UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 24-1820

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)

No. 24-1821

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

On Appeal from the United States District Court
for the District of New Jersey
(D.C. Civil Nos. 3:23-cv-03335 and 3:23-cv-03818)
District Judge: Honorable Zahid N. Quraishi

Argued on October 30, 2024

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

JUDGMENT

These causes came to be considered on the records from the United States District Court for the District of New Jersey and were argued on October 30, 2024.

On consideration whereof, it is hereby **ORDERED and ADJUDGED** that the orders of the District Court entered on April 29, 2024, be and are hereby **AFFIRMED**. Costs are taxed against Appellants. All of the above in accordance with the opinion of this Court.

ATTEST:

s/ Patricia S. Dodszuweit
Clerk

Dated: September 4, 2025

Certified as a true copy and issued in lieu of a formal mandate on October 27, 2025

Teste: Patricia A Dodszuweit
Clerk, U.S. Court of Appeals for the Third Circuit

OFFICE OF THE CLERK

PATRICIA S. DODSZUWEIT

CLERK

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FOR THE THIRD CIRCUIT
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October 27, 2025

Melissa E. Rhoads
United States District Court for the District of New Jersey
Clarkson S. Fisher Federal Building and United States Courthouse
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RE: Bristol Myers Squibb Co v. Secretary United States Department of HHS, et al
Case Number: 24-1820
District Court Case Number: 3:23-cv-03335

Dear District Clerk

Enclosed herewith is the certified judgment together with copy of the opinion or certified copy of the order in the above-captioned case(s). The certified judgment or order is issued in lieu of a formal mandate and is to be treated in all respects as a mandate.

Counsel are advised of the issuance of the mandate by copy of this letter. The certified judgment or order shows costs taxed, if any.

For the Court,

s/ Patricia S. Dodszuweit
Clerk

Date: October 27, 2025

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PRECEDENTIAL

UNITED STATES COURT OF APPEALS
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(Amended as per the Clerk's 09/13/2024 Order)

No. 24-1821

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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 &
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_____

On Appeal from the United States District Court
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District Judge: Honorable Zahid N. Quraishi

_____

Argued on October 30, 2024

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

(Opinion filed: September 4, 2025)

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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

[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.

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 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

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

[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.

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 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

[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.

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 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

[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.*

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 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

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

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 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 (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

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

prices the Companies have 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.[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 (citations omitted). A physical taking may involve real property or personal property. *Id.* at 152. Either way, when the government effects this type of physical appropriation, it "must pay for what it takes." *Id.* at 148 (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, there is no physical taking

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

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 (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] Recently, the Second Circuit applied these cases

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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

to reject a functionally identical takings challenge to the Program. *See Boehringer Ingelheim Pharms., Inc. v. HHS*, ___ F.4th ___, 2025 WL 2248727, at *8 (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

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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 "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

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 Boehringer*, 2025 WL 2248727, at *7 ("[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

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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.

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 (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. 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. 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.

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 (citation omitted). It likened the case to *Ruckelshaus v. Monsanto Company*, 467 U.S. 986 (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. 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. 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.

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 (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

[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 (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.

conclusion that the voluntary nature of Medicare participation precludes takings liability.[13]

The Companies also rely on *National Federation of Independent Business v. Sebelius*, 567 U.S. 519 (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. 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. 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.

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

[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. & 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).

States' role as distinct sovereigns.[14] Federalism prohibits the federal government from trampling on a State's prerogatives under the Tenth Amendment. *See id.* at 577–78; *Printz v. United States*, 521 U.S. 898, 918–22 (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 (1992) ("[T]he Tenth Amendment confirms that the power of the Federal

[14] *See, e.g.*, 567 U.S. at 577 ("Spending Clause legislation [may] not undermine the status of the States as independent sovereigns in our federal system."); *id.* at 577–78 ("[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 up)); *id.* at 578 ("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 ("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 ("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.").

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]

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

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[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 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

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 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

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

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]

[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 18 n.6; *see* 5 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.

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 19–22. Because the phrase "other good cause" appears following a specific ground upon which CMS may terminate an agreement—"a knowing and willful 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 (2023). Congress chose to include that flexible and capacious phrase

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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 (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*, 2025 WL 2248727, at *14.

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]

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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 22–23. 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

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 (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 v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (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)).

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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 (2016).

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 (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 (first citing *Nollan v. Cal. Coastal Comm'n*, 483 U.S. 825 (1987); and then citing *Dolan v. City of Tigard*, 512 U.S. 374 (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. 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 604–05. 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 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

[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.

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 (2018) ("*NIFLA*") (alteration omitted) (quoting *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 567 (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 (2017).

