IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF CONNECTICUT

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., 900 Ridgebury Road, Ridgefield, CT 06877,

Plaintiff,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, 200 Independence Avenue S.W., Washington, DC 20201;

XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services;

CENTERS FOR MEDICARE AND MEDICAID SERVICES, 7500 Security Boulevard, Baltimore, MD 21244; *and*

CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of Centers for Medicare and Medicaid Services,

Defendants.

Civil Action No. _____

COMPLAINT

To protect pharmaceutical innovation and patients who rely on the new treatments that innovation makes possible, Plaintiff Boehringer Ingelheim Pharmaceuticals, Inc. ("BI") brings this action for declaratory and injunctive relief against Defendants U.S. Department of Health and Human Services ("HHS"), Xavier Becerra, in his official capacity as the Secretary of HHS, the Centers for Medicare and Medicaid Services ("CMS"), and Chiquita Brooks-LaSure, in her official capacity as Administrator of CMS (collectively, "Defendants"), with respect to the "Drug Price Negotiation Program" ("Program") established by the Inflation Reduction Act ("IRA" or "the Act"), Pub. L. No. 117-169, §§ 11001–11004, 136 Stat. 1818, 1833–64 (2022) (codified in part at 42 U.S.C. §§ 1320f to 1320f-7).

INTRODUCTION

1. Patients in the United States have broader and faster access to pioneering treatments than patients in any other nation in the world. That unparalleled availability of innovative drugs makes it possible for patients with a wide range of conditions to live longer, healthier lives. And those treatment options are constantly improving and expanding, covering new patient populations, providing new ways to prevent diseases, and paving the way for new cures.

2. The pharmaceutical breakthroughs patients depend on are possible because manufacturers have made the substantial investments needed to achieve path-breaking innovations. Developing new medicines costs billions of dollars and typically takes more than a decade from start to finish. Only a tiny fraction of investigational medicines ever reach the market, and only a handful of those recover their development costs. As a result, continued innovation depends on

manufacturers' ability to reinvest returns from the handful of treatments that achieve commercial success into their research and development programs.

3. For decades, federal law has sustained the innovation process and served the broader public interest by providing carefully crafted incentives for developing new medicines and improving those medicines after they are first approved. The benefits of this framework ultimately flow to patients in the form of expanded treatment options and improved health outcomes.

4. BI plays a leading role in bringing about those benefits by continuously investing in new and improved medicines. In particular, the BI global family of companies (as defined below) develops innovative medicines that have changed the lives of millions of patients. BI has secured Food and Drug Administration ("FDA") approval for more than 45 drugs and biologics since 1983, and concentrates its research efforts in cardiometabolic disease, central nervous system disease, immunology and respiratory diseases, oncology and cancer immunology, and retinal health. That work is ongoing, with a particular focus on research and development of new treatments for under-served patient populations, including children and patients with rare diseases, as well as investigation of additional indications for previously approved medications.

5. The Inflation Reduction Act's Drug Price Negotiation Program upends the framework that has supported these innovations, and does so in a way that violates fundamental constitutional safeguards and undermines proper accountability. Contrary to its name, the Program does not involve genuine

negotiations between drug manufacturers and the Government regarding the price Medicare will pay for prescription drugs. Instead, the Program compels manufacturers, on pain of astronomical fines, to provide Medicare participants with "access" to their drugs at below-market rates dictated by CMS.

6. The effect of the Act's mandates is unmistakable: they will eviscerate the incentives necessary to develop future generations of cutting-edge medications. Patients will no longer be able to count on a steady stream of new treatments for rare diseases and other conditions with unmet medical needs, because manufacturers will have far fewer resources to discover them through broad-based clinical research. The same dynamic will affect patients who would benefit from new formulations of existing drugs, leaving them with unmet medical needs as a direct result of the Program. The Act goes to great lengths to conceal these adverse effects—and the political accountability that goes with them—by forcing manufacturers to embrace the fiction that the price controls imposed by CMS are the product of arms-length negotiations.

7. No court has ever upheld a regime like the one established by the IRA. Under longstanding precedent, Congress may direct federal agencies to impose price controls on regulated industries, but only if it includes provisions necessary to protect the significant public and private interests at stake. The governing statute must provide clear instructions to guide the agency's decisions, the body that conducts the proceeding must be impartial, the parties subject to the price controls must have an opportunity to be heard, the statute must include procedures to ensure that the prices

imposed are fair and not confiscatory, and the end result must be subject to judicial review.

8. The Program discards *all* of those bedrock safeguards, setting it apart from every other regulatory regime in modern American history. The Act does not establish enforceable guidelines for CMS's decisions, but instead allows the agency to set nearly any price it chooses, below the statutory ceiling prices fixed by Congress, based on any reason it chooses, without any lower limit. That open-ended delegation of power is doubly problematic because the statute causes CMS to have a clear conflict of interest: it not only selects drugs for the Program and sets the maximum prices for those drugs, but also *pays for* the drugs through Medicare and has a statutory duty to drive down prices. Other critical elements are missing as well: The Program lacks any mechanism to guard against imposition of confiscatory rates, and CMS has compounded that omission by refusing to accept public comment on core aspects of the Program's implementation. On top of all this, the statute takes the extraordinary step of attempting to prohibit judicial review of key CMS decisions, including which drugs to select and what the maximum prices for those drugs will be. The end result is a Program in which CMS is not subject to *any* meaningful external constraints on its action.

9. That unprecedented scheme will imminently cause serious, irreparable harm to BI and the patients it serves. The Act and applicable guidance make clear that CMS will select Jardiance®, a drug manufactured and marketed by BI, for the Program on September 1, 2023. BI brings this suit because the Program will violate

its constitutional and statutory rights in six ways. On their own, any one of these violations would be sufficient to justify invalidating the Program; together, they underscore the urgent need for judicial intervention.

10. *First*, the Program fails to meet fundamental requirements of the Due Process Clause of the Fifth Amendment, and relatedly violates the Constitution's separation of powers principles. Congress has impermissibly delegated sweeping authority to a federal agency to implement price controls without providing a clear standard to guide the agency's discretion or including other protections necessary to safeguard the public and private interests at stake, including patients' interest in ensuring the continued availability of innovative medications. Indeed, the Program provides manufacturers far *fewer* rights than parties subjected to wartime price controls. Congress has authority to adopt reasonable price regulations, but precedent makes clear that it cannot run roughshod over regulated parties' basic due process rights in doing so, as the Act repeatedly does here. *See infra* ¶¶ 93–112.

11. *Second*, the Program will take BI's constitutionally protected property without just compensation, in violation of the Fifth Amendment. The Program will force BI to provide Medicare participants "access" to Jardiance® products, thereby appropriating BI's rights in those products for the benefit of third parties. The Program is also expressly designed to avoid providing BI just compensation for those products. *See infra* ¶¶ 113–23.

12. *Third*, the Program will compel BI's speech in violation of the First Amendment. By requiring BI to sign an "agreement" stating that the company will

"negotiate" a "maximum fair price" for Jardiance®, the Act forces BI to promote the Government's false message that the Program involves negotiations and fair prices for selected drugs. Although the Government is free to express its own views regarding the Program, it may not seek to insulate its policies from political scrutiny by forcing BI to endorse those views. *See infra* ¶¶ 124–34.

13. *Fourth*, the Program seeks to reinforce its appropriation of manufacturers' property and commandeering of their speech by backing those demands with grossly excessive fines, in violation of the Eighth Amendment. The Act penalizes manufacturers that do not sign the Program "agreement," drafted exclusively by CMS and offered to manufacturers on a take-it-or-leave-it basis, by immediately making them subject to a mis-named "excise tax" on *every* domestic sale of the selected drug. The penalty begins at 186 percent of the drug's daily U.S. revenues and rapidly escalates to 1900 percent. Those draconian provisions impose fines two-and-a-half to twenty five times greater than the statutory penalty for criminal tax fraud, making clear that they are unconstitutionally excessive as a matter of law. Indeed, the penalties are so large that the Congressional Budget Office projected that they would raise *zero* revenue, showing that the "tax" is actually a penalty designed to compel manufacturers to submit to the Program's one-sided terms. *See infra* ¶¶ 135–45.

