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, ROBERT F. KENNEDY, JR., in his official capacity as Secretary of Health and Human Services, CENTERS FOR MEDICARE AND MEDICAID SERVICES, STEPHANIE CARLTON, in her official capacity as Acting 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

REPLY BRIEF FOR PLAINTIFF-APPELLANT

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INTRODUCTION

The Government defends a statute that does not exist. In the Government's telling, the Centers for Medicare and Medicaid Services ("CMS") acts as a "market participant" that negotiates prices "[j]ust like private individuals and businesses"; manufacturers can simply "walk away" if they do not agree with CMS's terms; and transactions are structured just as they are in other federal spending programs. Gov't Br. 10, 34, 40, 43, 45-47. That hypothetical statute may well be constitutionally sound, but it is not the one Congress enacted. The Inflation Reduction Act ("IRA") confers sweeping regulatory powers on CMS, forces Boehringer to accept whatever price CMS imposes, and incorporates an unprecedented combination of features that deprive Boehringer of core constitutional rights.

Contrary to the Government's assertions, CMS is no mere "market participant." Rather, CMS exercises coercive sovereign authority by prescribing binding rules and imposing severe penalties for noncompliance, including a 1900% excise tax escalating to hundreds of millions of dollars *per day*. CMS's regulatory powers are also reflected in the Manufacturer Agreement. Far from adopting "standard" terms that are "often memorialized in commercial contracts," Gov't Br.

58, the Agreement grants CMS authority to *unilaterally* revise the terms after the Agreement is executed—a right that no mere market participant enjoys.

When it comes to the Program, Boehringer is not a market participant either—it is the unwilling object of CMS's price-setting. The Government's claim (at 40) that Boehringer "wield[s] substantial power" in the Program's faux negotiation process defies economic logic. That might have been true if Boehringer could withdraw only the *selected* drug from Medicare if CMS's terms were not acceptable. But Congress was unwilling to take that chance. To ensure that manufacturers make selected drugs available on whatever terms CMS dictates, the IRA leaves manufacturers only illusory alternatives—incurring a crippling excise tax or withdrawing *all* their products from Medicare *and* Medicaid. By design, those "consequences" are so "severe" that submission to CMS's demands is "all but certain." *Nat'l Infusion Ctr. Ass'n v. Becerra*, 116 F.4th 488, 500 (5th Cir. 2024) (*NICA*).

The Government also errs in equating the Program with other federal drug programs. *None* of those programs: (1) authorize the relevant agency to target particular drugs for inclusion in the program; (2) leverage a manufacturer's participation in *all* of Medicare and Medicaid to secure concessions for a single drug; (3) impose massive excise tax penalties for nonparticipation; (4) preclude both administrative and judicial review of the agency's actions; ***or*** (5) require

manufacturers to sign contracts that endorse the agency's views regarding the fairness of the price. As Boehringer has explained, several of these features *independently* render the Program unconstitutional. And their *combination* makes that conclusion inescapable.

The Government does not meaningfully grapple with these points. Most of its brief proceeds on the erroneous assumption that the Program is voluntary. And the rest depends on the view that the Program operates in a Constitution-free zone. Regarding Boehringer's takings claim, the Government incorrectly argues that only physical seizures (*e.g.*, sending "trucks" to "haul away" Jardiance® products) qualify as *per se* takings. Regarding the due process claim, the Government adopts the remarkable position that *no* procedural safeguards are required because the Due Process Clause *does not apply*. Regarding the First Amendment claim, the Government insists that by compelling manufacturers to endorse its own normative message, the Program has only an incidental effect on speech, and thus does not implicate Boehringer's free-speech rights. And regarding the Administrative Procedure Act ("APA") claim, the Government largely defends the validity of CMS's *Guidance*—an effort that cannot save the separately issued and legally binding *Manufacturer Agreement* that Boehringer challenges. More broadly, the Government ignores that CMS's failure to comply with the APA exacerbates the

constitutional violations by depriving Boehringer of any meaningful opportunity to comment on the Agreement that vests unilateral powers in CMS.

At bottom, the Government asks the Court to ignore the statute that Congress enacted and its real-world effects. But courts are "not required to exhibit a naiveté from which ordinary citizens are free." *United States v. Stanchich*, 550 F.2d 1294, 1300 (2d Cir. 1977) (Friendly, J.). This Court should reverse.

ARGUMENT

I. The Program Violates the Takings Clause, the Due Process Clause, and the First Amendment.

A. The Government Fails to Distinguish *Cedar Point* and *Horne*, Confirming that the Program Violates the Takings Clause.

As the owner of Jardiance®, Boehringer retains the right to control the "possess[ion], use[,] and dispos[ition] of" its Jardiance® tablets. *Horne v. Dep't of Agriculture*, 576 U.S. 350, 360 (2015) (cleaned up). In other words, Boehringer has the right "to exclude others" from accessing those products against the company's will. *Kaiser Aetna v. United States*, 444 U.S. 164, 176 (1979). When CMS appropriates Boehringer's rights for the benefit of third parties, it effects a taking and "a simple, *per se* rule applies: The government must pay for what it takes." *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 149 (2021).

