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

BRISTOL MYERS SQUIBB COMPANY,

Plaintiff,

v.

XAVIER BECERRA, U.S. Secretary of Health & Human Services; CHIQUITA BROOKS-LASURE, Administrator of Centers for Medicare & Medicaid Services; U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES; CENTERS FOR MEDICARE & MEDICAID SERVICES,

Defendants.

Civil Action No. _____

COMPLAINT

INTRODUCTION

1. When Congress enacted the Medicare "Drug Price Negotiation Program" (the Program) in the Inflation Reduction Act (IRA) last summer, it did so under the guise of merely empowering Medicare to "negotiate" directly with pharmaceutical companies to enter voluntary price "agreements" for certain medications. In truth, however, Congress did something entirely different. Contrary to its name, the Program does not involve "negotiations" in any ordinary sense of the word. Nor does it result in real "agreements" between Medicare and pharmaceutical companies.

2. Rather, the Program creates an unprecedented regime whereby the Secretary of the U.S. Department of Health and Human Services (HHS) dictates a price at which pharmaceutical companies are compelled to sell their most innovative and

successful medicines or else face unconscionable penalties. Moreover, Congress sought to mask the reality of this Government-controlled scheme by forcing the companies to participate in a faux "negotiation" process and then express their "agreement" that whatever price HHS chooses is "the maximum fair price" for their medicines.

3. The Program works like this: HHS unilaterally selects a series of pharmaceuticals for inclusion. The manufacturer of each chosen pharmaceutical is then compelled to enter an "agreement" with HHS committing to provide the medicine to Medicare beneficiaries at whatever price the agency determines (in its purportedly unreviewable discretion) to be "fair." That price is capped at a fixed fraction of a benchmark market price for the pharmaceutical (and HHS is free to set the price even lower). If the company does not sign such an "agreement" by the statutory deadline, or does not ultimately "agree" that the price dictated by HHS is a "fair" price in a public contract, it must pay a penalty (which the IRA deceptively calls a "tax") that is multiples of the pharmaceutical's overall revenues—day after day, until the company relents.

4. Unlike a true "negotiation," this Program guarantees that the Government will secure the products it wants at the prices it dictates—the exponentially higher penalty makes that certain. This "negotiation" is akin to the Government telling you how much it will pay to buy your house (capped at a fraction of the assessed market value), and then forcing you to sign an agreement turning over the house and announcing that the heavily discounted price is "fair," all under duress of having to pay a tax that dwarfs the home's true market value.

5. This Program is unconstitutional. Most obviously, the Fifth Amendment requires the Government to pay "just compensation" if it takes private "property" for public use. This fundamental protection prevents Medicare from outright seizing a portion of each pharmaceutical company's inventory. But compelling the transfer of the inventory at a unilaterally dictated *discount* is no different, either functionally or legally. The singular purpose of the Program is to allow Medicare to secure the pharmaceuticals without paying their fair value. It uses the threat of crippling penalties to accomplish that objective. That amounts to a classic, *per se* physical taking without the "just compensation" that the Constitution demands.

6. That is not the only constitutional infirmity in the way the IRA is structured. Rather than candidly admitting to the American people that it imposed mandatory price controls and forced sales, Congress filtered the IRA's requirements through a façade of "agreements" through which pharmaceutical manufacturers must convey that they "agree" to HHS's dictated prices and that they "agree" that such prices are the "the maximum fair price[s]" for their medicines. In other words, instead of simply *directing* the companies on what they *must* do, the IRA uses the threat of penalties to coerce the companies to *say they agree* to do it all *voluntarily*. That is unprecedented—and intentional. This structure serves the political purpose of masking unilateral price caps as voluntary "agreements" formed through genuine "negotiations," when they are not. But, under the First Amendment, the Government cannot conscript citizens (including businesses) to parrot its preferred political messaging.

7. The IRA violates the Constitution by forcing pharmaceutical companies to turn over their most successful and innovative products at a huge discount, while publicly pronouncing the transaction to be "fair." And these constitutional violations do not become permissible simply because the companies choose to accept federal reimbursements for selling their products to Medicare and Medicaid—together accounting for approximately half of all patients taking these medications.

