APPENDIX

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APPENDIX A

PRECEDENTIAL

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, 3:23-cv-03818)
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 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

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

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

represent the highest expenditures under Medicare Part B or D. *AstraZeneca*, 137 F.4th at 120.[3]

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

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

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

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

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

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

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

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

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

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

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

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

[7] Although the parties and the dissent contend that a manufacturer only avoids excise taxes by withdrawing its drugs from Medicare and Medicaid entirely, the statute specifies the two programs from which a manufacturer must withdraw to avoid those excise taxes. References to the loss of all Medicare and Medicaid funding are therefore misplaced.

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

B

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

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

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

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

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 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).

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

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 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

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

to participate in the . . . Program, no taking has occurred.").

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

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

not an economically viable option," because "economic hardship is not equivalent to legal compulsion for purposes of takings analysis"); *Minn. Ass'n of Health Care Facilities, Inc. v. Minn. Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984) ("Despite the strong financial inducement to participate in Medicaid, a nursing home's decision to do so is nonetheless voluntary."); *St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875 (7th Cir. 1983) ("[T]he fact that practicalities may in some cases dictate participation does not make participation involuntary.").

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

II

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

First, the Companies invoke the Supreme Court's Takings Clause decision in *Horne v. Department of Agriculture*, 576 U.S. 350 (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 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

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

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

"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 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

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[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.").

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 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 to the Companies,

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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 taken effect and give

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 path to termination whenever a manufacturer submits notice of its decision not to participate in the Drug Price

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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).

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]

CMS issued the 2023 Revised Guidance two months before it announced the drugs selected for the

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[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. 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.

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 alongside just one example of a legally sufficient reason for CMS to terminate an agreement with a manufacturer. And it makes sense that Congress would permit CMS to use the speedier path to termination when CMS consents to a manufacturer's withdrawal, rather than when a manufacturer acts unilaterally.

Moreover, the Companies entered into their Coverage Gap Discount Program agreements before Congress enacted the IRA. At that time, the Companies could not have known that a future statute would condition excise taxes on the continued existence of their Coverage Gap agreements. Later,

when CMS selected the Companies' drugs for negotiation in August 2023, the Companies had to decide whether to participate in the Program or withdraw from their Coverage Gap agreements in order to suspend the IRA's excise taxes. The unforeseeable legal and economic significance of the Companies' Coverage Gap agreements supports CMS's conclusion that a manufacturer's decision not to participate in the Program constitutes "other good cause" supporting an expedited withdrawal from those agreements.[19]

If Congress wished to limit CMS's termination authority to instances of manufacturer misconduct, it knew how to do so. *See Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 394–95 (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]

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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 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).

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)).

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]

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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

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

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 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 professsionals 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,

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

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 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. Here, the Program regulates the price at which the companies will be

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

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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.

to imagine how any contract could effectuate the Program without using the terms "agree" or "negotiate," or equivalents that would draw the same objections from the Companies.[24] This is strong evidence that the objected-to terms regulate conduct, despite their presence in written instruments.

In essence, the Companies complain about contract terms they dislike but do not have the bargaining power to convince CMS to remove. But the terms of the contracts are meant to effectuate the Program, not to force the Companies to endorse a government-mandated message. *See FAIR*, 547 U.S. at 62. 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: 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

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 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

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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.

[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.

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

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

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[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.

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 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,

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[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.

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.

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

[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

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

But is there an escape hatch from this confiscatory tax? My colleagues think so, reasoning that a manufacturer can decline to participate in the Program by terminating Medicare and Medicaid coverage *of all its products*. *See* 26 U.S.C. § 5000D(c).

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.

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 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

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

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]

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[3] The majority cites cases rejecting the argument that participation in Medicare is involuntary because foregoing participation would hurt providers' profits. *See* Majority Op.

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* 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

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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.

[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.

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 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 trusting the federal government to follow through on CMS's promise. Cold comfort, indeed.

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

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

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

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

authority to offer this expedited exit option. The statutory provisions governing the Medicare Coverage Gap Discount Program and Manufacturer Discount Program describe two ways a manufacturer may exit those programs. A manufacturer may voluntarily withdraw by providing notice and waiting 11 to 23 months for its terminations to become effective. *See* 42 U.S.C. §§ 1395w-114a(b)(4)(B)(ii) and 1395w-114c(b)(4)(B)(ii). Or CMS may remove a manufacturer for engaging in misconduct. *See* 42 U.S.C. §§ 1395w-114a(b)(4)(B)(i) and 1395w114c(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

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§ 559; *see also* 42 U.S.C. § 1395hh(b)(2)(A) (similar). But Congress did not do so here. The question is "whether Congress has established procedures so clearly different from those required by the APA that it must have intended to displace" notice-and-comment rulemaking. *Asiana Airlines v. FAA*, 134 F.3d 393, 397 (D.C. Cir. 1998).

The statutory note fails that test. The terms "guidance" and "program instruction" refer to nonbinding interpretive rules and policy statements. *See, e.g.*, Admin. Conf. of the U.S., Recommendation 2017-5, Agency Guidance Through Policy Statements, 82 Fed. Reg. 61728, 61734 (Dec. 29, 2017); *see also Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96–97 (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.

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

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

[8] The majority contends that "good cause" is "a uniquely flexible and capacious concept, meaning simply a legally sufficient reason." Majority Op. Section III-A-II (citation omitted). But the ultimate source for that gloss is simply the definition of "good cause" as "[a] legally sufficient reason." *Cause*, Black's Law Dictionary (12th ed. 2024). Indeed, "good cause" is often a "burden placed on a litigant . . . to show why a request should be granted or an action excused." *Id.* While that standard leaves courts with some discretion, it cannot bear the extraordinary weight the majority and the Government place on it.

A contrary interpretation also would render the 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 struggled to explain how its reading of "good cause" would not mean anything and everything.[10]

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[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.

[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]

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

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

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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.

"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 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

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

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.

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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.

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.*

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

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 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

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manufacturer did not want to participate in the Program from day one. *See supra* Section IV-A-1.

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.*

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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]

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

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/J67SMVU4. The President also released a video "announc[ing] that the manufacturers of ten drugs are coming to the negotiating table to lower prices. They're taking steps to participate in the negotiating program so we can give seniors the best possible deal." The White House, *Biden-Harris Administration Takes Major Step Forward in Lowering Health Care Costs; Announces Manufacturers Participating in Drug Price Negotiation Program* (Oct. 3, 2023), https://perma.cc/N23L-CWVK. The White House similarly "announced that all manufacturers of all ten drugs selected for negotiation have signed agreements to participate." *Id.* And despite the excise tax precluding exit, CMS claimed that "entering into an Agreement is voluntary." CMS, *Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments*, at 27 (Mar. 15, 2023), https://perma.cc/SRN2-FQHF; *see also* 2023 Revised Guidance at 120.

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

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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).

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*, 561 U.S. at 195 ("[T]he expression

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

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.*

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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.

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 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.

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

APPENDIX B

NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

Civil Action No. 23-3335 (ZNQ) (JBD)

BRISTOL MYERS SQUIBB COMPANY,

Plaintiff,

v.

XAVIER BECERRA, *et al.,*

Defendants.

Civil Action No. 23-3818 (ZNQ) (JBD)

JANSSEN PHARMACEUTICALS, INC.,

Plaintiff,

v.

XAVIER BECERRA, *et al.,*

Defendants.

OPINION

QURAISHI, District Judge

THIS MATTER comes before the Court upon Cross-Motions for Summary Judgment. Plaintiff Bristol Myers Squibb Company ("BMS") and Plaintiff Janssen Pharmaceuticals, Inc. ("Janssen") (collectively, "Plaintiffs") each filed a Motion for

Summary Judgment. ("BMS's Motion", ECF No. 36; "Janssen's Motion", ECF No. 30) (collectively, "Plaintiffs' Motions for Summary Judgment"). Defendants Xavier Becerra, Chiquita Brooks-Lasure, U.S. Department of Health & Human Services ("HHS"), Centers for Medicare & Medicaid Services ("CMS"), and Ananda V. Burra (collectively, "Defendants") filed Cross-Motions for Summary Judgment ("Defendants' Cross-Motion for Summary Judgment") against BMS (ECF No. 38) and Janssen (ECF No. 33.) The Court has under consideration the following submissions:[1]

- BMS's brief in support of its Motion. ("BMS Moving Br.", ECF No. 36-3.)
- Janssen's brief in support of its Motion. ("Janssen Moving Br.", ECF No. 30-1.)
- Defendants' combined brief in opposition to Plaintiffs' Motions and in support of their Cross-Motion. ("Defs.' Cross-Br.", ECF No. 38-1)[2]

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[1] There are also several amicus briefs filed in both cases. The amici include: Fresenius Kabi USA, LLC, Public Citizen, Patients for Affordable Drugs Now, Doctors for America, Protect Our Care, Families USA, AARP and AARP Foundation, Intellectual Property Law And Health Law Scholars, American Public Health Association, American College of Physicians, Society of General Internal Medicine, American Geriatrics Society, American Society of Hematology, Constitutional Accountability Center, Economists and Scholars of Health Policy, Abrams Institute for Freedom of Expression, Alliance for Aging Research, and Nationally Recognized Healthcare and Medicare Experts.

[2] Defendants filed identical Cross-Briefs against BMS and Janssen, ECF Nos. 38-1 and 33-1, respectively. For the purpose of this Opinion, the Court cites to the brief filed at ECF No. 38-1.

- BMS's combined brief in opposition to Defendants' Cross-Motion and reply in support of its Motion. ("BMS' s Resp. Br.", ECF No. 80.)
- Janssen's combined brief in opposition to Defendants' Cross-Motion and reply in support of its Motion. ("Janssen's Resp. Br.", ECF No. 71.)
- Defendants' reply in support of their Cross-Motion. ("Defs.' Reply Br.", ECF No. 84)[3]

The Court has carefully considered the parties' submissions and held oral argument on March 7, 2024 ("Oral Arg. Tr.", ECF No. 107). For the reasons set forth below, the Court will GRANT Defendants' Cross-Motions for Summary Judgment and DENY Plaintiffs' Motions for Summary Judgment.

I. BACKGROUND AND PROCEDURAL HISTORY

A. GENERAL BACKGROUND

This action arises out of BMS and Janssen's claims challenging the constitutionality of the Drug Price Negotiation Program ("Program") created by the Inflation Reduction Act of 2022, Pub. L. No. 117-169 ("IRA"). *See* 42 U.S.C. § 1320f *et seq*. In considering a challenge against the Program brought by Plaintiffs AstraZeneca Pharmaceuticals LP and AstraZeneca AB, our sister court in Delaware carefully and meticulously provided a general background of the Program. *See AstraZeneca Pharms. LP v. Becerra,* Civ. No. 23-931,2024 WL 895036, at *1-5 (D. Del. Mar. 1, 2024) (explaining the history, enactment, and functions of the Program). Given the thoroughness of

[3] Defendants similarly filed identical Reply briefs against BMS and Janssen, ECF Nos. 84 and 75, respectively. For the purpose of this Opinion, the Court cites to the brief filed at ECF No. 84.

the court's factual background, and for judicial economy, this Court incorporates by reference the background of the Program set forth by the Delaware District Court.

B. PLAINTIFF SPECIFIC BACKGROUND & PROCEDURAL HISTORY

BMS initiated this action by filing a Complaint on June 16,2023. ("BMS Compl.", ECF No. 1.) Janssen filed its Complaint on July 18,2023. ("Janssen Compl.", ECF No. 1.) BMS and Janssen are both pharmaceutical manufacturers with their principal place of business in New Jersey. (BMS Compl. ¶ 11; Janssen Compl. ¶¶ 17–18.) Among other medications, BMS manufactures and sells Eliquis; Janssen manufactures and sells Xarelto. (BMS Compl. ¶ 12; Janssen Compl. ¶ 18.) Both medicines are used to prevent blood clots and reduce the risk of strokes. (BMS Compl. ¶ 12; Janssen Compl. ¶ 18.) Notably, Eliquis and Xarelto are both subject to the first round of Program as "negotiation eligible" drugs. [4] (BMS Compl. ¶ 12; Janssen Compl. ¶ 77.)

BMS and Janssen allege three claims in their Complaints. First, Plaintiffs allege that the Program is an uncompensated physical taking of personal property in violation of the Fifth Amendment's Taking Clause ("Takings Clause claim"). (BMS Compl. ¶¶ 93–101; Janssen Compl. ¶¶ 129–39). Next, Plaintiffs allege that the Program compels their speech in violation of the First Amendment ("Compelled Speech claim"). (BMS Compl. ¶¶ 102–07; Janssen Compl. ¶¶ 140–49.) Finally, Plaintiffs allege that the Program

[4] To be consistent with the language of the Program, for the purposes of this Opinion, the Court will use the term "drug" or "drugs" to refer to Eliquis and Xarelto.

is an unconstitutional condition on Medicare and Medicaid participation.[5] (BMS Compl. ¶ 88; Janssen Compl. ¶¶ 150–55.)

Plaintiffs and Defendants in both cases have "conferred, and agree that these cases present sufficiently similar legal questions about the constitutionality of a federal statute that can—and should—be resolved through coordinated dispositive motions, without the need for discovery." (ECF No. 34 at 1.) Accordingly, the Court dispensed with any submission of statements of disputed facts by the parties given they are strictly challenging the constitutionality of the Program. (ECF No. 35.)

II. JURISDICTION

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

III. LEGAL STANDARD

A motion for summary judgment may be granted when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). If there is "no genuine dispute over material facts," then courts "will order judgment to be entered in favor of the party deserving judgment in light of the law and undisputed facts." *Iberia Foods Corp. v. Romeo,* 150 F.3d 298 (3d Cir. 1998).

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[5] For the purposes of this Opinion, the Court uses the term Medicare when it refers to both Medicare and Medicaid.

IV. DISCUSSION[6]

The Court will address the following three issues raised by the parties. First, the Court will consider whether the Program is a physical taking in violation of the Fifth Amendment's Taking Clause. Next, the Court will consider whether the Program compels speech in violation of the First Amendment. Finally, the Court will consider whether the Program violates the unconstitutional conditions doctrine.

A. FIFTH AMENDMENT TAKINGS CLAUSE CLAIM

1. Parties' Positions

a) *Plaintiffs*

Plaintiffs' main position is that the Program effects a physical taking of Plaintiffs' drugs in violation of the Fifth Amendment. (BMS Moving Br. at 12.) Plaintiffs argue that their drugs are private property protected by the Takings Clause. (*Id.* at 24; Janssen Moving Br. at 26.) Next, Plaintiffs claim that the Program is not "a mere price cap" but rather a "forced transfer dressed up as a 'sale.'" (BMS Moving Br. at 13, 16.) Accordingly, Plaintiffs contend that "the Program's forced sales are functionally equivalent to physically seizing the medicine from the warehouse." (BMS Resp. Br. at 4.) Ultimately, Plaintiffs assert that "[t]he whole point of [the Program] is for the Government to avoid paying just compensation by paying far less than the fair market price" for the selected drugs. (BMS Moving Br. at 14–15.)

