24-2092

IN THE

United States Court of Appeals

FOR THE SECOND CIRCUIT

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,

Plaintiff-Appellant,

—against—

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, XAVIER BECERRA, In His Official Capacity as Secretary of Health and Human Services, CENTERS FOR MEDICARE AND MEDICAID SERVICES, CHIQUITA BROOKS-LASURE, In Her Official Capacity as Administrator of Centers for Medicare and Medicaid Services,

Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF CONNECTICUT
NO. 23-CV-01103, HON. MICHAEL P. SHEA

BRIEF AND SPECIAL APPENDIX FOR PLAINTIFF-APPELLANT

ROBERT A. LONG, JR.
KEVIN F. KING
THOMAS R. BRUGATO
BRADLEY E. ERVIN
MICHAEL M. MAYA
MAKADE C. CLAYPOOL
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street, NW
Washington, DC 20001
(202) 662-6000

Attorneys for Plaintiff-Appellant

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, counsel for Plaintiff-Appellant Boehringer Ingelheim Pharmaceuticals, Inc. states that nongovernmental corporate entity Boehringer Ingelheim Pharmaceuticals, Inc. is a wholly owned subsidiary, directly or indirectly, of Boehringer Ingelheim USA Corporation and Boehringer Ingelheim Corporation, both privately owned corporations. No publicly held corporation owns 10% or more of the stock of Boehringer Ingelheim Pharmaceuticals, Inc.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Constitutional Provisions

Other Authorities

INTRODUCTION

This appeal concerns provisions of the Inflation Reduction Act of 2022 ("IRA") designed to reduce Medicare spending on prescription drugs. Congress had many options at its disposal to achieve that objective. It could have set prices directly by statute, making manufacturers take-it-or-leave-it offers for their drugs. It could have directed the Centers for Medicare and Medicaid Services ("CMS"), which administers Medicare, to take the same step through rulemaking. Or it could have authorized CMS to engage in arms-length negotiations with manufacturers, in which each party could walk away if it does not agree to the other's terms.

Congress did not adopt any of those well-established approaches. Instead, it enacted the misleadingly named Medicare Drug Price Negotiation Program ("Program"), which seeks to provide seniors with innovative, widely prescribed drugs at only a fraction of the drugs' market value. Under the Program, CMS selects a group of drugs each year and presents manufacturers of those drugs with an ultimatum: Provide the selected drug to Medicare participants at a highly discounted price, or else incur an even greater economic toll in the form of a 1900% excise tax or complete exclusion of the selected drug *and* all the manufacturer's other drugs from Medicare *and* Medicaid. The Program thus leverages the Government's sovereign powers—its authority to levy taxes and impose requirements for Medicare

and Medicaid—to coerce manufacturers into handing over selected drugs on terms dictated by CMS.

Compounding that harm, the Program insulates CMS's actions from political and legal accountability in unprecedented ways. It affords manufacturers fewer procedural protections than emergency wartime price regulations. And it disguises the Program's command-and-control structure by compelling manufacturers to describe the process in terms of negotiated agreements. Under threat of the penalties described above, manufacturers must attest, in writing, that they "negotiate[d]" the prices set through the Program and "agree" that the prices are not only "fair," but the "maximum fair prices" for their drugs. These normative statements are not necessary to set drug prices—agencies routinely regulate prices without requiring businesses to describe the process as a negotiation or say that the prices are fair—but they advance other governmental objectives by influencing private markets and forcing manufacturers to shoulder responsibility for the Program's effects. Indeed, by requiring manufacturers to express the view that the artificially low prices set through the Program are the *maximum fair* prices, the IRA forces manufacturers to indict their own conduct—to pronounce that the market rates they have charged in the past and continue to charge outside of Medicare are *unfair*.

That scheme is unconstitutional as applied to Plaintiff-Appellant Boehringer Ingelheim Pharmaceuticals, Inc. In 2023, CMS selected Boehringer's drug

Jardiance® for the Program, subjecting the company to tens of billions in annual excise taxes or across-the-board exclusion from Medicare and Medicaid (which together account for almost half the U.S. prescription drug market) if it did not "negotiate" and "agree to" a "maximum fair price" far below the prevailing rate.

The Program effects a *per se* taking by granting Medicare participants the right to take possession of Boehringer's Jardiance® products on terms the company would never voluntarily accept. It denies Boehringer due process by omitting basic safeguards, such as review by an impartial decisionmaker applying ascertainable standards, that the Supreme Court has held are essential checks against arbitrary governmental action. And it abridges the First Amendment by compelling Boehringer to speak and act in ways that endorse the Government's preferred messages about drug pricing—an issue front-and-center in the national debate. In addition, CMS violated the Administrative Procedure Act ("APA") by failing to take public comments on the Manufacturer Agreement, which implements the Program's negotiation and "maximum fair price" provisions.

The District Court upheld the Program primarily on the ground that participation is voluntary. But Congress carefully constructed the Program to ensure that manufacturers like Boehringer cannot opt out. Once CMS selects a drug for the Program, the manufacturer faces a Hobson's choice between giving away its drug for a fraction of its market value, withdrawing all its drugs from Medicare and

Medicaid, or paying a tax so ruinous that the Congressional Budget Office estimated it would raise no revenue because no manufacturer could afford to pay it. Because the Program employs "coercion by economic pressure," the "asserted power of choice is illusory" and participation is "not in fact voluntary." *United States v. Butler*, 297 U.S. 1, 70-71 (1936).

Even if the Program were voluntary, it would still violate the unconstitutional conditions doctrine. That doctrine prohibits the Government from producing indirectly "a result which [it] could not command directly," *Speiser v. Randall*, 357 U.S. 513, 526 (1958), by requiring a regulated party to give up its constitutional rights in exchange for a discretionary benefit. The Program violates that principle by tying Boehringer's ability to sell *any* of its drugs through Medicare or Medicaid to waiver of the company's First and Fifth Amendment rights regarding Jardiance®.

Finally, the Government defends the Program as a constitutional means of reducing spending on prescription drugs. But even when Congress has a strong "desire to improve the public condition," that is not a license to do so by a "shorter cut than the constitutional way." *Horne v. Dep't of Agriculture*, 576 U.S. 350, 362 (2015) (*Horne II*) (quoting *Penn. Coal Co. v. Mahon*, 260 U.S. 393, 416 (1922) (Holmes, J.)). Congress could lawfully have pursued its goal in other ways, but those approaches would have involved significant tradeoffs. For example, if Congress had authorized true arms-length negotiations between CMS and

manufacturers, the parties might not reach agreement on some widely prescribed medications—leaving millions of seniors without Medicare coverage for treatments they depend on. The IRA prevents that outcome by leaving manufacturers with no choice but to acquiesce, while simultaneously compelling manufacturer speech to evade accountability for the Program's raw exercise of regulatory power. Because those provisions take unconstitutional shortcuts, this Court should hold that the Program is unlawful as applied to Boehringer and reverse the District Court's order entering summary judgment for the Government.

JURISDICTIONAL STATEMENT

The District Court had subject-matter jurisdiction under 28 U.S.C. § 1331. It entered final judgment on July 9, 2024, disposing of all of Boehringer's claims. Special Appendix ("SPA") 48. Boehringer timely filed a notice of appeal on July 26, 2024. Joint Appendix ("JA") 412. This Court has jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES

1. Whether the Program violates the Fifth Amendment's Takings Clause by appropriating Boehringer's property rights in its Jardiance® products.

2. Whether the Program violates the Fifth Amendment's Due Process Clause by depriving Boehringer of property without constitutionally adequate procedural safeguards.

3. Whether CMS acted unlawfully by issuing the Manufacturer Agreement without observing the notice-and-comment procedures required by the APA.

4. Whether the Program violates the First Amendment by compelling Boehringer to endorse the Government's messages regarding the Program.

5. Whether the Program violates the unconstitutional conditions doctrine by conditioning Boehringer's participation in Medicare and Medicaid on surrendering its First and Fifth Amendment rights with respect to Jardiance®.

STATEMENT OF THE CASE

This case presents constitutional and statutory challenges to the Program and its implementation by CMS. Boehringer filed suit on August 18, 2023, and timely appeals from the July 9, 2024 final judgment of the U.S. District Court for the District of Connecticut (Shea, C.J.) granting summary judgment to Defendants. *See* SPA48 (final judgment); 2024 WL 3292657 (D. Conn. July 3, 2024) (opinion, reprinted at SPA1-47); JA412 (notice of appeal).

I. Statutory and Regulatory Background

Medicare and Medicaid are among the largest programs administered by the federal government. Medicare provides health insurance coverage for seniors and consists of various parts, including Part B (which covers physician-administered drugs) and Part D (which covers self-administered prescription drugs). *See* 42

U.S.C. §§ 1395j *et seq.*, 1395w-101 *et seq.* Separately, Medicaid provides health-insurance for low-income Americans. *Id.* §§ 1396 *et seq.* Together these programs comprise "almost half the annual nationwide spending on prescription drugs." *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023).

Congress designed Medicare Part D to rely on market forces. CMS, which administers Medicare and Medicaid, contracts with privately operated insurance plans to implement Part D. In turn, insurers "negotiate [drug] prices with manufacturers" based on market factors to set "the prices paid for drugs covered by … Part D." *Nat'l Infusion Ctr. Ass'n v. Becerra*, 116 F.4th 488, 494 (5th Cir. 2024) (*NICA*). CMS then pays the insurers fixed amounts based on their anticipated drug spending. In other words, CMS does not purchase drugs, but instead reimburses insurers that cover the patients who buy the drugs, and regulates interactions between patients, providers, and insurance plans.

One critical aspect of Medicare Part D has changed since its creation. Before the IRA was enacted, CMS could neither "interfere" with negotiations between insurers and manufacturers nor "institute a price structure for the reimbursement of covered part D drugs." 42 U.S.C. § 1395w-111(i) (2003).

The IRA removed those prohibitions in 2022. *See* Pub. L. 117-169, §§ 11001-11004, 136 Stat. 1818, 1833-64. Under the IRA, CMS[1] is authorized to "institute a price structure" for the most widely prescribed drugs through the "Medicare Drug Price Negotiation Program." 42 U.S.C. § 1395w-111(i). The IRA thus shifted "the price-setting mechanism" for these drugs "from the free market to a government-run process." *NICA*, 116 F.4th at 494.

The Program comprises four stages: (1) CMS selects drugs for the Program; (2) manufacturers "enter into" "agreement[s]" with CMS to "negotiate" "maximum fair price[s]"; (3) the parties "agree to" a "maximum fair price" for each drug, which CMS publishes; and (4) manufacturers provide Medicare beneficiaries and their providers "access to" the selected drugs at "such price[s]." 42 U.S.C. §§ 1320f to 1320f-4.