8. For one thing, the IRA's mandates are enforced through monetary fines and penalties, not by imposing conditions on receipt of federal reimbursements. For another, manufacturers cannot "withdraw" from Medicare or Medicaid without giving notice up to *two years* in advance—which means that once a company's pharmaceutical is selected, it is too late to exit. For a third, Congress cannot leverage its Spending Clause power to coerce companies to forgo their rights. Hinging all Medicare and Medicaid participation on a faux "agreement" to sell a single medicine at an agency-dictated price is a quintessential example of an unconstitutional condition. It is constitutionally untenable to force companies to choose between abandoning their fundamental rights or cutting off tens of millions of patients from their medications.

9. In the end, the IRA's real victim is innovation—and, in turn, the millions of patients who are counting on the pharmaceutical industry to develop new therapies that save lives and improve health and wellbeing. Pharmaceutical manufacturers must take enormous financial risks to develop new medicines. The creation of such medicines requires billions of dollars of investment to fund extensive scientific research. And for

every success, many more ideas and experiments fail to produce a marketable medicine that secures approval from the Food and Drug Administration (FDA). Altogether, the realities of science allow only a tiny fraction of research projects to recoup their development costs. Because of that dynamic, manufacturers can afford to fund the research and development of future medicines only if the handful of products that succeed generate sufficient revenues to make those investments worthwhile. Yet the IRA targets precisely those most successful products, and dramatically undercuts their revenue stream. In doing so, the IRA will force pharmaceutical manufactuers to reduce their investments in potentially promising medicines and treatments. As a result, future life-saving treatments in areas such as cancer, Alzheimer's disease, and immunological and cardiovascular disease may never see the laboratory, much less achieve FDA approval, and will never reach the patients in need of such treatments.

10. This dystopian reality need not come to pass. This Court should declare that the Program effects compensable takings under the Fifth Amendment, and enjoin the Program's compelled "agreements" under the First Amendment.

PARTIES

11. Plaintiff Bristol Myers Squibb Company (BMS) is a U.S. pharmaceutical company with its principal place of business in Lawrenceville, New Jersey. BMS invests billions of dollars every year to research and develop medicines to address the unmet medical needs of patients with serious diseases, last year alone investing $9.5 billion in research and development and conducting over 460 clinical trials.

12. Among the life-saving medicines developed by BMS is Eliquis, which is used to prevent blood clots and strokes. Eliquis will be subject to the IRA's pricing scheme starting in 2023. Another BMS medicine, Opdivo—used to treat several types of cancer—will be chosen for a subsequent round of the Program. *See* S. Dickson & I. Hernandez, *Drugs likely subject to Medicare Negotiation, 2026-2028*, 29 JMCP 229, 230–31 (Mar. 2023) (Dickson & Hernandez). And others will inevitably follow. BMS is the NDA (new drug application) holder for both Eliquis and Opdivo.

13. BMS is committed to providing access to its life-saving therapies. In 2022 alone, BMS donated approximately $3 billion in free medicine to independent charitable organizations to support over 155,000 patients in the United States. BMS also provided approximately $742 million to support organizations that help patients and their families, improve healthcare, advance scientific understanding, and foster strong communities.

14. Defendant Xavier Becerra is the Secretary of HHS. He oversees the Medicare program and is responsible for administering the statutory provisions challenged here. He is sued in his official capacity only.

15. Defendant Chiquita Brooks-LaSure is the Administrator of the Centers for Medicare & Medicaid Services (CMS). She administers the Program on behalf of the Secretary. She is sued in her official capacity only.

16. Defendant HHS is an executive department of the Federal Government headquartered in Washington, D.C. HHS is responsible for administering Medicare and the IRA provisions challenged here.

17. Defendant 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

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

19. This Court may grant declaratory, injunctive, and other appropriate relief under 28 U.S.C. §§ 2201–02 and 5 U.S.C. §§ 703–06. Equitable relief is also authorized under this Court's inherent powers.