The Government claims (at 29) that there is no *per se* taking because CMS will not "sen[d] trucks" to "haul away" Jardiance® products from Boehringer's warehouses. But the Government need not physically seize property to effect a *per*

se taking; appropriating an owner's right to exclude for the benefit of a third party suffices. *See Cedar Point*, 594 U.S. at 144, 149-50. That is what the Program does. The statutory "access" requirement, 42 U.S.C. § 1320f-2(a), together with the Program's other provisions, strips Boehringer of its right to possess, dispose of, and exclude others from possessing its Jardiance® products by forcing Boehringer to transfer them to Medicare participants on terms dictated by CMS. *See* Opening Br. 22-24. The Program thus resembles the laws challenged in *Cedar Point*, which gave third parties access to private farmland, *see* 594 U.S. at 149, and *Horne*, which stripped growers of the "right to control th[e] disposition" of their raisins, 576 U.S. at 364. Accordingly, the Program effects a *per se* taking even if CMS itself does not seize Boehringer's Jardiance® products.

The Government fails to distinguish these controlling authorities. In a cursory footnote, the Government suggests that *Cedar Point* is inapposite because it addressed "[g]overnment action that physically appropriates property." Gov't Br. 31 n.3 (quoting 594 U.S. at 149). But as just explained, that accurately describes the Program. The Government also asserts (at 29) that "'access to [a] … price' is an entirely different thing from physical access to drugs." But that ignores reality: How could someone "access" a "price" without accessing the underlying product? *See Price*, Oxford English Dictionary (2024) ("The amount of money (or a material equivalent) expected, required, or given in payment *for a commodity* or service."

(emphasis added)). Indeed, that is how the IRA employs the term "price": Medicare beneficiaries can "access" the "maximum fair price" for Jardiance® only if they are provided "access" to Jardiance® itself. As the Government acknowledged in its briefing below, the Program "obligat[es] … manufacturers to *provide selected drugs* at negotiated prices." ECF 48-1 at 43 (emphasis added).[1]

Regarding *Horne*, the Government maintains (at 41-42) that the unconstitutional confiscation of raisins is unlike the Program because the only way the growers could avoid turning over their raisins or paying a fine was to exit the market altogether. Not so. In *Horne*, the growers were not forced to stop "[s]elling produce in interstate commerce" to avoid the relevant confiscation or fine; they could have sold their grapes to other buyers "as table grapes or for use in juice or wine." 576 U.S. at 365-66. But those options—much like Boehringer's illusory option to leave Medicare and Medicaid—did not defeat the takings claim. *See id.* (rejecting the Government's "[l]et them sell wine" defense). The Government also insists (at 42) that it is "offering something of value" to Boehringer here, whereas it had nothing valuable to offer the raisin growers in *Horne*. But in *Horne*, the raisin reserve program *did* provide growers with benefits. *See* 576 U.S. at 368 (program

[1] The Government has made similar concessions in other cases. *See, e.g.*, Defs.' Mem. Supp. Summ. J., *Janssen Pharms., Inc. v. Becerra*, No. 3:23-cv-3818, ECF 33-1 at 6 (D.N.J. Oct. 16, 2023) ("[M]anufacturer will then … provide Medicare beneficiaries access to the drug at the negotiated price.").

generated "higher consumer demand for raisins" through its "promotional activities").

Finally, the Government cites *Garelick* and other cases that predate *Horne* and do not govern here because the Program is not voluntary. *See infra* section II. But those cases are inapposite for additional reasons, including that they addressed only *regulatory* takings claims. *See, e.g.*, *Garelick v. Sullivan*, 987 F.2d 913, 916 (2d Cir. 1993) (physicians contended that pricing scheme was "a regulatory taking"). Given the "longstanding distinction between physical and regulatory takings" and the differing tests for those claims, it is "inappropriate to treat precedent from" regulatory takings cases "as controlling precedents for the evaluation of" Boehringer's *per se* takings claim. *Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg'l Plan. Agency*, 535 U.S. 302, 323 (2002). For example, unlike *per se* takings claims, regulatory takings claims often turn on whether a property owner's reasonable, investment-backed expectations were upended, *see Penn Central Transp. Co. v. City of New York*, 438 U.S. 104, 124 (1978)—a difficult showing if the owner voluntarily assumed the challenged property restriction, *see Palazzolo v. Rhode Island*, 533 U.S. 606, 632-34 (2001) (O'Connor, J., concurring) (acquiring property already encumbered by land-use restrictions did not defeat *per se* takings claim, but could weaken a regulatory takings claim given the relevance of investment-backed expectations).

B. The Program Is Not Exempt from the Due Process Clause.

The Program is structured to deprive Boehringer of "[t]he fundamental requirement of due process"—*i.e.*, "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). The Program does so by (1) granting an economically motivated regulator (CMS) price-setting authority, (2) insulating CMS's actions from administrative and judicial review, and (3) omitting ascertainable standards for CMS to follow when dictating the "maximum fair price." *See* Opening Br. 25-31. So far as Boehringer is aware, the near-total absence of guardrails on CMS's action sets the Program apart from every other modern federal price-setting program—including emergency wartime regulations. The Court should reject the Government's attempt to set a new low-water mark for due process protections.