14. *Fifth*, the Program violates the unconstitutional conditions doctrine. The Act dictates that the manufacturer of a drug selected for the Program may not market *any* of its products through Medicare and Medicaid unless it accepts the

Program's terms. As a result, the Act conditions a manufacturer's ability to participate in Medicare and Medicaid—which together account for nearly forty percent of the U.S. healthcare market—on giving up its constitutional rights, including its rights under the First and Fifth Amendments. That condition is grossly disproportionate to any interest the Government might have in regulating the future price of a single selected drug. *See infra* ¶¶ 146–58.

15. *Sixth*, CMS's implementation of the Program has compounded these significant flaws. CMS recently issued a 198-page "guidance" document, after "voluntarily" permitting interested parties to comment on parts of an initial draft of the document. But CMS refused to take public comment on other, centrally important parts of the guidance, including provisions that impose binding legal obligations on manufacturers and make them subject to substantial fines. Those characteristics demonstrate that the guidance document is actually a legislative rule that must go through notice-and-comment rulemaking. By failing to observe that mandatory procedure, CMS violated the Administrative Procedure Act, 5 U.S.C. §§ 501, *et seq*., and the Medicare statute, 42 U.S.C. § 1395hh(a)(2). *See infra* ¶¶ 159–79.

16. For all of these reasons, the Program is unlawful. While pharmaceutical manufacturers, including BI, will suffer significant harm as a result of the Program's coercive terms, ultimately patients will lose out as the Program stifles innovation and displaces the market forces that have supported pharmaceutical innovation for decades.

17. Congress "has broad powers, but the means it uses to achieve its ends must be 'consist[ent] with the letter and spirit of the [C]onstitution.'" *Horne v. Dep't. of Agric.*, 576 U.S. 350, 362 (2015) (quoting *McCulloch v. Maryland*, 17 U.S. (4 Wheat.) 316, 421 (1819)). As a result, even when Congress has a strong "desire to improve the public condition"—as it undoubtedly did in crafting the Program—that "is not enough to warrant achieving the desire by a shorter cut than the constitutional way." *Id.* (quoting *Pennsylvania Coal Co. v. Mahon*, 260 U.S. 393, 416 (1922) (Holmes, J.)). Because the Act repeatedly relies on shortcuts that infringe core constitutional protections, the Court should declare that the Program violates BI's rights under the First, Fifth, and Eighth Amendments and grant the other relief requested below.

PARTIES

18. Plaintiff Boehringer Ingelheim Pharmaceuticals, Inc. is incorporated in Delaware and has its principal place of business in Ridgefield, Connecticut. BI manufactures and sells empagliflozin—a medication that improves glycemic control in patients with type 2 diabetes, cardiovascular disease, and heart failure—under the trade name Jardiance®. BI owns a license for the patents claiming empagliflozin and its uses, under which BI markets empagliflozin products in the United States.

19. Defendant Department of Health and Human Services is a cabinet-level department of the United States Government, headquartered in Washington, D.C.

20. Defendant Xavier Becerra is the Secretary of HHS. Secretary Becerra is charged by statute with administering the Social Security Act, including Medicare,

Medicaid, and the Program. Secretary Becerra is sued in his official capacity as the Secretary of HHS.

21. Defendant Centers for Medicare and Medicaid Services is an agency of the United States Government within HHS. HHS has delegated the Secretary's authority to administer Medicare, Medicaid, and the Program to CMS. CMS is headquartered in Baltimore, MD.

22. Defendant Chiquita Brooks-LaSure is the Administrator of CMS and thus oversees CMS's implementation of the Program. Administrator Brooks-LaSure is sued in her official capacity as the Administrator of CMS.

JURISDICTION AND VENUE

23. This Court has subject-matter jurisdiction under 28 U.S.C. § 1331 because this action arises under the laws of the United States, including the United States Constitution.

24. This Court also has subject-matter jurisdiction pursuant to 28 U.S.C. § 1346(a) because a department of the United States is a Defendant, and because the United States has waived its sovereign immunity with respect to suits for declaratory and injunctive relief, *see* 5 U.S.C. § 702.

25. This Court may award declaratory relief pursuant to 28 U.S.C. §§ 2201–02, as well as any other equitable relief it deems appropriate under its inherent powers.

26. Venue is proper under 28 U.S.C. § 1391(e)(1) because Defendants are officers acting in their official capacities and corresponding agencies of the United States, and BI's principal place of business is located in Ridgefield, Connecticut.

27. BI has standing to bring this action because Jardiance® is among the ten most widely reimbursed drugs within Medicare Part D, meaning that BI and Jardiance® will be subject to the Program beginning September 1, 2023.

FACTUAL BACKGROUND

28. Jardiance® is a groundbreaking prescription medicine used to lower blood sugar in adults with type 2 diabetes. Jardiance® is also approved to reduce the risk of cardiovascular death in adults with type 2 diabetes or with heart failure.

29. Innovative prescription drugs like Jardiance® are the result of a complex process of research, development, and clinical trials that requires many years of painstaking work and intensive investment.

30. On average, a manufacturer spends more than $2.5 billion developing just one new medicine. That process typically takes 10 to 15 years from start to finish, and can sometimes take even longer.

31. The BI family of companies (consisting of BI and related entities globally) has manufactured and marketed pioneering treatments since 1885. Throughout their history, these companies have maintained a steadfast commitment to addressing areas of unmet medical needs, driving innovation, and engaging with communities and society to change lives for the better. In 2020, the BI family of companies invested $4.2 billion in research and development, covering work on approximately 100 projects across all phases of the research process, many of which address unmet medical needs. Those investments increased to $5.3 billion in 2022, a year in which more than 30 million people globally benefitted from therapies developed by the BI family of companies.

32. Innovators like BI face daunting odds when developing new drugs. For every 5,000 compounds that enter preclinical testing, only one will obtain FDA approval—a success rate of just 0.02 percent. Even when compounds reach clinical trials, only 12 percent are ultimately approved by FDA.

33. Jardiance® is one of the most exceptional success stories in innovative drug development. Having received initial FDA approval in 2014, BI has continued to invest in Jardiance® clinical research and related education to bring the drug's benefits to a wider range of patients through additional FDA-approved indications.[1] After Jardiance® was initially approved in 2014 "to improve glycemic control in adults with type 2 diabetes," BI pursued further research that resulted in approval for additional indications spanning type 2 diabetes, cardiovascular disease, and heart failure.[2]

34. In 2015, a Jardiance® landmark clinical trial became one of the most significant breakthroughs in the field of diabetes care and the first ever trial for any diabetes medication to show statistically significant reduction of adverse cardiovascular outcomes in people with type 2 diabetes and established

[1] An FDA-approved indication is a statement that a drug is approved to treat, prevent, mitigate, or cure a specific disease, condition, or symptom. Thus, when a medication is approved for multiple indications, it may be used to treat multiple conditions or diseases. *See Indications and Usage Section of Labeling for Human Prescription Drug and Biological Products — Content and Format* 16 (2018), https://www.fda.gov/media/114443/download. A complete list of indications for Jardiance® can be found in the drug's Prescribing Information, the most recent version of which is available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/204629s042lbl.pdf.

[2] Jardiance® (empagliflozin tablets) Prescribing Information at 1 (Aug. 2014), https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/204629s000lbl.pdf.

cardiovascular disease. This trial forever changed the way healthcare providers treat adults with type 2 diabetes, and led to change in the professional diabetes treatment guidelines in the United States and worldwide. In 2016, FDA relied on this landmark clinical trial to approve Jardiance® "to reduce the risk of cardiovascular death in adult patients with type 2 diabetes mellitus and established cardiovascular disease."[3]

35. In 2021, BI achieved another major breakthrough with Jardiance® based on a trial in adults with heart failure and preserved ejection fraction. This trial was the first ever to show undisputable benefit in this difficult-to-treat population despite failed attempts of many other medicines over a period of almost two decades. Evidence from this trial in addition to a related Jardiance® trial changed the paradigm of heart failure care and was quickly integrated into relevant professional guidelines.

36. FDA issued further approvals in 2021 and 2022 for use of Jardiance® "to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure," regardless of the presence or absence of type 2 diabetes.[4] Jardiance® has also been approved to treat expanded patient populations. Just this year, Jardiance® was approved to treat type 2 diabetes in children 10 years and older.[5]

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[3] Jardiance® (empagliflozin tablets) Prescribing Information at 1 (Dec. 2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/204629s008lbl.pdf.