20. Sovereign immunity poses no bar to this action for declaratory and injunctive relief. *See* 5 U.S.C. § 702.

21. There is an actual controversy between the parties. Based on Medicare Part D spending over the past 12 months, one of BMS's medicines, Eliquis, will be subject to the Program starting in September 2023. *See* Dickson & Hernandez, *supra*. Another BMS product, Opdivo, will be subject to the Program soon after. *See id.* And others will inevitably follow.

22. Venue is proper under 28 U.S.C. § 1391(e), because BMS's corporate headquarters is located within this District.

FACTUAL ALLEGATIONS

A. Background on the Medicare Program.

23. Through the Medicare program, the Federal Government operates one of the world's largest, and the most influential, health insurance programs. Medicare makes available to tens of millions of American beneficiaries the life-saving products developed by pharmaceutical companies like BMS.

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

25. Those eligible for Medicare Part B may also enroll in Medicare Part D, which allows beneficiaries to choose from various self-administered prescription pharmaceutical plans offered by private insurers that have contracted with the Government. Those contracts are awarded based on competitive bids, which specify the pharmaceutical costs the Government would reimburse upfront. 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, 205 (2020) (Knox).

26. Historically, Congress employed a free-market approach based on market-driven prices to calculate Medicare reimbursements. Under Medicare Part B, Congress calculated reimbursement using a market-based "average sales price" methodology. *See* 42 U.S.C. § 1395w–3a; Knox at 203.

27. And 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). "[I]ndividual Medicare Part D plans can and do negotiate prices with prescription drug manufacturers." Knox, *supra*, at 206. Plans are incentivized to do so because lower prices make it easier to secure Government approval for the plan, and render the plan more attractive to consumers. *See id.*

28. Congress established these market-based reimbursement systems because it recognized that pharmaceutical innovators depend on the revenues from the very small percentage of medicines that ultimately secure FDA approval and become marketable products in order to fund their research and development of a much larger volume of potential therapies, many of which never reach the market. The goal is to ensure that these companies can keep innovating and developing life-saving treatments for all Americans.

B. The Inflation Reduction Act.

29. By enacting the Program, the IRA fundamentally transforms the way the Government obtains and pays for prescription medicines under Medicare. As set forth below, the Program directs HHS to select certain medicines, dictate a discounted price for those medicines, and then coerce manufacturers using the threat of penalties disguised as "taxes" to sell the medicines at those discounted prices while declaring the terms to be "fair."

30. The new Program begins with drug selection. The Secretary must select 10 "negotiation-eligible" medicines by September 2023. 42 U.S.C. §§ 1320f(d), 1320f–1(a)(1). In February 2025 and February 2026, HHS must add 15 more medicines per year to the Program. *Id.* § 1320f–1(a)(2)–(3). Starting in February 2027, the Secretary must annually choose 20 new medicines to add. *Id.* § 1320f–1(a)(4).

31. This is a cumulative process, meaning new medicines are *added* to the Program each year. That is why projections show that half of all Medicare drug spending will be controlled by this new IRA price-setting process within ten years.

32. The selection of pharmaceuticals is based on total Medicare expenditures, with HHS choosing the products that cost the program the most over the prior year. *Id.* § 1320f–1(b)(1)(A). That selection mechanism ensures that the Program targets pharmaceutical companies' most successful products—those that are most valuable and most widely used—which are precisely the products the companies depend on to recoup their overall research and development investments.

33. Based on the statutory formula and publicly available data, HHS must and will select Eliquis, a groundbreaking BMS medicine used to prevent blood clots and strokes, as part of the first round of the Program in September 2023.

34. Independent analysts have also projected that HHS will select Opdivo, an immunotherapy developed by BMS that is widely used to treat various cancers, two years later. *See* Dickson & Hernandez, *supra*.

35. Once a medicine is chosen by HHS, its manufacturer is given 30 days to "enter" an "agreement[]" with the Secretary. 42 U.S.C. § 1320f–2(a). The "agreement" commits the manufacturer to participate in the Program's faux "negotiation" process and to reach agreement with HHS on a "maximum fair price" (MFP) for the drug. *Id.*

36. According to initial CMS guidance, that requirement will be effectuated through a signed agreement that sets forth the requirements governing 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).