The Government does not offer—and thus has forfeited—any argument that the Program provides constitutionally adequate procedural safeguards. Instead, the Government argues that *no* process is necessary because the Program does not implicate *any* constitutionally protected property interest, despite authorizing CMS to: prescribe a highly discounted price for Boehringer's drugs, require Boehringer to provide millions of beneficiaries with access to Jardiance® at that price, exclude Boehringer from nearly half the U.S. prescription drug market (or impose billions of dollars in excise tax penalties) if it does not accept that price, and levy civil monetary

penalties of up to $1 million per day if Boehringer does not comply with CMS's directives. Gov't Br. 44; *see* 42 U.S.C. § 1320f-6.

The Government's position is untenable. For one, it misreads (at 49-50) the Fifth Circuit's decision in *NICA*, which concluded that an association challenging the Program "ha[d] alleged sufficient facts to satisfy the *Mathews* test" in part because the "Program substantially impacts [the association] members' revenue and ability to stay in business." 116 F.4th at 503. The association could only have "satisf[ied] the *Mathews* test" if it had a constitutionally protected property interest. *See Mathews*, 424 U.S. at 332. The Government's position also overlooks the principle that imposition of a penalty for noncompliance is sufficient to trigger due process protections. *See Satcorp Int'l Grp. v. China Nat. Silk Imp. & Exp. Corp.*, 101 F.3d 3, 6 n.1 (2d Cir. 1996) ("[A] civil fine cannot stand when it is imposed without basic due process safeguards.").

More broadly, the Due Process Clause applies here because—contrary to the Government's assertions—the Program deprives Boehringer of constitutionally protected property interests, including its interests in physical doses of Jardiance®, the price at which it offers Jardiance®, and proprietary information regarding Jardiance®. *See* Opening Br. 26-27.

Physical Doses. The Government does not dispute that Boehringer has a cognizable interest in physical doses of Jardiance®. Instead, it asserts (at 44) that

Boehringer has not been *deprived* of that interest because "participation in the … Program is voluntary." As explained below, that is incorrect. *See infra* section II. In any event, voluntariness is no defense to a due process claim, as the Government has acknowledged in other IRA litigation.[2] If it were, the Government could operate federal benefits programs—in which participation is wholly voluntary—without any procedural protections. Instead, precedent holds that constitutional safeguards apply. *See, e.g.*, *Goldberg v. Kelly*, 397 U.S. 254, 261 (1970) (due process); *Skelly v. INS*, 168 F.3d 88, 91 (2d Cir. 1999) (equal protection).

Market-Based Price. The Program also deprives Boehringer of its right to set the price at which it offers Jardiance® products. *See* Opening Br. 26-27. The Government responds by attacking a straw man. Boehringer does not claim a right to sell its products to the Government "at a particular price," Gov't Br. 45, but Boehringer *does* have a protected property interest in the prices it charges for its products. Congress can regulate those prices, but when doing so it must heed "the

[2] *See* Oral Arg. 2:04:02-2:04:24, *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 (Government counsel acknowledging that the Government's defenses to "the due process claim" are "fundamentally not about voluntariness"); *see also Furlong v. Shalala*, 156 F.3d 384, 392-93 (2d Cir. 1998) (assessing doctors' due process claims, despite earlier finding that program was voluntary).

limits of due process." *Fed. Power Comm'n v. Nat. Gas Pipeline Co. of Am.*, 315 U.S. 575, 586 (1942).[3]

The Government attempts (at 48-49) to distinguish this body of precedent by arguing that the regulations at issue set prices for an entire market rather than just a particular segment. But in *Bowles v. Willingham*, 321 U.S. 503 (1944)—a due process challenge to wartime rent-control measures—there was "no requirement that the apartments in question be used for purposes" governed by the statute in question. *Id.* at 517-21. Similarly, in *Yakus v. United States*, 321 U.S. 414 (1944), the challenged provision regulated the market for wholesale beef, *see id.* at 418, but did not govern retail sales. Besides, the fact that the Program's price restrictions single out manufacturers and impose prices on specific drugs *heightens* the need for due process protections. *See generally Bi-Metallic Inv. Co. v. State Bd. of Equalization*, 239 U.S. 441, 445 (1915).

Proprietary Information. The Government concedes (at 45) that Boehringer "undoubtedly has a property interest in certain proprietary commercial information," but claims that there is no deprivation because submission of the information is

[3] This property interest is particularly relevant because the Program targets "single source" patent-protected drugs like Jardiance®. *See* 42 U.S.C. § 1320f-1(e). Patents are designed to allow "innovators" to "profi[t]" from their inventions, *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1374 (Fed. Cir. 2007), but the Program undermines that right by requiring discounts well below the market-clearing price, *see* 42 U.S.C. § 1320f-3(c)(3).

voluntary. But again, neither the Program—nor its attendant requirement to submit proprietary information for any drug that CMS selects—is voluntary. *See infra* section II. The sole authority cited by the Government on this issue (*Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984)) is inapposite because it did not involve the compelled submission of data and did not consider a due process claim. The Government also contends (at 45 n.5) that Boehringer has offered no "argument as to what additional process it would be due before it submits data to the government." But that argument fails because the Program affords Boehringer *no* process at all. Regardless, Boehringer has identified (at 28-29) multiple procedural deficiencies that directly interfere with Boehringer's interest in its proprietary information—for example, the fact that there is no judicial review of CMS's drug selection decisions (which trigger statutory obligations to disclose proprietary information). *See* Opening Br. 28-29.

