IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MERCK & CO., INC.,
126 East Lincoln Avenue
Rahway, NJ 07065; and

MERCK SHARP & DOHME LLC,
126 East Lincoln Avenue
Rahway, NJ 07065

Plaintiffs,

v.

XAVIER BECERRA, U.S. Secretary of Health & Human Services,
200 Independence Avenue S.W.,
Washington, DC 20201;

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES,
200 Independence Avenue S.W.
Washington, DC 20201;

CHIQUITA BROOKS-LASURE, Administrator of Centers for Medicare & Medicaid Services,
7500 Security Boulevard
Baltimore, MD 21244;

CENTERS FOR MEDICARE & MEDICAID SERVICES,
7500 Security Boulevard
Baltimore, MD 21244

Defendants.

Civ. No. 1:23-cv-01615-CKK

AMENDED COMPLAINT

INTRODUCTION

1. Last summer, as part of the Inflation Reduction Act (IRA), Congress established something called the "Drug Price Negotiation Program" for Medicare (the Program). The Program's name suggests a framework under which federal officials

sit down with prescription drug manufacturers and negotiate voluntary price agreements that will save money for American taxpayers while ensuring that the companies remain able to continue investing billions of dollars into research and development of new life-saving medicines. That is certainly how the Government—Congress, the President, and agency officials—have described and sold the Program to the American people. After all, who could oppose letting Medicare benefit from negotiated contracts, the basic building blocks of our market economy?

2. In reality, however, this "Drug Price Negotiation Program" is a sham. It involves neither genuine "negotiations" nor real "agreements." Rather, once HHS unilaterally selects a drug for inclusion in the program, its manufacturer is *compelled* to sign an "agreement" promising to sell the drug to Medicare beneficiaries at whatever "fair" price the agency *dictates*, which must represent at least a 25% to 60% discount. If a manufacturer refuses to participate in this "negotiation" or declines to "agree" to sell at the mandated price, it incurs a ruinous daily excise tax amounting to *multiples* of the drug's daily revenues. And once the Government successfully coerces entry into such an "agreement," that manufacturer becomes legally compelled to sell its most valuable products for a fraction of their value, on pain of yet more draconian penalties.

3. This is not "negotiation." It is tantamount to extortion. And it violates the Constitution in at least two obvious respects.

4. To start, the Fifth Amendment requires the Government to pay "just compensation" if it takes "property" for public use. Yet the singular purpose of this

scheme is for Medicare to obtain prescription drugs *without* paying fair market value. The IRA wields the threat of crippling penalties to force manufacturers to transfer their patented pharmaceutical products to Medicare beneficiaries, for public use. And the Act costumes these seizures as "sales" by forcing manufacturers to accept Government-dictated payments that represent a fraction of the drugs' fair value. By definition—and by design—that is not "just compensation." Requisitioning manufacturers' medicines in this manner is instead a classic *per se* taking.

5. Further, the IRA's mechanism for effecting this taking makes a mockery of the First Amendment. Congress could have accomplished its economic goals much more simply and honestly: by empowering HHS to set prices for covered drugs. The IRA instead operates through a façade of "negotiations" and "agreements" that require manufacturers to convey that they "agree" to HHS's "fair" prices. The only conceivable purpose of this circuitous regime is political deception—to allow the Government to pretend, as it already has done, that HHS's prices are not top-down mandates but the product of voluntary "agreements" with companies who concede they are "fair." Conscripting companies to legitimize government extortion is the sort of parroted orthodoxy that the First Amendment's compelled-speech doctrine forbids.

6. These constitutional violations cannot be swept under the rug by pretending that manufacturers have voluntarily subjected themselves to the Program by accepting reimbursements from Medicare and Medicaid. The IRA's mandates are enforced through excise taxes and monetary penalties, not exclusion from federal benefit programs. And while the excise tax is suspended if the manufacturer has no

relationship with Medicare or Medicaid, the IRA confirms this is not a genuine "condition" by delaying for up to 23 months a manufacturer's ability to terminate those relationships, making it literally impossible for manufacturers selected for initial inclusion in the Program to escape it. Regardless, leveraging all federal insurance benefits (amounting to over half of the prescription drug market) to coerce companies to abandon their First and Fifth Amendment rights is a quintessential unconstitutional condition. There is nothing voluntary about it.

7. If Congress truly wanted Medicare to "negotiate" drug prices, it had a clear constitutional path. Congress could simply have allowed HHS to specify a maximum price it would pay for a covered drug, or to employ its natural leverage to obtain favorable pricing in a true negotiation. But those options would have enabled manufacturers to walk away from the table, exposing the Government to enormous political backlash if certain medications became unavailable through Medicare. So, instead, the IRA uses severe penalties to requisition medicines while refusing to pay their fair value—and then coerces manufacturers to smile, play along, and pretend it is all part of a "fair" and voluntary exchange. This is political Kabuki theater.