[4] Jardiance® (empagliflozin tablets) Prescribing Information at 1 (Aug. 2021), https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/204629s026lbl.pdf; Jardiance® (empagliflozin tablets) Prescribing Information at 1 (Feb. 2022), https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/204629s039lbl.pdf.

[5] Press Release, Boehringer Ingelheim and Eli Lilly & Co., *US FDA Approves Jardiance® (empagliflozin) for the Treatment of Type 2 Diabetes in Children 10 Years and Older* (June 21, 2023), https://www.boehringer-ingelheim.com/us/press-

(continued…)

37. BI is continuing to pursue innovative new indications for Jardiance® in areas of significant unmet needs. For example, the European Union recently (in July 2023) approved Jardiance® for treatment of chronic kidney disease, which affects more than one in seven U.S. adults (an estimated 37 million Americans). Conditions like chronic kidney disease, type 2 diabetes, cardiovascular disease, and heart failure are often interconnected and frequently co-exist in the same person. Patients with chronic kidney disease are at increased risk of suffering heart attacks, being hospitalized, and needing specialized medical care such as going on dialysis or requiring a kidney transplant. These complications put significant pressures on healthcare resources and take heavy tolls on affected patients. BI has applied for FDA approval of Jardiance® to treat chronic kidney disease and plans to apply for approval for the prevention of heart failure for patients who have suffered myocardial infarction (i.e., heart attack), and anticipates that it will obtain those approvals in the near future—further enhancing the role Jardiance® plays in helping patients with complex, difficult-to-treat, and often overlapping conditions.

38. The 3,400 drugs under clinical development by U.S. biopharmaceutical companies as of 2020 account for almost half of all medicines under development globally. Further, the United States is the country with the earliest and highest

releases/fda-approves-new-treatment-option-t2d-children-10-and-older. In January 2011, BI and Eli Lilly and Company began an Alliance that centers on compounds representing several of the largest diabetes treatment classes. Depending on geographies, the companies either co-promote or separately promote the respective molecules each contributing to the Alliance.

number of launches for new drugs and, "among the 72 [new drugs] launched in 2021, a record 44 (over 60%) were characterized by the FDA as first-in-class."[6]

39. Because of the enormous costs and high failure rate associated with development of new drugs, continued investments in innovation depend on the revenues from the tiny fraction of drugs that receive FDA approval and achieve success in the marketplace. As one study observes, the small number "of successful projects that result in new commercialized drugs have to provide enough revenue to justify the investment" in the large number of "failed compounds."[7]

40. Indeed, only 20 to 30 percent of the drugs that reach the market recoup their research and development costs.[8]

41. In light of these challenges, federal law has long provided a framework that supports continued pharmaceutical innovation by respecting private agreements and granting new drugs market exclusivity for a limited period. The Patent Act, for

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[6] The IQVIA Institute, *Global Trends in R&D: Overview Through 2021* (Feb. 10, 2022), https://www.iqvia.com/insights/the-iqvia-institute/reports/global-trends-in-r-and-d-2022.

[7] Alexander Schuhmacher, et al., *Changing R&D Models in Research-Based Pharmaceutical Companies*, 14 Journal of Translational Medicine 105, 108 (2016), https://translational-medicine.biomedcentral.com/articles/10.1186/s12967-016-0838-4.

[8] *See* John A. Vernon & Joseph H. Golec, *Pharmaceutical Price Regulation: Public Perceptions, Economic Realities, and Empirical Evidence* 7, 11 (2008), https://www.aei.org/wp-content/uploads/2014/07/-pharmaceutical-price-regulation-public-perceptions_113401853979.pdf ("[O]nly three out of ten marketed drugs earn back their investments."); John A. Vernon et al., *Drug Development Costs When Financial Risk is Measured Using the Fama-French Three-Factor Model*, 19 Health Econ. 1002, 1004 (2010), http://moglen.law.columbia.edu/twiki/pub/LawNetSoc/BahradSokhansanjFirstPaper/19HealthEcon1002_drug_dev_costs_with_financial_risk_2010.pdf (finding that only 20 percent of new drugs attain revenues that exceed average R&D costs).

example, embodies "a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology … in return for the exclusive right to practice the invention for a period of years." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150–51 (1989). Other federal statutes and regulations provide exclusivity periods for developers of innovative medicines. *See, e.g.*, 21 U.S.C. §§ 355(c)(3)(E), (j)(5)(F), 355A.

42. These exclusivity periods ensure that successful drugs can generate enough revenue to support not only their own development costs, but also the research and development efforts necessary to discover and obtain regulatory approval of the next generation of breakthrough treatments.

43. The Program would upend that longstanding framework by imposing price controls and undermining manufacturers' exclusivity rights, but with none of the protections necessary to ensure that the prices imposed are reasonable and balance the significant public and private interests at stake. To the contrary, by imposing artificial, below-market prices set unilaterally at the discretion of government officials, the Program harms patients by undermining the ability of manufacturers to continue to invest in new medicines.

STATUTORY AND REGULATORY BACKGROUND

A. The Federal Health Insurance Programs Dominate the U.S. Healthcare Market.

44. Medicare and Medicaid are among the world's largest health-insurance programs. Together, they account for nearly 40 percent of the U.S. healthcare

market.[9] In these markets, the Government acts as a both a market participant and as a regulator, serving as an intermediary that pays for drugs ultimately provided to elderly, disabled, and lower-income patients.

45. Medicare provides health insurance coverage for millions of Americans ages 65 and above, as well as persons with long-term disabilities. *See* 42 U.S.C. §§ 1395–1395*lll*.

46. The Government pays for prescription drugs under both Part B and Part D of Medicare.

47. Under Part B, Medicare covers the costs of various healthcare products and services for its beneficiaries, including drugs administered by a physician. *See id*. § 1395k. Congress has long ensured that Part B payments are tied to market-based prices by setting rates based on a drug's "average sales price." *Id*. § 1395w-3a. This is a market-based figure that reflects the volume-weighted quarterly average of all manufacturer sales prices to U.S. purchasers (with limited exceptions), increased by a specified percentage.

48. Individuals eligible for Medicare Part B may also enroll in Medicare Part D, which provides health-insurance benefits for self-administered prescription drugs. Under Part D, the federal government pays sponsors of private health insurance plans for a portion of the costs of such drugs. In turn, plan sponsors pay

[9] *See* CMS, *National Health Expenditure Fact Sheet*, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet (last updated July 31, 2023).

pharmacies negotiated, market prices for covered drugs and negotiate competitive rebates from manufacturers.

49. When Congress created Medicare Part D, it included a provision prohibiting HHS from "interfer[ing] with the negotiations between drug manufacturers[,] pharmacies[,] and [private health plans]" regarding the price of Part D drugs. 42 U.S.C. § 1395w–111(i).

50. In addition to Jardiance®, BI manufactures numerous other drugs that are made available to patients through Medicare and Medicaid. BI makes all of its drugs and biologics—numbering more than 20—available through Medicare and Medicaid. BI's participation in the Medicare and Medicaid programs accounts for more than half of the company's net sales in the U.S. in many years.

51. Given their major role in the U.S. healthcare market, participation in Medicare and Medicaid is critical to BI's business and continuing ability to develop innovative treatments and pursue new indications for and formulations of previously approved medicines.

B. The Program Fundamentally Alters the U.S. Healthcare Market.

52. The IRA directs the Secretary of HHS to implement what the Act misleadingly describes as a "Drug Price Negotiation Program." 42 U.S.C. § 1320f(a). HHS has delegated the Secretary's authority to administer the Program to CMS.

53. In general, the Program imposes "maximum fair price[s]" for drugs available through Medicare. *Id.* § 1320f-2(a). The "maximum fair price" refers to the highest price that the manufacturer may charge Medicare participants for the selected drug. *See id.* § 1320f-2(a)(2).

54. In the first year of the Program, CMS must identify the "50 qualifying single source drugs with the highest total expenditures under [Medicare] [P]art D" and select from among that list ten drugs for participation in the Program. *Id.* § 1320f-1(a)(1), (d)(1)(A). Because overall Medicare expenditures is the only expressly identified criterion for drug selection, the main driver of which drugs are subject to the Program is sales volume, rather than cost to patients.