C. The Program's Speech Mandates Violate the First Amendment Because They Are Not Incidental to Ordinary Price Regulation.

The Program violates the First Amendment by forcing Boehringer to express the Government's normative message that the Program involves "negotiations" resulting in an "agreement" on a "maximum fair price" for Jardiance®. *See* Opening Br. 34-46. On this issue, the Government again resorts to arguing that the Program is voluntary. But it is not, and that would not defeat Boehringer's First Amendment claim in any event. *See infra* section II. In arguing (at 50-51) that the Program does

not subject Boehringer to "actual compulsion," the Government ignores that the standard requires only "indirect discouragement," *see* Opening Br. 54-55—a low bar that the Program easily clears.

On the merits, the Government insists (at 52) that the First Amendment is not implicated at all because the Program involves "typical price regulation" that only incidentally affects speech. But there is nothing typical about the Program. In other price-setting schemes, an agency sets prices through adjudication or rulemaking. *See, e.g.*, 15 U.S.C. § 717c (authorizing FERC to set rates for natural gas interstate pipelines after hearing); 16 U.S.C. § 824e (same with respect to electricity rates); 49 U.S.C. § 10704(a) (authorizing Surface Transportation Board to set rail carrier rates after hearing). Such schemes, unlike this Program, do not require parties to engage in performative negotiations and then endorse the Government's terms through normative statements about the price-setting process (*i.e.*, an "agreement" at the end of a "negotiation") or the prices themselves (*i.e.*, the "maximum fair price"), all under threat of penalty. These expressive elements are not incidental because Congress could have lowered drug prices *without* them. For example, Congress could have set prices directly via a statutory formula, as it has in other drug programs, *see, e.g.*, 42 U.S.C. § 1396r-8(c) (Medicaid rebate calculation), or it could have tasked CMS with setting prices through rulemaking, as in the "typical" price-setting schemes noted above.

The purpose of the speech-compelling provisions here is to enlist Boehringer in a public-relations campaign supporting the Program. *See* Br. for Amicus Institute for Free Speech, ECF 96 at 2-4; Opening Br. 41. Indeed, the Government acknowledges (at 47) that the Program "reflects Congress's judgment that Americans have been spending too much on high-cost prescription drugs." Requiring Boehringer to agree that the Program's highly discounted rate is the maximum fair price for Jardiance® forces the company to amplify that disputed, value-laden "judgment."

The Government also fails in its attempted analogies to other programs that require prices to be "fair." The Program is different because other frameworks cited by the Government do not require contractors to *endorse* a normative message; they merely obligate contractors to provide the relevant product or service at the established price. For example, the Government (at 56) cites *United States v. General Dynamics Corp.*, 19 F.3d 770 (2d Cir. 1994), for the proposition that Congress can lawfully require a contractor to agree that a price is "fair." But there, the Court did not address a First Amendment claim, and the relevant statute did not permit the government to set prices (let alone under threat of penalty) or require contractors to use any specific terminology in their submissions. Rather, the scheme in *General Dynamics* simply required contractors to submit information to facilitate a "find[ing]" *by the government* that the proposed prices were "fair and reasonable."

46 U.S.C. app. § 1152(a) (1994). Further, labeling a price "fair" is different from calling it the "*maximum* fair price": Only the latter suggests that any price above that level—including those charged by Boehringer outside Medicare, in the private market—is *unfair*.

The Government (at 55) also argues that "maximum fair price" is a statutory "term of art" and so not subject to the First Amendment. That argument is meritless. A legislature cannot evade the First Amendment by defining normatively charged statutory terms in a way that contradicts their ordinary meaning. *See* Opening Br. 44-45 (citing *Nat'l Ass'n of Mfrs. v. SEC*, 800 F.3d 518, 530 (D.C. Cir. 2015)); *Ent. Software Ass'n v. Blagojevich*, 469 F.3d 641, 652 (7th Cir. 2006) ("Even if one assumes that the State's definition … is precise, it is the State's definition—the [plaintiff] may have an entirely different definition of this term" and the compelled speech "ultimately communicates a subjective and highly controversial message"). The Government does not confront these authorities.

The Government separately asserts that the Manufacturer Agreement's disclaimer resolves any First Amendment concern. But disclaimers cannot negate a compelled-speech injury. *See Pacific Gas & Elec. Co. v. Pub. Utilities Comm'n of California*, 475 U.S. 1, 15 n.11 (1986) (*PG&E*). 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). The Government's attempt to brush aside *PG&E* also misses the mark. While a disclaimer might avoid confusion, "[i]t does nothing to reduce the risk that [the compelled speaker] will be forced to respond when there is strong disagreement with the substance of" the compelled message. *PG&E*, 475 U.S. at 15. Here, any counter-speech Boehringer offers (especially to explain in private transactions why the Program price was neither "negotiated" nor the "maximum" price that could "fair[ly]" be charged for Jardiance®) will be tainted with "evident hypocrisy" given Boehringer's forced adoption of the Government's message. *Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.*, 570 U.S. 205, 219 (2013) (*USAID*).