8. To vindicate fundamental constitutional values, this Court should declare that the Program effects compensable takings under the Fifth Amendment, and enjoin its compelled "agreements" under the First Amendment.

PARTIES

9. Plaintiff Merck & Co., Inc. is an American pharmaceutical company headquartered in Rahway, New Jersey. Merck invests billions of dollars every year

to develop life-saving drugs. Among them is Januvia, which is used to treat type 2 diabetes. Januvia is expected to be subject to the IRA's scheme starting in 2023. Other Merck products like Janumet (another diabetes drug) and Keytruda (a groundbreaking cancer treatment) are projected to be subject to the Program in the following cycles. *See* S. Dickson & I. Hernandez, *Drugs likely subject to Medicare Negotiation, 2026-2028*, 29 JMCP 229, 230–31 (Mar. 2023) (Dickson & Hernandez). Plaintiff Merck Sharp & Dohme LLC is the wholly owned subsidiary of Merck & Co., Inc. that holds the "new drug applications" (NDAs) for these drugs. This Amended Complaint refers to both entities collectively as "Merck."

10. Defendant Xavier Becerra is the U.S. Secretary of Health and Human Services. He oversees the Medicare program and is responsible for administering the statutory provisions challenged here. He is sued in his official capacity only.

11. Defendant U.S. Department of Health and Human Services (HHS) is an executive department of the Federal Government headquartered in the District of Columbia. HHS is responsible for administering Medicare and the IRA provisions challenged here.

12. Defendant Chiquita Brooks-LaSure is the Administrator of the Centers for Medicare and Medicaid Services. She administers the Program on behalf of the Secretary. She is sued in her official capacity only.

13. Defendant Centers for Medicare and Medicaid Services (CMS) is an administrative agency within HHS that administers Medicare, including the Program, on which it has already issued certain implementation guidance.

JURISDICTION AND VENUE

14. This Court has subject-matter jurisdiction pursuant to 28 U.S.C. § 1331 because this action arises under the laws of the United States.

15. This Court may grant declaratory relief, injunctive relief, and other appropriate relief pursuant to 28 U.S.C. §§ 2201–02 and 5 U.S.C. §§ 703–06. Equitable relief is also authorized under this Court's inherent powers. *See Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 327 (2015).

16. Sovereign immunity poses no bar to this action for declaratory and injunctive relief. *See* 5 U.S.C. § 702 (general waiver of sovereign immunity in suits for declaratory and injunctive relief).

17. There is an actual controversy between the parties. One of Merck's drugs, Januvia, is among the ten most widely reimbursed drugs within Medicare Part D, which means it will be subject to the Program starting in September 2023. *See* Dickson & Hernandez, *supra*. Two other Merck products, Janumet and Keytruda, are projected to be subject to the Program soon after. *See id.*

18. Venue is proper under 28 U.S.C. § 1391(e), because Defendant HHS is located within this District.

FACTUAL ALLEGATIONS

The Inflation Reduction Act jettisons market-based pricing in favor of forced sales disguised as voluntary negotiations.

19. The Federal Government operates one of the world's largest health insurance programs. Medicare makes available to tens of millions of Americans the life-saving medicines developed by pharmaceutical companies like Merck.

20. Under Medicare Part B, manufacturers sell medications that physicians then administer, and the Federal Government reimburses part of the costs.

21. Any individual eligible for Medicare Part B may also enroll in a benefit plan for self-administered prescription drugs under Medicare Part D. Under Medicare Part D, beneficiaries can choose from various drug plans offered by private insurers that have contracted with the Government. Those plans provide coverage for drugs, and the Government reimburses plan sponsors for most of the costs.

22. For both programs, Congress has long been committed to a free-market approach based on market-driven prices. When Congress created Medicare Part D in 2003, it prohibited HHS from "interfer[ing] with the negotiations between drug manufacturers" and buyers. 42 U.S.C. § 1395w–111(i)(1). And under Medicare Part B, Congress promised reimbursement using a market-based "average sales price" methodology. *See id.* § 1395w–3a; R. Knox, *More Prices, More Problems: Challenging Indication-Specific Pricing as a Solution to Prescription Drug Spending in the United States*, 18 YALE J. HEALTH POL'Y, L. & ETHICS 191, 203 (2020).

23. Last summer, however, Congress charted a radical new course. As set forth below, the IRA fundamentally transforms Medicare, replacing voluntary market transactions with forced sales coerced by the threat of staggering penalties.

The Inflation Reduction Act uses massive threatened penalties to coerce drug manufacturers to "negotiate" and "agree" to "fair" prices.

24. The first step in the operation of the new Program is drug selection. For the first round of the Program, the Secretary must select 10 "negotiation-eligible" drugs by September 2023. *See* 42 U.S.C. §§ 1320f(d), 1320f–1(a)(1). In each of

February 2025 and February 2026, HHS must select 15 additional drugs to subject to the Program. *Id.* § 1320f–1(a)(2)–(3). And then, starting in February 2027, the Secretary must annually choose 20 new drugs to add. *Id.* § 1320f–1(a)(4).