55. The Secretary must announce the ten drugs selected for the first year of the Program no later than September 1, 2023. *Id.* § 1320f(d)(1). The "maximum fair price[s]" for these drugs will take effect beginning on January 1, 2026. *Id.* §§1320f(d)(1), 1320f-2(a)(1), 1320f-3(g).

56. Once the Secretary selects a drug for the first year of the Program, the drug's manufacturer "shall enter into [an] agreemen[t]" with CMS no later than October 1, 2023, to "negotiat[e]" a "maximum fair price" for the drug. *Id.* §§ 1320f(d)(2)(A), 1320f-2(a)(1).

57. Manufacturers of selected drugs must submit highly confidential business information to CMS by October 2, 2023. *Id.* §§ 1320f(d)(5)(A), 1320f-2(a)(4), 1320f-3(b)(2)(A). This information includes, for example, information on drug research and development costs, unit costs of production and distribution of selected drugs, and market data and sales volume data for selected drugs.

58. During the "negotiation," the agency will make an initial "offer" of a "maximum fair price" for the selected drug, and the manufacturer may make a "counteroffer" within 30 days. *Id.* § 1320f-3(b)(2)(B)–(D). But these trappings of

arms-length bargaining are illusory for several reasons. To start, a manufacturer's counteroffer must "be justified based [exclusively] on" an enumerated set of factors that omits the drug's fair market value, thus excluding the most relevant data point from the purported "negotiation." *Id.* § 1320f-3(b)(2)(C). Moreover, CMS is free to disregard the manufacturer's counteroffer and select any price it chooses (subject to the price ceiling described below)—meaning that the "negotiation" will end with CMS dictating a price. *See id.* §§ 1320f-3(b)(2)(E), 1320f-4(a).

59. The Act prescribes a price ceiling for each selected drug, equal to the lower of (1) what Medicare Part D and Medicare Advantage plans pay for the drug (net of all rebates), or (2) a percentage of the price wholesalers pay for the drug. *See id.* § 1320f-3(c)(2)–(3). The latter, percentage-based price ceiling depends on how long the drug has been on the market. For drugs that have been approved by FDA for fewer than 12 years, the "maximum fair price" must be at least 25 percent below the price paid by wholesalers for the drug. *Id.* § 1320f-3(c)(3)(A). This mandatory discount increases to 35 percent for drugs that have been FDA-approved for at least 12 years, and to 60 percent for drugs that have been FDA-approved for at least 16 years. *See id.* § 1320f-3(c)(3)(C), (5).

60. For the vast majority of drugs, including Jardiance®, the Act does not prescribe a minimum price, meaning that CMS may select *any* price below the price ceiling—all the way down to one cent. *See id.* § 1320f-3(c)(4) (carving out a "[t]emporary floor," not applicable here, "for small biotech drugs").

61. The Act directs the Secretary to "ai[m] to achieve the lowest maximum fair price for each selected drug." *Id.* § 1320f-3(b)(1). As a result, the Act both allows and encourages CMS to establish a "maximum fair price" that falls well below the mandatory price ceiling applicable to the selected drug.

62. Although the Act directs CMS to "consider" various factors, such as the availability of "therapeutic alternatives," when "negotiating" the "maximum fair price," *id.* § 1320f-3(e), (e)(2), the Act does not require CMS to base the price it imposes on any specific factor or set of factors.

63. The "maximum fair price" is not established through proceedings before a neutral adjudicator. Instead, the Act authorizes CMS to unilaterally select the drugs that will be subject to the Program and dictate the maximum prices for those drugs. *See id.* § 1320f-4(a). CMS has a conflict of interest in making those determinations because it pays for the drugs through Medicare and has a statutory duty to seek the lowest permissible price, such that the agency has a vested interest in seeking artificially low prices. This structure blurs the distinction between CMS as a market *participant and purchaser* of selected drugs on the one hand, and CMS as a market *regulator* on the other hand, combining those functions in a single proceeding.

64. By September 1, 2024, the Secretary must publish CMS's chosen "maximum fair price" for each drug selected for the 2026 initial price applicability year. *Id.* §§ 1320f(d)(6), 1320f-4.

65. Beginning on January 1, 2026, the manufacturer of a selected drug must "provide" hospitals, physicians, and other service providers "access" to the drug at the "maximum fair price." *Id.* § 1320f-2(a). Manufacturers who fail to comply with that requirement face civil monetary penalties equal to *ten times* the difference between the market price and the "maximum fair price." *Id.* § 1320f-6d(a).

C. Manufacturers Have No Alternative to Participation in the Program.

66. Manufacturers of selected drugs have no practical alternative but to acquiesce in the Program's one-sided terms, including the prices dictated by CMS. The Act commands that manufacturers "shall … provide access to" their drugs at the "maximum fair price" dictated by CMS. 42 U.S.C. § 1320f-2(a)(1)-(2).

67. The Act purports to offer manufacturers a choice in the matter, stating that manufacturers may refuse to participate if they (1) pay a ruinous excise tax penalty of up to 1900 percent of the selected drug's daily domestic revenues, or (2) withdraw *all* of their products from Medicare and Medicaid, cutting the manufacturer out of nearly half the U.S. healthcare market and leaving countless patients without access to essential treatments.

68. Those supposed options do not exist as a practical matter. Indeed, Congress took great pains to ensure that manufacturers would have no choice but to comply with the Program's requirements. CMS *needs* manufacturers to remain in the Program in order to make the most widely used drugs available to Medicare beneficiaries, and the Members of Congress who supported the Act do not want to be blamed for legislation that causes patients to lose access to those treatments. That

imperative led Congress to design the Program in a way that blurs the lines of political accountability by making the Program appear to be voluntary on the surface, despite being mandatory in substance.

69. The upshot is that the Government cannot save the Program by describing it as voluntary.

70. *First*, if a manufacturer does not sign an "agreement" to "negotiate," it must pay a prohibitive penalty (misleadingly labelled as an "excise tax") on *every* domestic sale of the selected drug—whether that sale is through Medicare, Medicaid, another program, or on the private market—starting at 186 percent of the drug's daily U.S. revenues and quickly escalating to 1900 percent of daily U.S. revenues. *See* 26 U.S.C. § 5000D(d).[10] Those penalties are even more severe in practice because they are based on the drug's *gross* revenues—an approach that causes the maximum penalty to be much higher than 1900 percent of the *net* revenues manufacturers earn after subtracting rebates and discounts. *See* ¶ 48, *supra*.[11]

71. With respect to Jardiance®, the statutory penalties would amount to more than $500 million per week initially, and more than $5.5 billion per week after six months. The "option" to pay such penalties is no option at all. *See Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 582 (2012) ("*NFIB*"); *Union Pac. R.R., Co. v.*

[10] *See also* Congressional Research Service, Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376) at 4, tbl. 2 (2022), https://crsreports.congress.gov/product/pdf/R/R47202 (explaining how the tax rates are computed).

[11] For example, in a scenario where a drug sells for $10 but is subject to a negotiated 50 percent rebate, a 1900% penalty on the manufacturer's $10 per unit gross revenue would equate to a 3800% penalty on the manufacturer's $5 per unit net revenue.

Pub. Serv. Comm'n, 248 U.S. 67, 70 (1918) (governments cannot "impose an unconstitutional burden" on private parties "by the threat of penalties worse than it in case of a failure to accept it, and then to declare the acceptance voluntary").

72. Indeed, no reasonable manufacturer would incur the punitive "excise tax." Congress recognized that reality when it projected that nearly identical penalty provisions in a precursor bill to the IRA would generate "no revenue."[12] That projection reveals that participation in the Program is anything but voluntary, and that the excise tax is no tax at all, but in fact a penalty.

73. *Second*, the Act purports to allow manufacturers to escape the Program's mandates and penalties by withdrawing *all* of their products from Medicare and Medicaid. *See* 26 U.S.C. § 5000D(c). That is not a real alternative either, for several reasons.

74. To begin with, no rational manufacturer can afford to pull out of a market that accounts 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). That drastic step would deprive the manufacturer of the resources needed to continue developing innovative treatments in the future.