Finally, the Government asserts (at 54) that contracts do not implicate the First Amendment. Yet that ignores precedent recognizing that signing a contractual agreement can constitute speech protected by the First Amendment. *See*, *e.g.*, *id.* at 214 (assessing whether contract with federal agency complied with First Amendment). Here, the statements compelled by the IRA go well beyond "simply regulating the amount that [Boehringer] c[an] collect," *Expressions Hair Design v. Schneiderman*, 581 U.S. 37, 47 (2017); they require Boehringer to make disputed, normative statements about the procedure employed to set prices through the Program ("agreement" and "negotiation") and the "fair[ness]" of those prices. Thus,

while many contractual terms may not implicate the First Amendment, *these* compelled statements do.

II. The Government's Voluntariness Defense Fails.

The Government's overarching response to Boehringer's claims is that the Program is not subject to constitutional scrutiny because it is voluntary. *See* Gov't Br. 2, 31-32, 44, 50-51. According to the Government, CMS is just a "market participant" that "sets the terms of the government's offer to pay for certain drugs." *Id.* at 47. "If Boehringer is dissatisfied with" those terms, the Government says, "it can decline to sell its drugs to Medicare." *Id.* at 31.

That fictional narrative fails to account for the considerable regulatory power CMS exercises in implementing the Program, as well as longstanding precedent holding that action by regulated parties cannot be considered voluntary where, as here, the Government secures compliance through economic coercion. And even if the Program were voluntary, it would still violate the unconstitutional conditions doctrine.

A. The Program Is Not Voluntary Because CMS Exercises Regulatory Power and Employs Economic Coercion to Secure Compliance.

1. The Government's voluntariness defense rests on a mischaracterization of the Program. The Government claims (at 40-43) that the Program involves "genuine back-and-forth" between manufacturers and CMS. On this view, the Program is no different from garden variety procurement programs in which businesses can reject

the Government's terms. But in reality, the Program differs categorically from ordinary government procurement because it is structured to make it impossible for manufacturers to "wal[k] away" from the table. *NICA*, 116 F.4th at 500. If a defense contractor declines the Department of Defense's offer to buy one of its products, the contractor loses the sale but is not subject to additional penalties. The Program works differently: If Boehringer does not accept CMS's terms, it not only loses the ability to sell Jardiance® to Medicare beneficiaries, but must *also* incur billions of dollars in excise tax liability or withdraw all its *other* drugs from Medicare *and* Medicaid. *See* 26 U.S.C. § 5000D. These "consequences" are, and were designed to be, so "severe" that acquiescence is "all but certain." *NICA*, 116 F.4th at 500; Opening Br. 13-14. The Government's narrative omits the facts that *CMS* subjected Boehringer to the Program by selecting Jardiance®, that Boehringer has participated only under protest, and that any "back-and-forth" took place only in the shadow of these consequences. *See* Opening Br. 14. That coercive scheme is unlike any true arms-length negotiation.

The Government also contends (at 33) that its "bargaining terms" cannot pose any "constitutional concern" because CMS is simply "acting as a market participant." But as Boehringer explained (at 55-57), CMS does not rely on bargaining power alone. That might have been true had Congress given Boehringer the option to withdraw only Jardiance® from Medicare if CMS's terms were not

acceptable. The IRA, however, makes CMS a market *regulator* equipped with "coercive mechanism[s] available to no private party." *Am. Trucking Ass'n v. City of Los Angeles*, 569 U.S. 641, 651 (2013). The agency selects the drugs subject to the Program, imposes penalties on manufacturers that fail to comply with its demands, and arrogates to itself the right to unilaterally change the terms of the Manufacturer Agreement. Indeed, CMS does not purchase drugs directly as a market participant would; it *regulates* commercial activity along the pharmaceutical supply chain and then partially reimburses those who actually purchase Boehringer's drugs.[4] *See also* Br. of Amicus Teva Pharmaceuticals, ECF 64 at 26-29 (Program's "market-distorting effects" show that CMS is "not an ordinary market participant"). The Government offers no meaningful response to these arguments and authorities.

2. These characteristics distinguish the Program from the other federal drug programs cited by the Government (at 1, 9-10, 34). None of those programs involve an agency selecting particular private entities for participation and then levying massive penalties on entities that do not acquiesce in the agency's terms. Also, unlike the Program—which allows CMS to exact price concessions on a single drug by leveraging coverage for *all* of a manufacturer's drugs—the other programs apply

[4] A private market participant would face serious antitrust scrutiny if it tried to leverage significant market power to tie the purchase of *all* Boehringer drugs to a specified price for Jardiance®, as the Program essentially does here. *See Kaufman v. Time Warner*, 836 F.3d 137, 141 (2d Cir. 2016).

generally across a manufacturer's product portfolio. And while participation in the other programs is often a prerequisite for federal funding, *see, e.g.*, 42 U.S.C. §§ 1396r-8(a)(5)–(6), 1395cc(a)(1)(I)(i), the decision whether to enter those programs and accept funding conditions in the first place lies in the manufacturer's or provider's hand, not the Government's. Additionally, these other programs do not preclude administrative and judicial review of the relevant agency's determinations, nor do they require individuals to endorse the Government's characterizations of the programs or the fairness of the applicable prices.