37. Importantly, however, if a manufacturer refuses to "agree" to engage in the faux "negotiation" process by that statutory deadline, it must pay an escalating daily penalty (which the Act refers to as an "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). That penalty guarantees compliance by making it exponentially more expensive to pay the penalty than to "agree" to the Government's terms. Notably, the penalty is based on the targeted product's revenues from *all* sources, not just Medicare.

38. So, if BMS were to refuse to participate in the Government's scheme, it could incur in excess of $150 million in "excise-tax" penalties on the very first day it declines to enter an "agreement" relating to Eliquis, escalating to *in excess of $1.5 billion* per day after a few months of such resistance.

39. Confirming that these draconian penalties exist only to coerce compliance (as no company could afford to pay them), Congress itself projected this "tax" to raise "no revenue"—a stark admission. 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).

40. Once the manufacturer faced with that untenable choice commits to "negotiate," the process begins with the Secretary providing a "written initial offer … and a concise justification." 42 U.S.C. § 1320f–3(b)(1)(B). Notably, the law does not limit how low a price HHS can dictate, but it does cap how high an amount HHS may set. That ceiling is imposed at a percentage of a benchmark market price known as the "non-federal average manufacturer price," or "non-FAMP." Under the Program, the Secretary is permited to "offer" no more than 75% of non-FAMP for newer medicines, and no more than 40% of non-FAMP for medicines that have been on the market for over 16 years. *See id.* § 1320f–3(b)(2)(F), (c)(1)(C). In other words, the Program mandates that the Government secure a discount of at least 25% to 60% from this market-based benchmark, with no floor beneath which HHS cannot go.

41. Adding insult to injury, the IRA purports to bar judicial and administrative review of HHS's decisions about what prices to offer. *See* 42 U.S.C. § 1320f–7.

42. While the Program permits the manufacturer to make a "counter-offer," it restricts the factors that can be used to justify any such "counter-offer." *Id.* § 1320f–3(b)(2)(C)(ii), (e). Among other things, although manufacturers can cite the research

and development costs for the particular product requisitioned by the Government, they cannot account for the enormous costs incurred in researching the exponentially larger number of medicines that never result in marketable therapies.

43. But even more problematic is that HHS is free to simply ignore any such "counter-offer" and dictate what price the manufacturer must "agree" to. In particular, the IRA says that negotiations "shall end" by a fixed date—for the first round, by August 1, 2024, *id.* § 1320f-3(b)—by which point the manufacturer must submit "a response" to the Secretary's "final written offer, either accepting or rejecting [it]." CMS Initial Memo at 54.

44. Although that process simulates a "negotiation," the key difference is this: If the manufacturer does not "accept" the HHS offer of whatever price the agency has announced to be "fair," then the company is once again subject to indefinite daily tax penalties that are designed to destroy the entire economic value of the product (and then some). *See id.* § 1320f–2(a)(1); 26 U.S.C. § 5000D.

45. In short, these are negotiations and agreements in name only. Indeed, the unconscionability and duress that serve as pillars of the Program would render the agreements unenforcable under any contractual analysis.

46. As part of the resulting "agreement," the manufacturer must commit to provide Medicare beneficiaries with "access" to the covered pharmaceutical product at the dictated price. 42 U.S.C. § 1320f–2(a)(1). Failure to do so triggers enormous civil monetary penalties. *See id.* § 1320f–6(a); § 1320f–6(c).

47. 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 medicines while charging Medicare that discounted price. And that obligation extends indefinitely, unless and until HHS determines that a generic or biosimilar version of the product has been approved and marketed, *id.* § 1320f–1(c)(1), or the agency picks it for a similar "renegotiation," *id.* § 1320f–3(f).

C. The IRA's Threat to Innovation.

48. America's pharmaceutical companies, including BMS, are working to develop thousands of innovative new treatments. But there is no guarantee that those efforts will bear fruit. The research and development process requires tremendous investments in time, money, and experimentation. One study found that, on average, $2.5 billion in revenue is required to support the invention of one new drug product. *See* P. Dubois, et al., *Market Size and Pharmaceutical Innovation*, 46 RAND Journal of Econ. 844, 861 (2015).