1. Selection. The Program operates in annual cycles. In August 2023, CMS identified eligible drugs that accounted for the highest Medicare spending[2] and then selected the top ten drugs for the Program's first year. *Id.* § 1320f-1(a)(1), (d)(1)(A).

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[1] The Secretary of Health and Human Services delegated authority to administer the Program to CMS. *See* 88 Fed. Reg. 1390 (Jan. 10, 2023). Accordingly, we refer to CMS when discussing implementation of the Program.

[2] This computation reflected Medicare *overall spending*, not the *price per prescription* for each drug. Thus, widely prescribed drugs such as Jardiance® were included in the initial group of selected drugs, despite having a lower price per prescription than many other drugs.

Each subsequent year, CMS will select additional drugs from Medicare Part D, and eventually from Part B, expanding the Program. *See id.* § 1320f-1(a)(2)-(4).

2. Agreement. Once a drug is selected, a manufacturer has less than one month to "enter into" a "manufacturer agreemen[t]" with CMS. *Id.* §§ 1320f(d)(2)(B), 1320f-2(a). Under that "agreement," the manufacturer must "agree" to "negotiate … a maximum fair price" for its selected drug, submit pricing data and any other "information that [CMS] requires," provide third parties "access to the maximum fair price … with respect to [the] selected drug," and "compl[y] with" other "requirements determined by [CMS] to be necessary." *Id.* § 1320f-2(a) ("Manufacturer Agreement"). CMS unilaterally drafted the Manufacturer Agreement and presented it to manufacturers on a take-it-or-leave-it basis. JA126.

If a manufacturer declines to sign the Manufacturer Agreement, it is deemed "noncomplian[t]" and must pay an "escalating tax on all sales of the [selected] drug (not just Medicare sales) that starts at 185.7% of the drug's price and rises to 1,900%" after nine months. *NICA*, 116 F.4th at 495; 26 U.S.C. § 5000D; JA378 (explaining computation of tax). "The Congressional Budget Office estimated that [this excise tax penalty] would raise no revenue because no manufacturer could afford to pay it." *NICA*, 116 F.4th at 495; JA323.

The only way to avoid the excise tax penalty and the Program's requirements is to "opt out of Medicare [and Medicaid] … entirely, meaning [CMS] will not

reimburse patients or providers for any of the drugs that the manufacturer sells (whether or not those drugs are part of the Drug Pricing Program)." *NICA*, 116 F.4th at 495; 26 U.S.C. § 5000D(c)(1).

3. Negotiation. Once a manufacturer signs the agreement, it must provide confidential drug pricing information to CMS and any other "information that [CMS] requires to carry out the negotiation." 42 U.S.C. §§ 1320f-2(a)(4), 1320f-3(b)(2)(A). CMS then makes an initial offer for the selected drug's "maximum fair price," the manufacturer must accept that offer or make a "counteroffer," and CMS must accept the counteroffer or "respond in writing" with a final offer. *Id.* § 1320f-3(b)(2). The price set through the Program must be at least 25-60% below a benchmark market-based price paid by wholesalers, and CMS must "achieve the lowest maximum fair price for each selected drug" below that ceiling. *Id.* § 1320f-3(b)-(c). "[T]here is no limit to how low [this price] can be." *NICA*, 116 F.4th at 495. The "negotiation" process ends when the manufacturer signs an addendum accepting the price set through the Program. JA295-307.

If a manufacturer attempts to "walk away" or "fail[s] to reach an agreement with [CMS]," "the consequences … are severe." *NICA*, 116 F.4th at 495, 500. Failure to disclose information requested by CMS results in daily $1 million penalties. 42 U.S.C. § 1320f-6(c). Failure to continue the negotiation or agree to a "maximum fair price" also triggers the onerous excise tax penalty discussed above,

which can be suspended only if the manufacturer withdraws its entire drug portfolio from both Medicare and Medicaid. *See* 26 U.S.C. § 5000D.

After the "negotiation period" ends, CMS publicly discloses the "maximum fair price" for each drug. 42 U.S.C. §§ 1320f(d)(2)(B) & (6), 1320f-4(a). The "negotiation period" for the first ten selected drugs ended on August 1, 2024, and CMS published the "maximum fair price[s]" for those drugs, including Jardiance®, on August 29, 2024.[3]

4. Access. On January 1, 2026, the Program requires manufacturers to begin providing Medicare beneficiaries and their providers "access" to the selected drugs at or below the "maximum fair price." *Id.* § 1320f-2(a)(3). To facilitate that access, Part D insurance plans must include each selected drug on their list of covered medicines (the plan's "formulary"). *Id.* § 1395w-104(b)(3). Together, the access and formulary requirements ensure that every Medicare beneficiary can access a manufacturer's selected drug on the Program's terms. *See id.*

Again, manufacturers face massive penalties if they do not acquiesce. Manufacturers that violate terms of the Manufacturer Agreement face daily $1 million penalties. Manufacturers that sell selected drugs through Medicare for more

[3] *See* CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026* (Aug. 29, 2024), https://perma.cc/P7QG-DZHF.

than the "maximum fair price" are liable for penalties equal to ten times the amount charged over that price. *See id.* § 1320f-6.

A selected drug remains in the Program until CMS determines that it no longer qualifies—for example, when a generic version of the drug enters the market. *See id.* §§ 1320f-1(c)(1), 1320f-2(b). The IRA directs CMS to "implement" the first three years of the Program "by program instruction or other forms of program guidance." IRA § 11001(c), 136 Stat. at 1854. CMS promulgated "Revised Guidance" in June 2023 after seeking comment on other aspects of the Program. JA97. CMS did not, however, "provide a comment period on the [Manufacturer] Agreement." JA126. Instead, CMS released a final version of the Agreement on July 3, 2023, after other manufacturers sued to enjoin the Program. The Agreement states that the manufacturer "agree[s]" to "negotiate to determine … a maximum fair price for the Selected Drug," and an addendum executed at the conclusion of the "negotiation period" represents that the manufacturer has "engaged in negotiation" and "agrees" to a "maximum fair price" for the selected drug. JA297-302. The Agreement also states that CMS "retains authority to amend this Agreement to reflect changes in law, regulation, or guidance," JA299—language that allows CMS to unilaterally alter the manufacturer's obligations (by adopting new guidance) and convert informal guidance into binding law.

II. Factual Background

Boehringer is a leader in research and development of innovative pharmaceuticals. In 2022, more than 30 million patients worldwide were prescribed drugs developed by the Boehringer family of companies (including Plaintiff-Appellant and related entities). JA87. One of those medications, Jardiance®, has multiple approved uses, including lowering blood sugar in patients with type 2 diabetes and reducing the risk of cardiovascular death in adults with type 2 diabetes or heart disease. JA87. After Boehringer invested billions of dollars and years of research and development, FDA approved Jardiance® in 2014 and subsequently approved several additional indications in the years that followed, expanding the patient population that benefits from the product. JA87.

In 2023, CMS selected Jardiance® for the Program. Boehringer was required to sign the Manufacturer Agreement by October 1, 2023, and participate in the Program to avoid the noncompliance penalties described above. *See* JA88; 42 U.S.C. §§ 1320f(d)(2), 1320f-2(a). As Boehringer explained in an undisputed declaration, paying the excise-tax penalty was not an option because it would have started at more than $500 million per week and escalated to more than $5.5 billion per week after nine months. *See* JA89; 26 U.S.C. § 5000D(d). Withdrawing all of Boehringer's drugs from Medicare and Medicaid likewise was not an option because it would have deprived Boehringer of the revenues needed to continue researching

and developing new treatments. *See* JA89-90. Boehringer markets more than 20 drugs through Medicare and Medicaid, and more than half of Boehringer's net U.S. sales come from those programs. JA87-88. Withdrawal would also leave millions of patients without coverage for the drugs they depend on, undermining one of Boehringer's core values. JA90.

With no other option, Boehringer signed the Manufacturer Agreement under protest, furnished CMS with the confidential information it demanded, participated in the "negotiation" process, and "agreed" to the "maximum fair price" for Jardiance®. In August 2024, CMS announced that "negotiation" with Boehringer yielded a maximum fair price equal to 66% of the 2023 price.[4]

III. Procedural History

Boehringer filed this lawsuit in August 2023, arguing that the Program violates its rights under the First and Fifth Amendments, the APA, and the unconstitutional conditions doctrine. JA74-83.[5]

The District Court granted the Government summary judgment on all of Boehringer's claims. The court held that the Program does not effect a taking of

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[4] *Biden-Harris Administration Announces New, Lower Prices for First Drugs Selected for Medicare Price Negotiations to Lower Costs for Millions of Americans*, (Aug. 15, 2024), https://perma.cc/8VW8-EU3Y ("Price Announcement").

[5] Boehringer also asserted an Eighth Amendment claim but does not raise that issue on appeal.

Boehringer's property, deprive Boehringer of property without due process, or compel Boehringer's speech because participation in the Program is "voluntary." In the court's view, Boehringer could "opt out of Medicare and Medicaid" before "the deadline for signing the Manufacturer Agreement" and before "the maximum fair price goes into effect in 2026." SPA14-16, 31. The court reached this conclusion notwithstanding the Program's severe economic coercion because, in its view, only "legal compulsion" could cause a constitutional violation. SPA21-22. Although Boehringer cited Supreme Court precedent holding that economically coercive programs are not exempt from constitutional scrutiny, the District Court disregarded those decisions. SPA24-29.

With the exception of the due process claim, the District Court also rejected Boehringer's claims on their merits. The court held that the Program does not effect a taking because it "do[es] not permit the government to seize [Boehringer's] property (or to provide access to it by others) if [Boehringer] refuse[s] to turn it over." SPA27. Addressing Boehringer's compelled-speech claim, the court concluded that while the Program "require[s] … communicat[ion] in various ways," it regulates drug prices with only an "incidental" effect on speech. SPA31-32. The court disagreed that signing the Manufacturer Agreement involves protected speech because the Agreement "disclaim[s]" any expression by manufacturers. SPA33. With respect to the unconstitutional conditions doctrine, the court concluded that the

doctrine does not apply to Boehringer's Fifth Amendment claims and that Boehringer's First Amendment claim fails because the Program has only an incidental effect on speech. *See* SPA35-37. Finally, the court rejected Boehringer's APA claim, holding that Congress displaced the notice-and-comment requirement by directing CMS to implement the first three years of the Program through "guidance." SPA38-43.