For example, prices for drugs directly purchased by the Departments of Veterans Affairs and Defense are set by statutory formula; the agencies can seek reduced rates through negotiations, but there is no penalty if a manufacturer rejects those proposals and insists on the statutory rate. *See* 38 U.S.C. § 8126; *see also* Office of Procurement, Acquisition and Logistics, *Public Law 102-585, Veterans Health Care Act of 1992* (Nov. 4, 2024), https://perma.cc/JY6F-HH25. Under the 340B program, drug prices are determined by a statutory formula based on the prices that *manufacturers* decide to charge in the broader market; the prices are not dictated by a CMS "offer" that must be accepted to avoid severe excise tax penalties. The 340B program also has a fundamentally different history, having grown out of manufacturers' preexisting, voluntary practices of providing discounts to safety-net providers. *See* Nicholas C. Fisher, *The 340B Program: A Federal Program in*

Desperate Need of Revision After Two-and-a-Half Decades of Uncertainty, 22 J. Health Care L. & Pol'y 25, 29-30 (2019); *see* Opening Br. 7-8, 52; SPA70.

3. The Government also errs by insisting (at 27-28, 32-33) that only "legal compulsion"—*i.e.*, a formal legal requirement in statute, regulation, or order—can make a program subject to constitutional scrutiny. That position cannot be squared with Supreme Court precedent.

To start, the Government argues (at 35-38) that the coercion analysis in *National Federation of Independent Business v. Sebelius*, 567 U.S. 519 (2012) ("*NFIB*"), is limited to the federalism context. But *NFIB* does not support that cramped reading. The Court acknowledged that states' Tenth Amendment rights would have prevented Congress from mandating the Medicaid expansion at issue *directly*. *See id.* at 577-78. The question then became whether Congress could "us[e] financial inducements" to "*indirectly*" reach the same result. *Id.* (emphasis added). The Court held that Congress could not use "economic dragooning" or a financial "gun to the head" to leave states with "no real option but to acquiesce" in the Government's otherwise unconstitutional demands. *Id.* at 581-82. In other words, federalism supplied the constitutional protection, but coercion principles foreclosed Congress's indirect attempts to violate that protection. There is no principled reason why that coercion analysis would evaporate simply because the

relevant constitutional protections are located in the First and Fifth Amendments. *See* Opening Br. 50.

Beyond *NFIB*, many other Supreme Court cases have applied similar coercion principles to private parties. *See* Opening Br. 47-48. The Government dismisses (at 39-40) these cases as involving programs where the only way to avoid the challenged regulation was by "not doing business in the private market at all." But that is not accurate: In *Union Pacific Railroad Co. v. Public Service Commission*, 248 U.S. 67, 69-70 (1918), for example, the challenged regulation prohibited noncompliant railroads from issuing bonds, but did not bar them from continuing to operate in the commercial transportation market. The Supreme Court still rejected a voluntariness defense because the railroads had complied under economic "duress." *Id.* at 70. Similarly, in *United States v. Butler*, 297 U.S. 1, 70-71 (1936), farmers could "refuse to comply" with the relevant regulation and continue to sell their crops; the only "price of such refusal" was "the loss of benefits" in the form of subsidies. *See also id.* at 71 (noting that "there still remained a minority" of farmers who declined to participate in the program). The Supreme Court in *Butler* nevertheless determined that the regulation was economically coercive and therefore "not in fact voluntary." 297 U.S. at 70-71.[5]

[5] The Government's argument (at 40) that *Butler* invoked the later-rejected view that Congress cannot "regulate agricultural commodities directly" is also a distraction.

B. Regardless of Whether the Program Is Voluntary, It Imposes Unconstitutional Conditions.

Even if the Program were voluntary, the unconstitutional conditions doctrine would prevent CMS from indirectly violating Boehringer's constitutional rights. *See* Opening Br. 57-60.

The Government first attempts to avoid the doctrine altogether by asserting without support (at 46 n.6) that it "does not govern the commercial terms of procurement contracts." But the Supreme Court has applied the doctrine in that very context. *See* Opening Br. 57-58. The Government responds (at 60 n.7) that those cases concerned contracts for *services*, rather than goods. But it does not explain why that distinction would carry constitutional significance—particularly for an "overarching principle" of constitutional law like the unconstitutional conditions doctrine. *See Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013) (collecting cases). The Government also concedes (at 46 n.6) that procurement decisions are subject to due process and equal protection limitations, yet again fails to explain why the Constitution would apply in piecemeal fashion. The Government's strained efforts to avoid the doctrine illustrate why the Supreme Court

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Butler's voluntariness analysis did not turn on the specific congressional authority at issue; *Butler* held that whenever Congress cannot do something directly, it cannot "compel submission" indirectly by "economic pressure." 297 U.S. at 70-71. Far from being "abandoned," Gov't Br. 40, that principle is alive and well, *see NFIB*, 576 U.S. at 577-82.

expressed concern that recognizing false "distinction[s]" would allow government officials to "avoid constitutional liability simply by attaching different labels" to fundamentally similar contexts. *O'Hare Truck Service, Inc. v. City of Northlake*, 518 U.S. 712, 722 (1996).[6]

On the merits, the Government argues (at 61-63) that the Program does not violate the unconstitutional conditions doctrine because its "conditions are relevant to the program's purpose." The Government claims there is no constitutional violation here because the Program's performative negotiation process and compelled agreements are "integral to [its] functioning" and "do not impede Boehringer's ability to exercise its rights outside" the scope of the Program. *Id.* at 63. That argument mischaracterizes both the doctrine and the Program.