49. Despite these massive investments, the vast majority of new research projects do not even result in testable products. Indeed, only a fraction of 1% of the projects that enter preclinical testing eventually secure FDA approval—and only a fraction of *those* rare success stories recoup their investment costs. *See* J. Vernon & J. Golec, *Pharmaceutical Price Regulation: Public Perceptions, Economic Realities, and Empirical Evidence* 7–12 (2008). The ability to bring groundbreaking therapies to market thus depends on returns generated by just a handful of successful products.

50. Rather than encouraging BMS and other innovators to take the enormous risks necessary to bring life-saving medicines to patients who need them, the IRA penalizes those efforts. It targets precisely those rare breakthroughs that not only reach but revolutionize the market and become widely prescribed—and, thus, undergird and make possible the incredibly costly efforts to extend and improve human lives afflicted with disease.

51. As explained above, once such medicines have been on the market for a set period and have demonstrated their value to Medicare beneficiaries, the IRA will force manufacturers to sell them at Government-imposed discounted prices.

52. Given the sheer size of the Medicare market, this poses a grave and imminent threat to BMS's ability to fund new research. Again, the IRA places low price ceilings on such products, but no floors. As a result, manufacturers like BMS must operate—starting *now*—on the expectation that their most successful future products will be taken by the Government at well-below-market prices.

53. That impact on incentives is already rippling across the pharmaceutical industry. Research and development projects once deemed feasible are being abandoned, and the focus of research and development efforts are being skewed for reasons that have no connection to social welfare or patient health, but rather to the industry's survival.

54. For example, one manufacturer suspended development of a treatment for a rare eye disease because it would have fallen within the IRA's crosshairs. *See* J.

Grogan, *The Inflation Reduction Act is Already Killing Potential Cures*, WALL ST. J. (Nov. 3, 2022). Meanwhile, another company announced that, "in light of the [IRA]," certain blood cancer research "no longer met [the] threshold for continued investment." *Id.*

55. This pattern will only grow more pronounced in the years to come. One of America's great industries—a source of innovation the world depends on—will be seriously impaired. Life-saving treatments for diseases like cancer and Alzheimer's will remain undeveloped, and Americans will have fewer options to treat their most serious diseases.

D. The IRA's Uncompensated Taking of Property.

56. The basic premise of the Fifth Amendment's Takings Clause is that if the Government wants to appropriate private property—even for a legitimate, beneficial public use—it must pay "just compensation" to the owner. U.S. Const., amdt. V.

57. BMS's products are private "property" under that Clause. As the Supreme Court recently reaffirmed in a case involving appropriation of a share of raisin farmers' crops, "personal property" is just as "protected against physical appropriation" as "real property." *Horne v. Dep't of Agric.*, 576 U.S. 351, 358–59 (2015).

58. These medicines are also *patented*. A patent confers "exclusive property in the patented invention which cannot be appropriated or used by the government itself, without just compensation." *Id.* at 359; *see also 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.").

59. For both reasons, it is clear that the Government could not simply seize or appropriate a share of BMS's pharmaceutical inventory.

60. In effect, however, the IRA's scheme does the same thing. As explained above, the Program uses the threat of ruinous excise taxes to coerce BMS and other targeted manufacturers to transfer their patented pharmaceutical products to Medicare beneficiaries. Under the statute, BMS must provide "access" to those products—*i.e.*, turn them over. That compelled transfer is a classic, *per se*, physical taking of property because it deprives BMS of the "rights 'to possess, use and dispose of'" its property. *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 435 (1982).

61. To be sure, the IRA requires BMS to give its products to third parties (ultimately for the benefit of Medicare beneficiaries), not to the Government directly. But that does not make any legal difference. *See Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2072 (2021) (taking occurs whether the Government takes property "for itself or someone else"). And, of course, the Government—as insurer—is the ultimate financial beneficiary.

62. It is also true that the IRA provides *some* compensation to manufacturers like BMS—the statutorily capped amount that HHS picks as the MFP. But the Fifth Amendment requires the Government to pay "just compensation," which the Supreme Court has made clear is "the fair market value of the property at the time of the taking." *United States v. Reynolds*, 397 U.S. 14, 16 (1970).