[12] 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), https://www.jct.gov/publications/2021/jcx-47-21; *see also* Congressional Budget Office, *How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act* 10 (Feb. 2023), https://www.cbo.gov/publication/58850 ("CBO expects that drug manufacturers will comply with the negotiation process because the costs of not doing so are greater than the revenue loss from lower, negotiated prices.").

75. More fundamentally, wholesale withdrawal of a manufacturer's products would leave Medicare and Medicaid patients without access to medications they rely on to treat serious, life-threatening conditions. Hundreds of thousands of patients depend on BI medications—a relationship that implicates BI's core values, including improving human health and responsibility to the community.[13] Forcing BI to withdraw all of its drugs from Medicare and Medicaid would contravene those values and risk unnecessary harm to patients. For example, many patients would have to switch from their current medication to other treatments that may be less effective or cause adverse reactions.[14] In some instances, where BI's drug is the only one approved by FDA for a particular condition or patient population (as is the case with Spevigo®, which treats a rare, lifelong skin disease), forced withdrawal from Medicare and Medicaid would leave patients in those programs without insurance for *any* FDA-approved treatment. BI cannot turn its back on its ethical obligation to serve the patients who depend on its drugs to treat and manage serious medical conditions.

76. For those reasons, it "is not an honest answer" to suggest that BI could "escape" these harms "by withdrawing from the business of" providing its drugs to Medicare and Medicaid. *Mora v. Mejias*, 223 F.2d 814, 817 (1st Cir. 1955).

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[13] *The Core of our Leitbild*, Boehringer Ingelheim, https://www.boehringer-ingelheim.com/our-focus/core-leitbild (last accessed Aug. 15, 2023).

[14] Unit sales data shows that at least 40 percent of Jardiance® patients receive the drug through Medicare or Medicaid. If BI were forced to withdraw from Medicare and Medicaid, those patients would lose insurance coverage for Jardiance® and the life-saving benefits it provides.

77. Even if it were feasible for a manufacturer to withdraw all of its drugs from Medicare and Medicaid, the IRA makes it impossible to do so in time to avoid the draconian penalties described above. Specifically, the Act mandates that a manufacturer's request to withdraw from Medicare and Medicaid does not become "effective" until at least 11 months—and up to 23 months—after the request is submitted. *See, e.g.*, 42 U.S.C. § 1395w–114a(b)(4)(B)(ii).

78. CMS has sought to sidestep this problem by adopting, through guidance, a new expedited procedure for withdrawal from Medicare and Medicaid. *See* Final Guidance at 129–30.[15] But the procedure seeks to circumvent the minimum withdrawal delays established by statute, without explaining how CMS has authority to take that extraordinary step. CMS's guidance also conflates withdrawals initiated "[b]y a manufacturer" with those initiated instead "[b]y the Secretary," casting further doubt on the viability of the expedited withdrawal procedure. 42 U.S.C. § 1395w-114a(b)(4)(B)(i)–(ii).

79. The Program thus coerces manufacturers to "agree" to prices that must be significantly below a drug's market value, and therefore are by definition not fair.

80. Once a manufacturer enters that "agreement," it has no choice but to provide drugs at the "maximum fair price." That is because, as noted, manufacturers

[15] CMS, *Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026*, at 98, 108 (June 30, 2023), https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf ("Final Guidance").

who fail to do so face civil monetary penalties equal to *ten times* the difference between the market price and the "maximum fair price." *Id.* § 1320f-6d(a).

81. This price-setting scheme will have significant harmful impacts on drug innovation in the United States, and thus on the patients who depend on and benefit from that innovation. One study estimates that the Program will "reduce overall annual cancer R&D spending by about $18.1 billion, or 31.8%."[16] Altogether, the study concludes that the Program will cause "a reduction of $663 billion in R&D spending from 2022 through 2039 [and lead to] 135 fewer new drug approvals" during that period.

82. The resulting loss of innovation will harm patients in many ways. For example, the study cited above concludes that the Program will "ultimately raise, as opposed to lower, cancer mortality compared to the status quo [prior to the IRA] and thus be counterproductive" to tackling cancer. That outcome is particularly significant because cancer is consistently one of the leading causes of death in the United States. Other patient populations—particularly children and those with rare diseases—will be affected in the same way, as the Program chokes off manufacturers' ability to develop new drugs and new indications that address their needs.

[16] Tomas J. Philipson et al., *Policy Brief: The Impact of Recent White House Proposals on Cancer Research* 1 (June 2022), https://cpb-us-w2.wpmucdn.com/voices.uchicago.edu/dist/d/3128/files/2022/06/Cancer-Policy-Brief-June-27-no-tracking.pdf.

D. CMS Will Select Jardiance® for Participation in the Program.

83. BI will imminently be subject to the requirements described above because CMS will select Jardiance® for participation in the Program on September 1, 2023.

84. For the "initial price applicability year" of the Program in 2026, the Act requires the Secretary to select ten "negotiation-eligible" drugs by September 1, 2023. *Id.* §§ 1320f-1(a)(1), 1320f(d)(1).

85. The IRA defines a "negotiation-eligible" drug for 2026 and 2027 as a "qualifying single source drug" that is "among the 50 qualifying single source drugs with the highest total expenditures" under Medicare Part D. *Id.* § 1320f-1(b)(1)(A).

86. In turn, a "qualifying single source drug" includes covered Part D drugs that have been approved by FDA and on the market for at least seven years, subject to certain exceptions not relevant here. *Id.* § 1320f-1(e)(1)(A); *see also* 21 U.S.C. § 355.

87. Based on these criteria, Jardiance® will be "negotiation eligible" for the 2026 initial price applicability year.

88. According to CMS's Final Guidance, the agency "will select" the top ten drugs that account for the highest Medicare Part D spending. Final Guidance at 98, 108.

89. Jardiance® is one of these top ten drugs and thus will be selected on September 1, 2023.[17]

[17] Sean Dickson & Inmaculada Hernandez, *Drugs Likely Subject to Medicare Negotiation, 2026–2028*, 29(3) J Manag. Care Spec. Pharm. 229, 230 (2023) https://www.jmcp.org/doi/epdf/10.18553/jmcp.2023.29.3.229?role=tab ("For 2026, the top drugs projected for negotiation include … Jardiance ….").

THE PROGRAM VIOLATES BI'S CONSTITUTIONAL AND STATUTORY RIGHTS

A. The Program Violates Multiple Constitutional Provisions.

90. Article I vests "[a]ll legislative Powers" in the "Congress of the United States." U.S. Const. art. I, § 1. Although Congress may delegate authority to a federal agency to execute the laws, it must provide the agency "with standards guiding its actions such that a court could ascertain whether the will of Congress has been obeyed." *Skinner v. Mid-Am. Pipeline Co.*, 490 U.S. 212, 218 (1989).

91. The separation of powers is reinforced by constitutional provisions that protect the public interest, ensure political accountability, and safeguard the rights of those subject to regulation. While courts have occasionally relaxed the Constitution's requirements to accommodate the demands of the modern administrative state, the Supreme Court has refused to allow Congress to bypass constitutional protections designed to make the Executive and Legislative branches accountable for their actions. *See, e.g.*, *Free Enterprise Fund v. Public Company Accounting Oversight Board*, 561 U.S. 477 (2010); *Seila Law LLC v. Consumer Financial Protection Bureau*, 140 S. Ct. 2183 (2020).

92. The IRA's unprecedented drug pricing provisions delegate sweeping authority to federal officials, and in doing so depart from essential constitutional requirements by eliminating multiple layers of protections designed to protect both the public and the rights of regulated parties.

1. The Program Violates BI's Fifth Amendment Due Process Rights.

93. The Due Process Clause of the Fifth Amendment provides that "[n]o person shall be deprived of life, liberty, or property, without due process of law." U.S. Const. amend. V.

94. The Program implicates several property interests of BI, including (i) physical doses of Jardiance®, (ii) the patents covering Jardiance® and related intellectual property rights, (iii) the confidential and proprietary data BI will be forced to provide to CMS, and (iv) the enormous financial payments required to satisfy the excise tax and civil monetary penalty provisions.

95. Price-control regimes previously upheld by courts have differed in kind from the Program because they provided procedural and substantive protections utterly absent here. In particular, in other contexts where the Government has imposed price controls on an industry, even during wartime, Congress has addressed the significant due process concerns by ensuring that prices were set at levels that are fair and not unduly discriminatory.