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[6] Given the substantial similarity between BMS and Janssen's legal claims, arguments, and briefs, for the purpose of this Opinion, the Court will primarily cite to the briefs filed by BMS.

Plaintiffs explain that this compelled transfer occurs through the following scheme. First, pharmaceutical companies, like Plaintiffs, that are selected to participate in the Program must comply and agree to sell the selected drugs at the maximum fair price. (*Id.* at 7.) If Plaintiffs do not agree with the maximum fair price and want to sell the selected drug to Medicare at a different price, then Plaintiffs will incur a very high tax[7] on all of their drug sales from all sources. (*Id.* at 8.) Second, the only way a manufacturer could avoid the tax is if they withdraw from all Medicare sales entirely.[8] (BMS Resp. Br. at 6.) Finally, even if Plaintiffs withdraw from selling to

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[7] The parties view the excise tax differently. Plaintiffs' position is that the excise tax starts at 186% and can go up to 1900%. (*See* BMS Moving Br. at 8.) In contrast, Defendants claim that the excise tax is 95%. (*See* BMS Moving Br. at 8.)

[8] Plaintiffs claim that they could not withdraw from the Program within adequate time to avoid the tax because the Program requires a manufacturer to give at least 11 months, and as many as 23 months, notice of termination; this deadline would have been January 2022, months before the Program was even enacted. (BMS Moving Br. at 32.) Defendants explain that there two ways in which Defendants can still withdraw from the Program. First, Defendants explained that under the 11-to-23-month statutory period, Plaintiffs remain eligible to file their notice of termination by "no later than January 30th, 2025 to be out of Medicare in time for the first sales that are actually subject to the maximum fair price." (Oral Arg. Tr. 61:22-62:6.) Second, pursuant to CMS's Revised Guidance, the HHS Secretary can terminate a manufacturer's agreement "before the manufacturer would incur liability for any excise tax, so long as the manufacturer notifies CMS of its desire to withdraw at least 30 days in advance of when that tax would otherwise begin to accrue." (Defs.' Cross-Br. at 7.) Defendants also explained that a manufacturer can satisfy the good cause requirement under the second method of withdrawal by simply expressing their desire to no longer participate in the Program. (Oral Arg. Tr. 62:19-23.)

Medicare, it would not defeat their argument the Program is still a physical taking under Supreme Court precedent set by *Home v. Department of Agriculture,* 576 U.S. 350 (2015). Plaintiffs argue that just because this forced transfer is "dressed-up" as a sale does not protect it from a Takings Clause claim. (BMS Moving Br. at 13.)

b) Defendants

In contrast, Defendants argue that the Program is not a physical taking and Plaintiffs incorrectly characterize it as a forced transfer. Instead, Defendants underscore that "neither the [Program] nor any other part of Medicare 'legally compel[s]' manufacturers to negotiate with CMS or sell their drugs to Medicare beneficiaries." (Defs.' Cross-Br. at 11 (quoting *Dayton Area Chamber of Corn. v. Becerra,* No. 3:23-cv-156, 2023 WL 6378423, at *11 (S.D. Ohio Sept. 29, 2023))). For a claim to be valid under the Takings Clause, a property owner must be "legally compelled" to participate in a price-regulated activity. (*Id.* at 12, 19.) Here, pharmaceutical manufacturers can "opt out" of the Program in several ways, including (1) fully divesting "their interests in the drugs subject to negotiation before 2026" or (2) withdrawing from the Medicare markets. (*Id.* at 2.)

Instead, Defendants argue that participation in Medicare is voluntary. (*Id.* at 12 (quoting *Livingston Care Ctr., Inc. v. United States,* 934 F.2d 719, 720 (6th Cir. 1991))). Further, Defendants explain that the Program is a "valid exercise of Congress's constitutional authority to control the government's spending as a market participant." (*Id.* at 11.)

Defendants distinguish *Horne* on the basis that Plaintiffs in this case can avoid the statutory regime.

Defendants explain that unlike the plaintiffs in *Home,* Plaintiffs can sell their drugs to the wider market at their discretion if they do not choose to participate in the Program. Defendants also note that no statutory provision requires entities to sell their property to a government, especially when the government is acting as a market participant. (*Id.* at 12–13.) As such, when the government determines the price it is willing to pay, or "imposes caps on the amount the government will reimburse," the government "deprives [entities] of no property interest for the purposes of the Fifth Amendment." (*Id.* at 13.)

Further, Defendants argue that when Congress enacted the IRA, it did so pursuant to its powers under the Spending Clause, which "operates based on consent: in return for federal funds, the [recipients] agree to comply with federally imposed conditions.' (*Id.*; quoting *Cummings v. Premier Rehab Keller, PLLC,* 142 S. Ct. 1562, 1570 (2022)). Finally, Defendants contend that Plaintiffs' argument that they cannot withdraw from the programs are "academic" because neither Plaintiff has expressed intent to withdraw from the program. (*Id.* at 15.)

2. Analysis

The Fifth Amendment's Takings Clause prohibits the government from taking private property for public use without just compensation. *River Valley Heights Corp. v. Twp. of W. Amwell,* Civ. No. 21-2042, 2023 WL 1433634, at *2 (3d Cir. Feb. 1, 2023); *see also* U.S. Const. amend. V. ("nor shall private property be taken for public use, without just compensation"). "The paradigmatic taking requiring just compensation is a direct government appropriation . . . of private property." *Home,* U.S. at 358 (quoting *Lingle v. Chevron U.S.A. Inc.,* 544 U.S. 528, 537 (2005)).

Requirements that a private owner "reserve" portions of their personal property for the use of the government are a "clear physical taking." *Id.* at 361. Property owners subject to a reserve requirement "lose the entire 'bundle' of property rights in the appropriated [property]—the rights to possess, use and dispose of them." *Id.* at 361–62 (quoting *Loretto v. Teleprompter Manhattan CATV Corp.,* 458 U.S. 419, 432 (1982)).

The fact that a property owner may be entitled to net proceeds from a sale of their physical property "does not mean there has been no physical taking," particularly when the value of any contingent interest in the property is at the "discretion of the taker." *Id.* at 363. The government's "categorical duty to pay just compensation" upon a governmental taking remains the same whether applied to government appropriation of personal property or real property. *Id.* at 358. Historically, patents have received the same protection in federal courts as other types of property. "[A patent] confers upon the patentee an exclusive property in the patented invention which cannot be appropriated or used by the government itself, without just compensation, any more than it can appropriate or use without compensation land which has been patented to a private purchaser." *Id.* at 359–60 (quoting *James v. Campbell,* 104 U.S. 356, 358 (1882)).

Although courts have devised formulas and structures for evaluating claims under the Fifth Amendment, "[t]here is no abstract or fixed point at which judicial intervention under the Takings Clause becomes appropriate." *Andrus v. Allard,* 444 U.S. 51, 65 (1979). "Resolution of each case . . . ultimately calls as much for the exercise of judgment as for the application of logic." *Id.*

The Court's analysis of Plaintiffs' Taking Clause claim takes place in two stages. First, the Court addresses whether the Program constitutes a physical taking in violation of the Fifth Amendment. Second, the Court addresses whether Plaintiffs' participation in the Program is voluntary.

a) *The Program is Not a Physical Taking*

The crux of Plaintiffs' principal argument is that the Program is a physical taking. To support their position, Plaintiffs rely heavily on the Supreme Court's decision in *Home*. 576 U.S. 350 (2015).

The Horne family were raisin growers and handlers. *Id.* at 356. Under the United States Department of Agriculture's California Raisin Marketing Order, the Homes, like all growers and handlers, were required to set aside a percentage of their crop for the government's use. *Id.* at 354. The government would not pay for this reserve, and it could choose to sell, allocate, or otherwise dispose of the reserved raisins. *Id.* The Raisin Administrative Committee (the "Raisin Committee") determined the allocation to be set aside, and then acquired title to the reserve raisins. *Id.*

Under the Marketing Order, raisins were sold "in noncompetitive markets . . . to exporters, federal agencies, or foreign governments" or the government "donate[d] them to charitable causes; release[d] them to growers who agree to reduce their raisin production; or dispose[d] of them by any other means consistent with the raisin program." *Id.* at 355 (internal quotation omitted). The growers retained a contingent interest in the raisins, and if they were sold, the growers received the net proceeds of the sales from the Raisin Committee. *Id.* at 363. Notably, in the years

examined by the Supreme Court in *Horne,* the proceeds were either less than the cost of the production of the raisins or there were no proceeds at all. *Id.* at 355.

If growers, like the Hornes, did not create a raisin reserve for the government, they were assessed a fine "equal to the market value of the missing raisins." *Id.* at 356. In the Homes' case, they refused to set aside a raisin reserve, and when trucks sent by the government came to pick up the raisins, the trucks were turned away. *Id.* The Homes were then assessed the fine, upon which they proceeded to federal court. *Id.* Neither side in *Home* contested that the government would have been within its powers to entirely bar the Homes from growing raisins in the first place. *Id.* at 362.

Ultimately, the Supreme Court held that the "reserve requirement imposed by the Raisin Committee is a clear physical taking" and that the Takings Clause applied as much to personal property as it did to real property. *Id.* at 361. The Court explained that "[t]he Government's formal demand that the Homes turn over a percentage of their raisin crop without charge, for the Government's control and use, is 'of such a unique character that it is a taking without regard to other factors that a court might ordinarily examine.'" *Id.* at 362 (quoting *Loretto v. Teleprompter Manhattan CATV Corp.,* 458 U.S. 419,426–35 (1982)). The Court further held "[t]he fact that the growers retain a contingent interest of indeterminate value [in the reserve raisins] does not mean there has been no physical taking." *Id.* at 363. The Court also observed that this physical taking made the *Horne* case entirely distinct from cases focused on the regulation of sales. *Id.* at 362. Though

"a physical taking of raisins and a regulatory limit on production may have the same impact on a grower," the "Constitution . . . is concerned with means as well as ends." *Id.* By requiring that growers set aside portions of their crop without paying just compensation, the government transgressed its powers under the Fifth Amendment. *Id.* at 363. Finally, the requirement to relinquish "specific, identifiable property as a 'condition' on permission to engage in commerce effects a per se taking." *Id.* at 365 (internal quotations omitted). The fact that the Homes chose to participate in the raisin market was not a defense against the taking, and the Court held that it could not "reasonably be characterized as part of a . . . voluntary exchange . . . for the 'benefit' of being allowed to sell" the remaining raisin crop. *Id.* at 366.

Unfortunately for Plaintiffs in this case, *Home* is inapposite to their plight for several reasons. Unlike *Home,* there is no physical appropriation taking place and, setting aside their factual arguments, Plaintiffs fail to show how they are being *legally* compelled to participate in the Program.

Various sections of the Program explain that manufacturers and CMS engage in negotiations to determine "a maximum fair price for such selected drug of the manufacturer *in order for the manufacturer to provide access to such [maximum fair] price . . . .*" 42 U.S.C. § 1320f-2(a)(1), (a)(2), (a)(3) (emphasis added). Plaintiffs claim that the "Program's forced sales are functionally equivalent to physically seizing" the drug because the Program obligates the transfer of drugs to "Medicare at rates the Government dictates and to which [Plaintiffs] would never ordinarily agree." (BMS Resp. Br. at 4–5.) Plaintiffs also contend that to "provide 'access' to the

'maximum fair price' for the drug, Plaintiffs "must physically provide [the drug] at that price." (*Id.* at 7.) In other words, "[y]ou can't have access to a price without access to a [drug]." (Oral Arg. Tr. 19:6–7.) Defendants, however, characterize Plaintiffs' interpretation of the Program as "a fairly thin read on which to infer that actual commercial transactions need to take place at that price." (*Id.* 59:12–14.) Pointing to § 1320f-6 of the Program, Defendants explain that it creates an "if-then" relationship: if a manufacturer sell a drug, then the manufacturer can only charge a price at or below the negotiated maximum fair price for that drug. (*Id.* 60:6–12.)

Despite Plaintiffs' attempts to liken the Program to the reserve requirement in *Home,* the two are markedly different. Plaintiffs in this case distort their position to liken it to the passive role of the raisin growers who are *required* to "give a percentage of their crop to the Government, free of charge" by way of an agricultural regulatory program marketing order. *Horne,* 576 U.S. at 354. The regulatory program in *Home* markedly differs in that it "regulated all sales of raisins on the open market" and compelled raisin growers to set aside reserve raisins for the government's use if growers sold their raisins at all. (Oral Arg. Tr. at 67:4–5.) Thus, Plaintiffs' reliance on *Home* strategically overlooks the obvious point that the only way for raisin growers to avoid the reserve requirement was to stop selling raisins altogether. *Home,* 576 U.S. at 365. That is not the case here. The Program applies solely to sales to Medicare. There is no statutory provision that imposes a requirement that pharmaceutical manufacturers must set aside, keep, or otherwise reserve any of their drugs for the government's use, for the use of Medicare

beneficiaries, or any other entity's use. Nor, as Plaintiffs conceded at oral argument, does the Program require a manufacturer to physically transmit or transport drugs at the agreed price. (Oral Arg. Tr. 58:1213.)

Plaintiffs repeatedly highlight the tax penalties that a manufacturer will incur if it does not sell the drug at the agreed price.[9] However, as they also admitted at oral argument, Plaintiffs are free to opt out of Medicare entirely and sell their drugs to anyone but the government, or to divest their interest in the selected drug, or to remain in the Program but not make any sales to Medicare. (*Id.* 72:4–6.)

Plaintiffs separately argue that the Program is a Fifth Amendment violation under the *per se* takings rule expressed in *Cedar Point Nursery v. Hassid.* 594 U.S. 139 (2021). According to their theory, "a 'classic' or *per se* taking occurs when the Government forces a property owner to transfer possession or title, whether to 'itself or someone else.'" (BMS Moving Br. at 13 (quoting *Cedar Point,* 594 U.S. at 146). The statutory access to their drug at specific prices set by the government, in their view, "forces" the manufacturers to transfer the selected drugs "to those third parties at the price demanded by the Government—[the

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[9] Janssen relies on *Horne* for the proposition that legal compulsion is not required to establish a constitutional violation. (Janssen Resp. Br. at 2.) And, even if legal compulsion was required, Plaintiffs contend that they have satisfied that showing because the Program compels Plaintiffs to "comply with the Program's requirements for at least a minimum period or else pay the excise tax." (*Id.* at 2-3.) However, as the Court explained, there are still several opportunities for Janssen to withdraw from the Program and avoid any excise tax.

manufacturers] cannot refuse to deal on those terms." (*Id.* at 24.)