25. The selection of drugs is cumulative. In other words, each year HHS picks an *additional* 10, 15, or 20 new drugs to add to the Program. As a result, projections show that, within ten years, half of all Medicare drug spending will be controlled by this new IRA price-setting process.

26. For "negotiation-eligible drugs," the IRA establishes a simple ranking system to determine selection. The rankings are based on "total expenditures" under Medicare over the prior 12-month period. *Id.* § 1320f–1(b)(1)(A). For the first two annual rounds of drug selection, the Secretary must consider "total expenditures" under Medicare Part D. *Id.* § 1320f–1(b)(2). After that, the Secretary must consider "total expenditures" under Medicare Parts B and D. *Id.* § 1320f–1(b)(1).

27. Under the 2023 formula, HHS is expected to select Merck's Januvia as part of the first round of the Program. Based on current spending levels, HHS is also expected to select additional Merck drugs—diabetes treatment Janumet and the groundbreaking cancer drug Keytruda—in the two subsequent cycles. *See* Dickson & Hernandez, *supra*. And given the annually expanding nature of the Program, more Merck products will inevitably be swept in, too.

28. After HHS lists the initial ten covered drugs in September 2023, Merck and other affected manufacturers will have only 30 days—until October 1, 2023—to "enter into agreements" with the Secretary, whereby they agree to participate in the

statute's sham negotiation process and ultimately accept a "maximum fair price" (MFP) at which they must sell the drug. 42 U.S.C. § 1320f–2(a). CMS plans to implement this requirement through a signed agreement that will set forth the requirements governing the manufacturer's participation in the Program. *See* CMS, *Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2026*, at 26 (Mar. 15, 2023) (CMS Initial Memo).

29. A manufacturer that signs this agreement necessarily communicates to the public that it is embarking on *bona fide* "negotiations" that will end in an agreed-upon "fair price."

30. The negotiations are a sham, however, because they are coerced through massive threatened penalties. If a manufacturer refuses to "agree" to negotiate, it must pay an escalating daily "excise tax" that starts at 186% and eventually reaches 1,900% of the drug's daily revenues. *See* 26 U.S.C. § 5000D; Cong. Rsch. Serv., Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376) at 4, tbl. 2 (2022). So a manufacturer who refuses to play ball must turn over a *multiple* of the covered drug's *total* revenues—not just revenues from Medicare or other government sources.

31. These rates would generate millions of dollars in penalties *every day*. Merck, for instance, could incur *tens of millions* of dollars in excise-tax penalties on the very first day of refusal to enter an "agreement" relating to Januvia, escalating to *hundreds of millions* of dollars per day after a few months of such resistance.

32. Unsurprisingly, Congress projected this "tax" to raise "no revenue": non-compliance would be too devastating. *See* Joint Comm. on Tax'n, Estimated Budget Effects of the Revenue Provisions Of Title XIII — Committee On Ways And Means, of H.R. 5376, The "Build Back Better Act," Fiscal Years 2022–2031, at 8 (Nov. 19, 2021). It is not really a "tax," but rather a stick to guarantee universal compliance.

33. Once a manufacturer threatened with these massive penalties "agrees" to "negotiate," it must turn over extensive and detailed confidential information "in a form and manner specified by the Secretary." 42 U.S.C. § 1320f–2(a)(4). A manufacturer that fails to timely provide all information demanded by the Secretary is subject to $1 million-per-day penalties. *Id.* §§ 1320f–2(a)(4)–(5), 1320f–6(b).

34. Armed with that information, the Secretary next provides a "written initial offer … and a concise justification." *Id.* § 1320f–3(b)(1)(B).

35. The IRA requires HHS to offer a price below a statutory ceiling based on a percentage of a benchmark market price—the non-federal average manufacturer price (or non-FAMP). The *ceiling* is 75% of non-FAMP for more recently approved drugs, and just 40% for drugs that have been approved for 12–16 years. *Id.* § 1320f–3(b)(2)(F), (c)(1)(C). In other words, the Program contemplates that the Government will usurp for itself a discount of at least 25% to 60% from this market-based price. And, of course, HHS is free to go below those ceilings—there is no *floor*.

36. The IRA permits the manufacturer to make a counteroffer, though it can be based only on limited statutory factors. *Id.* § 1320f–3(b)(2)(C)(ii), (e). Notably, manufacturers can cite the research and development costs "for the drug" that is

being commandeered by the Government—but cannot account for the enormous costs incurred in researching the exponentially larger number of drugs that never result in marketable products. *Id.* The Program thus ignores how manufacturers must use their few successes to recoup the losses from their many inevitable failures.

37. After some limited back-and-forth, negotiations for the Program's first round "shall end" by August 1, 2024. *Id.* § 1320f-3(b). By that date, the manufacturer must submit "a response" to the Secretary's "final written offer, either accepting or rejecting [it]." CMS Initial Memo 54.