63. The IRA's price-setting mechanism bears no connection to fair market value. To the contrary, the IRA objectively and deliberately departs from measurable market value by compensating manufacturers at a minimum 25% discount (and, with no floor, perhaps far steeper) from non-FAMP. Securing that discount for the Government's benefit is precisely the point. These terms ensure the Government will requisition BMS's medicines without paying just compensation.

64. The specific MFP may ultimately bear on the amount of damages to which BMS is entitled, but it does not change the reality that the IRA effectuates a physical taking without providing just compensation. The same was true in *Horne*: The law there provided for potential compensation down the road, but the Supreme Court was clear that any such payment merely impacted the computation of damages. *See* 576 U.S. at 364.

65. In short, just as the statute in *Horne* effected a classic *per se* taking by requiring raisin farmers to turn over a portion of their crops to the Government, the IRA does the same by compelling pharmaceutical manufacturers to surrender their patented medicines to third parties for the Government's benefit. In both cases, "[t]he Government has a categorical duty to pay just compensation." *Id.* at 358.

E. The IRA's Compulsion To Speak.

66. As explained above, the Program does not involve genuine "negotiations" or voluntary "agreements," because it uses the threat of enormous penalties in order to induce the manufacturers to participate in the process and sign on the dotted line.

67. For political purposes, however, Congress chose to structure the Program to create the appearance of manufacturer consent. It would have been simple enough to authorize HHS to set maximum prices for covered medicines. But that would have exposed the IRA as a top-down set of price controls, which are not politically popular because of their association with shortages and health-care waiting times.

68. Indeed, while a 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," support dropped by over 30 points when the respondents were asked about a regime that "effectively allow[s] the federal government to set the prices of drugs." National Tracking Poll #2109099, Morning Consult (Sept. 2021), at 13, 17.

69. That explains why the Government has consistently mischaracterized the Program as involving only voluntary negotiations and consensual agreements. The IRA's supporters frequently repeated that the statute envisions nothing more than voluntary dealmaking. And the President has since echoed this false characterization. On signing the IRA, the President claimed it gave Medicare merely "the power to negotiate lower prescription drug prices." Remarks by Pres. Biden on Medicare and the Inflation Reduction Act (Sept. 27, 2022), ("[A]fter years of Big Pharma blocking it, Medicare will finally get the power to negotiate lower prescription drug prices."); *see also* State of the Union Address (Feb. 7, 2023) ("[The IRA] finally giv[es] Medicare the power to negotiate drug prices … bringing down prescription drug costs.").

70. Of course, the Government is free to spread its own messages and beliefs whether BMS agrees with them or not. But what the IRA cannot do is compel BMS to become a spokesperson for promoting the Government's value judgments.

71. That is just what the IRA does. Again, instead of just mandating that BMS and other companies sell at the dictated price, the statute compels them to engage in performative "negotiations" and "agreements." Those processes ultimately require manufacturers to endorse and express the viewpoint that they "agree" to HHS-dictated prices, and that those prices are "fair." 42 U.S.C. § 1320f–2(a), (a)(1).

72. This forced messaging promotes the impression that innovators acquiesce in prices that are actually imposed by HHS fiat and to which the companies *must* "agree" in order to avoid vast excise-tax penalties. That may advance a political agenda—letting the Government repeatedly tell the American public that everyone has agreed on lower "fair" prices—but it is legally impermissible under the First Amendment.

73. One of the core purposes of the First Amendment is to protect citizens (including businesses) from being forced to violate their convictions by espousing 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). When the Government coerces a person into articulating views he rejects, that "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).

74. The First Amendment also serves to ensure a transparent marketplace of ideas by shielding open public debate from 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." *Turner Broad.*, 512 U.S. at 641. The First Amendment prevents 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).

75. The IRA's negotiation-and-agreement regime violates those principles. By forcing manufacturers to "agree" with HHS on a "maximum fair 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.

76. BMS understands from over a century and a half of industry experience that its medicines must be priced to 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. Accordingly, BMS does *not* "agree" that forced sales at innovation-stifling discounts are "fair" to anyone, least of all patients.

77. But to avoid massive liability, BMS must promote the Government's counternarrative. That is antithetical to the First Amendment, under which BMS 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).