Cedar Point Nursery is another agricultural case. The eponymous nursery grew strawberries. 594 U.S. at 144. At issue was whether a state labor relations board regulation effected an impermissible taking because it provided a "right of access to union organizers to the premises of an agricultural employer for the purpose of meeting and talking with employees and soliciting their report." 594 U.S. at 144 (quoting Cal. Code Regs., tit. 8, § 20900(e).) The Supreme Court succinctly clarified that the "essential question" underlying a physical takings claim is "whether the government has physically taken property for itself or someone else—by whatever means—or has instead restricted a property owner's ability to use his own property." 594 U.S. at 149. Here, the Program neither requires nor forces Plaintiffs to give or sell their drugs to Defendants. As Defendants correctly note, the Program "does not authorize the government to requisition a manufacturer's drugs or other property. Nor does the IRA require a manufacturer to relinquish any drug it does not wish to sell." (Defs.' Cross-Br. at 2.) As such, the Court finds that the Program does not qualify as *a per se* taking under *Cedar Point.*

b) Plaintiffs' Participation in the Program is Voluntary

For their part, Defendants largely argue that the Program is not a taking because Plaintiffs' participation in the Program is voluntary. (*See generally* Defs.' Cross-Br; Defs.' Reply Br.) Plaintiffs disagree. Plaintiffs reiterate that their takings claim is premised on a physical taking, not a regulatory taking. (Oral Arg. Tr. 29:4–7.) Accordingly, Plaintiffs argue that because the Program effectuates a physical

taking, it should not be treated as a condition on participation and the voluntariness principles set forth in *Horne* and *Valancourt Books, LLC v. Garland,* 82 F.4th 1222 (D.C. Cir. 2023), are applicable. (*Id.* 25:16–26:5.)

Before addressing Plaintiffs' narrow arguments specifically relating to the Program, the Court will first review the voluntary nature of participation in Medicare more broadly. As an initial matter, the parties have not identified any authority holding that participation in the Medicare system is involuntary. (*See, e.g.*, *id.* 12:8–11 (The Court asked Plaintiffs if they had "found any case law in this circuit or any other that holds that the participation in the Medicare system is not voluntary?" and Plaintiffs responded, "No"). The Court, despite diligent efforts, was likewise unable to identify any such authority. If anything, the contrary appears true; at least one court of appeals has consistently held that participation by healthcare providers in Medicare is voluntary. *See Livingston Care Ctr., Inc. v. U.S.,* 934 F.2d 719, 720 (6th Cir. 1991) ("[P]articipation in the Medicare program is a voluntary undertaking."); *Baptist Hosp. East v. Secy of HHS,* 802 F.2d 860, 869–70 (6th Cir. 1986) ("[P]articipation in the Medicare program is wholly voluntary.").

More recently and more to the point, other district courts that have considered the same challenge to the Program have found that a manufacturer's participation in the Program is voluntary.[10] The

[10] There have been several challenges brought against the Program across various district courts. In this Opinion, the Court specifically refers to the district court decisions from the Southern District of Ohio in *Dayton Area Chamber of Com. v. Becerra,* Civ. No. 3:23-cv-156, 2023 WL 6378423 (S.D. Ohio Sept.

Southern District of Ohio considered challenges to the Program in the context of an emergent preliminary injunction seeking to enjoin the implementation of the Program. *Dayton Area Chamber of Com.,* 2023 WL 6378423, at *1. The district court stated that "participation in Medicare, no matter how vital it may be to a business model, is a completely voluntary choice." *Dayton Area Chamber of Com.,* 2023 WL 6378423, at *11 (S.D. Ohio Sept. 29, 2023) (citing *Baptist Hosp.,* 802 F.2d 860 at 869). The court further found that "[a]s there is no constitutional right (or requirement) to engage in business with the government, the consequences of that participation cannot be considered a constitutional violation." *Dayton Area Chamber of Corn.,* 2023 WL 6378423. at *11 .

More recently, as noted above, our sister court in Delaware heard another challenge to the Program. *AstraZeneca Pharms.,* 2024 WL 895036. It agreed with the Southern District of Ohio. In that case, plaintiff AstraZeneca Pharmaceuticals LP claimed, inter alia, that the Program violated its Fifth Amendment due process rights. *Id.* at *13. In relevant part, the district court found that "[n]either the IRA nor any other federal law requires AstraZeneca to sell its drugs to Medicare beneficiaries. On the contrary, 'participation in the Medicare program is a voluntary undertaking.'"

29, 2023), and the District of Delaware in *AstraZeneca Pharms. LP v. Becerra,* Civ. No. 23-931, 2024 WL 895036 (D. Del. Mar. 1, 2024). The Court clarifies that though the courts in *Dayton Area Chamber of Com.* and *AstraZeneca* did not address the identical constitutional challenges brought by Plaintiffs in the present action, the courts' findings regarding voluntariness are nevertheless relevant and applicable here.

Id. at *15 (quoting *Livingston Care Ctr.,* 934 F.2d at 720.)

Plaintiffs emphasize the "massive penalty" they would incur should they reject the maximum fair price. Plaintiffs argue that the government has total control over the market for pharmaceuticals and that "[c]ompletely withdrawing from almost half the domestic pharmaceutical market is not commercially feasible." (Janssen Moving Br. at 11.) Courts have roundly rejected such arguments. *See Baptist Hosp.,* 802 F.2d 860 at 869–70 ("If any provider fears that its participation will drive it to insolvency, it may withdraw from participation."); *Livingston Care Ctr.,* 934 F.2d 719, 721 (6th Cir. 1991) ("Providers of health care who choose to participate in the federally sponsored program for the aged and disabled do so with no guarantee of solvency. Just as those who choose to serve individuals not covered by Medicare assume the risks of the private market, those who opt to participate in Medicare are not assured of revenues.") (citation omitted); *Minnesota Ass'n of Health Care Facilities, Inc. v. Minnesota Dept 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. This voluntariness forecloses the possibility that the statute could result in an imposed taking of private property which would give rise to the constitutional right of just compensation . . . .).

Nonetheless, Plaintiffs are dismissive of the adverse case law. They argue that it is not applicable because the cases are (1) "outdated" given of the Supreme Court's decision in *Home,* (2) "off-point" because the cases do not address schemes that

resemble the Program, and (3) "limited" because they analyzed voluntariness in the context of Due Process and regulatory takings claims. (BMS Resp. Br. at 23–26.) Instead, Plaintiffs urge the Court to view the Program as a "physical taking backed by a penalty," not a condition, and to again find *Horne* instructive. (Oral Arg. Tr. 25:21–22.) To the extent Plaintiffs argue that *Home* is instructive and that the Court should analyze the Program as a physical taking, the Court has already rejected that analogy.

Plaintiffs also point to *Valancourt,* a recent D.C. Circuit case finding that the "mandatory deposit requirement" of Section 407 of the Copyright Act was a physical taking in violation of the Takings Clause. 82 F.4th at 1231. Section 407 states that "the owner of copyright or of the exclusive right of publication in a work published in the United States shall deposit, within three months after the date of such publication . . . two complete copies of the best edition" of the work "for the use or disposition of the Library of Congress." *Id.* at 1227 (quoting 17 U.S.C. § 407(a)(1), (b)). A copyright owner who fails to make the "required deposit" faces several fines. *Id.* (citing 17 U.S.C. § 407(d)(1)—(2), (d)(3). The court of appeals held this constituted an impermissible taking. Notably, the court's decision is narrow, and in its own words "is tied to the particular circumstances" of Section 407. *Id.* at 1239.

Setting aside the express narrowness of the *Valancourt* decision, it is also readily distinguishable from Plaintiffs' case. The mandatory deposit requirement in *Valancourt,* like the reserve requirement in *Home,* is part of a regime that parties could not readily exit. The court explained that when the deposit occurs, the copyright owners "lose the

entire 'bundle' of property rights" in the copies and they "receive no additional benefit for the works they forfeit." *Id.* At 1231–32 (citations omitted). Further, the deposit requirement was enforced via a demand letter that did not indicate another "option other than surrendering the property at issue or paying a fine, and in which Valancourt had no indication from any other source of the existence of a costless option to disavow copyright protection and thereby avoid complying with the sole options described in the demand letter." *Id.* at 1239. The Program in this case bears none of these features.

Again, manufacturers selected to participate in the Program will not face any fee, tax, or fine if they initially choose not to participate in the Program. Despite Plaintiffs' attempts to frame their plight as such, their options go beyond either (1) participating in the Program or (2) paying a fine. There are alternatives for Plaintiffs to explore should they choose, including exiting from sales to Medicare in the first instance. Plaintiffs who do so can continue to sell their drugs to any purchaser other than the federal government. Selling to Medicare is a choice Plaintiffs can accept or not accept. This is true for any negotiation between a purchaser and a seller. The plaintiffs in *Home* and *Valancourt* were never given that choice. Accordingly, there is no "obligatory legal framework" here that Plaintiffs can only exit by paying a fine. (Oral Arg. Tr. 69:6–20.)

Along these lines, there is a final distinguishing factor between the Program and the physical takings in the cases Plaintiffs cite. Plaintiffs contend that the Program taxes nonparticipating manufacturers and punishes private parties "by shutting them out of other markets," which is a "quintessential exercise of

sovereign power." (BMS Resp. Br. at 20.) However, as Defendants correctly note, the Program is akin to other Medicare reimbursement limits, and reflects a valid exercise of Congress's constitutional authority to control the government's spending as a market participant. (Defs.' Cross-Br. at 11.) The Program is not regulating how the market operates, it arises in the context of Congress acting as a "proprietor of its own assets as opposed to regulating how a market is going to operate." (Oral Arg. Tr. 66:23–67:23.) The government has the fundamental right to decide how it will spend taxpayer money. *South Dakota v. Dole,* 483 U.S. 203, 206–08. Likewise, Plaintiffs have the fundamental right to decide whether they want to sell their drug to a specific purchaser under the conditions set. Here, the Court is not persuaded by Plaintiffs' arguments that its participation in the Medicare program is involuntary. The Court agrees with the courts in the Southern District of Ohio, Delaware, and the established case law across several circuits holding that there can be no taking when participating in Medicare is voluntary and it rejects Plaintiffs' attempts to suggest otherwise.

In short, Defendants are not taking drugs from Plaintiffs. BMS and Janssen want to sell their drugs to Medicare, a significant (but not the sole) buyer of pharmaceuticals in the United States. Selling to Medicare may be less profitable than it was before the institution of the Program, but that does not make Defendants' decision to participate any less voluntary. For the reasons provided, the Court concludes that the Program does not result in a physical taking nor direct appropriation of Plaintiffs' drugs.

B. FIRST AMENDMENT COMPELLED SPEECH CLAIM

1. Parties' Positions

Plaintiffs argue that unconstitutional Compelled Speech begins when the Program forces them to engage in "sham 'negotiations' that result in "faux 'agreements.'" (BMS Moving Br. at 21.) Once Plaintiffs sign the agreement, they are then forced to publicly express Defendants' preferred message that the resulting sales at below-market prices is "fair." (*Id.*) They point to the template "Medicare Drug Price Negotiation Program Agreement" ("Template Agreement") and argue that its use of certain terms such as "agreement," "negotiate," and "maximum fair price" re-enforces this message, which is driven by Defendants' political objectives. (*Id.*, Decl. of Toni-Ann Citera Ex. B, ECF No. 36-2.) Plaintiffs argue that the Program's agreements are more than ordinary commercial contracts because they convey an implicit agreement by Plaintiffs that they are "negotiating" and an explicit agreement by Plaintiffs that the below-market maximum fair price is actually a "fair price." (*Id.* at 25.) Overall, Plaintiffs contend that the agreements suggest that Plaintiffs are "choosing to give the Government a massive break on the price" of the drugs, even though Plaintiffs insist they are not. (*Id.*)

Like with Plaintiffs' Takings Claim, Defendants argue that Plaintiffs' Compelled Speech claim fails because their participation in the Program is voluntary. Accordingly, Defendants contend that "because the Negotiation Program is entirely voluntary, it does not compel any manufacturer to do anything at all—either by signing an agreement or otherwise." (Defs,' Cross-Br. at 31.) Notwithstanding

the voluntary nature of the Program, Defendants also argue that signing the agreements does not compel Plaintiff's speech because the Program regulates conduct, not speech. Additionally, Defendants argue that the agreements are not expressive "merely because they were written and *could* be incorrectly understood as conveying a message." (Defs.' Reply Br. at 40.) Defendants maintain that the Program's agreements are "purely commercial arrangements" that "exist solely to memorialize manufacturers' voluntary undertaking of a commitment to participate in the [Program]—and ultimately, to charge Medicare beneficiaries no more than the negotiated prices." (*Id.* at 37–38.)

2. Analysis

A threshold issue for their Compelled Speech claim is whether Plaintiffs are compelled to participate in the Program. Setting aside the broader issue of whether the Program itself constitutes speech for First Amendment purposes for the moment, the Third Circuit instructs that "a violation of the First Amendment right against compelled speech occurs only in the context of actual compulsion." *C.N. v. Ridgewood Bd. of Educ.,* 430 F.3d 159, 189 (3d Cir. 2005). "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." *Id.* (quoting *Phelan v. Laramie Cnty. Cmty. Coll. Bd. of Trs.,* 235 F.3d 1243, 1244–47 (10th Cir. 2000)). At oral argument, Plaintiffs posited that the excise tax penalty is "what creates the First Amendment problem" and that if that penalty is stricken, then Plaintiffs no longer have a First Amendment claim. (Oral Arg. Tr. 124:4–9.) Like their

Takings Clause claim, Plaintiffs' Compelled Speech claim is premised on the theory that the Program is inherently involuntary and that Plaintiffs do *"not* voluntarily agree" with any aspect of the Program. (BMS Moving Br. at 24.) However, for the reasons provided, the Court has already concluded that the Program is voluntary and that Plaintiffs are not being compelled or forced to participate in the Program. Accordingly, the Court rejects Plaintiffs' arguments that rely on involuntariness as the basis of their compelled speech claim.

a) The Program Regulates Conduct, Not Speech

First, contrary to Plaintiffs' interpretation, the Program regulates conduct, not speech. Any effect on Plaintiffs' speech in this case is merely incidental.[11]

"It is settled law that ' [g]overnment action that . . . requires the utterance of a particular message favored by the Government, contravenes th[e] essential right' to refrain from speaking protected by the First Amendment." *Ridgewood Bd. of Educ.,* 430 F.3d at 187 (quoting *Turner Broad. Sys., Inc. v. F.C.C.,* 512 U.S. 622, 641 (1994)). "[L]eading First Amendment precedents have established the principle that freedom of speech prohibits the government from telling people what they must say." *Rumsfeld v. F. for*

[11] Plaintiffs' own inconsistent positions as to the Program's purpose reflects their strained Compelled Speech claim. Initially, with respect to their Takings Cause claim, Plaintiffs argued that the Program mandated and compelled the transfer of the physical drugs themselves. In contrast, with respect to their Compelled Speech claim, Plaintiffs argue that the "only thing the statute mandates is the agreement, the speech, and then that is what gives rise to the obligation relating to pricing and conduct." (Oral Arg. Tr. 100:9–11.)