96. For example, in *Yakus v. United States*, 321 U.S. 414 (1944), the Supreme Court upheld the Emergency Price Control Act of January 30, 1942, 56 Stat. 23. Similarly, in *Bowles v. Willingham*, 321 U.S. 503 (1944), the Court upheld the rent control provisions of the same Act. *Id.* at 509–510, 521. In upholding these wartime provisions, the Court emphasized that the Emergency Price Control Act afforded market participants important rights—rights that are not provided under the Program.

97. *First*, the Emergency Price Control Act required that the maximum prices (and rents) established under the Emergency Price Control Act be "fair and equitable." *Yakus*, 321 U.S. at 423; *Bowles*, 321 U.S. at 513. Although the "fair and equitable" criterion was not a model of specificity, the Program lacks even that basic element. Not only does the IRA fail to impose any meaningful constraint on *how* CMS determines a "maximum fair price," it does not even require that the prices dictated by CMS *be* fair and equitable.

98. The IRA does not establish a floor for the "maximum fair prices" dictated by CMS, meaning that nothing prevents CMS from imposing a price of one penny per dose. By granting CMS "authority to be unfair and inequitable," the Program is unconstitutional. *Amalgamated Meat Cutters & Butchers Workmen v. Connally*, 337 F. Supp. 737, 755 (D.D.C. 1971).

99. The IRA also creates an obvious conflict of interest arising from CMS's dual role as the entity that sets the price for drugs selected for the Program and the entity that pays for those drugs. "The probability of actual bias on the part of the judge or decisionmaker is too high to be constitutionally tolerable" when "the adjudicator has a pecuniary interest in the outcome." *Withrow v. Larkin*, 421 U.S. 35, 47 (1975). That is the case here: CMS has an interest in setting the prices it pays as low as possible, and in addition it has a statutory obligation to "achieve the lowest maximum fair price for each selected drug." 42 U.S.C. § 1320f-3(b)(1).

100. In sharp contrast, a party aggrieved by the wartime Price Administrator's decisionmaking had access to review by multiple layers of impartial

authorities: the Price Administrator, a special court of appeals, and ultimately the Supreme Court. *See Yakus*, 321 U.S. at 418–19.

101. Congress has done here what it refrained from doing in the past: telling "the [Secretary] to fix [prices] . . . at whatever levels he pleases," *Bowles*, 321 U.S. at 514, with no standards "sufficiently definite and precise to enable Congress, the courts and the public to ascertain whether the [Secretary], in fixing the designated prices, has conformed to those standards," *Yakus*, 321 U.S. at 426.

102. *Second*, past regimes provided a meaningful administrative hearing process, allowing regulated parties to provide evidence relating to the relevant legal standard used for setting prices. *See Yakus*, 321 U.S. at 436.

103. The IRA, by contrast, does not afford manufacturers a meaningful administrative process. A drug manufacturer may counter the Secretary's opening offer, but the Secretary need only "respond in writing to such counteroffer." 42 U.S.C. § 1320f-3(b)(2)(D). With no effective limitations placed on the nature of the Secretary's response, a manufacturer "negotiating" with CMS has none of the rights it would have in a typical administrative proceeding.

104. Further, the IRA does not assure a manufacturer access to all data relied upon by CMS, including in determining its initial offer. Instead, the IRA imposes only a vague requirement that CMS provide a "concise justification based on the factors . . . that were used in developing [the initial] offer." *Id.* § 1320f-3(b)(2)(B).

105. For some data, CMS offers only a flimsy statement that it will "aim" to share relevant data "when feasible." Final Guidance at 63. That approach falls short

of due process requirements. "[W]hen an agency takes official or administrative notice of facts, a litigant must be given an adequate opportunity to respond." *Heckler v. Campbell*, 461 U.S. 458, 467 (1983). Due process compels the same conclusion. *See Ohio Bell Tel. Co. v. Pub. Utils. Comm'n*, 301 U.S. 292, 302 (1937).

106. Nor is there any requirement that this "final offer" be based on a reasoned analysis, that it be fair or equitable, or that CMS meaningfully consider the manufacturer's counteroffer and justification. Under the Act, CMS will make a "final offer" that it unilaterally determines; the manufacturer must either "accept[] or reject[] the final offer by July 31, 2024." Final Guidance at 158.

107. *Third*, past price setting regimes have ensured that agencies act within the scope of their delegated authority by providing for judicial review. *See Yakus*, 321 U.S. at 433, 435; *Bowles*, 321 U.S. at 516; *see also Lockery v. Phillips,* 319 U.S. 182, 188–89 (1943); *Amalgamated Meat Cutters*, 337 F. Supp. at 759.

108. In contrast, the IRA expressly bars judicial review of the "maximum fair price" and other key agency determinations, such as selection of drugs for the Program. 42 U.S.C. § 1320f-7(3).

109. *Fourth*, past regimes did not compel manufacturers to sell, or impose penalties on those who declined to participate. *See Yakus*, 321 U.S. at 438. As described above, the Program compels manufacturers to participate, based on the combination of the Act's excise tax penalties and the vast size of the Medicare and Medicaid market.

110. *Fifth*, price-setting regimes upheld in prior cases have included safeguards to ensure that the resulting rates are "not confiscatory in the constitutional sense." *Fed. Power Comm'n v. Texaco, Inc.*, 417 U.S. 380, 391–92 (1974); *see also FCC v. Fla. Power Corp.*, 480 U.S. 245, 253 (1987). The Act lacks such a safeguard, and as noted above, permits CMS to select any "maximum fair price" below the statutory price ceiling, all the way down to one cent, regardless of the selected drug's development costs or fair market value.

111. *Finally*, CMS's implementation of this Program has only exacerbated these due process failings. As discussed below, CMS declined to allow for public comment on key aspects of its implementing "guidance" for the Program. Moreover, the Program "agreement" CMS proposes to force manufacturers to sign would arrogate even more power to the agency. For example, the "agreement" provides CMS with unilateral "authority to amend this Agreement" to reflect changes in its own "guidance," potentially without any advance notice to the manufacturer.[18]

112. Viewed as a whole, the IRA fails to satisfy basic requirements of procedural due process.

2. The Program Effects a Physical Taking of BI's Patented Jardiance® Product in Violation of the Fifth Amendment.

113. The Fifth Amendment prohibits the Government from taking private property for public use, without just compensation. U.S. CONST. amend. V. When the

[18] CMS, *Medicare Drug Price Negotiation Program Agreement* § IV(b), at 4, https://www.cms.gov/files/document/inflation-reduction-act-manufacturer-agreement-template.pdf ("Manufacturer Agreement").

Government takes private property, it has a categorical duty to pay for that property. *Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2077 (2021)

114. Personal property is protected under the Takings Clause to the same extent as real property. *See Horne*, 576 U.S. at 359.

115. Jardiance® products are personal property belonging to BI.

116. If the Government "appropriates" BI's property "for the enjoyment of third parties," it must pay BI just compensation. *Cedar Point Nursery*, 141 S. Ct. at 2072.

117. BI's patent rights "to exclude others from making, using or vending" Jardiance® are also protected under the Takings Clause. *Talbot v. Quaker-State Oil Refin. Co.*, 104 F.2d 967, 968 (3d Cir. 1939) (quoting *Crown Die & Tool Co. v. Nye Tool & Mach. Works*, 261 U.S. 24, 35–37 (1923)); *see also Horne*, 576 U.S. at 359–60.

118. Governmental appropriations of property arise in at least two ways: by compelling its "physical surrender," *Horne*, 576 U.S. at 364, or by impinging on the owner's "right[s] to access" and "exclude" others from using that property. *Cedar Point Nursery*, 141 S. Ct. at 2072. The Program results in both forms of appropriation.

119. The IRA requires manufacturers, as part of their "agreement" with CMS, to "provid[e]" eligible beneficiaries (and their hospitals, doctors, providers, suppliers, etc.) "access to" selected drugs at the "maximum fair price" prescribed by CMS. 42 U.S.C. § 1320f-2(a)(3). The Program also imposes additional access requirements established by statute or CMS, including requirements modified or

adopted by CMS after a manufacturer signs the Manufacturer Agreement. *See, e.g.*, 42 U.S.C. § 1320f-6(c); Manufacturer Agreement § IV(b).