To start, the unconstitutional conditions doctrine is broader than the Government admits. The doctrine has deep roots; it prevents the Government from achieving indirectly "a result which [it] could not command directly." *Speiser v. Randall*, 357 U.S. 513, 526 (1958); *see* Opening Br. 57-58. As such, the Government cannot require individuals to "surrender a [constitutional] right in

[6] The Government suggests (at 60) that Boehringer cannot bring an unconstitutional conditions claim because it is "n[ot] a beneficiary of discretionary benefits." Yet elsewhere, the Government asserts (at 42) that the Program "offer[s] something of value" to Boehringer. And below, the Government acknowledged that the ability to "mak[e] sales of … drugs to Medicare beneficiaries" is a "valuable government benefit." ECF 48-1 at 31-32.

exchange for a valuable privilege which [it] threatens to otherwise withhold." *Frost v. R.R. Comm'n*, 217 U.S. 583, 593 (1926); *accord Koontz*, 570 U.S. at 606 (doctrine "forbids burdening the Constitution's enumerated rights by coercively withholding benefits from those who exercise them"). Applying those principles here, Congress could not directly violate Boehringer's First and Fifth Amendment rights, so it cannot indirectly achieve the same results by conditioning Medicare and Medicaid funding on Boehringer relinquishing those rights. *See* Opening Br. 58-59; *Horne*, 576 U.S. at 366; Br. of Amicus Atlantic Legal Foundation, ECF 65 at 15-17.

Further, a program's conditions are not permissible merely because they are "relevant" or "integral." *See* Gov't Br. 61, 63. For that standard, the Government relies on *Rust v. Sullivan*, 500 U.S. 173 (1991). But *Rust* preceded *USAID*, which *rejected* the view that conditions pass muster so long as they are "relevant to the objectives of the program." 570 U.S. at 214. The Court explained that such a loose standard would allow governments to "manipulat[e]" a program "to subsume the challenged condition," reducing the protections of the Constitution "to a simple semantic exercise." *Id.* at 214-15 (cleaned up). Instead, the Court looked to whether a condition was "doing something more" than necessary to accomplish the program's objectives, and thus impermissibly "reach[ing] outside it." *Id.* at 218. The compulsory anti-prostitution policies challenged in *USAID* would have

advanced the aid program's goal of reducing transmission of HIV, but those policies nevertheless violated grant recipients' constitutional rights. *See id*.

These same principles confirm that the Program's conditions are invalid. Even assuming that the Program's conditions are relevant to lowering drug prices, Congress could have regulated drug prices *without* coercively taking Boehringer's property, stripping away all procedural safeguards, and forcing Boehringer to "pledge allegiance to the Government's" narrative. *USAID*, 570 U.S. at 220. Accordingly, these conditions "must be doing something more" than is necessary to further the Program's objectives—causing them to "fal[l] on the unconstitutional side of the line." *Id.* at 217-18. For similar reasons, the Government also errs in asserting (at 63) that the Program's conditions "d[o] not reach outside it." The Program's conditions have clear spillover effects outside the Program itself. By forcing Boehringer to "agree" to a "maximum fair price," the Program compels Boehringer to indict its own conduct by characterizing as unfair the higher market rates it has charged in the past and continues to charge outside Medicare. And now that CMS has published the "maximum fair price" for Jardiance®,[7] these public statements will cause downward pressure on prices in *commercial* markets as well.

[7] *See* CMS, *Medicare Drug Price Negotiation: IPAY 2026 MFP Explanations* (Feb. 5, 2025), https://perma.cc/UEA5-6QAT.

The Government's contention that the Program's conditions are wholly internal to the statutory scheme also ignores how the unconstitutional conditions doctrine applies in different substantive areas. For example, in the takings context, the Supreme Court has applied the nexus-and-proportionality framework,[8] which confirms that the Government may not leverage unrelated funding for *all* Boehringer's drugs in Medicare *and* Medicaid to force Boehringer to relinquish its rights with respect to Jardiance®. *See* Opening Br. 59. And in the First Amendment context, *USAID* clarified that a condition "by its very nature" reaches outside the scope of a program—and is therefore constitutionally impermissible—when it requires a party to "adopt as [its] ow[n] the Government's view on an issue of public concern." *Id.* at 217-18. These rules govern here. *See* Opening Br. 59.