SUMMARY OF ARGUMENT

I.A. The Program effects a *per se* taking by granting Medicare participants access to Jardiance® products on terms Boehringer would never voluntarily accept. The Program thus appropriates Boehringer's right to exclude others from possessing its property, in violation of the principles articulated in *Horne II* and *Cedar Point Nursery v. Hassid*, 594 U.S. 139 (2021). The District Court misread *Horne II* as requiring a physical seizure of property for a *per se* taking to occur. Yet Supreme Court precedent emphasizes that appropriating property rights effects a taking regardless of how the appropriation "comes garbed." *Id.* at 149. The District Court also incorrectly cabined *Horne II* to situations where a plaintiff must acquiesce to a taking or exit the market altogether—a predicate unsupported by precedent or the facts of *Horne II*.

B. The Program violates Boehringer's due process rights because it lacks basic safeguards against the erroneous deprivation of Boehringer's property. The

Fifth Amendment guarantees a fair hearing conducted by an impartial decisionmaker, but the Program lacks those protections. CMS is the sole arbiter of the "maximum fair price" for selected drugs despite its financial interest in that price, creating an inherent conflict of interest. In addition, the IRA prohibits administrative and judicial review of CMS's action, making it impossible to correct agency errors. CMS compounded these shortcomings by issuing the Manufacturer Agreement, which creates binding legal obligations for manufacturers, without taking public comments. Contrary to the District Court's conclusion, the IRA's direction to implement the Program through "guidance" does not override the APA's notice-and-comment requirement.

C. The Program violates the First Amendment by compelling Boehringer to endorse the Government's preferred messages about the Program. The IRA requires Boehringer to engage in a faux negotiation process that masks CMS's regulatory price-setting role; to state in writing that it "negotiate[d]" and "agree[s]" to the price set through the Program; and to describe that price as the "maximum fair price" for Jardiance®. Boehringer disagrees with those statements, which distort the national debate about drug pricing and blur the lines of accountability for the Program's effects. The Program unlawfully "compels [Boehringer] to speak [the Government's] preferred messages" about a contested issue of public concern. *303 Creative LLC v. Elenis*, 600 U.S. 570, 586 (2023).

The District Court erred in concluding that the Program has only an incidental effect on speech. The Program's compelled statements are not incidental effects of price regulation because the statements are not necessary to set maximum drug prices. Congress could achieve *the exact same effect on Medicare prices* without requiring manufacturers to describe the process as a negotiation or say that the prices set through the Program are fair. The gratuitous speech mandates are unprecedented as well: No other federal price-regulation scheme requires regulated parties to vouch for the fairness of the prices set by the Government or engage in performative negotiations backed by crippling penalties for noncompliance.

II.A. The Government's primary defense is that there is no constitutional violation because participation in the Program is voluntary. But that ignores the IRA's use of economic penalties to coerce manufacturers into submitting to the Program's terms. The Supreme Court has repeatedly held that a program is involuntary—and thus subject to constitutional scrutiny—where, as here, it employs "economic coercion" to secure compliance. *Butler*, 297 U.S. at 70-71. Boehringer can avoid the Program's requirements only by incurring debilitating excise tax liabilities or withdrawing all its drugs from Medicare and Medicaid—steps that would demolish the company's ability to continue developing innovative drugs and serving patients. Thus, the theoretical opt-out mechanisms cited by the District Court are illusory and do not negate Boehringer's claims.

B. Regardless, the ability to withdraw from Medicare and Medicaid is legally irrelevant. The plaintiffs in *Horne II* entered the raisin market voluntarily, had options to avoid the taking by paying penalties or selling their grapes for other uses, and yet still prevailed. It is thus no defense to say, as the District Court did, that Boehringer could avoid the Program's appropriation of its property rights by incurring even greater losses in the form of enterprise-crippling excise tax and other penalties.

The District Court held that legal compulsion is necessary to state a takings claim, based on an incorrect application of *Garelick v. Sullivan*, 987 F.2d 913 (2d Cir. 1993). *Garelick*'s rationale predates and was subsequently rejected by the Supreme Court's decision in *Horne II*. Even if *Garelick* were still good law, it addresses a version of Medicare that no longer exists, only applies to regulatory takings claims (which are not at issue here), and is otherwise distinguishable.

C. The Government asserts that CMS acts as a mere market participant, free from First and Fifth Amendment constraints. That ignores how the Program works. CMS exercises sovereign, regulatory powers in implementing the Program, including by imposing severe penalties for noncompliance. No mere market participant wields such powers. Moreover, precedent shows that government actions in the procurement context remain subject to constitutional scrutiny. *See, e.g.*, *O'Hare Truck Serv., Inc. v. City of Northlake*, 518 U.S. 712, 721 (1996).

III. Even if the Program were voluntary, it would still violate the unconstitutional conditions doctrine. That doctrine prohibits CMS from using the threat of excluding *all of* Boehringer's drugs from Medicare and Medicaid to pressure Boehringer into surrendering its rights regarding Jardiance®. The District Court rejected Boehringer's First Amendment unconstitutional conditions argument on the ground that the Program has an incidental effect on speech, but that rationale fails for the reasons given in Part I.C. And while the District Court held that the unconstitutional conditions doctrine does not apply to Boehringer's Fifth Amendment claims, that conclusion fails to account for countervailing precedent and the staggering implications of its categorical exemption.

STANDARD OF REVIEW

This Court "review[s] de novo a district court's decision to grant summary judgment, construing the evidence in the light most favorable to the party against whom summary judgment was granted and drawing all reasonable inferences in that party's favor." *Covington Specialty Ins. Co. v. Indian Lookout Country Club, Inc.*, 62 F.4th 748, 752 (2d Cir. 2023).

ARGUMENT

I. The Medicare Drug Pricing Program Violates the Constitution and the APA.

A. The Program Effects a *Per Se* Taking of Boehringer's Rights in its Jardiance® Products.

1. The Takings Clause requires the Government to provide "just compensation" whenever it "take[s]" private property for public use. U.S. Const. amend. V. The "essential question" when evaluating a *per se* takings claim is whether the Government has "appropriat[ed]" property rights "for itself or a third party." *Cedar Point*, 594 U.S. at 148-49. The Program does just that by giving Medicare participants a right to take possession of Boehringer's Jardiance® products on the Government's terms.[6]

Horne II establishes the principle that governs this case. There, a federal law required raisin growers to "physical[ly] surrender" a portion of their crops "to the Government, free of charge." 576 U.S. at 366, 364. When the Hornes declined to comply, "[t]he Government sent trucks … to pick up the raisins," the Hornes "refused entry," and the Government imposed fines for "disobeying." *Id.* at 356. The Government never physically seized the Hornes' raisins, but the challenged law was nevertheless "a clear physical taking" because of its effect on property rights:

[6] Boehringer has asserted only a *per se* takings claim. *See* JA75-77.

The growers no longer retained their right to "control [the] disposition" of their property. *Id.* at 361-62, 364.

The Supreme Court applied the same effects-based analysis in *Cedar Point*. A California statute had granted union organizers a "right [to] access … the premises of an agricultural employer" for several days each year. 594 U.S. at 144. The statute was a *per se* taking because it "appropriate[d]" the employers' "right to exclude" by granting organizers a "right to invade the [employers'] property" on the state's terms. *Id.* at 149-50.

The Program effects a taking of Boehringer's property rights in its Jardiance® products—i.e., physical doses of the drug—under that effects-based analysis. Boehringer owns the right to exclude others from possessing its Jardiance® products, *see Cedar Point*, 594 U.S. at 149-52, and "to possess, use and dispose of" those products, *Horne II*, 576 U.S. at 361-62. The Program appropriates those rights by requiring Boehringer to grant Medicare beneficiaries and their providers "access to the maximum fair price" for Jardiance®, 42 U.S.C. § 1320f-2(a)(3), and also requiring every Part D insurance plan to include Jardiance® on its formulary, *id.* § 1395w-104(b)(3)(1). Together, those provisions give every Medicare enrollee a right to take possession of Jardiance® products on terms set by the Government.

The Program reinforces the taking by imposing massive penalties for failing to hand over Jardiance® on those terms. *See* 26 U.S.C. § 5000D (penalties for failing

to participate and agree to price set through the Program); 42 U.S.C. § 1320f-6(a) (penalties for failing to "provide access" to drug at the "maximum fair price"). The end result is a forced transfer: Boehringer must provide its property to Medicare participants on terms the company would never voluntarily accept.[7]

2. The District Court rejected Boehringer's takings claim primarily because it viewed Program participation as voluntary. SPA14-29. Because that rationale cuts across several claims, we address it separately in Part II below. This section addresses the District Court's other reasons for rejecting Boehringer's takings claim.

The District Court incorrectly limited *Horne II* to cases involving physical seizure of property. According to the court, the law at issue in *Horne II* effected a taking because "the government enforced i[t] … by physically appropriating the Hornes' raisins," whereas CMS does not physically seize Boehringer's drugs under the Program. SPA26.

That rationale fails several times over. To start, the Government did not seize any raisins in *Horne II*; it imposed penalties on growers for refusing to turn over their property. *See* 576 U.S. at 356. More generally, *per se* takings are not limited to physical seizures of property. In *Cedar Point*, California gave third parties a

[7] The Program also ensures that Boehringer will not be justly compensated by capping the "maximum fair price" well below market-based prices. *See* 42 U.S.C. § 1320f-3(c)(1).

"right to invade" land and consequently appropriated the employers' right to exclude, without seizing any property. *See* 594 U.S. at 149. Had actual seizure mattered, the Supreme Court would not have clarified that a *per se* taking can occur no matter how it "comes garbed." *Id.* Other cases confirm that appropriating property rights can cause a *per se* taking without physical seizure. *See, e.g.*, *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 440 (1982); *Nollan v. Cal. Coastal Comm'n*, 483 U.S. 825, 828 (1987); *FCC v. Fla. Power Corp.*, 480 U.S. 245, 251-52 & n.6 (1987).

The District Court also distinguished *Horne II* by characterizing the Program as adversely affecting Boehringer only when it "chooses to sell" Jardiance®. SPA26. But that misunderstands the way the Program works. Unlike laws that "regulat[e]" the "voluntary decision … to [sell] property," SPA26 n.11, the IRA allows Medicare enrollees to demand access to, and take possession of, Jardiance® products—and it coerces Boehringer into acceding to those demands. While perhaps garbed differently, this compelled "transfer of property … to another private party" is the same type of "classic taking" present in *Horne II*. *Stop the Beach Renourishment, Inc. v. Fla. Dep't of Env't Prot.*, 560 U.S. 702, 713 (2010).

It was equally inaccurate for the District Court to write off *Horne II* on the theory that the growers "were barred from the entire market for raisins if they did not comply with the reserve requirement," whereas Boehringer can withdraw from

Medicare and Medicaid and continue to sell Jardiance® in the private market. SPA24. The theoretical possibility of withdrawing from Medicare and Medicaid is illusory, as discussed in Part II.A below. Regardless, the growers had options to sell their grapes to other buyers "as table grapes or for use in juice or wine," *see Horne II*, 576 U.S. at 365, just as Boehringer could sell Jardiance® products to non-Medicare patients. *Horne II* rejected this "[l]et them sell wine" defense as "wrong as a matter of law," *id.*, and the same is true of the District Court's rationale here.