120. The IRA thus effects a physical taking of Jardiance® products by compelling BI to grant third parties access to those products on terms imposed by CMS. *See Nollan v. Cal. Coastal Comm'n*, 483 U.S. 825, 831 (1987). In other words, the IRA deprives BI of its rights to possess and control the disposition of its Jardiance® products and compels BI to surrender those products for use by third parties. *See Cedar Point Nursery*, 141 S. Ct. at 2072. Because the IRA will force BI to transfer its property to third parties and provides those third parties with a "right of access" to Jardiance®, the IRA inflicts a physical taking of BI's property.

121. The fact that BI will receive some compensation does not alter the takings analysis. "[W]hen there has been a physical appropriation, [courts] do not ask whether it deprives the owner of all economically valuable use of the item taken." *Horne*, 576 U.S. at 363 (cleaned up). At most, the fact that BI will receive some remuneration "bears only on the amount of compensation," not on whether a taking has occurred. *Cedar Point Nursery*, 141 S. Ct. at 2074.

122. The practical result of the Program would be no different if the Government seized large quantities of Jardiance® from BI's warehouses and left behind whatever amount of compensation the Government deemed appropriate.

123. Because the "agreement" called for under the Program is effectively compelled, the agreement does not insulate the IRA's mandate from a Fifth Amendment takings analysis. *See* ¶¶ 63–75, *supra*.

3. The Program Compels Speech in Violation of the First Amendment.

124. The Program also violates the First Amendment by compelling BI to endorse the Government's preferred rhetoric regarding the Program. "[F]reedom of speech 'includes both the right to speak freely and the right to refrain from speaking at all.'" *Janus v. Am. Fed'n of State, Cnty., & Mun. Emps., Council 31*, 138 S. Ct. 2448, 2463 (2018) (quoting *Wooley v. Maynard*, 430 U.S. 705, 714 (1977)).

125. The IRA forces manufacturers to speak by requiring them to "agree," in writing, that they are entering into a "negotiation" that will result in an agreed-upon "maximum fair price." 42 U.S.C. § 1320f–2(a), (a)(1). While the Government may seek to persuade the public that the drug prices it mandates are fair and freely negotiated, it may not turn manufacturers into a "vehicle for spreading a message with which [they] disagree[]." *Pac. Gas & Elec. Co. v. Pub. Utils. Comm'n*, 475 U.S. 1, 17 (1986).

126. BI strongly disagrees that the Program involves genuine agreements and negotiations, and likewise disagrees that the prices imposed under the Program are "fair."

127. A true negotiation ends in a binding contract only when both parties voluntarily agree to the terms. *See* Black's Law Dictionary (11th ed. 2019) (defining "negotiation" as "[a] consensual bargaining process in which the parties attempt to reach agreement on a disputed or potentially disputed matter."). The performative "negotiation" mandated by the Program, in contrast, involves CMS's unilateral selection of the price it will pay for selected drugs.

128. Fairness connotes "impartiality" or "disinteres[t]." *See* Black's Law Dictionary (11th ed. 2019). The prices established through the Program are not set through proceedings before a neutral adjudicator, but rather are imposed by the same agency that pays for the selected drugs, and without any meaningful administrative hearing or opportunity for judicial review.

129. "'Fair market value' is '[t]he price that a seller is willing to accept and a buyer is willing to pay on the open market and in an arm's-length transaction.'" *Redus Fla. Com., LLC v. Coll. Station Retail Ctr.*, LLC, 777 F.3d 1187, 1196 (11th Cir. 2014) (quoting Black's Law Dictionary 1691 (9th ed. 2009)). The IRA instead requires the "maximum fair price[s]" to be *at least* 25 percent below the average price paid by non-federal wholesalers, and likewise requires CMS to "achieve the lowest" price "for each selected drug." 42 U.S.C. §§ 1320f-3(b)-(c).

130. CMS has tried to paper over the First Amendment violation by including in the Manufacturer Agreement a provision stating that "by signing this Agreement, the Manufacturer does not make any statement regarding or endorsement of CMS's views . . . Use of the term 'maximum fair price' and other statutory terms throughout this Agreement reflects the parties' intention that such terms be given the meaning specified in the statute and does not reflect any party's views regarding the colloquial meaning of those terms." Manufacturer Agreement § IV(f). That provision does not cure the First Amendment violation for at least four reasons.

131. *First*, the Government may not insulate itself from the First Amendment's prohibition on compelled speech by stating that the speaker may hold

a belief different from the compelled speech. *Cf. W. Va. State Bd. of Educ. v. Barnette*, 319 U.S. 624, 633 (1943) (compelled speech is unconstitutional even if the speaker may utter the compelled "words without belief and by a gesture barren of meaning"). The compelled-speech doctrine thus prohibits the Government from "requiring the utterance" of any message regardless of content, and the disclaimer simply adds additional unconstitutionally compelled speech. *See Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 641 (1994).

132. *Second*, the public will remain under the impression that manufacturers have "agree[d]" to "negotiate" a "maximum fair price" despite the disclaimer. The disclaimer thus prevents manufacturers from "compet[ing]" in the "open marketplace [of] ideas … without government interference." *N.Y. State Bd. of Elections v. Lopez Torres*, 552 U.S. 196, 208 (2008).

133. *Third*, the IRA states that the manufacturers will agree to a "maximum fair price," and the inclusion of a contract provision cannot undercut the compelled nature of the speech mandated by statute.

134. *Fourth*, the coercive nature of the Program agreement means that any supposed waiver of First Amendment rights is unenforceable.

4. The Program Imposes Excessive Fines in Violation of the Eighth Amendment.

135. A key feature of the IRA is a massive penalty, disguised as an excise tax, levied on manufacturers who do not participate in the Program. That penalty violates the Excessive Fines Clause of the Eighth Amendment.

136. A monetary sanction is a "fine[]" within the meaning of the Eighth Amendment if it "serv[es] in part to punish," *Austin v. United States*, 509 U.S. 602, 610 (1993), for example by "[d]eterr[ing]" disfavored conduct, *United States v. Bajakajian*, 524 U.S. 321, 329 (1998).

137. The IRA's "excise tax" is a fine within the meaning of the Excessive Fines Clause because it is punitive and coercive. The penalties deter manufacturers from declining to participate in the Program's sham negotiation process or refusing to accept the CMS-imposed "maximum fair price."

138. A fine labeled as a "tax" is still a fine for constitutional purposes because its "practical characteristics" control. *NFIB*, 567 U.S. at 565. Where a purported "tax" imposes an "exceedingly heavy burden" and is not expected to raise revenue, it is not a tax for constitutional purposes. *See id.* The Act's excise tax penalty falls within that definition because it is so onerous that no manufacturer would ever willingly incur it—as illustrated by the Congressional Budget Office's projection that a nearly identical provision would not raise a single dollar of revenue.

139. The "excise tax" penalty is not only a "fine"; it is unconstitutionally "excessive."

140. "The touchstone of the constitutional inquiry under the Excessive Fines Clause is the principle of proportionality: the amount of the forfeiture must bear some relationship to the gravity of the offense that it is designed to punish." *Bajakajian*, 524 U.S. at 334 (1998) (citing *Austin*, 509 U.S. at 622–23).

141. In evaluating proportionality, the Supreme Court has considered "the degree of the defendant's reprehensibility or culpability; the relationship between the penalty and the harm to the victim caused by the defendant's actions; and the sanctions imposed in other cases for comparable misconduct." *Cooper Indus. v. Leatherman Tool Grp., Inc.*, 532 U.S. 424, 435 (2001) (citations omitted).

142. *First*, the "offense" that is being punished—declining to participate in an unconstitutionally coercive scheme—does not entail any "reprehensibility or culpability." *Cooper Indus.*, 532 U.S. at 435. To the contrary, it involves the exercise of constitutionally protected rights and traditional principles of contracting in a free market.

143. *Second*, there is no reasonable relationship between the enormous size of the excise-tax penalty and the "harm" caused by a manufacturer's failure to participate in the Program's sham negotiations. Each day that a manufacturer remains noncompliant, it faces a penalty that is a multiple of total daily domestic revenues for the selected drug, starting at 186 percent of those revenues and escalating to an astronomical 1900 percent within six months. *See* 26 U.S.C. § 5000D(b)(1), (d).