38. Nothing obligates HHS to account for a manufacturer's counteroffer in its final offer, or prevents HHS from adhering to the same price contained in its initial offer. And the IRA purports to bar judicial review of (among other things) HHS's decisions about what prices to offer. *See* 42 U.S.C. § 1320f–7.

39. In all events, this entire process is utterly meaningless because, at this stage too, the IRA coerces manufacturers to "agree" to whatever price HHS ultimately picks. If the manufacturer does not "agree to" the final price offer that HHS considers "fair," *id.* § 1320f–2(a)(1), the manufacturer must pay daily penalties—indefinitely—under the same draconian formula described above, which by definition captures the entire economic value of the drug and then some. *See* 26 U.S.C. § 5000D.

40. The IRA is thus prophetic: The manufacturer *will* "agree." And when a manufacturer (misleadingly) conveys its "agree[ment] to" HHS's price, it props up the façade of voluntary arms-length bargaining and endorses the message—built into the IRA's "maximum fair price" slogan—that market prices would be *unfair*.

41. Not only are these negotiations disingenuous, they are also *secret*. CMS has announced that manufacturers "shall not disclose to the public any information in the initial offer or any subsequent offer by CMS, the ceiling price contained in any offer, … any information contained in any concise justification provided with an offer[,] [or] … any information exchanged verbally during the negotiation period." CMS Initial Memo 30. CMS will also "prohibit audio or video recording of any oral conversations between CMS and a … Manufacturer." *Id.* Manufacturers will thus be barred from informing the public as to how these fake "negotiations" proceed.

Once coerced into entering "agremeents" with HHS, manufacturers are indefinitely bound to sell their products at below-market prices.

42. As part of this coerced "agree[ment]" to below-market "fair" prices, the manufacturer must promise to provide "access to such price" to eligible individuals and entities. 42 U.S.C. § 1320f–2(a)(1). Failure to do so triggers civil monetary penalties of ten times the difference between the price the manufacturer actually charges and the mandated price, *id.* § 1320f–6(a), plus $1 million-per-day penalties for violation of the negotiated price "agreement," *id.* § 1320f–6(c).

43. The IRA and its "agreements" therefore do not merely prohibit charging more than the HHS-dictated MFP; they compel the manufacturer to provide Medicare beneficiaries with "access" to the drugs at that discounted price.

44. Once HHS compels a manufacturer to sell at the dictated price, sales must continue at that price (indexed only for inflation, *id.* § 1320f–4(b)(1)(A)) until a generic or biosimilar version of the drug is approved and marketed, *id.* § 1320f–1(c)(1), or the drug is picked for a "renegotiation," *id.* § 1320f–3(f).

45. In short, once a manufacturer is sucked into the IRA's vortex of forced below-market sales, it has at its disposal no evident means of escape.

For political benefit, the Government has falsely characterized the IRA as involving voluntary negotiations.

46. The IRA's convoluted process of sham negotiations and agreements raises an obvious question: Why did Congress proceed this way? Congress could have pursued its economic goals in a more direct fashion, by simply imposing price caps or using Medicare's market power to induce discounts through genuine negotiation.

47. Those options, however, would have left the door open for manufacturers to walk away from the table—to refuse to contract with Medicare over a particular drug if the price was not acceptable. And that would have carried a *political* cost—by angering seniors unable to access their medications. True negotiations, or even price caps without forced sales, were thus unpalatable for the Government.

48. Even still, Congress could have set prices and mandated sales without forcing companies to engage in sham "negotiations" or to "agree" with the final price. That would still have been an unconstitutional taking—but a far simpler one.

49. The only plausible explanation for the choice embodied in the Program's "agreement" structure is again political. Congress evidently saw upside in rebranding top-down price controls and mandates—interventions often associated with rationing and shortages—as negotiated, voluntary agreements.

50. The verb "negotiate" means "[t]o communicate or confer (with another or others) for the purpose of arranging some matter *by mutual agreement*; to discuss a matter with a view to some compromise or settlement." Oxford English Dictionary

(3d ed. 2003) (emphasis added). Nobody would describe a process in which one party can impose its wishes unilaterally on the other as a "negotiation." Yet the IRA labels its scheme a "*Negotiation* Program" and uses the word "negotiation" dozens of times.

51. Consistent with the statute's deceptive wording, the Government has consistently mischaracterized the Program as involving only voluntary negotiations and agreements. The deception began in Congress, where the IRA's supporters frequently repeated the lie that the statute envisions voluntary dealmaking.