78. The IRA's contrived display of "agreements" also distorts public debate by bolstering and insulating the message that HHS's prices are "fair." Again, 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.

79. Even if BMS or others could engage in a media campaign to counter the false message conveyed by these coerced "agreements," the Supreme Court has long held that "the government [cannot] require speakers to affirm in one breath that which they deny in the next." *Id.* at 16; *see also Glickman v. Wileman Bros. & Elliott, Inc.*, 521 U.S. 457, 471 (1997) (compelled speech violates the First Amendment if it forces company "to respond to a hostile message"). That itself burdens the freedom of speech.

80. Further underscoring the IRA's deceptive goals, CMS has announced that its "negotiations" will be held in secret, with manufacturers subject to a gag order. CMS has ordered 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 faux "negotiations" actually proceed. That confirms the goal of misleading the public about the true nature of this pricing regime.

81. Because the IRA compels speech, it must satisfy heightened scrutiny to survive. But these speech burdens do not advance any legitimate (much less substantial or compelling) government interest. Deceiving the public does not reduce prices, advance innovation, or protect the public fisc. Unlike safety warnings or other purely factual and uncontroversial compelled disclosures, there is no public health interest in running the IRA's mandates through a set of "agreements."

82. Congress could have sought to accomplish its *economic* goals by simply empowering HHS to use its purchasing power to reach genuine agreements, or even to unilaterally impose price caps that Medicare would pay for covered medicines. The Act's structure is instead driven entirely by politics and perception—as its rollout attests. 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.

83. But there is no genuine bargain here—just empty slogans that companies are compelled to communicate. That violates the First Amendment.

F. The IRA Does Not Impose Lawful "Conditions" on Medicare.

84. These constitutional violations cannot be excused by pointing out that pharmaceutical manufacturers can theoretically avoid the IRA's tax penalties by simply exiting the Medicare and Medicaid programs. That misapprehends the nature of Congress's Spending Power and the careful limits that the Supreme Court has imposed to prevent its abuse.

85. For one thing, while Congress may impose conditions on private entities that accept federal funds, "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) (emphasis added). That ensures the "recipient voluntarily and knowingly accept[ed] the terms" offered by the Government. *Id.*

86. Here, the IRA does not set forth conditions on Medicare or Medicaid reimbursement, or provide for exclusion from those benefit programs if a manufacturer does not cooperate. Rather, the statute commands manufacturers to comply and levies monetary penalties for failure to do so. On the back end, the statute "suspends" its tax penalty if a manufacturer has completely extricated itself from both Medicare and Medicad—not merely for the product at issue but for *all* of its products. 26 U.S.C. § 5000D(c). But that indirect, convoluted scheme does not "unambiguously" condition a manufacturer's receipt of federal funding on its acceptance of the IRA's mandates.

87. For another thing, even this choice is illusory. BMS will be compelled, under threat of nine- and ultimately ten-figure daily excise-tax penalties, to sign an agreement submitting to forced sales of Eliquis by October 1, 2023. Yet the IRA delays a manufacturer's ability to terminate its Medicare participation for between 11 and 23 months. 42 U.S.C. § 1395w–114a(b)(4)(B)(ii). Thus, to avoid being penalized for failure to sign the October 1 "agreement," BMS would have needed to withdraw by January 31, 2022—*months before the IRA was even enacted*. This timeline confirms that the IRA imposes mandates and employs threats; it does not set true "conditions."

88. Finally, conditioning the receipt of Medicare payments on abandonment of First and Fifth Amendment rights is unconstitutional. Under the doctrine of unconstitutional conditions, the Government may condition a benefit on forfeiture of a property right only if doing so substantially advances a purpose related to that benefit, and is "rough[ly] proportiona[l]" to it. *Dolan v. City of Tigard*, 512 U.S. 374, 391 (1994).

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

90. Coercing sales of *one* pharmaceutical product at discount prices does not substantially advance the purposes of countless other transactions whereby Medicare and Medicaid pay for *different* products. Leveraging the Government's market power over certain transactions to coerce terms on an entirely distinct transaction is an abuse of the Spending Clause. *See Harris v. McRae*, 448 U.S. 297, 317 n. 19 (1980) (noting "substantial constitutional question would arise if Congress had attempted to withhold all Medicaid benefits" based on exercise of a constitutional right).