B. The Program Deprives Boehringer of Procedural Protections Required by the Due Process Clause and the APA.

1. The Program Violates the Due Process Clause.

"The fundamental requirement of due process is the opportunity to be heard 'at a meaningful time and in a meaningful manner,'" *Mathews v. Eldridge*, 424 U.S. 319, 333 (1976) (cleaned up), by a "neutral and detached" decisionmaker, *Concrete Pipe & Prods. of Cal., Inc. v. Constr. Laborers Pension Tr. for S. Cal.*, 508 U.S. 602, 617-18 (1993). The IRA violates that requirement by charging CMS—which has an economic stake in the outcome of the negotiation—with carrying out the Program, insulating CMS's actions from administrative and judicial review, and failing to provide ascertainable standards for CMS to follow when setting the "maximum fair price." These omissions "create a substantial risk of erroneous deprivation" of Boehringer's property interests. *NICA*, 116 F.4th at 503.

Apart from arguing that the Program does not deprive Boehringer of property, neither the District Court nor the Government below defended the Program's lack of procedural safeguards. To Boehringer's knowledge, no court has ever upheld a pricing scheme that deprives regulated parties of core procedural safeguards as the Program does here.

i. The Program has deprived (or will deprive) Boehringer of three constitutionally protected property interests.

First, as explained in Part I.A, Boehringer has a cognizable interest in physical doses of Jardiance®, including the rights to control the disposition of these drugs and exclude others from possessing them. The Program overrides those rights by granting third parties the right to access Jardiance® products over Boehringer's objection. *See* 42 U.S.C. § 1320f-2(a).

Second, Boehringer has a property interest in deciding "the price at which [it] will sell" its Jardiance® products. *Old Dearborn Distrib. Co. v. Seagram-Distillers Corp.*, 299 U.S. 183, 192 (1936). Courts have long analyzed price-control regimes through the lens of procedural due process, even where no one is compelled to engage in a sale. *See Bowles v. Willingham*, 321 U.S. 503, 517 (1944); *Yakus v. United States*, 321 U.S. 414, 438 (1944). Consistent with this approach, the Fifth Circuit has recognized that the Program implicates protected property interests by causing a "revenue decrease as a result of allegedly unconstitutional government

action." *NICA*, 116 F.4th at 503. By imposing an artificially reduced price for Jardiance®, the Program deprives Boehringer of this right.

Third, Boehringer has a property interest in its confidential data regarding Jardiance®. The IRA requires Boehringer to provide any "information that [CMS] requires to carry out the negotiation," 42 U.S.C. § 1320f-2(a)(4), and CMS has demanded this information, including how much Boehringer has spent researching and developing Jardiance®, the extent to which it has recouped those costs, and unit costs for production and distribution of the drug. *See* JA228, 283-93. Because these confidential data are valuable to Boehringer and would be valuable to its competitors, they are protected under trade-secrets laws[8] and the Fifth Amendment. *See Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1001-03 (1984); *see also* JA90-91. By requiring Boehringer to disclose trade secrets that CMS can use to undermine Boehringer's interests in the negotiation process, the Program deprives Boehringer of this property as well.

ii. The Program's procedures are constitutionally inadequate. When Congress authorizes agencies to set prices, it has a constitutional obligation to ensure that the resulting prices are not arbitrary, confiscatory, or unduly discriminatory. The Program shirks that obligation by adopting a one-sided scheme that places no

[8] *See, e.g.*, Conn. Gen. Stat. Ann. §§ 35-50 *et seq.*; 18 U.S.C. § 1836.

meaningful external constraints on CMS. Indeed, the Program provides even fewer safeguards than emergency wartime price-control regimes that represent the low-water mark for due process protections. *See Bowles*, 321 U.S. 503; *Yakus*, 321 U.S. 414. Four features of the Program demonstrate that it violates Boehringer's due process rights.

First, CMS is not an impartial decisionmaker. It sets the "maximum fair price[s]" under the Program despite having a financial interest in reducing those prices. "Due process requires a[n] … impartial tribunal," no matter the "form of proceeding." *Peters v. Kiff*, 407 U.S. 493, 501 (1972); *see also Concrete Pipe*, 508 U.S. at 617; *Heldman ex rel. T.H. v. Sobol*, 962 F.2d 148, 154 (2d Cir. 1992). Adjudication conducted by a decisionmaker with a "pecuniary interest in the outcome" thus violates due process. *Tumey v. Ohio*, 273 U.S. 510, 535 (1927). Here, the "negotiation" is irrevocably tainted because CMS determines the "maximum fair price" for selected drugs while also making payments to Part D insurance plans based on that "maximum fair price." The IRA compounds the problem by directing CMS to pursue "*the lowest* maximum fair price for each selected drug." 42 U.S.C. § 1320f-3(b)(1) (emphasis added).

Second, the IRA bars administrative and judicial review of CMS's "maximum fair price" determination, as well as other key CMS actions. *Id.* § 1320f-7(3). As a result, those actions are not subject to any review by an impartial decisionmaker.

Yet there must be "an opportunity … for judicial review which satisfies the demands of due process." *Yakus*, 321 U.S. at 444; *Bowles*, 321 U.S. at 521 ("provid[ing] for judicial review after the regulations or orders have been made effective" satisfies due process). The inability to seek review on "the back end" of the proceeding creates "a substantial risk" that Boehringer will be "erroneously depriv[ed]" of its property rights. *NICA*, 116 F.4th at 503.[9]

Third, the negotiation process denies Boehringer an opportunity to respond to the evidence on which CMS relies in setting the "maximum fair price." Due process requires the Government to provide regulated parties with access to the evidence against them and an "opportunity to meet it." *Mathews*, 424 U.S. at 348 (cleaned up); *see Townley v. Hecker*, 748 F.2d 109, 114 (2d Cir. 1984). But the IRA does not require CMS to disclose the evidence on which it relies; instead, CMS need only state a "concise justification" for its initial offer. 42 U.S.C. §§ 1320f-3(b)(2)(B), 1320f-4(a)(2)(B). That superficial approach falls short of the constitutional

[9] This lack of review further distinguishes the Program from other federal drug programs. *See, e.g.*, *Coal. for Common Sense in Gov't Procurement v. Sec'y of Veterans Affs.*, 464 F.3d 1306, 1316 (Fed. Cir. 2006) (recognizing "jurisdiction under [38 U.S.C. § 502] to review substantive and interpretative rules" implementing the TRICARE pharmacy benefits program).

minimum. *See Ohio Bell Tel. Co. v. Pub. Utils. Comm'n*, 301 U.S. 292, 300-02 (1937).[10]

Fourth, the IRA does not provide ascertainable standards to guide CMS in setting the "maximum fair price." Protection "against arbitrary action" is the "touchstone of due process." *Wolff v. McDonnell*, 418 U.S. 539, 558 (1974). Government action therefore must be limited by "ascertainable standards" to avoid vesting agencies with "absolute and uncontrolled discretion" and "invit[ing] … abuse." *Holmes v. N.Y.C. Hous. Auth.*, 398 F.2d 262, 265 (2d Cir. 1968). In other words, "the standards prescribed by the" IRA must be "adequate" to meaningfully evaluate CMS's decisionmaking. *Bowles*, 321 U.S. at 516. Government action unconstrained by such limiting principles offends not only due process, but also the constitutional separation of powers. *See Holmes*, 398 F.2d at 264-65; *accord McClendon v. Rosetti*, 460 F.2d 111, 115-16 (2d Cir. 1972).

Although the IRA lists "factors" that CMS "shall consider," 42 U.S.C. § 1320f-3(e), "there are no criteria for how to weigh these considerations," nor any means to ensure that CMS has, in fact, weighed them, *NICA*, 116 F.4th at 495. Moreover, the IRA defines "maximum fair price" as any price established following

[10] CMS must eventually provide an "explanation for the maximum fair price," but not until months after the "negotiation period" concludes. 42 U.S.C. §§ 1320f-3(b)(2)(E), 1320f-4(a)(2).

the faux negotiations—there is no requirement that the price be supported by evidence or provide constitutionally adequate (i.e., non-confiscatory) compensation. *See* 42 U.S.C. § 1320f(c)(3). Nothing in the statute curbs CMS's ability to choose a price "at whatever levels [it] pleases." *Bowles*, 321 U.S. at 514. Indeed, while the IRA prescribes a ceiling on the "maximum fair price," 42 U.S.C. § 1320f-3(c), it imposes no floor. The IRA thus fails not only to adequately cabin CMS's discretion, but also to prevent the agency from setting prices at levels so low as to transgress "constitutional limitations." *In re Permian Basin Area Rate Cases*, 390 U.S. 747, 769 (1968).

The end result is that there is no mechanism to ensure that CMS implements the Program in a way that comports with the statutory requirements enacted by Congress. No court has ever upheld a price-regulation scheme that goes to such great lengths in dispensing with procedural safeguards for private rights, and this Court should not take that extraordinary step.

2. CMS Violated the APA's Notice-and-Comment Requirement in Issuing the Manufacturer Agreement.

CMS compounded these deficiencies by violating the APA. On July 3, 2023, CMS issued a one-size-fits-all Manufacturer Agreement, stating that the document was "the final text" and that the agency would not "provid[e] a comment period." JA126. The APA requires "legislative rule[s]" that "impos[e] legally binding obligations … on regulated parties—and that would be the basis for an enforcement

action for violations of those obligations or requirements"—to follow notice-and-comment procedures. *Nat'l Mining Ass'n v. McCarthy*, 758 F.3d 243, 251 (D.C. Cir. 2014); *see also White v. Shalala*, 7 F.3d 296, 303 (2d Cir. 1993). The Manufacturer Agreement is a legislative rule because it alters manufacturers' rights and imposes enforceable legal obligations on them, including a duty to "comply with requirements determined by CMS to be necessary for purposes of administering the" Program and to follow all future CMS guidance (effectively transforming that guidance into binding law). JA296-99.[11] CMS therefore violated the APA by issuing the Manufacturer Agreement without observing notice-and-comment procedures.

The District Court held that the IRA displaces notice-and-comment procedures because section 11001(c) directs CMS to "implement" the Program during its first three years "by program instruction or other forms of program guidance." SPA40-43. That is incorrect for two reasons.