Acad. & Institutional Rts., Inc., 547 U.S. 47, 61 (2006). Separately, courts have also routinely found that a statute regulates "conduct, not speech" when it affects what someone "must *do* . . . [and] not what they may or may not *say.*" *FAIR,* 547 U.S. at 60 (emphasis in original); *see also Sorrell v. IMS Health Inc.,* 564 U.S. 552, 567 (2011) ("It is true that restrictions on protected expression are distinct from restrictions on economic activity or, more generally, on nonexpressive conduct."). Plaintiffs claim that the Program "fits really neatly" into the pattern of First Amendment case law holding that the government cannot "compel a person to speak its own preferred messages," but the Court disagrees. (Oral Arg. Tr. 99:2–8; *303 Creative LLC v. Elenis,* 143 S. Ct. 2298, 2312 (2023)).

Plaintiffs point to *Expressions Hair Design v. Schneiderman* where the Supreme Court found a New York price regulation improperly regulated speech. 581 U.S. 37 (2017). The price regulation at issue, N.Y. Gen. Bus. Law § 518, prohibits merchants from imposing surcharges to customers who pay with a credit card but permits merchants to offer discounts to customers who pay with cash. *Id.* at 40. For example, if a merchant wants to sell an item for $10, the merchant can charge $10 to a buyer paying with cash. *Id.* at 47. However, if the merchant wants to charge a buyer paying with a credit card an additional 3% surcharge to account for a credit transaction fee, the merchant must convey that price as a single sticker price of $10.30 as opposed to "$10, with a 3% credit card surcharge." *Id.* On appeal, the Second Circuit concluded that § 518 did not violate the First Amendment because it regulated conduct, not speech. *Id.* at 46–47. The Second Circuit opined that "price controls regulate conduct alone" and that a "law

regulating the relationship between two prices regulates speech no more than a law regulating a single price." *Id.* The Supreme Court agreed with the Second Circuit that "§ 518 regulates a relationship between a sticker price and the price charged to credit card users." *Id.* at 47–48. However, the Supreme Court drew a different conclusion: "[i]n regulating the communication of prices rather than prices themselves, § 518 regulates speech." *Id.* at 48. The Supreme Court distinguished § 518 from a "typical price regulation" because the law does not simply regulate the amount of money a merchant could collect for a sale. *Id.* at 47. In that scenario, the law regulates the merchant's conduct and any "written or oral communications" the merchant uses to collect the money, such as identifying an item's price on a menu, are "only incidental to its primary effect on conduct." *Id.*

Critical to the holding in *Expressions,* though, is that § 518 "tells merchants nothing about the amount they are allowed to collect from a cash or credit card payer" but rather the law regulates how merchants communicate their prices. *Id.* Section 518 did not restrict what merchants could charge. Instead, the law constrained the ways that merchants could communicate their prices to buyers. The case before this Court is arguably the inverse of the one in *Expressions.* The primary purpose of the Program is to determine the price manufacturers may charge for those specific drugs they choose to sell to Medicare. The agreements and negotiations are incidental mechanisms the government is using to set those prices. In sum, the Court finds that the Program permissibly regulates Plaintiffs' commercial conduct, not their communication of information.

b) *Signing the Program's Agreements does not Constitute Expressive Conduct*

Plaintiffs' real issue, then, is with the terminology Congress used within the Program's agreements. Plaintiffs object to several terms used in the Template Agreement, including "negotiate," "agree," and "maximum fair price." Plaintiffs' key concern is that by agreeing to the final drug price, they are openly admitting that the price is the "maximum fair price." (BMS Resp. Br. at 30.) That "message" runs against Plaintiffs' sincere belief that the drug prices are not fair. Therefore, unlike a traditional price regulation that would merely communicate a price, Plaintiffs contend that the agreements are expressive because they convey the government's preferred message. The Court, however, rejects Plaintiffs position for several reasons.

First, the Program's agreements are ordinary commercial contracts. Here, pharmaceutical manufacturers, like Plaintiffs, choose to participate in the Program. They accordingly execute the required contracts to confirm their agreement with Defendants. While it is true that the "creation and dissemination of information are speech for First Amendment purposes," Plaintiffs do not point to any authority supporting the proposition that a contract is expressive simply because it contains information. *Sorrell,* 564 U.S. at 570. Even Plaintiffs acknowledge that "many contracts do not express views or convey beliefs." (BMS Moving Br. at 25.) Nor do manufacturers' signatures on the agreements evidence any expressive conduct. Plaintiffs strain to analogize the impact of a manufacturer's signature on the Template Agreement to an individual's signature on a voting referendum. (BMS Resp. Br. at 33 (citing

John Doe No. 1 v. Reed, 561 U.S. 186 (2010)). A voter's signature on a political petition, however, is unique because an "individual expresses a view on a political matter when he signs a petition." *Reed,* 561 U.S. at 194. "Even if the signer is agnostic as to the merits of the underlying law, his signature still expresses the political view that the question should be considered 'by the whole electorate.'" *Id.* at 195. Given that the Template Agreement itself is not expressive, the Court finds that a manufacturer's signature does not convey any message beyond its agreement with Defendants to the terms of the contract.

Importantly, the terms that Plaintiffs object to are statutory terms of art that are defined in the Program's statutory text. (Oral Arg. Tr. 107:21–108:9.) To accept Plaintiffs' position that the terminology used in the agreements forces Plaintiffs to convey a message requires construing the terms beyond the context of the agreement and beyond their statutorily defined meanings. As Defendants explained at oral argument, the terms are "ported over from the statute, they are defined by the statute, and they are [in the agreements] to make clear that manufacturers are agreeing to abide—they are contracting to abide by the same technical understanding of these terms." (*Id.* 108:5–8.) The term "maximum fair price" is defined in § 1320f(c)(3). When "maximum fair price" is used in the agreements, its meaning reflects its statutorily defined definition, not a colloquial meaning of "maximum fair price." *See Meese v. Keene,* 481 U.S. 465, 484 (1987) ("It is axiomatic that the statutory definition of the term excludes unstated meanings of that term."). In *Meese,* the Supreme Court rejected a First Amendment challenge against a statute that used the term "political propaganda" as the statutory

name to categorize certain films. *Id.* at 467. In holding that the term be interpreted by its statutory definition, the Supreme Court warned that legislation should be construed "as it is written, not as it might be read by a layman, or as it might be understood by someone who has not even read it." *Meese,* 481 U.S. at 485. Consistent with this guidance, the Court here similarly declines Plaintiffs' invitation to interpret the Program's terms beyond the scope of their statutory meaning.

Notably, nothing in the statute prevents Plaintiffs from publicly criticizing the Program or the final drug prices. Plaintiffs say they fear a "counternarrative" that they "would charge *more* than a 'fair' price for [the selected drugs] if not for the [Program's] mandated 'negotiations.'" (BMS Moving Br. at 26.) These, however, are public relations problems not constitutional problems.[12]

For the above reasons, the Court finds that the Program regulates conduct, not speech, and Plaintiffs are not engaging in expressive conduct by participating in the Program or by signing the agreements. As a result, the Court does not address

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[12] Plaintiffs also claim that the disclaimer in the Template Agreement "does nothing to solve the compelled speech problem." (BMS Resp. Br. at 36.) Plaintiffs' argument assumes that the agreements are expressive and that the disclaimer is curing a potential compelled speech violation. However, the agreements are not expressive and the disclaimer clarifies that the "[u]se of the term "maximum fair price" and other statutory terms throughout this Agreement reflects the parties' intention that such terms be given the meaning specified in the statute and does not reflect any party's views regarding the colloquial meaning of those terms." (Template Agreement at 4.)

whether the Program survives First Amendment scrutiny. *Expressions,* 581 U.S. at 48.

C. UNCONSTITUTIONAL CONDITIONS DOCTRINE CLAIM

Having concluded that the Program is not a physical taking, that the Program does not compel Plaintiffs' speech, and that Plaintiffs' participation in the Program is voluntary, the Court next considers whether the Program violates the unconstitutional conditions doctrine.

Plaintiffs argue that, even if their participation in the Program were voluntary, the Program would still violate the unconstitutional conditions doctrine. They contend that the Program "is not immunized from constitutional scrutiny merely because it's labeled as a condition on participation in a voluntary program." (Oral Arg. Tr. 41:3–5.) Specifically, participating in the Program mandates Plaintiffs to (1) publicly endorse the government's preferred message, in violation of the First Amendment, and (2) transfer the right to access Eliquis and Xarelto to third parties on government-dictated terms, in violation of the Fifth Amendment. (BMS Moving Br. at 39.) These, Plaintiffs insist, represent unconstitutional conditions.

The unconstitutional conditions doctrine "vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up." *Koontz v. St. Johns River Water Mgmt. Dist.,* 570 U.S. 595, 604 (2013). Plaintiffs' doctrine claim suffers a fatal flaw: as Defendants succinctly observed at oral argument, "there's no constitutional right in danger of being trampled." (Oral Arg. Tr. 58:2–4.) "A predicate for any

unconstitutional conditions claim is that the government could not have constitutionally ordered the person asserting the claim to do what it attempted to pressure that person into doing." *Koontz,* 570 U.S. at 612. Here, for the various reasons discussed, the Court has already found that the Program does *not* constitute a physical taking in violation of the Fifth Amendment, nor does the Program regulate speech or compel Plaintiffs to convey any government message in violation of the First Amendment. *See, e.g., Sanofi-Aventis US., LLC v. HHS,* 570 F. Supp. 3d 129, 210 (D.N.J. 2021), *rev'd in part on other grounds,* 58 F.4th 696 (3d Cir. 2023) ("To the extent that [plaintiff] has not established either a physical or regulatory taking under the Violation Letters, as I find here, the unconstitutional conditions doctrine is inapplicable."). On that basis, the Court finds the unconstitutional doctrine does not apply under these circumstances and declines to consider Plaintiffs' claim further.

V. CONCLUSION

For the reasons stated above, the Court will GRANT Defendants' Cross-Motions for Summary Judgment and DENY Plaintiffs' Motions for Summary Judgment. An appropriate Order will follow.

Date: April 29, 2024

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

APPENDIX C

42 U.S.C. §§ 1320f–1320f-6

§ 1320f. Establishment of program

(a) In general

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

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

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

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

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

(b) Definitions relating to timing

For purposes of this part:

(1) Initial price applicability year

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

(2) Price applicability period

The term "price applicability period" means, with respect to a qualifying single source drug, the period beginning with the first initial price applicability

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

year with respect to which such drug is a selected drug and ending with the last year during which the drug is a selected drug.

(3) Selected drug publication date

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

(4) Negotiation period

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

(A) beginning on the sooner of—

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

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

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

(c) Other definitions

For purposes of this part:

(1) Manufacturer

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

(2) Maximum fair price eligible individual

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

(A) in the case such drug is dispensed to the individual at a pharmacy, by a mail order service, or by another dispenser, an individual who is enrolled in a prescription drug plan under part D of subchapter XVIII or an MA–PD plan under part C of such subchapter if coverage is provided under such plan for such selected drug; and

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

(3) Maximum fair price

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

(4) Reference product

The term "reference product" has the meaning given such term in section 262(i) of this title.

(5) Total expenditures

The term "total expenditures" includes, in the case of expenditures with respect to part D of subchapter XVIII, the total gross covered prescription drug costs (as defined in section 1395w-115(b)(3) of this title). The term "total expenditures" excludes, in the case of expenditures with respect to part B of such subchapter, expenditures for a drug or biological product that are bundled or packaged into the payment for another service.

(6) Unit

The term "unit" means, with respect to a drug or biological product, the lowest identifiable amount (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological product that is dispensed or furnished.

d) Timing for initial price applicability year 2026

Notwithstanding the provisions of this part, in he case of initial price applicability year 2026, he following rules shall apply for purposes of implementing the program:

(1) Subsection (b)(3) shall be applied by substituting "September 1, 2023" for ", with respect to each initial price applicability year, February 1 of the year that begins 2 years prior to such year".

(2) Subsection (b)(4) shall be applied—

(A) in subparagraph (A)(ii), by substituting "October 1, 2023" for "February 28 following the selected drug publication date with respect to such selected drug"; and

(B) in subparagraph (B), by substituting "August 1, 2024" for "November 1 of the year that

begins 2 years prior to the initial price applicability year".

(3) Section 1320f-1 of this title shall be applied—

(A) in subsection (b)(1)(A), by substituting "during the period beginning on June 1, 2022, and ending on May 31, 2023" for "during the most recent period of 12 months prior to the selected drug publication date (but ending not later than October 31 of the year prior to the year of such drug publication date), with respect to such year, for which data are available"; and

(B) in subsection (d)(1)(A), by substituting "during the period beginning on June 1, 2022, and ending on May 31, 2023" for "during the most recent period for which data are available of at least 12 months prior to the selected drug publication date (but ending no later than October 31 of the year prior to the year of such drug publication date), with respect to such year".[2]

(4) Section 1320f-2(a) of this title shall be applied by substituting "October 1, 2023" for "February 28 following the selected drug publication date with respect to such selected drug".

(5) Section 1320f-3(b)(2) of this title shall be applied—

(A) in subparagraph (A), by substituting "October 2, 2023" for "March 1 of the year of the

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[2] So in original. Probably should read as follows: "during the most recent 12-month period for which data are available prior to such selected drug publication date (but ending no later than October 31 of the year prior to the year of such drug publication date)".

selected drug publication date, with respect to the selected drug";

(B) in subparagraph (B), by substituting "February 1, 2024" for "the June 1 following the selected drug publication date"; and

(C) in subparagraph (E), by substituting "August 1, 2024" for "the first day of November following the selected drug publication date, with respect to the initial price applicability year".

(6) Section 1320f-4(a)(1) of this title shall be applied by substituting "September 1, 2024" for "November 30 of the year that is 2 years prior to such initial price applicability year".

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

(a) In general

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

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

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

such negotiation-eligible drugs with respect to such year);

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

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

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

(b) Selection of drugs

(1) In general

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

(A) Rank negotiation-eligible drugs described in subsection (d)(1) according to the total expenditures for such drugs under parts B and D of subchapter XVIII, as determined by the Secretary, during the most recent period of 12

months prior to the selected drug publication date (but ending not later than October 31 of the year prior to the year of such drug publication date), with respect to such year, for which data are available, with the negotiation-eligible drugs with the highest total expenditures being ranked the highest.

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

(C) In the case of a biological product for which the inclusion of the biological product as a selected drug on a list published under subsection (a) has been delayed under subsection (f)(2), remove such biological product from the rankings under subparagraph (A) before making the selections under subparagraph (B).