52. The Administration has echoed this false characterization. Upon signing the IRA, the President claimed that the statute merely gave Medicare "the power to negotiate lower prescription drug prices." Remarks by Pres. Biden on Medicare and the Inflation Reduction Act (Sept. 27, 2022), http://bit.ly/3VlGApz ("[A]fter years of Big Pharma blocking it, Medicare will finally get the power to negotiate lower prescription drug prices."). And the President repeated the same claim during his 2023 State of the Union Address. *See* Pres. Biden's State of the Union Address (Feb. 7, 2023) https://www.whitehouse.gov/state-of-the-union-2023/ ("[The IRA] finally giv[es] Medicare the power to negotiate drug prices … bringing down prescription drug costs.").

53. HHS and CMS have often repeated that mischaracterization. *See, e.g.*, CMS, *Fact Sheet: The Inflation Reduction Act Lowers Health Care Costs for Millions of Americans* (Oct. 5, 2022), http://bit.ly/3gnSQqH. Perhaps most gallingly, in its recent guidance, CMS "note[d] that entering into an Agreement [to sell at the chosen

price] is voluntary"—just one sentence after reminding manufacturers that they would face massive penalties for *failing* to agree. CMS Initial Memo 27.

54. Absent from these speeches and statements is any acknowledgement that the IRA effectively empowers HHS to unilaterally impose its preferred price.

55. Confessing that truth would dispel the myth that the IRA involves only voluntary negotiations. And that would undoubtedly make the IRA less popular among the American public. One recent poll found that 79% of Americans support "allowing the federal government to directly negotiate with drug companies to get a lower price on medications." National Tracking Poll #2109099, Morning Consult (Sept. 16–19 2021), at 13. But when asked about a regime that "effectively allow[s] the federal government to set the prices of drugs," support plunged by over 30%. *Id.* at 17.

56. The IRA's regime of sham negotiations and compelled speech thus serves an attractive political purpose for its sponsors: enabling the Government to evade accountability for its actions. This same motivation explains CMS's insistence on secrecy during the "negotiations." *See supra* ¶ 41. If the public knew what actually transpired during those "negotiations," the word might suddenly appear less apt.

Under the IRA, the Government will appropriate Merck's property without paying just compensation, in violation of the Takings Clause.

57. The Takings Clause provides: "[N]or shall private property be taken for public use, without just compensation." U.S. Const., amdt. V. Under that Clause, if the Federal Government wants to requisition private property for public benefit, it can do so—but must pay the fair value of that property.

58. Patented pharmaceuticals are undoubtedly "private property" under the Takings Clause. The drugs themselves are quintessential personal property, which is protected from uncompensated takings. *See Horne v. Dep't of Agric.*, 576 U.S. 351, 358–59 (2015) ("Nothing in [Anglo-American] history suggests that personal property was any less protected against physical appropriation than real property."). Appropriations of personal property like crops and horses during the American Revolution were, indeed, among the primary reasons the Framers adopted the Takings Clause. *See id.*

59. Pharmaceutical drugs are doubly protected because they are also patented. Federal patents create property rights protected by the Takings Clause. *See Horne*, 576 U.S. at 359 (patent confers "an exclusive property in the patented invention which cannot be appropriated or used by the government itself, without just compensation" (quoting *James v. Campbell*, 104 U.S. 356, 358 (1882)); *Hartford-Empire Co. v. United States*, 323 U.S. 386, 415 (1945) ("That a patent is property, protected against appropriation both by individuals and government, has long been settled."). That is why Medicare cannot just manufacture its own versions of Merck's drugs for beneficiaries; it must procure them from Merck.

60. Under the IRA, the Government will take Merck's patented products by forcing Merck to provide third parties with "access" to those products at steeply discounted prices. That compelled transfer of title effects a classic, *per se* taking. *See, e.g.*, *Horne*, 576 U.S. at 362; *Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2072 (2021) (taking occurs whether the Government takes property "for itself or someone

else"). This Program deprives Merck of the "rights 'to possess, use and dispose of'" its property. *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 435 (1982).

61. Just as the statute in *Horne* effected a classic *per se* taking by requiring raisin farmers to turn over a portion of their crop to the Federal Government, *see* 576 U.S. at 361, the IRA's forced-sale regime does the same by compelling drug manufacturers to surrender their patented drugs to third parties for the Government's benefit.

62. "The Government has a categorical duty to pay just compensation" when it "appropriat[es] … personal property." *Id.* at 358.

63. Because the IRA appropriates manufacturers' patented drugs, the Government must pay "just compensation"—"the fair market value of the property at the time of the taking." *United States v. Reynolds*, 397 U.S. 14, 16 (1970).

64. By design, however, the IRA compensates manufacturers at artificially low rates—at least a 25% discount (and potentially far steeper) from the non-FAMP price, based solely on the HHS Secretary's *noblesse oblige*. Securing that discount for the benefit of the Government's insurance program is precisely the point. These terms ensure the Government will requisition Merck's drugs without paying the just compensation that the Constitution demands.

The IRA compels Merck to affirm the Government's message in violation of the First Amendment.