III. The Program Violates the APA Because the Manufacturer Agreement Is an Invalid Legislative Rule.

The Manufacturer Agreement is invalid because it is a legislative rule that was promulgated without the notice-and-comment procedures required by the APA. *See* Opening Br. 31-34. The Government does not dispute that the Manufacturer Agreement is a legislative rule. Nor could it, given that the Agreement "impose[s]

[8] The Government incorrectly dismisses (at 60 n.8) nexus-and-proportionality principles as irrelevant. While the Supreme Court has most frequently applied those principles in the land-use context, *see Koontz*, 570 U.S. at 604, it has not restricted them to that area. The Government does not dispute that unconstitutional conditions cases in other contexts rely on similar principles. *See* Opening Br. 60.

legally binding obligations" on manufacturers. *Nat'l Min. Ass'n v. McCarthy*, 758 F.3d 243, 251 (D.C. Cir. 2014). Instead, the Government largely focuses on defending the validity of the Guidance—a separate agency action whose validity Boehringer does not challenge.

The Government maintains (at 67) that the Agreement falls within the scope of section 11001(c) of the IRA, which directs CMS to "implement" the Program through 2028 "by program instruction or other forms of program guidance." Pub. L. No. 117-169, § 11001(c), 136 Stat. 1818, 1854. Yet the Government does not explain how the Agreement, which prescribes a manufacturer's duties under the Program, could be considered a type of "instruction" or "guidance." That deficiency alone renders the Government's position untenable. *See Soliman v. Subway Franchisee Advert. Fund Tr.*, 101 F.4th 176, 184 (2d Cir. 2024); Opening Br. 32-33 (IRA distinguishes the Manufacturer Agreement from "instructions" and "guidance").

The Government also insists (at 67) that the Agreement is valid because its "material terms … are contained in the guidance that CMS issued." Yet the Agreement goes well beyond the Guidance by, among other things: providing that "CMS retains authority to amend th[e] Agreement" at any time without the manufacturer's consent, Manufacturer Agreement §§ II(e), IV(b); adopting language aimed at insulating CMS from First Amendment challenges, *id.* § IV(f); and

expressly "limit[ing]" "the Manufacturer's remedies for any breach," *id.* § IV(i). In any event, the APA does not allow the Government to save an invalid agency action (*e.g.*, the Manufacturer Agreement) by pointing to *another* agency action that is purportedly valid (*e.g.*, the Guidance). The same principle forecloses the Government's contention (at 66 n.9) that it somehow complied with the APA's notice-and-comment requirements with respect to the *Agreement* by inviting comments on the *Guidance*—particularly where the Agreement was published months *after* the close of the comment period on the Guidance. *See* ECF 92 at 45. Contrary to the Government's suggestion (at 66 n.9), CMS never took comments on key provisions of the Agreement.

Even if the Agreement could somehow be considered an "instruction" or "guidance" under section 11001(c), the Government fails to demonstrate how that provision displaces the APA's notice-and-comment requirement. A "[s]ubsequent statute may not be held to supersede or modify [the APA] … except to the extent that it does so *expressly*." 5 U.S.C. § 559 (emphasis added). Although no "magic words" are needed, Gov't Br. 65, the subsequent statute must at a minimum "specif[y] procedures … that cannot be reconciled with" the APA's requirements, *Asiana Airlines v. FAA*, 134 F.3d 393, 398 (D.C. Cir. 1998). Section 11001(c) can be reconciled with the APA because agency "guidance" can be promulgated—and

sometimes *must* be promulgated—through notice-and-comment procedures. *See* Opening Br. 34.

Last, the Government asserts (at 66) that section 11001(c) would be "meaningless" unless it displaced the APA's notice-and-comment requirements. That does not follow. The provision is most naturally read as a direction to implement the Program through guidance as opposed to other forms of agency action, such as adjudication. Without the direction that section 11001(c) provides, CMS would presumptively have discretion regarding the means of implementation. *See NLRB v. Bell Aerospace Co. Div. of Textron*, 416 U.S. 267, 294 (1974) (generally, "the choice between rulemaking and adjudication lies in the first instance within the [agency's] discretion"). Section 11001(c) cabins that discretion.

The APA violation is also no mere technical error. The APA's notice-and-comment requirement is essential to ensuring that government agencies act reasonably and remain publicly accountable. *See Batterton v. Marshall*, 648 F.2d 694, 703 n.47 (D.C. Cir. 1980) (APA's legislative history "explicitly states that due to the unrepresentative nature of an administrative agency, 'public participation … in the rulemaking process is essential in order to permit administrative agencies to inform themselves, and to afford safeguards to private interests.'" (quoting S. Doc. No. 248, 79th Cong., 2d Sess. 19-20 (1946))). By promulgating a legally binding "Agreement" without complying with the APA's

notice-and-comment requirement, CMS exacerbated the statute's constitutional infirmities—and in particular, its lack of adequate procedural safeguards.

CONCLUSION

For the above reasons and those given in Boehringer's opening brief, this Court should reverse.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitations of Circuit Rule 32.1(a)(4)(B) because it contains 6,968 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.

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February 14, 2025

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 Appellate Case Management System ("ACMS") on February 14, 2025. I certify that all participants in the case are registered ACMS users and that service will be accomplished by the ACMS. 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.

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