(2) High spend part D drugs for 2026 and 2027

With respect to the initial price applicability year 2026 and with respect to the initial price applicability year 2027, the Secretary shall apply paragraph (1) as if the reference to "negotiation-eligible drugs described in subsection (d)(1)" were a reference to "negotiation-eligible drugs described in subsection (d)(1)(A)" and as if the reference to "total expenditures for such drugs under parts B and D of subchapter XVIII" were a reference to "total expenditures for such drugs under part D of subchapter XVIII".

(3) Inclusion of delayed biological products

Pursuant to subparagraphs (B)(ii)(I) and (C)(i) of subsection (f)(2), the Secretary shall select and include on the list published under subsection (a)

the biological products described in such subparagraphs. Such biological products shall count towards the required number of drugs to be selected under subsection (a)(1).

(c) Selected drug

(1) In general

For purposes of this part, in accordance with subsection (e)(2) and subject to paragraph (2), each negotiation-eligible drug included on the list published under subsection (a) with respect to an initial price applicability year shall be referred to as a "selected drug" with respect to such year and each subsequent year beginning before the first year that begins at least 9 months after the date on which the Secretary determines at least one drug or biological product—

(A) is approved or licensed (as applicable)—

(i) under section 355(j) of title 21 using such drug as the listed drug; or

(ii) under section 262(k) of this title using such drug as the reference product; and

(B) is marketed pursuant to such approval or licensure.

(2) Clarification

A negotiation-eligible drug—

(A) that is included on the list published under subsection (a) with respect to an initial price applicability year; and

(B) for which the Secretary makes a determination described in paragraph (1) before

or during the negotiation period with respect to such initial price applicability year;

shall not be subject to the negotiation process under section 1320f-3 of this title with respect to such negotiation period and shall continue to be considered a selected drug under this part with respect to the number of negotiation-eligible drugs published on the list under subsection (a) with respect to such initial price applicability year.

(d) Negotiation-eligible drug

(1) In general

For purposes of this part, subject to paragraph (2), the term "negotiation-eligible drug" means, with respect to the selected drug publication date with respect to an initial price applicability year, a qualifying single source drug, as defined in subsection (e), that is described in either of the following subparagraphs (or, with respect to the initial price applicability year 2026 or 2027, that is described in subparagraph (A)):

(A) Part D high spend drugs

The qualifying single source drug is, determined in accordance with subsection (e)(2), among the 50 qualifying single source drugs with the highest total expenditures under part D of subchapter XVIII, as determined by the Secretary in accordance with paragraph (3), during the most recent 12-month period for which data are available prior to such selected drug publication date (but ending no later than October 31 of the year prior to the year of such drug publication date).

(B) Part B high spend drugs

The qualifying single source drug is, determined in accordance with subsection (e)(2), among the 50 qualifying single source drugs with the highest total expenditures under part B of subchapter XVIII, as determined by the Secretary in accordance with paragraph (3), during such most recent 12-month period, as described in subparagraph (A).

(2) Exception for small biotech drugs

(A) In general

Subject to subparagraph (C), the term "negotiation-eligible drug" shall not include, with respect to the initial price applicability years 2026, 2027, and 2028, a qualifying single source drug that meets either of the following:

(i) Part D drugs

The total expenditures for the qualifying single source drug under part D of subchapter XVIII, as determined by the Secretary in accordance with paragraph (3)(B), during 2021

(I) are equal to or less than 1 percent of the total expenditures under such part D, as so determined, for all covered part D drugs (as defined in section 1395w-102(e) of this title) during such year; and

(II) are equal to at least 80 percent of the total expenditures under such part D, as so determined, for all covered part D drugs for which the manufacturer of the drug has an agreement in effect under section 1395w-114a of this title during such year.

(ii) Part B drugs

The total expenditures for the qualifying single source drug under part B of subchapter XVIII, as determined by the Secretary in accordance with paragraph (3)(B), during 2021—

(I) are equal to or less than 1 percent of the total expenditures under such part B, as so determined, for all qualifying single source drugs for which payment may be made under such part B during such year; and

(II) are equal to at least 80 percent of the total expenditures under such part B, as so determined, for all qualifying single source drugs of the manufacturer for which payment may be made under such part B during such year.

(B) Clarifications relating to manufacturers

(i) Aggregation rule

All persons treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 shall be treated as one manufacturer for purposes of this paragraph.

(ii) Limitation

A drug shall not be considered to be a qualifying single source drug described in clause (i) or (ii) of subparagraph (A) if the manufacturer of such drug is acquired after 2021 by another manufacturer that does not meet the definition of a specified Manufacturer under section 1395w-114c(g)(4)(B)(ii) of this

title, effective at the beginning of the plan year immediately following such acquisition or, in the case of an acquisition before 2025, effective January 1, 2025.

(C) Drugs not included as small biotech drugs

A new formulation, such as an extended release formulation, of a qualifying single source drug shall not be considered a qualifying single source drug described in subparagraph (A).

(3) Clarifications and determinations

(A) Previously selected drugs and small biotech drugs excluded

In applying subparagraphs (A) and (B) of paragraph (1), the Secretary shall not consider or count—

(i) drugs that are already selected drugs; and

(ii) for initial price applicability years 2026, 2027, and 2028, qualifying single source drugs described in paragraph (2)(A).

(B) Use of data

In determining whether a qualifying single source drug satisfies any of the criteria described in paragraph (1) or (2), the Secretary shall use data that is aggregated across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation, and not based on the specific formulation or package size or package type of the drug.

(e) Qualifying single source drug

(1) In general

For purposes of this part, the term "qualifying single source drug" means, with respect to an initial price applicability year, subject to paragraphs (2) and (3), a covered part D drug (as defined in section 1395w-102(e) of this title) that is described in any of the following or a drug or biological product for which payment may be made under part B of subchapter XVIII that is described in any of the following:

(A) Drug products

A drug—

(i) that is approved under section 355(c) of title 21 and is marketed pursuant to such approval;

(ii) for which, as of the selected drug publication date with respect to such initial price applicability year, at least 7 years will have elapsed since the date of such approval; and

(iii) that is not the listed drug for any drug that is approved and marketed under section 355(j) of such title.

(B) Biological products

A biological product—

(i) that is licensed under section 262(a) of this title and is marketed under section 262 of this title;

(ii) for which, as of the selected drug publication date with respect to such initial

price applicability year, at least 11 years will have elapsed since the date of such licensure; and that is not the reference product for any biological product that is licensed and marketed under section 262(k) of this title.

(2) Treatment of authorized generic drugs

(A) In general

In the case of a qualifying single source drug described in subparagraph (A) or (B) of paragraph (1) that is the listed drug (as such term is used in section 355(j) of title 21) or a product described in clause (ii) of subparagraph (B), with respect to an authorized generic drug, in applying the provisions of this part, such authorized generic drug and such listed drug or such product shall be treated as the same qualifying single source drug.

(B) Authorized generic drug defined

For purposes of this paragraph, the term "authorized generic drug" means

(i) in the case of a drug, an authorized generic drug (as such term is defined in section 355(t)(3) of title 21); and

(ii) in the case of a biological product, a product that—

(I) has been licensed under section 262(a) of this title;[3] and

(II) is marketed, sold, or distributed directly or indirectly to retail class of trade under a different labeling, packaging (other than repackaging as the reference product in

[3] See References in Text note below.

blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trade mark than the reference product.

(3) Exclusions

In this part, the term "qualifying single source drug" does not include any of the following:

(A) Certain orphan drugs

A drug that is designated as a drug for only one rare disease or condition under section 360bb of title 21 and for which the only approved indication (or indications) is for such disease or condition.

(B) Low spend medicare drugs

A drug or biological product with respect to which the total expenditures under parts B and D of subchapter XVIII, as determined by the Secretary in accordance with subsection (d)(3)(B)—

(i) with respect to initial price applicability year 2026, is less than, during the period beginning on June 1, 2022, and ending on May 31, 2023, $200,000,000;

(ii) with respect to initial price applicability year 2027, is less than, during the most recent 12-month period applicable under subparagraphs (A) and (B) of subsection (d)(1) for such year, the dollar amount specified in clause (i) increased by the annual percentage increase in the consumer price index for all urban consumers (all items; United States city average) for the period beginning on June 1, 2023, and ending on September 30, 2024; or

(iii) with respect to a subsequent initial price applicability year, is less than, during the most recent 12-month period applicable under subparagraphs (A) and (B) of subsection (d)(1) for such year, the dollar amount specified in this subparagraph for the previous initial price applicability year increased by the annual percentage increase in such consumer price index for the 12-month period ending on September 30 of the year prior to the year of the selected drug publication date with respect to such subsequent initial price applicability year.

(C) Plasma-derived products

A biological product that is derived from human whole blood or plasma.

(f) Special rule to delay selection and negotiation of biologics for biosimilar market entry

(1) Application

(A) In general

Subject to subparagraph (B), in the case of a biological product that would (but for this subsection) be an extended-monopoly drug (as defined in section 1320f-3(c)(4) of this title) included as a selected drug on the list published under subsection (a) with respect to an initial price applicability year, the rules described in paragraph (2) shall apply if the Secretary determines that there is a high likelihood (as described in paragraph (3)) that a biosimilar biological product (for which such biological product will be the reference product) will be licensed and marketed under section 262(k) of this title before the date that is 2 years after the

selected drug publication date with respect to such initial price applicability year.

(B) Request required

(i) In general

The Secretary shall not provide for a delay under—

(I) paragraph (2)(A) unless a request is made for such a delay by a manufacturer of a biosimilar biological product prior to the selected drug publication date for the list published under subsection (a) with respect to the initial price applicability year for which the biological product may have been included as a selected drug on such list but for subparagraph (2)(A); or

(II) paragraph (2)(B)(iii) unless a request is made for such a delay by such a manufacturer prior to the selected drug publication date for the list published under subsection (a) with respect to the initial price applicability year that is 1 year after the initial price applicability year for which the biological product described in sub-section (a) would have been included as a selected drug on such list but for paragraph (2)(A).

(ii) Information and documents

(I) In general

A request made under clause (i) shall be submitted to the Secretary by such manufacturer at a time and in a form and manner specified by the Secretary, and contain—

(aa) information and documents necessary for the Secretary to make determinations under this subsection, as specified by the Secretary and including, to the extent available, items described in subclause (III); and

(bb) all agreements related to the biosimilar biological product filed with the Federal Trade Commission or the Assistant Attorney General pursuant to subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

(II) Additional information and documents

After the Secretary has reviewed the request and materials submitted under subclause (I), the manufacturer shall submit any additional information and documents requested by the Secretary necessary to make determinations under this subsection.

(III) Items described

The items described in this clause are the following:

(aa) The manufacturing schedule for such biosimilar biological product submitted to the Food and Drug Administration during its review of the application under such section 262(k) of this title.

(bb) Disclosures (in filings by the manufacturer of such biosimilar biological product with the Securities and Exchange Commission required under section 78*l*(b),

78*l*(g), 78m(a), or 78*o*(d) of title 15 about capital investment, revenue expectations, and actions taken by the manufacturer that are typical of the normal course of business in the year (or the 2 years, as applicable) before marketing of a biosimilar biological product) that pertain to the marketing of such biosimilar biological product, or comparable documentation that is distributed to the shareholders of privately held companies.

(C) Aggregation rule

(i) In general

All persons treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986, or in a partnership, shall be treated as one manufacturer for purposes of paragraph (2)(D)(iv).

(ii) Partnership defined

In clause (i), the term "partnership" means a syndicate, group, pool, joint venture, or other organization through or by means of which any business, financial operation, or venture is carried on by the manufacturer of the biological product and the manufacturer of the biosimilar biological product.

(2) Rules described

The rules described in this paragraph are the following:

(A) Delayed selection and negotiation for 1 year

If a determination of high likelihood is made under paragraph (3), the Secretary shall delay the inclusion of the biological product as a selected drug on the list published under subsection (a) until such list is published with respect to the initial price applicability year that is 1 year after the initial price applicability year for which the biological product would have been included as a selected drug on such list.

(B) If not licensed and marketed during the initial delay

(i) In general

If, during the time period between the selected drug publication date on which the biological product would have been included on the list as a selected drug pursuant to subsection (a) but for subparagraph (A) and the selected drug publication date with respect to the initial price applicability year that is 1 year after the initial price applicability year for which such biological product would have been included as a selected drug on such list, the Secretary determines that the biosimilar biological product for which the manufacturer submitted the request under paragraph (1)(B)(i)(II) (and for which the Secretary previously made a high likelihood determination under paragraph (3)) has not been licensed and marketed under section 262(k) of this title, the Secretary shall, at the request of such manufacturer—

(I) reevaluate whether there is a high likelihood (as described in paragraph (3)) that such biosimilar biological product will be

licensed and marketed under such section 262(k) before the date that is 2 years after the selected drug publication date for which such biological product would have been included as a selected drug on such list published but for subparagraph (A); and

(II) evaluate whether, on the basis of clear and convincing evidence, the manufacturer of such biosimilar biological product has made a significant amount of progress (as determined by the Secretary) towards both such licensure and the marketing of such biosimilar biological product (based on information from items described in subclauses (I)(bb) and (II) of paragraph (1)(B)(ii)) since the receipt by the Secretary of the request made by such manufacturer under paragraph (1)(B)(i)(I).

(ii) Selection and negotiation

If the Secretary determines that there is not a high likelihood that such biosimilar biological product will be licensed and marketed as described in clause (i)(I) or there has not been a significant amount of progress as described in clause (i)(II)—

(I) the Secretary shall include the biological product as a selected drug on the list published under subsection (a) with respect to the initial price applicability year that is 1 year after the initial price applicability year for which such biological product would have been included as a selected drug on such list but for subparagraph (A); and

(II) the manufacturer of such biological product shall pay a rebate under paragraph (4) with respect to the year for which such manufacturer would have provided access to a maximum fair price for such biological product but for subparagraph (A).

(iii) Second 1-year delay

If the Secretary determines that there is a high likelihood that such biosimilar biological product will be licensed and marketed (as described in clause (i)(I)) and a significant amount of progress has been made by the manufacturer of such biosimilar biological product towards such licensure and marketing (as described in clause (i)(II)), the Secretary shall delay the inclusion of the biological product as a selected drug on the list published under subsection (a) until the selected drug publication date of such list with respect to the initial price applicability year that is 2 years after the initial price applicability year for which such biological product would have been included as a selected drug on such list but for this subsection.

(C) If not licensed and marketed during the year two delay

If, during the time period between the selected drug publication date of the list for which the biological product would have been included as a selected drug but for subparagraph (B)(iii) and the selected drug publication date with respect to the initial price applicability year that is 2 years after the initial price applicability year for which such biological product would have been included as a

selected drug on such list but for this subsection, the Secretary determines that such biosimilar biological product has not been licensed and marketed—

(i) the Secretary shall include such biological product as a selected drug on such list with respect to the initial price applicability year that is 2 years after the initial price applicability year for which such biological product would have been included as a selected drug on such list; and

(ii) the manufacturer of such biological product shall pay a rebate under paragraph (4) with respect to the years for which such manufacturer would have provided access to a maximum fair price for such biological product but for this subsection.