65. The IRA also compels speech by coercing manufacturers into becoming mouthpieces for the Government's public-relations campaign. By laundering its mandates through performative "negotiations" and "agreements," the Act requires

manufacturers to endorse and express the view that they "agree" to HHS-dictated forced prices, and that those prices are "fair." 42 U.S.C. § 1320f–2(a), (a)(1).

66. The scheme's aim is to deceive the American public. Its forced messaging promotes the (false) impression that manufacturers acquiesce in—indeed, *agree with*—prices imposed by HHS decree. By draping unilateral Government action in the garb of (secret) arms-length bargaining, the IRA subjugates free expression to political slogans. And by requiring euphemistic talk of "negotiation" and "agreement," the IRA spares its champions the task of justifying bureaucrat-mandated price caps.

67. But while the Government can mislead about its machinations, it cannot force those it governs to do the same. Our Constitution does not countenance compelled speech in service of state propaganda.

68. One of the core purposes of the First Amendment is to protect citizens and businesses from being forced to violate their convictions by mouthing messages they reject. "At the heart of the First Amendment lies the principle that each person should decide for himself or herself the ideas and beliefs deserving of expression, consideration, and adherence." *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 641 (1994). Accordingly, when the Government coerces a person into articulating views he finds false or offensive, that compulsion "invades the sphere of intellect and spirit" that the First Amendment "reserve[s] from all official control." *W. Va. State Bd. of Educ. v. Barnette*, 319 U.S. 624, 642 (1943).

69. The First Amendment also serves to ensure a transparent marketplace of ideas by shielding freewheeling public debate from self-serving state distortions. When Congress "requires the utterance of a particular message favored by the Government," it "seeks not to advance a legitimate regulatory goal, but to … manipulate the public debate through coercion rather than persuasion." *Turner Broad.*, 512 U.S. at 641. The First Amendment prevents such corruption of "the processes through which political discourse or public opinion is formed." *Expressions Hair Design v. Schneiderman*, 581 U.S. 37, 49 (2017) (Breyer, J., concurring).

70. In short, when the Government seeks to influence the public, it must do so as a genuine participant in the marketplace of ideas. It cannot seize additional megaphones by commandeering the voices of others.

71. The IRA's dystopian parody of "negotiation" violates those principles. *First*, by forcing manufacturers to "agree" with HHS on a "maximum fair price"—as opposed to just forcing manufacturers to sell at that price—the Program compels those businesses to parrot an ideological message inimical to their own views. *See* 42 U.S.C. § 1320f–2(a)(1); CMS Initial Memo 27, 54.

72. Merck, for example, understands that its products must be priced to incentivize and support the incredibly expensive process of researching, developing, and securing FDA approval for life-saving medicines—most of which never become marketable products. The "fairness" of a price must be informed by these economic realities—not Government labels. Simply put, Merck does not "agree" that forced sales at innovation-stifling discounts are "fair" to *anyone*—including patients.

73. But to avoid massive liability, Merck must peddle the Government's counternarrative. That is antithetical to the First Amendment, under which Merck cannot be made a "vehicle for spreading a message with which it disagrees." *Pac. Gas & Elec. Co. v. Pub. Utilities Comm'n of Cal.*, 475 U.S. 1, 17 (1986) (plurality). "For corporations as for individuals, the choice to speak includes within it the choice of what not to say," and "the government [cannot] require speakers to affirm in one breath that which they deny in the next." *Id.* at 16. The IRA betrays that basic promise.

74. *Second*, the IRA's contrived display of "negotiated agreements" distorts public debate. Forcing its targets to portray themselves as willing participants creates and insulates the message that HHS's prices are "fair." And the agency's prohibition on any public disclosure of the "negotiation" exacerbates that problem by interfering with manufacturers' efforts to correct the misperception. To be sure, the Government is entitled to persuade the public that drug prices would be "unfair" absent the IRA. But the Government cannot compel regulated parties to feign agreement with the Program's aims or to broadcast its supposed benefits.

75. The IRA's burdens on expression do not advance any legitimate (much less substantial or compelling) government interest. Deceiving the public does not reduce drug prices, advance innovation, or protect the public fisc. There was no need to set up an ersatz "negotiation" process or require manufacturers to "agree" to HHS's preferred price. To repeat, Congress could have accomplished its economic goals by simply empowering HHS to use its purchasing power to reach genuine agreements,

or even to unilaterally impose maximum prices Medicare would pay for covered drugs. That just would not have satisfied the Government's *political* goals.

76. The Act's structure is instead driven entirely by perception and avoiding accountability—as its rollout attests. From the President on down, the Government has trumpeted this new opportunity to "negotiate" lower prices. After all, Americans expect their Government to advance their interests at bargaining tables of all sorts—from corporate boardrooms to international summits.

77. But there is no bargain here. An IRA price "agreement" is a bureaucratic diktat in disguise, backed by coercive state sanctions rather than mutual consent. And the First Amendment does not recognize political theater as a justification for forced expression.

The IRA provides no way for Merck to avoid its scheme of forced sales and compelled speech.