First, the Agreement does not fall within the scope of section 11001(c). The IRA distinguishes between the Agreement and "program instruction[s] or other forms of program guidance." *See, e.g.*, 42 U.S.C. §§ 1320f-2 (imposing specific

[11] The contractual nature of the Manufacturer Agreement does not alter the analysis, as the District Court correctly acknowledged. *See Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1053-54 (D.C. Cir. 1987); SPA39.

requirements for manufacturer agreements), 1320f-6(c) (imposing civil monetary penalties for "[v]iolations of certain terms of [the] agreement," but not the guidance or program instructions). And as a matter of plain language, a legally binding agreement backed by penalties cannot be described as "guidance" or "program instruction." Moreover, the Agreement was issued separately from and goes beyond what CMS labeled as "guidance." *Compare* JA96, *with* JA295. The District Court disregarded these distinctions.

Second, even if the Agreement were "guidance" or "program instruction," section 11001(c) lacks the elements necessary to displace the notice-and-comment requirement. Congress may exempt agency action from that requirement only through "a specific directive to adopt procedures other than those of the APA." *Asiana Airlines v. FAA*, 134 F.3d 393, 397 (D.C. Cir. 1998). Such displacement "must be express" to make "clear" that Congress made "a substantive change." *Id.* Unlike other Medicare statutes, the IRA does not contain express language disclaiming the APA's applicability.[12] Although the District Court thought the IRA's reference to "guidance" "contemplat[ed]" a different process, SPA40, mere "contemplat[ion]" is not enough to expressly displace the APA. *See Asiana Airlines*,

[12] *See, e.g.*, 42 U.S.C. § 1320a-7c(a)(6)(J) ("*Notwithstanding any other provision of law*, the Secretary may implement the partnership established by subparagraph (A) by program instruction or otherwise." (emphasis added)); *id.* §§ 1395cc-7(c), 1395m(u)(7)(G), 1395w-4(k)(2)(A), 1395-3a(c)(5)(C) (similar).

134 F.3d at 397; 5 U.S.C. § 559 (statute cannot "modify this subchapter … except to the extent that it does so expressly"). Nor does a reference to "guidance" clearly denote replacement procedures, especially where agency action labeled as "guidance" can still trigger the APA's notice-and-comment requirement. *See Azar v. Allina Health Servs.*, 587 U.S. 566, 575 (2019).

CMS's disregard of the notice-and-comment requirement is particularly problematic because the Manufacturer Agreement further undermines Boehringer's due process rights. For example, the Agreement purports to allow CMS to unilaterally amend the document's terms, even after it is executed. *See* JA299 (requiring signatories to comply with future CMS guidance). Boehringer would have urged CMS to omit these provisions, which would render ordinary commercial contracts illusory, *see, e.g.*, *Morrison v. Amway Corp.*, 517 F.3d 248, 257-58 (5th Cir. 2008), had the agency taken public comment.

C. The Program Violates the First Amendment by Compelling Boehringer to Endorse the Government's Characterization of the Program.

The Program compels Boehringer not only to turn over its property for a fraction of its market value, but also to state in writing *that it negotiated and agrees with those terms*. That violates Boehringer's "right to refrain from speaking," *Janus v. Am. Fed'n of State, Cnty. & Mun. Emps. Council 31*, 585 U.S. 878, 892 (2018), by forcing the company to endorse the Government's preferred messages about the

Program. Indeed, by requiring Boehringer to attest that the price set through the Program is the "maximum fair price" for Jardiance®, the IRA forces Boehringer to attest that the market prices it has charged in the past (and continues to charge in private markets) are unfair.

1. The Program Unlawfully Compels Speech on a Matter of Public Concern.

"[T]he First Amendment protects the right to decide what to say and what not to say." *Burns v. Martuscello*, 890 F.3d 77, 84 (2d Cir. 2018) (cleaned up). That rule prohibits the Government from manipulating the marketplace of ideas by "compel[ing] a person to speak its own preferred messages." *Elenis*, 600 U.S. at 586. Laws "that requir[e] the utterance of a particular message favored by the Government contraven[e]" the First Amendment because they "pose the inherent risk that the Government seeks not to advance a legitimate regulatory goal, but to … manipulate the public debate through coercion rather than persuasion." *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 641 (1994). The right not to speak applies with special force to laws that, like the IRA, "require [individuals] to make statements [they] believ[e] are false," *Jackler v. Byrne*, 658 F.3d 225, 241 (2d. Cir. 2011), and "compe[l]" regulated parties to carry the Government's message "on matters of substantial public concern," *Janus*, 585 U.S. at 884.

Given the importance of this right, speech mandates are subject to "the most exacting scrutiny." *Turner*, 512 U.S. at 642. Particularly for issues of public concern

such as drug pricing, speech mandates are permissible only if they are a "narrowly tailored means of serving a compelling [governmental] interest." *Pac. Gas & Elec. Co. v. Pub. Utils. Comm'n*, 475 U.S. 1, 17, 19 (1986) (plurality opinion) (*PG&E*). Below, the Government did not contend that the Program satisfies that demanding test, forfeiting the argument on appeal. Boehringer's claim thus rises or falls on a single issue: Does the First Amendment apply at all?

The answer is "yes." The First Amendment applies because the IRA compels Boehringer to make expressive statements that advance the Government's preferred messages regarding the Program. The statements, in other words, enlist Boehringer in a public-relations campaign in support of the Program.

By statute, Boehringer was required to sign the Manufacturer Agreement by October 1, 2023, or pay crippling excise tax penalties. *See* 26 U.S.C. § 5000D; 42 U.S.C. § 1320f(d)(2).[13] The statute further required Boehringer to state that it "agree[d]" to the Program's terms and would participate in "negotiations" with CMS regarding a "maximum fair price." 42 U.S.C. §§ 1320f-2(a)(1), 1320f-3(b); JA78. Boehringer was then required to sign an addendum by August 1, 2024, to avoid the

[13] These penalties, along with the other adverse consequences of failing to sign the Manufacturer Agreement, establish that the statements are compelled speech for First Amendment purposes. *See infra* pp. 54-55.

same penalties—this time attesting that Boehringer "agreed" to a "maximum fair price" following a period of "negotiations" with CMS. JA302-04.

Boehringer signed both documents under protest, reserving the rights asserted in this litigation. Yet by affixing its signatures, Boehringer was forced to endorse the Government's preferred framing of the Program as involving a negotiation to establish a fair price for Jardiance® products.

Boehringer does not agree that the Program involves "negotiation[s]." *See, e.g.*, 42 U.S.C. § 1320f-2; JA90. In a genuine negotiation, each party can accept or reject the other side's terms—and can walk away if there is no agreement. *See NICA*, 116 F.4th at 500. That element is absent here. While the Program may superficially resemble a negotiation, the "severe" consequences for manufacturers that do not reach "agreement" effectively ensure that manufacturers cannot walk away. *Id.*

Boehringer also disagrees that the prices set through the Program are "fair," much less the "maximum fair price[s]." Under the Constitution and as a matter of common usage, the fair price for a product is its "market value." *Horne II*, 576 U.S. at 369 (citation omitted). But the IRA requires prices set through the Program to be at least 25-60% below the market-based rate paid by wholesalers, and CMS must go as far below that ceiling as possible. 42 U.S.C. § 1320f-3(b)(1), (c). Further, the statute artificially constrains the data that CMS and the manufacturer may consider during the negotiation, omitting from the list of relevant factors the market value of

the drug and the manufacturer's research and development costs for other drugs—including many of the 99.98% of candidates that never reach the market. *See id.* § 1320f-3(b)(2)(B), (b)(2)(C)(ii)(II), (e); JA55.

Nor did Boehringer "agree" to participate in the Program—it was coerced into doing so. As noted above, Boehringer signed the Manufacturer Agreement under protest, and only as a means of avoiding even larger penalties. *See* JA90. Boehringer is thus situated similarly to the plaintiff in *Agency for International Development v. Alliance for Open Society International, Inc.*, 570 U.S. 205, 210 (2013) (*USAID*), which had to "agree" to objectionable views in an "award document" to avoid losing federal grant funds.

Signing the Manufacturer Agreement and participating in the negotiations falsely conveys that Boehringer "manifest[s] [its] assent" to each of these messages. *Thomas James Assocs., Inc. v. Jameson*, 102 F.3d 60, 65 n.2 (2d Cir. 1996); *see also John Doe No. 1 v. Reed*, 561 U.S. 186, 194-95 (2010) (signing a petition expresses views and thus implicates First Amendment rights); *USAID*, 570 U.S. at 214-21 (assessing whether contract with federal agency complied with First Amendment). By compelling Boehringer's speech, the IRA "vitiat[es]" Boehringer's right to decide which messages it will and will not speak. *Burns*, 890 F.3d at 84.

2. The District Court Erred in Holding that the Program Only Incidentally Affects Speech.

The District Court described the Program as a "typical price regulation" that regulates conduct and has only an "incidenta[l] burden" on Boehringer's speech. SPA30-31 (citation omitted).[14]

i. That conclusion rests on a faulty understanding of the statements compelled by the Program. Those statements are not "just an incidental means to CMS' goal of regulating drug prices" and are not limited to "regulat[ing] the price [Boehringer] may charge." SPA31-32 & n.16. Other price-setting programs involve a straightforward exercise in which an agency considers relevant data and sets a price—e.g., through rulemaking. The Program works in a fundamentally different way by prescribing not only how much Boehringer may charge, but also *what Boehringer must say* about that price.

Illustrating that point, Congress could have achieved the same effect on drug prices without requiring Boehringer to make subjective statements about the prices or the underlying procedure. For example, Congress could have authorized CMS to set prices directly, without requiring manufacturers to call them the "maximum fair price" or forcing manufacturers to say that the prices were agreed to through

[14] The District Court also found no First Amendment violation because "participation in the Program is voluntary." SPA31. That rationale fails for the reasons discussed in Part II below.

negotiation. The Program's negotiation framework has the same fiscal effect as direct price regulation, but it is politically quite different because there is broad public support for negotiating Medicare drug prices but also widespread opposition to top-down government price-setting.[15] The Program's compelled statements serve no purpose other than to influence that debate.

The compelled statements also distinguish the Program from other federal price-regulation schemes. For example, the Federal Energy Regulatory Commission "determine[s] the just and reasonable rate" for natural gas, 15 U.S.C. § 717d(a), and the Surface Transportation Board "prescribe[s] the maximum rate" a rail carrier may charge to transport cargo, 49 U.S.C. § 10704(a)(1). Neither of those programs—or countless others that employ a similar framework—compel regulated parties to characterize the process as a negotiation or say that the resulting price is fair. The agency thus bears clear responsibility for the price caps and their effects. In contrast, the IRA blurs the lines of accountability by compelling manufacturers to take partial ownership for the Program's consequences. The Program is, in short, meaningfully different from the "typical price regulations" cited by the District Court. SPA31.