(D) Limitations on delays

(i) Limited to 2 years

In no case shall the Secretary delay the inclusion of a biological product on the list published under subsection (a) for more than 2 years.

(ii) Exclusion of biological products that transitioned to a long-monopoly drug during the delay

In the case of a biological product for which the inclusion on the list published pursuant to subsection (a) was delayed by 1 year under subparagraph (A) and for which there would have been a change in status to a long-monopoly drug (as defined in section 1320f-3(c)(5) of this title) if such biological product had been a

selected drug, in no case may the Secretary provide for a second 1-year delay under subparagraph (B)(iii).

(iii) Exclusion of biological products if more than 1 year since licensure

In no case shall the Secretary delay the inclusion of a biological product on the list published under subsection (a) if more than 1 year has elapsed since the biosimilar biological product has been licensed under section 262(k) of this title and marketing has not commenced for such biosimilar biological product.

(iv) Certain manufacturers of biosimilar biological products excluded

In no case shall the Secretary delay the inclusion of a biological product as a selected drug on the list published under subsection (a) if Secretary determined that the manufacturer of the biosimilar biological product described in paragraph (1)(A)—

(I) is the same as the manufacturer of the reference product described in such paragraph or is treated as being the same pursuant to paragraph (1)(C); or

(II) has, based on information from items described in paragraph (1)(B)(ii)(I)(bb), entered into any agreement described in such paragraph with the manufacturer of the reference product described in paragraph (1)(A) that—

(aa) requires or incentivizes the manufacturer of the biosimilar biological

product to submit a request described in paragraph (1)(B); or

(bb) restricts the quantity (either directly or indirectly) of the biosimilar biological product that may be sold in the United States over a specified period of time.

(3) High likelihood

For purposes of this subsection, there is a high likelihood described in paragraph (1) or paragraph (2), as applicable, if the Secretary finds that—

(A) an application for licensure under section 262(k) of this title for the biosimilar biological product has been accepted for review or approved by the Food and Drug Administration; and

(B) information from items described in sub clauses [4] (I)(bb) and (III) of paragraph (1)(B)(ii) submitted to the Secretary by the manufacturer requesting a delay under such paragraph provides clear and convincing evidence that such biosimilar biological product will, within the time period specified under paragraph (1)(A) or (2)(B)(i)(I), be marketed.

(4) Rebate

(A) In general

For purposes of subparagraphs (B)(ii)(II) and (C)(ii) of paragraph (2), in the case of a biological product for which the inclusion on the list under subsection (a) was delayed under this subsection and for which the Secretary has negotiated and

[4] So in original

entered into an agreement under section 1320f-2 of this title with respect to such biological product, the manufacturer shall be required to pay a rebate to the Secretary at such time and in such manner as determined by the Secretary.

(B) Amount

Subject to subparagraph (C), the amount of the rebate under subparagraph (A) with respect to a biological product shall be equal to the estimated amount—

(i) in the case of a biological product that is a covered part D drug (as defined in section 1395w-102(e) of this title), that is the sum of the products of—

(I) 75 percent of the amount by which—

(aa) the average manufacturer price, as reported by the manufacturer of such covered part D drug under section 1396r-8 of this title (or, if not reported by such manufacturer under section 1396r-8 of this title, as reported by such manufacturer to the Secretary pursuant to the agreement under section 1320f-2(a) of this title) for such biological product, with respect to each of the calendar quarters of the price applicability period that would have applied but for this subsection; exceeds

(bb) in the initial price applicability year that would have applied but for a delay under—

(AA) paragraph (2)(A), the maximum fair price negotiated under section 1320f-3 of this title for such

biological product under such agreement; or

(BB) paragraph (2)(B)(iii), such maximum fair price, increased as described in section 1320f-4(b)(1)(A) of this title; and

(II) the number of units dispensed under part D of subchapter XVIII for such covered part D drug during each such calendar quarter of such price applicability period; and

(ii) in the case of a biological product for which payment may be made under part B of subchapter XVIII, that is the sum of the products of—

(I) 80 percent of the amount by which—

(aa) the payment amount for such biological product under section 1395w-3a(b) of this title, with respect to each of the calendar quarters of the price applicability period that would have applied but for this subsection; exceeds

(bb) in the initial price applicability year that would have applied but for a delay under—

(AA) paragraph (2)(A), the maximum fair price negotiated under section 1320f-3 of this title for such biological product under such agreement; or

(BB) paragraph (2)(B)(iii), such maximum fair price, increased as

described in section 1320f-4(b)(1)(A) of this title; and

(II) the number of units (excluding units that are packaged into the payment amount for an item or service and are not separately payable under such part B) of the billing and payment code of such biological product administered or furnished under such part B during each such calendar quarter of such price applicability period.

(C) Special rule for delayed biological products that are long-monopoly drugs

(i) In general

In the case of a biological product with respect to which a rebate is required to be paid under this paragraph, if such biological product qualifies as a long-monopoly drug (as defined in section 1320f-3(c)(5) of this title) at the time of its inclusion on the list published under subsection (a), in determining the amount of the rebate for such biological product under subparagraph (B), the amount described in clause shall be substituted for the maximum fair price described in clause (i)(I) or (ii)(I) of such subparagraph (B), as applicable.

(ii) Amount described

The amount described in this clause is an amount equal to 65 percent of the average non-Federal average manufacturer price for the biological product for 2021 (or, in the case that there is not an average non-Federal average manufacturer price available for such biological product for 2021, for the first full year following

the market entry for such biological product), increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year prior to the selected drug publication date with respect to the initial price applicability year that would have applied but for this subsection.

(D) Rebate deposits

Amounts paid as rebates under this paragraph shall be deposited into—

(i) in the case payment is made for such biological product under part B of subchapter XVIII, the Federal Supplementary Medical Insurance Trust Fund established under section 1395t of this title; and

(ii) in the case such biological product is a covered part D drug (as defined in section 1395w-102(e) of this title), the Medicare Prescription Drug Account under section 1395w-116 of this title in such Trust Fund.

(5) Definitions of biosimilar biological product

In this subsection, the term "biosimilar biological product" has the meaning given such term in section 1395w-3a(c)(6) of this title.

§ 1320f-2. Manufacturer agreements

(a) In general

For purposes of section 1320f(a)(2) of this title, the Secretary shall enter into agreements with manufacturers of selected drugs with respect to a price

applicability period, by not later than February 28 following the selected drug publication date with respect to such selected drug, under which—

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

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

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

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

manufacturer to provide access to such maximum fair price (as so renegotiated)—

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

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

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

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

described in paragraph (1)(A) or (2)(A), as applicable; and

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

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

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

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

(C) information that the Secretary requires to carry out section 1320f-1(f) of this title, including rebates under paragraph (4) of such section; and

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

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

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

(c) Confidentiality of information

Information submitted to the Secretary under this part by a manufacturer of a selected drug that is proprietary information of such manufacturer (as determined by the Secretary) shall be used only by the Secretary or disclosed to and used by the Comptroller General of the United States for purposes of carrying out this part.

(d) Nonduplication with 340B ceiling price

Under an agreement entered into under this section, the manufacturer of a selected drug—

(1) shall not be required to provide access to the maximum fair price under subsection (a)(3), with respect to such selected drug and maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed such selected drug at a covered entity described in section 340B(a)(4) of the Public Health Service Act [42 U.S.C. 256b(a)(4)], to such covered entity if such selected drug is subject to an agreement described in section 340B(a)(1) of such Act [42 U.S.C. 256b(a)(1)] and the ceiling price (defined in section 340B(a)(1) of such Act [42 U.S.C. 256b(a)(1)]) is lower than the maximum fair price for such selected drug; and

(2) shall be required to provide access to the maximum fair price to such covered entity with

respect to maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed such selected drug at such entity at such ceiling price in a non-duplicated amount to the ceiling price if such maximum fair price is below the ceiling price for such selected drug.

§ 1320f-3. Negotiation and renegotiation process

(a) In general

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

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

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

(b) Negotiation process requirements

(1) Methodology and process

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

(2) Specific elements of negotiation process

As part of the negotiation process under this section, with respect to a selected drug and the negotiation period with respect to the initial price applicability year with respect to such drug, the following shall apply:

(A) Submission of information

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

(B) Initial offer by Secretary

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

(C) Response to initial offer

(i) In general

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

(ii) Counteroffer requirements

If a manufacturer proposes a counteroffer, such counteroffer—

(I) shall be in writing; and

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

(D) Response to counteroffer

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

(E) Deadline

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

(F) Limitations on offer amount

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

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

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

(c) Ceiling for maximum fair price

(1) General ceiling

(A) In general

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

(B) Subparagraph (B) amount

An amount equal to the following:

(i) Covered part D drug

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

(ii) Part B drug or biological

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

(C) Subparagraph (C) amount

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

(i) Initial price applicability year 2026

In the case of a selected drug with respect to which such initial price applicability year is 2026, the average non-Federal average

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

(ii) Initial price applicability year 2027 and subsequent years

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

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

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

(2) Plan specific enrollment weighted amount

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

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

(B) a fraction—

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

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

(3) Applicable percent described

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

(A) Short-monopoly drugs and vaccines

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

(B) Extended-monopoly drugs

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

(C) Long-monopoly drugs

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

(4) Extended-monopoly drug defined

(A) In general

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

(B) Exclusions

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

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

(ii) A selected drug for which a manufacturer had an agreement under this part with the Secretary with respect to an initial price applicability year that is before 2030.

(C) Clarification

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

selected drug meets the definition of a long-monopoly drug.

(5) Long-monopoly drug defined

(A) In general

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

(B) Exclusion

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

(6) Average non-Federal average manufacturer price

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

(d) Temporary floor for small biotech drugs

In the case of a selected drug that is a qualifying single source drug described in section 1320f-1(d)(2) of this title and with respect to which the first initial price applicability year of the price applicability period with respect to such drug is 2029 or 2030, the maximum fair price negotiated under this section for such drug for such initial price applicability year may

not be less than 66 percent of the average non-Federal average manufacturer price for such drug (as defined in subsection (c)(6)) for 2021 (or, in the case that there is not an average non-Federal average manufacturer price available for such drug for 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year prior to the selected drug publication date with respect to the initial price applicability year.

(e) Factors

For purposes of negotiating the maximum fair price of a selected drug under this part with the manufacturer of the drug, the Secretary shall consider the following factors, as applicable to the drug, as the basis for determining the offers and counteroffers under subsection (b) for the drug:

(1) Manufacturer-specific data

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

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

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

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

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

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

(2) Evidence about alternative treatments

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

(A) The extent to which such drug represents a therapeutic advance as compared to existing therapeutic alternatives and the costs of such existing therapeutic alternatives.

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

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

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

In using evidence described in subparagraph (C), the Secretary shall not use evidence from

comparative clinical effectiveness research in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.

(f) Renegotiation process

(1) In general

In the case of a renegotiation-eligible drug (as defined in paragraph (2)) that is selected under paragraph (3), the Secretary shall provide for a process of renegotiation (for years (beginning with 2028) during the price applicability period, with respect to such drug) of the maximum fair price for such drug consistent with paragraph (4).

(2) Renegotiation-eligible drug defined

In this section, the term "renegotiation-eligible drug" means a selected drug that is any of the following:

(A) Addition of new indication

A selected drug for which a new indication is added to the drug.

(B) Change of status to an extended-monopoly drug

A selected drug that—

(i) is not an extended-monopoly or a long-monopoly drug; and

(ii) for which there is a change in status to that of an extended-monopoly drug.

(C) Change of status to a long-monopoly drug

A selected drug that—

(i) is not a long-monopoly drug; and

(ii) for which there is a change in status to that of a long-monopoly drug.

(D) Material changes

A selected drug for which the Secretary determines there has been a material change of any of the factors described in paragraph (1) or (2) of subsection (e).

(3) Selection of drugs for renegotiation

For each year (beginning with 2028), the Secretary shall select among renegotiation-eligible drugs for renegotiation as follows:

(A) All extended-monopoly negotiation-eligible drugs

The Secretary shall select all renegotiation-eligible drugs described in paragraph (2)(B).

(B) All long-monopoly negotiation-eligible drugs

The Secretary shall select all renegotiation-eligible drugs described in paragraph (2)(C).

(C) Remaining drugs

Among the remaining renegotiation-eligible drugs described in subparagraphs (A) and (D) of paragraph (2), the Secretary shall select renegotiation-eligible drugs for which the Secretary expects renegotiation is likely to result in a significant change in the maximum fair price otherwise negotiated.

(4) Renegotiation process

(A) In general

The Secretary shall specify the process for renegotiation of maximum fair prices with the manufacturer of a renegotiation-eligible drug selected for renegotiation under this subsection.

(B) Consistent with negotiation process

The process specified under subparagraph (A) shall, to the extent practicable, be consistent with the methodology and process established under subsection (b) and in accordance with subsections (c), (d), and (e), and for purposes of applying subsections (c)(1)(A) and (d), the reference to the first initial price applicability year of the price applicability period with respect to such drug shall be treated as the first initial price applicability year of such period for which the maximum fair price established pursuant to such renegotiation applies, including for applying subsection (c)(3)(B) in the case of renegotiation-eligible drugs described in paragraph (3)(A) of this subsection and subsection (c)(3)(C) in the case of renegotiation-eligible drugs described in paragraph (3)(B) of this subsection.

(5) Clarification

A renegotiation-eligible drug for which the Secretary makes a determination described in section 1320f-1(c)(1)[5] of this title before or during the period of renegotiation shall not be subject to the renegotiation process under this section.

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[5] So in original. Probably means subparagraph (A) or (B) of paragraph (1) of section 1320f-1(e) of this title.

(g) Clarification

The maximum fair price for a selected drug described in subparagraph (A) or (B) of paragraph (1) shall take effect no later than the first day of the first calendar quarter that begins after the date described in subparagraph [6] (A) or (B), as applicable.

§ 1320f-4. Publication of maximum fair prices

(a) In general

With respect to an initial price applicability year and a selected drug with respect to such year—(1) not later than November 30 of the year that is 2 years prior to such initial price applicability year, the Secretary shall publish the maximum fair price for such drug negotiated with the manufacturer of such drug under this part; and

(2) not later than March 1 of the year prior to such initial price applicability year, the Secretary shall publish, subject to section 1320f-2(c) of this title, the explanation for the maximum fair price with respect to the factors as applied under section 1320f-3(e) of this title for such drug described in paragraph (1).