"While drawing the line between speech and conduct can be difficult, [courts] have long drawn it . . . ." *NIFLA*, 585 U.S. at 769. 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 (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 (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 (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 (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. 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. 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. 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 "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 (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. 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

[22] The Court also noted that the Solomon Amendment only compels speech "if, and to the extent, the school provides such speech for other recruiters." 547 U.S. at 62. *See infra* Section IV.B.

to it as a "cash discount" was permissible, while calling it a "credit card surcharge" was not. *See id.* at 44. 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. Because the law allowed merchants to charge whatever they wanted, it regulated only speech, not conduct. *Id.* at 47. 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 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 (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 33–34. 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. 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. 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*, 319 U.S. 624 (1943), and *Wooley v. Maynard*, 430 U.S. 705 (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. 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. 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.

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 (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 (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

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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.

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. Notably, the Companies also remain free to criticize the Program outside of the contracts used to effectuate it. *See id.* at 60 ("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 ("[N]othing in the Solomon Amendment restricts what the law schools may say about the military's policies.").[25]

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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 (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).

[25] Separately, Janssen argues that its "forced participation in the Program" is an independent First Amendment violation:

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 result from declining to

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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.

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

[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.

from students without threatening punishment or discipline for failure to respond. *C.N.*, 430 F.3d at 189.[28]

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. 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; *cf. Wooley v. Maynard*, 430 U.S. 705, 715 (1977) (finding a state "in effect require[d]" speech by mandating that drivers display a motto on their

[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).

[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.

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 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 (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.

[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.

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. 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. 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. Second, it was overbroad; it limited the organization's First Amendment activity conducted "on its own time and dime." *Id.* at 218. 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 (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 (1991); *see also Speiser v. Randall*, 357 U.S. 513 (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 (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. 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. 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.

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; *cf. Sheetz*, 601 U.S. at 275–76.

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 ("[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.

Bristol Myers Squibb Co. v. Sec'y HHS & *Janssen Pharms. Inc. v. Sec'y HHS*, Nos. 24-1820 & 24-1821

_____

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 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,*

[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), (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.

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 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]

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

[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-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.*

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 (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 (citation omitted). So the Companies have a right to decline to sell the doses of their drugs that sit in warehouses to Medicare beneficiaries.

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. 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 (2013) (*Horne I*); *cf. E. Enters. v. Apfel*, 524 U.S. 498, 529 (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]

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. 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*

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

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; *cf. Cedar Point Nursery v. Hassid*, 594 U.S. 139, 144 (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 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 (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

[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.

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.

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 (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. 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

[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.").

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 authority to offer

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[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 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).

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* 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

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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 (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.

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 (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]

A contrary interpretation also would render the

[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." *Cause*, Black's Law Dictionary (12th ed. 2024). Indeed, "good

voluntary termination provisions "insignificant, if not wholly superfluous," *Walker*, 533 U.S. at 174, 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 (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" 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

[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.

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 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. § 5000D(b)(1). Likewise, it would have imposed

[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.

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. 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 ("[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.

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 (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 (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 (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 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

[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.

forbid flag burning. *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 567 (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 (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 (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. 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. Any speech was "plainly incidental." *Id.* at 62. 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.

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. Nonetheless, the mandate did not violate the First Amendment because the compelled speech was "not inherently expressive." *Id.* at 64. The Court reasoned that "[n]othing about recruiting suggests that law schools agree with any speech by recruiters." *Id.* at 65.

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. Instead, the Act directly compels speech—rather than regulate conduct—so it is subject to First Amendment scrutiny. *FAIR*, 547 U.S. at 62.

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. So I must determine whether that compelled speech is expressive. *See id.* at 61–68. 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 (2010); *Agency for Int'l Dev. v. All. for Open Soc'y Int'l*, 570 U.S. 205, 210, 218 (2013) (*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 (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] *Johnson*, 491 U.S. at 406. 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

[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 (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 term—"political propaganda"—did not appear on the form that the regulated parties had to sign. *Id.* at 471. 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).

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 directing CMS to do likewise. *See Expressions Hair Design*, 581 U.S. at 47. 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*,

[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 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 (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.

561 U.S. at 195 ("[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.

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 (1986) (plurality opinion); *Hurley*, 515 U.S. at 576. The Government cannot "require speakers to affirm in one breath that which they deny in the next." *Hurley*, 515 U.S. at 576 (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. 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 (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 (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 (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 (1987). First, I must determine whether the rest of the statute will operate as Congress intended. *Id.* at 685. 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.

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 (citation omitted).

Second, there is no evidence that Congress would not have enacted the remaining provisions standing alone. *See id.* at 685. 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. 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

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

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.