average manufacturer price

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

* * *

(e) Factors

For purposes of negotiating the maximum fair price of a selected drug under this part with the

manufacturer of the drug, the Secretary shall consider the following factors, as applicable to the drug, as the basis for determining the offers and counteroffers under subsection (b) for the drug:

(1) Manufacturer-specific data

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

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

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

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

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

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

(2) Evidence about alternative treatments

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

(A) The extent to which such drug represents a therapeutic advance as compared to existing therapeutic alternatives

and the costs of such existing therapeutic alternatives.

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

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

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

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

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42 U.S.C. § 1320f-6

§ 1320f-6. Civil monetary penalties

(a) Violations relating to offering of maximum fair price

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

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

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

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

or supplier and the maximum fair price for such drug for such year.

(b) Violations relating to providing rebates

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

(c) Violations of certain terms of agreement

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

(d) False information

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

(e) Application

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

42 U.S.C. § 1395w-114a

§ 1395w-114a. Medicare coverage gap discount program

* * *

(b) Terms of agreement

* * *

(4) Length of agreement

* * *

(B) Termination

(i) By the Secretary

The Secretary may provide for termination of an agreement under this section for a knowing and willful violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 30 days after the date of notice to the manufacturer of such termination. The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, and such hearing shall take place prior to the effective date of the termination with sufficient time for such effective date to be repealed if the Secretary determines appropriate.

(ii) By a manufacturer

A manufacturer may terminate an agreement under this section for any reason. Any such termination shall be effective, with respect to a plan year—

(I) if the termination occurs before January 30 of a plan year, as of the day after the end of the plan year; and

(II) if the termination occurs on or after January 30 of a plan year, as of the day after the end of the succeeding plan year.

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42 U.S.C. § 1395w-114c

§ 1395w-114c. Manufacturer discount program

* * *

(b) Terms of agreement

* * *

(4) Length of agreement

* * *

(B) Termination

(i) By the Secretary

The Secretary shall provide for termination of an agreement under this section for a knowing and willful violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 30 days after the date of notice to the manufacturer of such termination. The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, and such hearing shall take place prior to the effective date of the termination with sufficient time for such effective date to be repealed if the Secretary determines appropriate.

(ii) By a manufacturer

A manufacturer may terminate an agreement under this section for any reason. Any such termination shall be effective, with respect to a plan year—

(I) if the termination occurs before January 31 of a plan year, as of the day after the end of the plan year; and

(II) if the termination occurs on or after January 31 of a plan year, as of the day after the end of the succeeding plan year.

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