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[15] *Compare* Morning Consult, National Tracking Poll #2109099, at 13 (Sept. 16-19, 2021), https://perma.cc/9XCL-JECJ (American public supports "allowing the federal government to directly negotiate with drug companies to get a lower price on medications"), *with id.* at 17 (less than half of Americans support "effectively allowing the federal government to set the prices of drugs").

The Government recently acknowledged as much in related litigation, stating that it could not identify any other federal price-regulation program that compels private parties to describe the prices as "fair."[16]

The Program stands apart from other pricing programs for another reason: It compels speech on drug pricing, a widely debated "issue of public concern." *USAID*, 570 U.S. at 218. The President and other senior officials have invoked the Program's negotiation theme in connection with that debate. For example, the President remarked in his 2024 State of the Union Address that the Program "giv[es] Medicare the power to negotiate drug prices" and puts an end to "exorbitant prices."[17] After manufacturers of all ten drugs selected for the Program's first year signed the Manufacturer Agreement, the White House proclaimed that Boehringer and the other companies had "com[e] to the negotiating table."[18] "[T]ypical price

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[16] Oral Arg. 1:07:07-1:08:48, *AstraZeneca Pharms., LP v Becerra*, No. 24-1819 (3d Cir. Oct. 30, 2024), https://www2.ca3.uscourts.gov/oralargument/audio/24-1819-1820-1821_Astazeneca-BristolMyers-Janssenv.SecretaryUSDeptHHS.mp3.

[17] State of the Union Address (Feb. 7, 2023), https://perma.cc/9MXK-WRS7. Other officials have disagreed with those views. During debate on the IRA, one Senator argued against the Program's "system of bureaucratic drug price controls" because it involves "negotiation in name only" and makes manufacturers "an offer [they] can't refuse." 168 Cong. Rec. S4155-56 (Aug. 6, 2022) (remarks of Sen. Crapo).

[18] 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/96N9-7ZS3.

regulations," SPA31, do not contribute to national debates or feature prominently in the State of the Union Address.

The statements quoted above (and scores of others like them[19]) reveal, and indeed rely upon, the expressive nature of the Program's compelled speech. One can credibly assert that manufacturers have "come to the negotiating table" and that "Medicare will no longer have to pay … exorbitant prices" only because manufacturers have signed agreements to negotiate and agreed to new, below-market "maximum fair prices."

ii. The District Court also misapplied *Rumsfeld v. FAIR*, 547 U.S. 47, 62 (2006), and *Expressions Hair Design v. Schneiderman*, 581 U.S. 37, 47 (2017). *Rumsfeld* recognized that conduct regulations that have a "plainly incidental" effect on speech do not offend the First Amendment. 547 U.S. at 62. The Court thus held that a law requiring universities to provide military recruiters the same access as "other recruiters" and "sen[d] scheduling e-mails" for meetings with military recruiters was permissible, in large part because it "did not dictate the content of the speech at all." *Id.*; *cf. Sorrell v. IMS Health Inc.*, 564 U.S. 552, 567 (2011) ("ordinance against outdoor fires [that] might forbid burning a flag" would only incidentally affect speech). The IRA, in contrast, dictates the content of

[19] *See, e.g.*, Price Announcement, *supra* n.4 (characterizing manufacturers as having "agreed to negotiated prices").

Boehringer's speech and goes much further than requiring the company to provide Jardiance® at the price established through the Program.

The provisions challenged here are strikingly similar to those at issue in *Expressions Hair Design*. There, the law prohibited businesses that use a "single sticker price" from displaying a surcharge price for customers who pay using a credit card. 581 U.S. at 41, 47. Unlike a "typical price regulation," which "would simply regulate the amount that a store could collect," the New York law "regulate[d] how sellers may *communicate* their prices." *Id.* at 47 (emphasis added). The fact that the law concerned prices did not insulate it from First Amendment scrutiny because it "regulat[ed] the communication of prices rather than prices themselves." *Id.* at 48.

So too here. The compelled statements Boehringer challenges regulate how it communicates *about* the prices set through the Program—Boehringer must make normative statements that it negotiated with CMS and agreed to a maximum fair price for Jardiance®. None of those statements affects the "prices themselves." *Id.* If the IRA had required Boehringer to sign a document merely agreeing to comply with a price set by CMS—as Congress has done in other contexts, *see, e.g.*, 38 U.S.C. § 8126(a)(2) (pharmaceutical procurement contracts with Department of Veterans Affairs)—*Rumsfeld* might apply. But because Congress went further than that, *Expressions Hair Design* controls and the Government's "incidental effect" defense fails.

3. The Program Violates the First Amendment by Compelling Boehringer to Engage in Expressive Conduct.

In addition to compelling *speech*, the Program unconstitutionally compels the company to engage in expressive *conduct*.

CMS's selection of Jardiance® triggered an obligation for Boehringer to participate in the Program's negotiation process. 42 U.S.C. §§ 1320f-2(a), 1320f-3(b). That process involves elements designed to make the Program resemble a genuine negotiation, including an exchange of offers. *Id.* § 1320f-3(b)(2)(A)-(E). Together, these procedures required Boehringer to engage in expressive conduct that advances the Government's messages regarding the Program. *See Texas v. Johnson*, 491 U.S. 397, 404-05 (1989) (courts evaluate expressive conduct in "the context in which it occurred," including "the likelihood … that the message would be understood by those who viewed it").

The District Court rejected that claim, holding that Boehringer's Program participation is not sufficiently expressive for three reasons, all faulty.

First, the District Court asserted that Boehringer's conduct is not expressive because the Manufacturer Agreement incorporates terms defined in the IRA. SPA33. But that reinforces Boehringer's argument: The statutory language implemented through the Manufacturer Agreement requires Boehringer to convey that the Program involves genuine negotiation. The actions Boehringer had to take in conducting those negotiations, such as making a counteroffer, *see* 42 U.S.C.

§ 1320f-3(b)(2)(C), support that message. Moreover, simply using defined statutory terms cannot shield compelled speech from constitutional scrutiny. *See Nat'l Ass'n of Mfrs. v. SEC*, 800 F.3d 518, 530 (D.C. Cir. 2015).

Second, the District Court misapplied the *Johnson* test, under which conduct "fall[s] within the scope of the [First Amendment]" if it is "sufficiently imbued with elements of communication." 491 U.S. at 404. Contrary to the District Court's conclusion, the Program *does* "forc[e]" Boehringer to "convey a particularized message" through its participation. SPA33. As described above, the actions Boehringer had to take as part of the "negotiation process," 42 U.S.C. § 1320f-3(b)(2), conveyed—indeed, were *designed* to convey—that Boehringer agrees with and bears partial responsibility for the price set through the Program.

Contrary to the District Court's assertion, that expression is far more than a mere "kernel." SPA33. The fact that the President and other officials continue to cite Boehringer's participation to support their messages about CMS's "power to negotiate drug prices" and bring manufacturers "to the negotiating table"[20] underscores the communicative effect of that participation. This sustained, prominent attention to the implications of manufacturers' participation belies the

[20] *See supra* nn.17-18.

District Court's attempt to analogize the Program's compelled expressive conduct to "walking down the street." SPA33.

Third, the District Court held that the disclaimer in the Manufacturer Agreement negated any message Boehringer's participation might have expressed. SPA31, 32 n.16, 33. The Manufacturer Agreement contains a clause, drafted unilaterally by CMS, stating that "[u]se of the term 'maximum fair price' and other statutory terms throughout [the] 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 meeting of those terms." JA299. That language is no defense: It is blackletter law that disclaimers cannot negate a compelled-speech injury. *See PG&E*, 475 U.S. at 15 n.11. Were the rule otherwise, the Government could "infringe on anyone's First Amendment interest at will, so long as the mechanism of such infringement allows the speaker to issue a general disclaimer." *Circle Sch. v. Pappert*, 381 F.3d 172, 182 (3d Cir. 2004). That rule reinforces the broader principle that the Government cannot "require speakers to affirm in one breath that which they deny in the next." *PG&E*, 475 U.S. at 16; *see also USAID*, 570 U.S. at 220-21 (counter-speech allows regulated parties to "express [contrary] beliefs only at the price of evident hypocrisy").

II. The District Court Erroneously Rejected Boehringer's Constitutional Claims on the Theory that the Program Is Voluntary.

The Government has argued that the Program is immunized from constitutional challenge because manufacturers like Boehringer can avoid participating in the Program by "opt[ing] out of Medicare and Medicaid," and CMS "has broad leeway to impose conditions" when acting as a market participant. The District Court accepted these arguments, holding that the Program cannot violate Boehringer's rights because it is voluntary. *See* SPA21-30. That conclusion is incorrect for three reasons: (1) participation in the Program is coerced, not voluntary; (2) the theoretical ability to withdraw Boehringer's entire drug portfolio from Medicare and Medicaid is legally irrelevant; and (3) CMS implements the IRA in its sovereign, regulatory capacity.

A. Boehringer's Participation Is Coerced, Not Voluntary.

When the Government coerces participation in a federal program, that participation is not voluntary. The Supreme Court has long rejected government attempts to "impose an unconstitutional burde[n]" on private parties "by threat of [even greater] penalties" and then "declare the acceptance [of those burdens] voluntary." *Union Pac. R.R. Co. v. Pub. Serv. Comm'n*, 248 U.S. 67, 70 (1918). In *Butler*, the Government argued that "voluntary co-operation" made its cotton program "constitutionally sound" even if "compulsory," but the Supreme Court disagreed: By employing "coercion by economic pressure[, t]he asserted power of

choice [was] illusory," making the program "not in fact voluntary." 297 U.S. at 70-71; *see also Carter v. Carter Coal Co.*, 298 U.S. 238, 289 (1936) (program threatened substantial penalties "to compel compliance," such that "yielding to compulsion" to avoid the penalties "lack[ed] the essential element of consent").

The Supreme Court applied this longstanding anti-coercion principle in *National Federation of Independent Businesses v. Sebelius*, 567 U.S. 519 (2012) (*NFIB*). There, states had the "choice" to accept onerous new Medicaid requirements or lose federal funding comprising 10% of their budgets. *Id.* at 588. But that "economic dragooning" left states "with no real option but to acquiesce." *Id.* By threatening to revoke *all* of a noncompliant state's existing Medicaid funding, Congress failed to provide a "genuine choice" and impermissibly coerced compliance. *Id.* at 581-88.

The IRA is similarly coercive, making any "choice" to avoid the Program illusory. According to the Government, Boehringer could (1) refuse to sign the Manufacturer Agreement and pay an enormous excise tax penalty; (2) divest its interest in Jardiance®; or (3) withdraw all its products from all parts of Medicare and Medicaid. *See* SPA14.[21] However, the undisputed record shows that Boehringer has "no real option" but to participate in the Program. *NFIB*, 567 U.S. at 582.