78. Nor can the Government claim that manufacturers have voluntarily submitted to the IRA's draconian and deceptive scheme, or otherwise given up their constitutional rights, merely by accepting Medicare or Medicaid reimbursements for their products.

79. Congress has the power to impose conditions on private entities that accept federal funds, but "if Congress intends to impose a condition on the grant of federal moneys, it must do so unambiguously." *Cummings v. Premier Rehab Keller, P.L.L.C.*, 142 S. Ct. 1562, 1570 (2022). That requirement ensures that the "recipient voluntarily and knowingly accept[ed] the terms" offered by the Government. *Id.*

80. Here, the IRA does not even pretend that its demands—surrender your property and say you did so willingly—are conditions for reimbursement under Medicare or Medicaid. The statute does not set forth conditions, or even provide for termination of reimbursements going forward if a manufacturer does not cooperate. Rather, it *commands* manufacturers to comply with the scheme and levies *immense monetary penalties* for failure to do so. Put differently, there is no offer for Merck to accept because the IRA does not make one.

81. To be sure, the IRA "suspends" its ruinous tax penalty if a manufacturer has *no* Medicare or Medicaid rebate agreements in effect—not merely for the drug at issue but for *any* of the manufacturer's drugs. 26 U.S.C. § 5000D(c). But that indirect, convoluted scheme cannot be said to "unambiguously" condition the receipt of federal funding on a manufacturer's acceptance of the IRA's mandates.

82. That is especially true because even this Hobson's choice—like much else in the IRA—proves illusory. Merck will be compelled, under threat of eight-figure daily excise-tax penalties, to sign an agreement submitting to forced sales of Januvia by October 1, 2023. Yet the IRA delays a manufacturer's ability to terminate its Medicare Part D agreements for between 11 and 23 months. 42 U.S.C. § 1395w–114a(b)(4)(B)(ii). To avoid being penalized for failure to sign the October 1, 2023, "agreement," Merck would therefore have needed to terminate all relevant Medicare contracts by January 31, 2022—*months before the IRA was even enacted*. Of course, Merck could not have known to do so. That reality confirms that the IRA imposes mandates, not "conditions."

83. Even if the IRA could somehow be construed as adding conditions to the receipt of Medicare and Medicaid reimbursements, such conditions would plainly be unconstitutional. A permissible condition (as opposed to unconstitutional coercion) must substantially advance a purpose related to the underlying benefit, and be "rough[ly] proportiona[l]" in degree to the benefit. *Dolan v. City of Tigard*, 512 U.S. 374, 391 (1994). Otherwise the Government could readily leverage its vast Spending Clause powers to induce the forfeiture of any and all constitutional rights.

84. Here, due to the interlinked nature of federal insurance programs, *see* 42 U.S.C. §§ 1395w–153(a)(1), 1396r-8(a)(1), (c), extricating itself from the IRA's tax penalty would preclude a manufacturer from receiving *any* payments for *any* drugs reimbursed by Medicare Part B, Medicare Part D, or Medicaid.

85. Coercing sales of *one* drug at discount prices does not substantially advance the purposes of countless distinct transactions whereby Medicare and Medicaid pay for *other* products. And terminating *all* of the latter payments is obviously a penalty for the refusal to forfeit constitutional rights—not a "rough[ly] proportiona[l]" condition. *Dolan*, 512 U.S. at 391. This threat is unconstitutionally coercive—a "gun to the head"—because it leverages vast, unrelated benefits to induce distinct transactions that the Government wants. *Nat'l Fed'n of Indep. Business v. Sebelius*, 567 U.S. 519, 581 (2012) (*NFIB*).

86. Medicare and Medicaid account "for almost half the annual nationwide spending on prescription drugs." *Sanofi Aventis U.S., LLC v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023). No rational manufacturer could simply withdraw from half of the U.S.

prescription drug market, leaving tens of millions of patients without their medicines. Holding hostage access to half of the U.S. drug market is not a legitimate condition; it is "'economic dragooning'" amounting to "'a gun to the head.'" *Doe v. Univ. of Sciences*, 961 F.3d 203, 213 (3d Cir. 2020) (quoting *NFIB*, 567 U.S. at 581–82).

CLAIMS

Count One: Uncompensated Takings in Violation of the Fifth Amendment

87. Merck realleges all prior and subsequent paragraphs.

88. The Fifth Amendment requires the Federal Government to pay "just compensation" when it takes property. U.S. Const. amend. V.

89. Under the IRA, the Government will requisition Merck's patented pharmaceutical products and transfer them to Medicare beneficiaries through forced sales. Those forced sales—coerced by the threat of draconian penalties that the Government has admitted no manufacturer could ever rationally afford to pay—will deprive Merck of possession and title to its personal property.