(b) Updates

(1) Subsequent year maximum fair prices

For a selected drug, for each year subsequent to the first initial price applicability year of the price applicability period with respect to such drug, with respect to which an agreement for such drug is in effect under section 1320f-2 of this title, not later than November 30 of the year that is 2 years

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[6] So in original. Probably should be preceded by "such".

prior to such subsequent year, the Secretary shall publish the maximum fair price applicable to such drug and year, which shall be—(A) subject to subparagraph (B), the amount equal to the maximum fair price published for such drug for the previous year, increased by the annual percentage increase in the consumer price index for all urban consumers (all items; United States city average) for the 12-month period ending with the July immediately preceding such November 30; or

(B) in the case the maximum fair price for such drug was renegotiated, for the first year for which such price as so renegotiated applies, such renegotiated maximum fair price.

(2) Prices negotiated after deadline

In the case of a selected drug with respect to an initial price applicability year for which the maximum fair price is determined under this part after the date of publication under this section, the Secretary shall publish such maximum fair price by not later than 30 days after the date such maximum price is so determined.

§ 1320f-5. Administrative duties and compliance monitoring

(a) Administrative duties

For purposes of section 1320f(a)(4) of this title, the administrative duties described in this section are the following:

(1) The establishment of procedures to ensure that the maximum fair price for a selected drug is applied before—

(A) any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of maximum fair price eligible individuals; and

(B) any other discounts.

(2) The establishment of procedures to compute and apply the maximum fair price across different strengths and dosage forms of a selected drug and not based on the specific formulation or package size or package type of such drug.

(3) The establishment of procedures to carry out the provisions of this part, as applicable, with respect to—

(A) maximum fair price eligible individuals who are enrolled in a prescription drug plan under part D of subchapter XVIII or an MA–PD plan under part C of such subchapter; and

(B) maximum fair price eligible individuals who are enrolled under part B of such subchapter, including who are enrolled in an MA plan under part C of such subchapter.

(4) The establishment of a negotiation process and renegotiation process in accordance with section 1320f-3 of this title.

(5) The establishment of a process for manufacturers to submit information described in section 1320f-3(b)(2)(A) of this title.

(6) The sharing with the Secretary of the Treasury of such information as is necessary to determine the tax imposed by section 5000D of the

Internal Revenue Code of 1986, including the application of such tax to a manufacturer, producer, or importer or the determination of any date described in section 5000D(c)(1) of such Code. For purposes of the preceding sentence, such information shall include—(A) the date on which the Secretary receives notification of any termination of an agreement under the Medicare coverage gap discount program under section 1395w-114a of this title and the date on which any subsequent agreement under such program is entered into;

(B) the date on which the Secretary receives notification of any termination of an agreement under the manufacturer discount program under section 1395w-114c of this title and the date on which any subsequent agreement under such program is entered into; and

(C) the date on which the Secretary receives notification of any termination of a rebate agreement described in section 1396r-8(b) of this title and the date on which any subsequent rebate agreement described in such section is entered into.

(7) The establishment of procedures for purposes of applying subsections (d)(2)(B) and (f)(1)(C) of section 1320f-1 of this title.

(b) Compliance monitoring

The Secretary shall monitor compliance by a manufacturer with the terms of an agreement under section 1320f-2 of this title and establish a mechanism through which violations of such terms shall be reported.

§ 1320f-6. Civil monetary penalties

(a) Violations relating to offering of maximum fair price

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

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

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

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

(b) Violations relating to providing rebates

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

(c) Violations of certain terms of agreement

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

(d) False information

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

(e) Application

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

§ 1320f-7. Limitation on Administrative and Judicial Review.

There shall be no administrative or judicial review of any of the following:

(1) The determination of a unit, with respect to a drug or biological product, pursuant to section 1320f(c)(6) of this title.

(2) The selection of drugs under section 1320f–1(b) of this title, the determination of negotiation-eligible drugs under section 1320f–1(d) of this title, and the determination of qualifying single source drugs under section 1320f–1(e) of this title the application of section 1320f–1(f) of this title.

(3) The determination of a maximum fair price under subsection (b) or (f) of section 1320f–3 of this title.

(4) The determination of renegotiation-eligible drugs under section 1320f–3(f)(2) of this title and the selection of renegotiation-eligible drugs under section 1320f–3(f)(3) of this title.

APPENDIX D

26 U.S.C. § 5000D

§ 5000D. Designated drugs during noncompliance periods

(a) In general

(1) 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—such tax, divided by

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

(b) Noncompliance periods

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

(1) The period beginning on the March 1st (or, in the case of initial price applicability year 2026, the October 2nd) immediately following the date on which such drug is included on the list published under section 1192(a) of the Social Security Act and ending on the earlier of—(A) the first date on which the manufacturer of such designated drug has in place an agreement described in section 1193(a) of such Act with respect to such drug, or

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

(2) The period beginning on the November 2nd immediately following the March 1st described in paragraph (1) (or, in the case of initial price applicability year 2026, the August 2nd immediately following the October 2nd described in such paragraph) and ending on the earlier of—

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

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

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

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

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

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

(c) Suspension of tax

(1) In general

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

(A) beginning on the first date on which—

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

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

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

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

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

(2) Applicable agreement

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

(A) An agreement under—

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

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

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

(d) Applicable percentage

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

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

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

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

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

(e) Definitions

For purposes of this section—

(1) Designated drug

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

(2) United States

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

(3) Other terms

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

(f) Special rules

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

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

(2) Anti-abuse rule

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

(g) Exports

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

(h) Regulations

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

APPENDIX E

MEDICARE DRUG PRICE
NEGOTIATION PROGRAM AGREEMENT
(hereinafter referred to as the "Agreement")

Between

the Centers for Medicare & Medicaid Services (CMS), pursuant to delegated authority of the Secretary of Health and Human Services

And

[Full Name of Manufacturer]
(hereinafter referred to as the "Manufacturer")

For

[Name of Selected Drug]
(hereinafter referred to as the "Selected Drug")

WHEREAS, pursuant to sections 1191 through 1198 of the Social Security Act ("the Act"), as set forth in the Inflation Reduction Act (IRA), Pub. L. 117-169, CMS is responsible for the administration of the Medicare Drug Price Negotiation Program (hereinafter referred to as the "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; and

WHEREAS, CMS has designated the Manufacturer as the Primary Manufacturer, as defined in applicable guidance or regulations adopted in accordance with section 1193 of the Act, of the Selected Drug, and CMS has included the Selected Drug on the list of selected drugs published on [Date]; and

WHEREAS, the Manufacturer, if it reaches agreement with CMS, intends to provide access to the determined price pursuant to section 1193 of the Act and in accordance with how the price is computed and applied across different strengths and dosage forms of the Selected Drug as identified by CMS and updated, as applicable, in accordance with sections 1194(f), 1195(b), and 1196(a)(2) of the Act and applicable guidance and regulations, including where the Selected Drug is sold or marketed by any Secondary Manufacturers as defined in applicable guidance or regulations;

NOW THEREFORE, CMS, on behalf of the Department of Health and Human Services, and the Manufacturer, on its own behalf, in accordance with sections 1191 through 1198 of the Act, and all applicable guidance and regulations, hereby agree to the following:

I. Definitions

All terms included in this Agreement shall have the meaning given to them under the provisions of sections 1191 through 1198 of the Act and any applicable guidance and regulations implementing those provisions, except where such terms are expressly defined in this Agreement.

II. CMS and Manufacturer Responsibilities

CMS shall administer the Negotiation Program and the Manufacturer agrees to comply with all applicable requirements and conditions for the Negotiation Program set forth in sections 1191 through 1198 of the Act and all applicable guidance and regulations implementing those provisions and any changes to the Act that affect the Negotiation Program.

Without limiting the foregoing, CMS and the Manufacturer agree:

a) During the negotiation period for the initial price applicability year for the Selected Drug, in accordance with section 1194 of the Act and applicable guidance and regulations CMS and the Manufacturer shall negotiate to determine (and, by not later than the last date of such period, agree to) a maximum fair price for the Selected Drug of the Manufacturer in order for the Manufacturer to provide access to such price—

   i. to maximum fair price eligible individuals who with respect to the Selected Drug are described in subparagraph (A) of section 1191(c)(2) of the Act and are dispensed the Selected Drug (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed the Selected Drug) during, subject to paragraph (b) of this section, the price applicability period; and

   ii. to hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to the Selected Drug are described in subparagraph (B) of section 1191(c)(2) of the Act and are furnished or administered the Selected Drug during, subject to paragraph (b) of this section, the price applicability period.

b) As applicable, CMS and the Manufacturer shall, in accordance with section 1194 of the Act and applicable guidance and regulations, renegotiate (and, by not later than the last date of the period

of renegotiation, agree to) the maximum fair price for the Selected Drug, in order for the Manufacturer to provide access to such maximum fair price (as so renegotiated)—

i. to maximum fair price eligible individuals who with respect to the Selected Drug are described in subparagraph (A) of section 1191(c)(2) of the Act and are dispensed the Selected Drug (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed the Selected Drug) during any year during the price applicability period (beginning after such renegotiation) with respect to such Selected Drug; and

ii. to hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to the Selected Drug are described in subparagraph (B) of section 1191(c)(2) of the Act and are furnished or administered the Selected Drug during any year during the price applicability period (beginning after such renegotiation) with respect to such Selected Drug.

c) Subject to paragraph (f) of this section and in accordance with applicable guidance and regulations, access to the maximum fair price (including as renegotiated pursuant to paragraph (b) of this section), with respect to such a Selected Drug, shall be provided by the Manufacturer to—

i. maximum fair price eligible individuals, who with respect to the Selected Drug are described

in subparagraph (A) of section 1191(c)(2) of the Act, at the pharmacy, mail order service, or other dispenser at the point-of-sale of the Selected Drug (and shall be provided by the Manufacturer to the pharmacy, mail order service, or other dispenser, with respect to such maximum fair price eligible individuals who are dispensed the Selected Drug), as described in paragraph (a)(i) or (b)(i) of this section, as applicable; and

ii. hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to the Selected Drug are described in subparagraph (B) of section 1191(c)(2) of the Act and are furnished or administered the Selected Drug, as described in paragraph (a)(ii) or (b)(ii) of this section, as applicable.

d) The Manufacturer shall submit to CMS, in a form and manner specified by CMS and in accordance with applicable guidance and regulations, for the negotiation period for the price applicability period (and, if applicable, before any period of renegotiation pursuant to section 1194(f) of the Act), and for section 1192(f) of the Act, with respect to the Selected Drug—

i. information on the non-Federal average manufacturer price (as defined in section 8126(h)(5) of title 38, United States Code) for the Selected Drug for the applicable year or period;

ii. information that CMS requires to carry out the negotiation (or renegotiation) process under sections 1191 through 1198 of the Act; and

iii. information that CMS requires to carry out section 1192(f) of the Act, including rebates under section 1192(f)(4) of the Act.

e) The Manufacturer shall comply with requirements determined by CMS to be necessary for purposes of administering the Negotiation Program and monitoring compliance with the Negotiation Program, including in accordance with applicable guidance and regulations.

f) Under this Agreement and in accordance with applicable guidance and regulations, the Manufacturer—

i. Shall not be required to provide access to the maximum fair price under paragraph (c), with respect to the Selected Drug and maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed the Selected Drug at a covered entity described in section 340B(a)(4) of the Public Health Service Act, to such covered entity if the Selected Drug is subject to an agreement described in section 340B(a)(1) of such Act and the ceiling price (defined in section 340B(a)(1) of such Act) is lower than the maximum fair price for such selected drug; and

ii. Shall be required to provide access to the maximum fair price to such covered entity with respect to maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed the Selected Drug at such entity at such ceiling price in a nonduplicated amount to the ceiling price if such maximum fair price is below the ceiling price for the Selected Drug.

g) In accordance with section 1193(c) of the Act and applicable guidance and regulations, information submitted to CMS under the Negotiation Program by the Manufacturer that is proprietary information of such Manufacturer, as determined by CMS, shall be used only by CMS or disclosed to and used by the Comptroller General of the United States to carry out such Negotiation Program, unless otherwise required by law.

III. Effective Date, Term and Termination

a) This Agreement shall have an effective date of the date this Agreement is signed by both parties.

b) The term of this Agreement shall be from the effective date until the termination date, which shall be the earlier of the first day that the Selected Drug is no longer a selected drug pursuant to CMS' determination in accordance with section 1192(c) of the Act and applicable guidance and regulations, or the date that the Agreement is terminated by either party in accordance with applicable guidance and regulations.

c) Notwithstanding the termination of this Agreement, certain requirements and obligations shall continue to apply in accordance with applicable guidance and regulations.

IV. General Provisions

a) This Agreement contains the entire agreement of the parties with respect to the subject matter of this Agreement and supersedes all prior oral and written representations, agreements, and understandings of the parties. If CMS and the

Manufacturer reach agreement on a price for the Selected Drug pursuant to section II(a) or II(b) of this Agreement, CMS and the Manufacturer shall execute an addendum setting forth the price for the Selected Drug that will apply for purposes of this Agreement.

b) CMS retains authority to amend this Agreement to reflect changes in law, regulation, or guidance. When possible, CMS shall give the Manufacturer at least 60-day notice of any change to the Agreement.

c) Any notice required to be given by either party pursuant to the terms and provisions of this Agreement shall be sent by email. CMS shall provide the appropriate email address for notice in guidance, rulemaking, or other publications. The Manufacturer shall provide the appropriate email address(es) for notice to CMS in a form and manner specified by CMS.

d) Nothing in this Agreement shall prohibit the Manufacturer from transferring the Selected Drug and obligations of this Agreement to another entity in accordance with applicable guidance and regulations.

e) Nothing in this Agreement shall limit the Manufacturer from providing access under the Medicare program to a price lower than the price determined pursuant to this Agreement.

f) 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.

g) Nothing in this Agreement shall be construed to require or authorize the commission of any act contrary to law. If any provision of this Agreement is found to be invalid by a court of law with competent jurisdiction, this Agreement will be construed in all respects as if any invalid or unenforceable provisions were eliminated, and without any effect on any other provision.

h) No failure by any party to insist upon the strict performance of any requirement, obligation or condition of this Agreement shall constitute a waiver of any such requirement, obligation or condition.

i) This Agreement shall be construed in accordance with Federal law and any ambiguities shall be interpreted in the manner that best effectuates the statute. Any litigation relating to this Agreement, to the extent that jurisdiction and a cause of action would otherwise be available for such litigation, shall be resolved in Federal court. Actions by the Manufacturer for damages are not permitted pursuant to this Agreement, and the Manufacturer's remedies for any breach are limited to termination of the Agreement or other action consistent with applicable statutes, regulations, or guidance.

j) CMS and the Manufacturer acknowledge and agree that in accordance with section 1197 of the Act and 26 U.S.C. § 5000D, the Manufacturer may be subject to civil monetary penalties and an excise tax, as applicable, for failure to meet the

requirements of the Negotiation Program, including violations of this Agreement.

k) Neither party shall be liable for failure to perform its obligations under this Agreement if such failure is occasioned by a contingency beyond such party's reasonable control, includeing, but not limited to, lockouts, riots, wars, fires, floods or storms (a "Force Majeure Event"). A party claiming a right to excused performance under this section shall promptly notify the other party in writing of the extent of its inability to perform, which notice shall specify the Force Majeure Event that prevents such performance and include a timeline for remediation. The party failing to perform shall use reasonable efforts to avoid or remove the cause of the Force Majeure Event and shall resume performance under the Agreement promptly upon the cessation of the Force Majeure Event.