91. Moreover, this alleged condition is plainly not "rough[ly] proportiona[l]" under *Dolan*, 512 U.S. at 391. Just the opposite—it is cross-collateralized in a way that makes clear that the Government's objective is to deter and penalize manufacturers' refusal to forfeit their rights.

92. In short, the IRA's threat is unconstitutionally coerceive—a "gun to the head"—because it leverages vast, unrelated benefits to induce the transactions that the Government wants. *Nat'l Fed'n of Indep. Business v. Sebelius*, 567 U.S. 519, 581 (2012) (*NFIB*). 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). Withdrawing from half of the U.S. prescription drug market, leaving tens of millions of patients without their medications, is simply not a tenable option. Nor is holding hostage access to half of the U.S. pharmaceutical market a legitimate condition. It is instead "'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 (Fifth Amendment)

93. BMS realleges all prior and subsequent paragraphs.

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

95. BMS's patented pharmaceutical products, including Eliquis and Opdivo, are protected personal property under the Fifth Amendment and Takings Clause.

96. The IRA will requisition those products and transfer them to Medicare beneficiaries. Those forced sales—coerced by the threat of draconian penalties that the Government has admitted no manufacturer could ever afford to pay—will deprive BMS of possession and title to its personal property. That is a *per se* taking.

97. That triggers "a categorical duty to pay just compensation." *Horne*, 576 U.S. at 358. "[J]ust compensation" requires the Government to pay the fair market value of medicines that it appropriates. *Reynolds*, 397 U.S. at 16. The IRA, however, requires HHS to arrogate discounts that necessarily fall below market value, and grants the agency unchecked discretion to provide even less remuneration. The entire purpose of the Act is to secure medicines like Eliquis for Medicare beneficiaries at heavily discounted prices, so the Government—the ultimate payor—can save money. The statute is thus designed specifically *not* to provide just compensation.

98. Declaratory relief is "appropriate." 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).

99. Declaratory relief is also appropriate because an *ex post* suit for damages would be "utterly pointless," as "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).

100. Moreover, declaratory relief is appropriate where it would "resolve the uncertainty" that "gave rise to the controversy"; promote "convenience of the parties," especially relative to "other remedies" that may be available; and further "the public interest." *Reifer v. Westport Ins. Corp.*, 751 F.3d 129, 140 (3d Cir. 2014). All of those criteria are satisfied here.

101. Accordingly, the Court should declare that the Program will effect takings of BMS's private property without providing for "just compensation" under the Fifth Amendment.

Count Two: Compelled Speech (First Amendment)

102. BMS realleges all prior and subsequent paragraphs.

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

104. The IRA will compel BMS to speak by forcing it to communicate that it has "agreed" to an HHS-mandated price, and to endorse the view that HHS's price is "maximum fair price" for the medicine. BMS does not agree with those statements or the value judgments they reflect.

105. The Government's only apparent interest in compelling this speech is to reap political benefits by camouflaging forced sales as voluntary negotiations. Indeed, Congress could have authorized HHS to genuinely negotiate (or even unilaterally set) prices, or capped the prices at which manufacturers could sell their medicines, without sham "negotiations" or "agreements" coerced by tens or hundreds of millions of dollars in daily fines. The IRA's convoluted alternative regime appears designed to mislead the public, evade accountability, and promote an attractive political slogan. That is neither a compelling nor a legitimate government interest.

106. An injunction is necessary. "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 a permanent injunction against the IRA's compelled "agreements."

107. The Court should declare that the IRA's 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 BMS to sign an initial "[m]anufacturer agreement[]," 42 U.S.C. § 1320f–2(a), or to "agree to" a "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 BMS may be unconstitutionally coerced to enter before this case is adjudicated.

PRAYER FOR RELIEF

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

1. Declaring that the Program effects takings without assuring the provision of just compensation under the Fifth Amendment;

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

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

4. Declaring any such agreements that BMS 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: June 16, 2023

Respectfully submitted,

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