[21] During the proceedings below, the Government raised a fourth option: stop selling Jardiance® to Medicare beneficiaries, while continuing to market all of Boehringer's

If Boehringer had "opted" to pay the excise tax penalty, it would have paid hundreds of millions of dollars per week initially, and billions per week after a few months. *See* JA89. Given these enormous amounts, it is no surprise that the Congressional Budget Office estimated that the tax would generate "*no* revenue" because "no manufacturer could afford to pay it." *NICA*, 116 F.4th at 495.

Had Boehringer divested Jardiance® entirely, it would have lost all rights to this life-saving drug. The District Court made clear why this option is legally irrelevant: "The government cannot evade a Fifth Amendment challenge by requiring manufacturers to choose between losing any property rights they have through Government appropriation and losing them through divestment." SPA19.

Had Boehringer withdrawn all of its drugs from Medicare and Medicaid, the company would have lost more than half its U.S. net sales, and more than one million patients would have lost coverage for more than 20 Boehringer drugs. *See* JA87-88, 89-90. That harm far exceeds the threatened 10% budget cut that constituted "economic dragooning" in *NFIB*. 567 U.S. at 582. This purported option takes advantage of "basic economic rationality": For a diversified manufacturer like

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other drugs through Medicare and Medicaid. *See* SPA14, 20. The District Court observed that this purported option "may only exist in theory." SPA20 n.10. In fact, it does not exist at all because it would render superfluous Congress's decision to suspend the excise tax only if a manufacturer withdraws its *entire* portfolio from Medicare and Medicaid. *See* 26 U.S.C. § 5000D(c).

Boehringer, acquiescing to CMS's demands for one drug will always be "preferable to losing the Medicare [and Medicaid] market for all of its drugs." *NICA*, 116 F.4th at 500.

In short, the IRA makes it "all but certain" that manufacturers will "adopt the price that [CMS] offers" by making the cost of not participating in the Program far more "severe" than the cost of participation. *Id.*

The District Court discounted *NFIB*'s significance because that case involved federalism concerns. *See NFIB*, 567 U.S. at 576-78. Yet *NFIB* applied a broader coercion principle that protects private parties, not just states—as illustrated by *Union Pacific*, *Carter*, and *Butler*.[22] *Butler*, for example, held that a program coerced private cotton growers when it sought to "indirectly accomplish" unlawful "ends by taxing and spending to purchase compliance." 297 U.S. at 64-65, 74-75. And at least one court has applied *NFIB*'s "basic point" in the private-party context, holding that CMS could not coerce nursing homes to forgo arbitration agreements by "threatening to withdraw Medicare and Medicaid funding entirely from any facility that continues to use arbitration." *Am. Health Care Ass'n v. Burwell*, 217 F. Supp. 3d 921, 929 (N.D. Miss. 2016).

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[22] The District Court "question[ed] whether [these cases] remain good law." SPA29 n.14. But unless and until the Supreme Court overrules them—which has not happened—they are "binding" precedent that lower courts "lac[k] authority to disregard." *Vasquez v. Garland*, 80 F.4th 422, 436 (2d Cir. 2023).

B. Boehringer's Theoretical Ability to Withdraw from Medicare and Medicaid Is Legally Irrelevant.

The District Court dismissed the evidence of coercion, relying on *Garelick v. Sullivan*, 987 F.2d 913 (2d Cir. 1993), to conclude that Boehringer's option to withdraw from Medicare and Medicaid makes the Program voluntary. *See* SPA21. Not only is *Garelick* inapposite, but the Supreme Court has rejected its reasoning in the takings context, and it does not apply in the due process or free speech contexts.

1. *Garelick* involved anesthesiologists who voluntarily participated in Medicare but argued that statutory limits on the amounts they could bill to patients effected a regulatory taking. *See* 987 F.2d at 916. As a regulatory takings case, *Garelick* is not "controlling precedent" for Boehringer's *per se* takings claim. *Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg'l Plan. Agency*, 535 U.S. 302, 323 (2002). *Garelick* also did not involve allegations that the plaintiffs were coerced into participating in Medicare, nor were there coercive mechanisms similar to those employed by the Program here (e.g., devastating noncompliance penalties). At most, the plaintiffs argued that not participating in Medicare would create "economic hardship," 987 F.2d at 917, but they did not argue that economic pressures were so high as to make their "power of choice" "illusory," *see Butler*, 297 U.S. at 70-71; *see also NICA*, 116 F.4th at 500. *Garelick* thus had no occasion to reach the issues presented here.

Nor did *Garelick* involve the type of structural change to Medicare effected by the IRA. For nearly 20 years, CMS could not "interfere" in drug pricing negotiations between manufacturers and Part D insurance plans. 42 U.S.C. § 1395w-111(i) (2003). The IRA changed that by authorizing CMS to "institute a price structure" for Part D drugs. *See id.* § 1395w-111(i). For the first time, CMS selects manufacturers for participation in the Program and subjects them to penalties for noncompliance—either through the excise tax or across-the-board exclusion from Medicare and Medicaid. *See supra* Part II.A. Thus, at a minimum the Court must analyze whether *this* version of Medicare is voluntary.

2. *Garelick*'s legal compulsion rationale also conflicts with subsequent Supreme Court precedent. In *Horne*, the Government argued, and both lower courts held, that there was no *per se* taking because participation in the raisin market was voluntary. *See Horne v. Dep't of Agriculture*, 569 U.S. 513, 522 (2013) (*Horne I*); *Horne II*, 576 U.S. at 357, 365. The Supreme Court rejected those arguments as "prov[ing] too much": Allowing the Government to circumvent Fifth Amendment protections anytime someone "voluntarily ch[ose] to participate in [a] market" would allow "property rights [to] be … easily manipulated." *Horne II*, 576 U.S. at 365 (cleaned up); *see also Loretto*, 458 U.S. at 439 n.17 (apartment building owner suffered taking from forced installation of cable equipment even though owner could "ceas[e] to rent the building to tenants"). *Horne II* thus displaces *Garelick*'s legal-

compulsion requirement. *See United States v. Afriyie*, 27 F.4th 161, 168 (2d Cir. 2022) (panel decisions are not binding when "an intervening Supreme Court decision casts doubt on [this Court's] controlling precedent" (cleaned up)).

The District Court brushed aside this conflict because *Horne II* and *Garelick* involved different statutes. *See* SPA24. That misunderstands the inquiry. This Court does not evaluate whether "the intervening decision … address[es] the precise issue already decided by [this Circuit]," but whether there is "a conflict, incompatibility, or inconsistency between this Circuit's precedent and the intervening Supreme Court decision." *Afriyie*, 27 F.4th at 168 (cleaned up). Such an inconsistency exists here. Had legal compulsion mattered in *Horne II*, the Supreme Court would have rejected the growers' takings claims. Moreover, the factual distinction cited by the District Court—i.e., that noncompliant raisin growers would have been barred from the entire market, whereas Boehringer could still sell Jardiance® outside of Medicare—played *no* role in *Horne II*'s reasoning. Instead, *Horne II* considered, and rejected as irrelevant, the growers' ability to sell the same grapes to other buyers, just as Boehringer could sell Jardiance® to non-Medicare patients. *See* 576 U.S. at 365.[23]

[23] The District Court also erroneously suggested that *74 Pinehurst LLC v. New York*, 59 F.4th 557 (2d Cir. 2023), demonstrated *Garelick*'s continued vitality post-*Horne II*. *See* SPA24. Yet *74 Pinehurst* neither cited *Garelick*'s legal-compulsion requirement nor considered *Horne II*'s rejection thereof.

3. Nor does *Garelick* control Boehringer's other claims. *Garelick* did not extend its legal compulsion requirement to due process or compelled-speech claims—this Court applied that requirement only in the regulatory takings context. *See* 987 F.2d 913.

Additionally, the Government recently acknowledged in related litigation that voluntariness is not a defense to due process claims,[24] and this Court has analyzed due process claims without applying *Garelick*. *See, e.g.*, *Furlong v. Shalala*, 156 F.3d 384, 392-93 (2d Cir. 1998) (citing, but not relying on, *Garelick* when analyzing due process claim). Moreover, the Supreme Court consistently has considered due process challenges to price-control regimes even where property owners were not legally compelled to participate. *See, e.g.*, *Bowles*, 321 U.S. at 517 (adjudicating due process claim despite "no requirement that the apartments in question be used for purposes which bring them under the Act"); *Yakus*, 321 U.S. at 438 (similar). The same approach applies here notwithstanding *Garelick*.

In the compelled-speech context, the Government's action need not be "actually coercive." *USAID*, 470 U.S. at 214; *see also C.N. v. Ridgewood Bd. of Educ.*, 430 F.3d 159, 189 (3d Cir. 2005) (law "need not take the form of a direct threat or a gun to the head" to compel speech). Instead, "indirect discouragement"

[24] *See AstraZeneca* Oral Arg., *supra* n.16, at 2:04:09-27.

such as taxes, fees, or exclusion from a program is sufficient. *Axson-Flynn v. Johnson*, 356 F.3d 1277, 1290 (10th Cir. 2004) (cleaned up). Because the Program employs severe "discincentive[s]" and "penalt[ies]" to coerce manufacturers into endorsing the Government's message, Boehringer has shown that the IRA compels its speech.[25]

C. CMS Implements the Program as a Regulator, Not a Mere Market Participant.

The District Court concluded that CMS "can use its power as a dominant buyer to demand lower prices from drug manufacturers" because it has "broad leeway to impose conditions on its own purchases of goods and services." SPA21, 25-26. That reasoning misunderstands CMS's role and would have sweeping consequences the District Court failed to consider.

1. CMS acts as a regulator under the IRA. Congress could have created a program involving genuine arms-length price negotiations between CMS and

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[25] Even if legal compulsion were necessary in the First Amendment context, it exists here because Boehringer could not have withdrawn from the Program before the deadlines to sign the Manufacturer Agreement and participate in the negotiation process. *See* 26 U.S.C. § 5000D(c)(2); 42 U.S.C. § 1395w-114a(b)(4)(B)(ii) (delaying effective date of manufacturer withdrawal by 11 to 23 months). CMS attempted to circumvent this waiting period by offering, in guidance, to shorten the withdrawal period to 30 days, *see* JA226-27, but that guidance conflicts with the statute. The IRA suspends the excise tax only when a *manufacturer* terminates its Medicare and Medicaid agreements, *see* 26 U.S.C. § 5000D(c) (requiring "notice" to Secretary of manufacturer's "terminations of all applicable agreements"), and the IRA delays termination "by a *manufacturer*" by 11 to 23 months, *see* 42 U.S.C. § 1395w-114a(b)(4)(B)(ii) (emphasis added).

manufacturers, in which CMS could exclude a drug from Part D if the manufacturer's terms were not acceptable. But that is not the Program Congress enacted. The IRA augments CMS's market power by giving the agency a significant regulatory role in implementing the Program. Specifically, CMS has authority to select drugs for the Program, issue requirements manufacturers must follow, and impose penalties on any manufacturer that fails to comply or tries to walk away. *See* 42 U.S.C. §§ 1320f-1, 1320f-2(a)(5), 1320f-6; 26 U.S.C. § 5000D. CMS also claims authority to amend the Manufacturer Agreement without Boehringer's consent. JA295-307.