V. Signatures

FOR THE MANUFACTURER

A. By signing this Agreement, the Manufacturer agrees to abide by all provisions set forth in this Agreement and acknowledges having received notice of potential penalties for violation of the terms of the Agreement.

B. The undersigned individual hereby attests that he or she is authorized by the Manufacturer to execute this Agreement with regard to the Selected Drug and to legally bind the Manufacturer on whose behalf he or she is executing the Agreement to all terms and conditions specified herein. The undersigned individual further attests that he or

she has obtained access in the CMS Health Plan Management System (CMS HPMS) as an authorized representative to be signatory for the Manufacturer and that the individual's CMS HPMS access credentials contain the same information regarding the undersigned individual as the information set forth below.

By:

Print Name: _____

Signature: _____

Title: _____

Date: _____

P-Number: _____

Manufacturer Address: _____

_____

FOR THE CENTERS FOR MEDICARE & MEDICAID SERVICES

By: _____

Print Name: _____

Signature: _____

Title: _____

Date: _____

Addendum 1: Negotiated Maximum Fair Price

MEDICARE DRUG PRICE NEGOTIATION PROGRAM AGREEMENT NEGOTIATED MAXIMUM FAIR PRICE ADDENDUM
(hereinafter referred to as the "Addendum")

Between

the Centers for Medicare & Medicaid Services (CMS), pursuant to delegated authority of the Secretary of Health and Human Services

And

[Full Name of Manufacturer]
(hereinafter referred to as the "Manufacturer")

For

[Name of Selected Drug]
(hereinafter referred to as the "Selected Drug")

WHEREAS, the Manufacturer has in effect a Medicare Drug Price Negotiation Agreement (the "Agreement"), which the Manufacturer entered into with CMS on [Date], to negotiate to determine a price (referred to as "maximum fair price" in the Social Security Act ("the Act")) for the Selected Drug under the Negotiation Program; and

WHEREAS, the Manufacturer and CMS have engaged in negotiation of the price for the Selected Drug in accordance with the negotiation process set forth in section 1194 of the Act and applicable guidance and regulations; and

WHEREAS, the Manufacturer and CMS now agree to a price for the Selected Drug, as published by CMS in accordance with section 1195(a) of the Act and updated in accordance with sections 1195(b) and 1196(a)(2) of the Act and applicable guidance and

regulations, which will apply for purposes of the Agreement;

NOW THEREFORE, the Manufacturer and CMS agree to this Addendum, such that the following terms are hereby incorporated as part of the Agreement:

a) The parties agree to a price of [$] for the Selected Drug per 30-day equivalent supply, weighted across dosage forms and strengths.
b) The parties agree that the price set forth in clause (a) shall apply to the dosage forms and strengths of the Selected Drug as identified on the list of National Drug Codes (NDCs) maintained by CMS as may be updated with information from the manufacturer in accordance with section 1193 of the Act and applicable guidance and regulations.
c) The parties agree that the price set forth in clause (a), which in accordance with section 1196(a)(2) of the Act and applicable guidance and regulations is computed and applied by CMS across the different strengths and dosage forms of the Selected Drug as set forth in clause (b), is binding and shall apply as specified in the Agreement and in accordance with the Act and any applicable guidance and regulations.

Signatures

FOR THE MANUFACTURER

A. By signing below, the Manufacturer agrees to this Addendum to the Agreement and acknowledges having received notice of potential penalties for violation of the terms of the Addendum and the Agreement.

B. The undersigned individual hereby attests that he or she is authorized by the Manufacturer to execute this Agreement with regard to the Selected Drug and to legally bind the Manufacturer on whose behalf he or she is executing the Agreement to all terms and conditions specified herein. The undersigned individual further attests that he or she has obtained access in the CMS Health Plan Management System (CMS HPMS) as an authorized representative to be signatory for the Manufacturer and that the individual's CMS HPMS access credentials contain the same information regarding the undersigned individual as the information set forth below.

By:

Print Name: _____

Signature: _____

Title: _____

Date: _____

P-Number: _____

Manufacturer Address: _____

FOR THE CENTERS FOR MEDICARE & MEDICAID SERVICES

By:

Name: _____

Signature: _____

Title: _____

Date: _____

APPENDIX F

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
TRENTON VICINAGE

Civil Action No. 23-cv-03818-ZNQ-JBD

JANSSEN PHARMACEUTICALS, INC.,

Plaintiff,

v.

XAVIER BECERRA, Secretary of Health and Human Services, *et al.*,

Defendants.

DECLARATION OF BLASINE PENKOWSKI
IN SUPPORT OF PLAINTIFF'S MOTION
FOR SUMMARY JUDGMENT

I, Blasine Penkowski, declare as follows pursuant to 28 U.S.C. § 1746:

1. I am Chief Strategic Customer Officer for the North American operations of the Janssen Pharmaceutical Companies ("Janssen Companies"), which include Plaintiff Janssen Pharmaceuticals, Inc. ("Janssen"), and have held that position since January 2015. I submit this declaration in support of Janssen's Motion for Summary Judgment.

2. As Chief Strategic Customer Officer, I am responsible for, among other things, Janssen's customer strategy development and Janssen's operations relating to the Drug Price Negotiation Program (the "Program") established by the Inflation

Reduction Act (the "Act"). Prior to my current position, I served as Vice President, Customer Strategy at Janssen North America and in senior strategic leadership roles at AbbVie Inc. and Abbott Laboratories.

3. This declaration is based on my personal knowledge regarding the effects of the Program on Janssen, as well as information assembled by authorized Janssen employees, upon whom I have relied. Subject to these limitations, the facts contained in this Declaration are true and correct to the best of my knowledge, information, and belief.

Janssen's Xarelto® Products

4. Since 2016, the Janssen Companies have invested more than $65 billion in researching and developing innovative new drugs and biologics, including $11.6 billion in 2022 alone.[1]

5. These investments have allowed the Janssen Companies to obtain Food and Drug Administration ("FDA") approval for eight new medications and 52 additional indications or new product formulations since 2016.

6. Janssen is the exclusive U.S. licensee of the patents that claim rivaroxaban and its use, and it has the exclusive right to market Xarelto® (rivaroxaban) products in the United States. Pursuant to that license, Janssen manufactures and sells Xarelto®, a

[1] Additional details regarding the Janssen Companies' investments in pioneering drug treatments are available in the 2022 U.S. Pricing Transparency Brief, available at https://transparencyreport.janssen.com/_document/2022-janssen-transparency-report-pdf?id=00000188-267e-d95e-abca-7e7e58750000.

direct oral anticoagulant that treats and helps prevent blood clots and reduces the risk of stroke.

7. In 2022, nearly 3 million patients in the United States filled a combined total of almost 11 million prescriptions for Xarelto®. Medicare has accounted for more than half of Xarelto® prescriptions between 2021 and 2023, with Medicaid and Medicare together accounting for more than 60% of U.S. Xarelto® prescriptions during that period.

Janssen's Broader Participation in Medicare and Medicaid

8. Including its Xarelto® products, Janssen manufactures and sells 21 drugs through Medicare and Medicaid, measured by unique New Drug Application and Biologic License Application Numbers. [2] Including Janssen's drugs, the broader group of Janssen Companies manufacture and sell 53 drugs through Medicare and Medicaid, measured in the same way.

9. The sale of products in Medicare and Medicaid made up approximately 40% of the Janssen Companies' gross pharmaceutical revenues in 2022. For Janssen specifically, the share of Medicare and Medicaid sales was even more pronounced, with approximately 50% of prescriptions filled for Janssen products and approximately 65% of its gross sales in 2022 attributable to those federal programs.

10. In 2023, the Janssen Companies estimate that more than 4.5 million patients will fill prescriptions for the Janssen Companies' pharmaceutical products. Millions of those patients will obtain Janssen

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[2] This figure includes Ditropan XL (NDA 020897) which, while discontinued, remains available in Medicare and Medicaid.

products, like Xarelto®, through Medicare and Medicaid.

11. Because Medicare and Medicaid comprise a very large portion of both the U.S. pharmaceutical market and Janssen's business, Janssen's ability to participate in these markets is critical to its continued ability to innovate and compete.

The Program's Effects on Janssen

12. Xarelto® is a self-administered drug marketed by Janssen through Medicare Part D.

13. Because FDA approved Xarelto® on July 1, 2011, it will have been approved for at least seven years as of September 1, 2023, and thus will constitute a "qualifying single-source drug" under the Program. *See* 42 U.S.C. § 1320f-1(e)(1)(A). CMS has announced that it "will select" the ten drugs with the highest Medicare Part D sales for the Program's first year. *See* Declaration of Jeffrey S. Chiesa ("Chiesa Decl.") Ex. A § 30.3.

14. Independent analyses have consistently concluded that Xarelto® is among the top ten drugs with respect to Medicare Part D expenditures, and that CMS will therefore select Xarelto® for the Program in 2023. *See, e.g.*, Chiesa Decl. Ex. C (identifying Xarelto® as the second-highest drug among the top ten and thus as a drug "[s]ubject to negotiation" for the Program's first year); Expert Declaration of Professor Craig Garthwaite, *Nat'l Infusion Center Ass'n et al. v. Becerra*, No. 1:23-cv-00707, ECF No. 35-1, App'x D (W.D. Tex. Aug. 10, 2023) (similarly identifying Xarelto® as the second-highest drug among the top ten and thus as one of the ten drugs that will be subject to the Program beginning in September 2023).

15. When CMS selects the ten highest-spend Medicare Part D qualifying single-source drugs for the Program on September 1, 2023, Xarelto® will be selected, based on the studies noted above and additional Medicare spending data available to Janssen.

16. Once CMS selects Xarelto® for the first year of the Program, Janssen will have until October 1, 2023, to sign a "Manufacturer Agreement" to "negotiate" a "maximum fair price" with CMS. *See* 42 U.S.C. §§ 1320f(d)(2)(A), 1320f-2. Failing to sign that Agreement would subject Janssen to a daily "excise tax" penalty on every domestic sale of Xarelto® both in and out of Medicare. *See* 26 U.S.C. § 5000D.

17. For the first 90 days of noncompliance, Janssen would have to pay a daily "excise tax" penalty equal to 185.71% of Xarelto® gross U.S. sales. Based on projected sales data, that penalty would amount to more than $50 million per day, or more than $4.5 billion over the course of the first 90 days of noncompliance.

18. If Janssen were to not comply with the Program's requirements for longer than 270 days, domestic sales of Xarelto® would be subject to a 1900% daily "excise tax" penalty. At this rate, and based on projected sales data, Janssen would be liable for penalties more than $600 million per day. In total, the penalties for the first year of noncompliance would amount to more than $90 billion.

19. These projected tax burdens are in line with what Janssen would have owed had the "excise tax" penalty been applied to Janssen's Xarelto® sales for 2022. Based on actual Xarelto® sales data, if the "excise tax" penalty had applied beginning on the first

day of that year and continued in effect through the final day of that year, Janssen's total liability would have been more than $75 billion.

20. The economic burden of the "excise tax" penalty would be so severe that during the first year of noncompliance the penalty would be more than three times greater than the 2022 total U.S. adjusted net earnings of Johnson & Johnson, Janssen's ultimate parent company, across all of Johnson & Johnson's products (including non-pharmaceutical products).

21. Aside from submitting to the Program, the only way to avoid these penalties is for Janssen, to withdraw all of its products from both Medicare and Medicaid. *See* 26 U.S.C. § 5000D(c). That step would mean removing all 21 of Janssen's Medicare and Medicaid drugs from those programs, losing at least half of the prescriptions filled for Janssen's products, and thus forgoing access to a substantial proportion of Janssen's annual revenues (approximately 65% of gross sales in 2022). Most detrimentally, forcing Janssen to withdraw from Medicare and Medicaid would leave millions of patients at risk without insurance coverage for the Janssen medicines they have come to depend on.

22. Given the economic and patient-harming consequences of not submitting to the Program, Janssen will have no choice but to comply once CMS selects Xarelto®—a course of action Janssen would not take but for the punitive consequences of not complying.

23. Accordingly, Janssen's participation in the Program is not voluntary, nor is there any mutual "agreement" with CMS regarding Janssen's participation in the Program. Despite its views,

Janssen will be forced to convey that the Program is voluntary and that it agreed to participate by signing the Manufacturer Agreement with CMS.

24. After Janssen is compelled to sign the Manufacturer Agreement, the "negotiation" phase of the Program begins. *See* 42 U.S.C. § 1320f-3. Janssen disagrees that this process will involve a "negotiation" because an actual negotiation produces a binding contract only when both parties freely agree on its terms, especially price. Under the Program, however, Janssen will have no choice but to accept the "maximum fair price" and other terms (such as the provisions of the Manufacturer Agreement) unilaterally dictated by CMS.

25. The Act also states that the Program will result in a "maximum fair price" for selected drugs like Xarelto®. But Janssen disagrees that the price dictated through the Program will be "fair." Because Xarelto® will fall within the Act's definition of a short-term monopoly drug, it will be subject to an automatic discount of at least 25% from the average price paid by non-federal wholesalers for Xarelto®. *See id.* § 1320f-3(c)(3)(A). The Act requires CMS to set the "lowest maximum fair price" below the statutory ceiling, without any floor (i.e., all the way down to $0). *See id.* § 1320f-3(b)(1). As a result of these provisions, the Program will result in a "maximum fair price" that is far below what Janssen views as "fair."

26. Despite its views, the Act and the Manufacturer Agreement will force Janssen to convey that it will engage in voluntary "negotiations" with CMS and that those "negotiations" will result in a "fair" price for Xarelto®. And because CMS will compel Janssen to sign an addendum to the Manufacturer Agreement at the conclusion of the "negotiation" process

memorializing this purportedly agreed-upon price, Janssen will again be forced to convey the Government's views rather than its own.

27. By depriving Janssen of the ability to earn anything resembling market returns on Xarelto® products, the Act will significantly undermine Janssen's ability to innovate and compete over the long-term. In particular, the Act will limit the ability of Janssen and the Janssen Pharmaceutical Companies to develop pioneering new drugs, which in turn generate the revenues necessary to support development of the next generation of transformational and accessible treatments. As a result, the Act will undermine Janssen's ability to improve human health for patient populations with unmet medical needs.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Executed this 16th day of August, 2023.

/s/ Blasine Penkowski
Blasine Penkowski
Chief Strategic Customer Officer,
Janssen North America
Janssen Pharmaceuticals, Inc.,
as part of the Janssen
Pharmaceutical Companies
Titusville, New Jersey