90. Because the IRA thus "appropriate[s] [Merck's] personal property," the Government "has a categorical duty to pay just compensation." *Horne*, 576 U.S. at 358. "[J]ust compensation" requires the Government to pay Merck the fair market value of drugs that it appropriates. *See Reynolds*, 397 U.S. at 16.

91. By design, however, the IRA does not provide just compensation, because it requires HHS to seize minimum discounts from market benchmark prices and grants the agency vast discretion to provide even less remuneration. The entire purpose of the Act is to secure drugs like Merck's for Medicare beneficiaries at heavily

discounted prices, so the Government—the ultimate payor—can save money. "[T]his wolf comes as a wolf." *Morrison v. Olson*, 487 U.S. 654, 699 (1988) (Scalia, J., dissenting).

92. Declaratory relief is "appropriate" in this case. 28 U.S.C. § 2201. Declaratory relief for takings claims is available when a statute does not provide "advance assurance of adequate compensation in the event of a taking." *Duke Power Co. v. Envt'l Study Grp.*, 438 U.S. 59, 71 n.15 (1978).

93. Declaratory relief is also appropriate because awaiting an *ex post* suit for just compensation under these circumstances "would entail an utterly pointless set of activities"—"Congress could not have contemplated" that "every dollar [saved] pursant to the [IRA] would be presumed to generate a dollar of … compensation." *E. Enters. v. Apfel*, 524 U.S. 498, 521 (1998) (plurality).

94. Moreover, declaratory relief is appropriate where it would "finally settle the controversy between the parties," resolve an issue of great "public importance," promote "the convenience of the parties," and be judicially manageable given "the degree of adverseness between the parties." *Morgan Drexen, Inc. v. CFPB*, 785 F.3d 684, 696–97 (D.C. Cir. 2015). All of those criteria are satisfied here.

95. Accordingly, the Court should declare that the Program will effect takings without providing "just compensation" under the Fifth Amendment. The computation of that just compensation can occur in future actions seeking monetary relief if the proper quantum of compensation is ultimately disputed.

Count Two: Compelled Speech in Violation of the First Amendment

96. Merck realleges all prior and subsequent paragraphs.

97. The First Amendment protects both the right to speak and the right to refrain from speaking. *See Agency for Int'l Dev. v. Alliance for Open Soc'y Int'l, Inc.*, 570 U.S. 205, 213 (2013).

98. Laws that compel private speech are presumptively unconstitutional and may stand only if narrowly tailored to serve compelling interests.

99. The IRA compels Merck to speak by forcing it to communicate that it has "agreed" to an HHS-mandated price, and to endorse the viewpoint that HHS's price is "fair" while any higher market-based price would be *unfair*.

100. The Government's only apparent interest in compelling this speech is to reap political benefits by camouflaging a system of unilateral price controls and forced sales as one of voluntary negotiations. Confirming that impermissible motive, the Government also plans to impede Merck's ability to engage in counterspeech by prohibiting public disclosure of how the IRA's sham negotiations proceeded.

101. Deceptive political messaging is neither compelling nor legitimate. Nor is the Government's compelled-speech Kabuki narrowly tailored to potentially legitimate interests in price regulation. Congress could have authorized HHS to genuinely negotiate or even unilaterally set prices, or (unlawfully) compelled manufacturers to sell their products at dictated prices, without sham "negotiations" or "agreements" coerced by tens or hundreds of millions of dollars in daily fines.

Congress resorted to this more circuitous regime of compelled speech to evade accountability and fashion an attractive political slogan.

102. An injunction is warranted. "The loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." *Elrod v. Burns*, 427 U.S. 347, 373 (1976). And because the Government can offer no legitimate justification for the IRA's performance art, the equities and the public interest also favor an injunction.

103. Accordingly, the Court should declare that the statutory requirements that manufacturers "agree" to "maximum fair prices" are unconstitutional and enjoin Defendants from enforcing them. In particular, the Court should enjoin Defendants from forcing Merck to sign an initial "[m]anufacturer agreement[]." 42 U.S.C. § 1320f–2(a). It should also enjoin Defendants from forcing Merck to "agree to" the "maximum fair price" developed through the Program. *See id.* § 1320f–2(a)(1), (a)(2). And the Court should declare null and void any such agreements that Merck is unconstitutionally coerced to enter before this case is finally adjudicated.

PRAYER FOR RELIEF

Now, therefore, Merck requests a judgment in its favor as follows:

1. Declaring that the Program effects takings without providing for just compensation under the Fifth Amendment;

2. Declaring that the Program compels speech in violation of the First Amendment;

3. Enjoining Defendants from forcing Merck to sign an initial "manufacturer agreement" or to "agree" to prices set by the Program;

4. Declaring any such agreements that Merck has been compelled to enter under the IRA's unconstitutional threat of penalties to be null and void;

5. Awarding reasonable attorneys' fees and costs, plus interest accruing thereon, under 28 U.S.C. § 2412; and

6. Granting such other and further relief as the Court may deem appropriate.

Dated: October 19, 2023

Respectfully submitted,

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