Because CMS exercises *sovereign* powers by "employ[ing] … coercive mechanism[s] available to no private party," *Am. Trucking Ass'n v. City of Los Angeles*, 569 U.S. 641, 651 (2013), it is a "market regulator," not a market participant, *United Haulers Ass'n v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 438 F.3d 150, 157 (2d Cir. 2006). Accordingly, a market-participant theory cannot excuse the Program's constitutional violations. The District Court erred in concluding otherwise. *See* SPA25-26.

2. The District Court also misapplied the law. Courts sometimes distinguish between Government action taken pursuant to sovereign and proprietary capacities. *See* SPA25-26. But many of these cases concern a government's regulation of its own employees, *see, e.g.*, *Engquist v. Or. Dep't of Agric.*, 553 U.S. 591, 598 (2008),

and none of them overrides the Supreme Court's coercion precedent described above. Moreover, the cases do not support the sweeping implications of the District Court's reasoning, under which *all* procurement activities would be exempt from compliance with the First and Fifth Amendments.

If the District Court's approach were correct, the Government could use procurement contracts to make unconstitutional demands or engage in unconstitutional conduct. For example, the Government could insert itself as the predominant purchaser of electric vehicles in the United States and then require all manufacturers, as a condition of selling cars to the Government, to donate a percentage of each sale to a specific political candidate's campaign. Or it could retaliate against a contractor's political speech by denying the contractor's bid. In reality, however, courts have deemed these situations unconstitutional despite arising in the procurement context. *See, e.g.*, *O'Hare*, 518 U.S. at 720 (First Amendment prohibits termination of private contractors for refusing to contribute to a political candidate); *Oscar Renda Contracting Inc. v. City of Lubbock*, 463 F.3d 378, 385 (5th Cir. 2006) (independent contractor "is protected by the First Amendment if its bid is rejected in retaliation of its exercise of protected speech").

III. The Program Would Violate the Unconstitutional Conditions Doctrine Even If Participation Were Voluntary.

If the Court concludes that the Program is voluntary, that would not end the constitutional inquiry. The unconstitutional conditions doctrine is an "overarching

principle" of constitutional law that prevents the Government from ransoming valuable benefits to "coerc[e] people into giving … up" their constitutional rights. *Koontz*, 570 U.S. at 604; *see also Perry v. Sindermann*, 408 U.S. 593, 597 (1972). The doctrine protects a wide variety of constitutional rights, including First and Fifth Amendment rights. *See Koontz*, 570 U.S. at 604 (collecting cases). Its protections also apply when the Government contracts for goods or services. *See, e.g.*, *O'Hare*, 518 U.S. at 721; *Bd. of Cnty. Comm'rs v. Umbehr*, 518 U.S. 668, 678-79 (1996).

As the District Court acknowledged, voluntary participation in the Program "is not dispositive," SPA34, because the unconstitutional conditions doctrine applies even when a party "has no 'right' to a valuable governmental benefit," yet seeks the benefit voluntarily. *Perry*, 408 U.S. at 597; *O'Connor v. Pierson*, 426 F.3d 187, 201 (2d Cir. 2005) (similar). Here, even if the Program could be viewed as voluntary, it unconstitutionally conditions Boehringer's ability to participate in Medicare and Medicaid on relinquishing its constitutional rights.

1. Regarding Boehringer's takings claim, precedent establishes that *directly* requiring an owner to transfer property to a third party effects a *per se* taking. *See supra* Part I.A. The unconstitutional conditions doctrine precludes the Government from achieving the same result "indirectly." *Speiser*, 357 U.S. at 526. That is the case here. The IRA conditions Boehringer's ability to market *any* products through Medicare and Medicaid on participating in the Program and relinquishing property

rights in its Jardiance® products. That indirect appropriation of property is an unconstitutional condition. *See Horne II*, 576 U.S. at 366. Indeed, *NFIB* shows that conditions which leverage "existing" revenue streams to secure the Government's demands are even more constitutionally suspect. *See* 567 U.S. at 585.

Applying the related nexus-and-proportionality test from *Dolan v. City of Tigard*, 512 U.S. 374, 391 (1994), yields the same conclusion. Under that test, the Court considers whether the Program's conditions are related and proportional to CMS's interest in establishing a "maximum fair price" for Jardiance®. Neither requirement is satisfied here. There is not a sufficient nexus because the Program seeks a confiscatory, below-market price for Jardiance® by leveraging unrelated funding for other drugs that treat distinct health problems and serve distinct patient populations. Similarly, there is not sufficient proportionality because the IRA relies on an all-for-one tradeoff in which all of Boehringer's drugs are excluded from Medicare and Medicaid unless the company acquiesces in the "maximum fair price" for a single drug (Jardiance®).

The District Court suggested that *Monsanto* renders the unconstitutional conditions doctrine inapplicable outside the land-use context. *See* SPA36. Not so. *Monsanto* did not expressly narrow this doctrine, and *Koontz* more recently reiterated that it continues to apply in contexts outside land-use permitting. *See* 570 U.S. at 604. At most, *Monsanto* stands for the proposition that a truly voluntary

exchange "can hardly be called a taking," 467 U.S. at 1007—a principle that has no applicability where the Government threatens significant, unrelated funding streams to secure waiver of constitutional rights, as the Program does here. *See NFIB*, 567 U.S. at 585, 587.

The District Court also held that the Program does not violate the unconstitutional conditions doctrine because the Program's requirements are "closely related to the government's goal of controlling spending in the Medicare program." SPA38. But that oversimplifies the inquiry. As noted above, courts also consider whether conditions are proportional to the Government's goals. *See, e.g.*, *Dolan*, 512 U.S. at 385, 391; *NFIB*, 567 U.S. at 580 (asking whether "financial inducement … pass[es] the point at which pressure turns into compulsion" (cleaned up)); *Mem'l Hosp. v. Maricopa County*, 415 U.S. 250, 257-63 & n.15 (1974) (comparing "the extent to which the" condition affected plaintiffs' rights and the strength of the Government's interests). It might have been proportional for Congress to withdraw Medicare coverage *for a selected drug* if its manufacturer objects to the price set through the Program. But Congress went much further, threatening funding for Boehringer's entire portfolio of unrelated drugs in both Medicare and Medicaid. Neither the District Court nor the Government has explained how eliminating coverage for *other* drugs furthers the Government's goal of reducing spending on one drug.

2. The conclusion is the same in the due process context. The Government cannot deprive Boehringer of its property rights without due process, *see supra* Part I.B, so it cannot coerce Boehringer into giving up those rights indirectly.

The District Court did not assess this claim on the merits, instead asserting that the unconstitutional conditions doctrine rarely, if ever, protects due process rights, and that applying the doctrine would invite a flood of litigation. SPA36. Neither assertion is true. Courts have applied the unconstitutional conditions doctrine in the due process context.[26] That comes as no surprise—the Supreme Court has never cabined this "overarching principle" of constitutional law to only a subset of constitutional rights. *Koontz*, 570 U.S. at 604. Moreover, ruling for Boehringer on this argument would not affect "nearly every government purchase from a private sector firm," SPA37, because the overwhelming majority of purchases are governed by laws that, unlike the IRA, provide constitutionally adequate process.

3. The Program also unconstitutionally conditions Medicare and Medicaid participation on relinquishment of Boehringer's First Amendment rights. In *USAID*, the Supreme Court clarified that while Congress can "specify the *activities* [it] wants

[26] *See, e.g.*, *R.S.W.W., Inc. v. City of Keego Harbor*, 397 F.3d 427, 434 (6th Cir. 2005); *In re Asbestos Prods. Liab. Litig. (No. VI)*, 384 F. Supp. 3d 532 (E.D. Pa. 2019).

to subsidize"—even activities that implicate speech—it cannot regulate the "grantee." 570 U.S. at 214-17. The Court then explained that requiring a "recipient to adopt a particular belief as a condition of funding … as their own" involves regulating the grantee, because such a mandate would allow the grantee to "express [contrary] beliefs only at the price of evident hypocrisy." *Id.* at 217-18, 220-21.

So too here. Instead of regulating only specific activities, such as providing third parties access to Jardiance® at a specific price, the Program compels Boehringer to adopt the Government's characterizations of the Program: that the price was determined through arms-length negotiation, was agreed upon by both parties, and is the maximum price Boehringer can fairly charge. *See supra* Part I.C. Because each of these penalty-backed requirements obligates Boehringer to essentially "pledge allegiance to the Government's" views about the Program, *USAID*, 570 U.S. at 220, and because those views affect Boehringer outside Medicare (i.e., in the private market), the Program imposes an unconstitutional condition on Medicaid and Medicare participation.

CONCLUSION

For these reasons, this Court should reverse the District Court's judgment and hold that the Program violates Boehringer's rights under the First and Fifth Amendments and the APA.

Respectfully submitted,

/s/ Kevin F. King
Robert A. Long, Jr.
Kevin F. King
Thomas R. Brugato
Michael A. Maya
Bradley K. Ervin
MaKade C. Claypool
Covington & Burling LLP
850 Tenth Street, NW
Washington, DC 20001
(202) 662-6000

Counsel for Plaintiff-Appellant Boehringer Ingelheim Pharmaceuticals, Inc.

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitations of Circuit Rule 32.1(a)(4)(A) because it contains 13,948 words, exclusive of the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f). This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman and 14 point font.

/s/ Kevin F. King
Kevin F. King

Counsel for Plaintiff-Appellant
Boehringer Ingelheim
Pharmaceuticals, Inc.

November 4, 2024

CERTIFICATE OF SERVICE

I hereby certify that I caused the foregoing brief to be filed with the Clerk of the Court for the United States Court of Appeals for the Second Circuit by using the CM/ECF system on November 4, 2024. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system. I also certify that I caused six copies of the foregoing brief to be delivered to the Clerk of Court for the United States Court of Appeals for the Second Circuit via overnight courier.

/s/ Kevin F. King
Kevin F. King

Counsel for Plaintiff-Appellant
Boehringer Ingelheim
Pharmaceuticals, Inc.

SPECIAL APPENDIX