144. Those penalties are grossly disproportionate to the Government's interest in regulating the future price of a single drug because they: (1) apply not as a fraction of the underlying value but as a multiplier—*i.e.*, a figure greater than 100%; (2) apply to all domestic sales of the relevant drug, not just sales through Medicare; (3) apply to *total* daily revenues, not just to the difference between the market price

and the Government-imposed "maximum fair price"; (4) have no upper limit, continuing to accumulate for every day of noncompliance; and (5) apply as soon as a manufacturer fails to sign an "agreement" to "negotiate" (in October 2023), or fails to accept the Government-imposed "maximum fair price" (in August 2024), long before the Government-imposed price would take effect (in January 2026).

145. *Third*, no other statute appears to impose similar sanctions "for comparable misconduct." *Cooper Indus.*, 532 U.S. at 435. As a point of comparison, the penalty for civil tax *fraud* is "an amount equal to *75 percent* of the portion of the underpayment which is attributable to fraud." 26 U.S.C. § 6663(a) (emphasis added).

5. The IRA Unconstitutionally Conditions Participation in Medicare and Medicaid on BI's Relinquishment of Its Constitutional Rights.

146. For the reasons described above, the purported "voluntary" nature of the Program is illusory: manufacturers have no choice but to submit to the Program's terms. But even if opting out of Medicare and Medicaid were a viable option, the Program would still be unconstitutional because the IRA unconstitutionally conditions a manufacturer's ability to participate in Medicare and Medicaid on relinquishment of the manufacturer's constitutional rights.

147. "[T]he unconstitutional conditions doctrine forbids burdening the Constitution's enumerated rights by coercively withholding benefits from those who exercise them." *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 606 (2013). In other words, the Government may not place a condition on a benefit to "produce a result which (it) could not command directly." *Perry v. Sindermann*, 408 U.S. 593, 597 (1972) (quotation marks omitted).

148. The unconstitutional conditions doctrine applies even when "a person has no 'right' to a valuable governmental benefit and even though the government may deny him the benefit for any number of reasons." *Id.*

149. For example, in the due process context, the unconstitutional conditions doctrine applies "to prohibit the government from conditioning benefits on a citizen's agreement to surrender due process rights." *R.S.W.W., Inc. v. City of Keego Harbor*, 397 F.3d 427, 434 (6th Cir. 2005).

150. In the Takings Clause context, the Government may condition a benefit on the uncompensated taking of property only if "there is a 'nexus' and 'rough proportionality' between the property that the government demands and the social costs" of the granted benefit. *Koontz*, 570 U.S. at 605–06.

151. In the First Amendment context, "the Government may not deny a benefit to a person on a basis that infringes his constitutionally protected ... freedom of speech even if he has no entitlement to that benefit." *Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.*, 570 U.S. 205, 214 (2013) (cleaned up).

152. The Program imposes conditions that "produce a result which [the Government] could not command directly," *Perry*, 408 U.S. at 597 (quotation marks omitted), with respect to the deprivation of BI's due process, property, and free speech rights.

153. *First*, the IRA unconstitutionally conditions BI's right to market products through Medicare and Medicaid on the company's agreement to surrender its property without due process of law. As explained above, the Program permits

the Government to subject Jardiance® to onerous, below-market price controls without a hearing before an impartial tribunal, without requiring CMS's terms to be fair or equitable, and without affording the other procedural protections that courts have held are necessary to comply with the Fifth Amendment.

154. *Second*, the IRA impermissibly conditions BI's right to market products through Medicare and Medicaid on BI's acquiescence to the Government's uncompensated physical taking of BI's protected property rights.

155. If BI wishes to continue marketing Jardiance® through Medicare and Medicaid, it must (1) acquiesce in the Program's forced transfer of BI's Jardiance® products to third parties through the statutory "access" right, or (2) pay astronomical penalties (up to 1900% of the daily domestic revenue for Jardiance®) for failing to comply with the Government's terms. Given the magnitude of the tax, that supposed choice is no choice at all. Thus, BI's only option to continue participating in Medicare and Medicaid would be to accede to the Government's appropriation of Jardiance® products for the benefit of third parties.

156. There is neither a "nexus" nor "rough proportionality" between the Government's physical taking of BI's property and the Government's interest in regulating access to Medicare and Medicaid.

157. There is no nexus because if BI does not accept the condition, the company would have to terminate its Medicare and Medicaid agreements, thereby *decreasing* access to critically important medications. The condition does not address a "social cost" of permitting BI to sell its medications through Medicare and Medicaid.

Koontz, 570 U.S. at 605–06. Nor is the condition proportional because, under the IRA, BI will not be permitted to market *any* of its medications through Medicare or Medicaid unless BI agrees to the Government's appropriation of a right to "access" Jardiance® products.

158. *Third*, "[b]y demanding that [manufacturers who participate in Medicare and Medicaid] adopt—as their own—the Government's view on an issue of public concern," the Government is unconstitutionally conditioning access to Medicare and Medicaid on the relinquishment of BI's free speech rights. *Agency for Int'l Dev.*, 570 U.S. at 218. Under the IRA, if BI desires to continue marketing any of its products to Medicare and Medicaid beneficiaries without incurring ruinous tax penalties, it must promote the Government's views as its own. *See* 26 U.S.C. § 5000D(c). The Government may not condition BI's right to market products through Medicare and Medicaid on BI's promotion of Government messaging.

B. CMS's "Guidance" for Implementing the Program Is a Legislative Rule Promulgated in Violation of the Administrative Procedure Act and Medicare Statute.

159. CMS's Guidance regarding implementation of the Program, and Section 30 specifically, is a legislative rule that was unlawfully promulgated without notice and the opportunity for public comment.

160. Under the Administrative Procedure Act ("APA"), agency action that "purports to impose legally binding obligations or prohibitions on regulated parties—and that would be the basis for an enforcement action for violations of those obligations or requirements" is a "legislative rule" that must be promulgated using notice and comment procedures. *Nat'l Mining Ass'n v. McCarthy*, 758 F.3d 243, 251

(D.C. Cir. 2014). Likewise, under the Medicare statute, notice and comment is required for any "rule, requirement, or other statement of policy . . . that establishes or changes a substantive legal standard." 42 U.S.C. § 1395hh(a)(2).

161. On March 15, 2023, CMS released a 91-page initial "guidance" document addressing the agency's implementation of the Program. On June 30, 2023, CMS issued a revised, final version of that guidance document.

162. Section 30 of the Guidance details how, for the initial price applicability year 2026, CMS will select drugs for "negotiation." Final Guidance at 97–118 (hereinafter "Section 30").

163. Section 30 thus outlines the substantive standards that govern CMS's threshold selection decisions—which in turn trigger the Program's full suite of coercive measures for manufacturers whose drugs are selected.

164. The Guidance, including Section 30, is a legislative rule that must be adopted through notice-and-comment rulemaking because it imposes legally binding obligations that are enforced through imposition of "excise tax" penalties and additional civil monetary penalties.

165. Despite the APA and Medicare statute's notice-and-comment requirements, CMS declared that Section 30 of the Guidance would be "final, without a comment solicitation." Initial Guidance at 2; *see also id.* at 5. CMS also asserted that the Guidance was not "subject to the notice-and-comment requirement of the Administrative Procedure Act or the Medicare statute." *Id.*

166. CMS asserted that it was lawful for Section 30 to be "final" without notice and comment for two reasons.

167. *First*, CMS cited "the Congressional direction in section 11001(c) of the IRA to implement the Negotiation Program for 2026, 2027, and 2028 by program instruction or other forms of program guidance." Initial Guidance at 2; *see* IRA § 11001(c).

168. But under the APA, a "[s]ubsequent statute may not be held to supersede or modify [the notice-and-comment requirements] … except to the extent that it does so expressly." 5 U.S.C. § 559. The IRA's direction that CMS implement the Program through "guidance" is not an express exemption from APA's generally applicable notice-and-comment requirements. Binding "guidance" like the CMS Guidance at issue here is often held to be a legislative rule subject to notice-and-comment requirements. *See, e.g., Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1023 (D.C. Cir. 2000); *NRDC v. EPA*, 22 F.3d 1125, 1146 (D.C. Cir. 1994); *see also Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1814–15 (2019).

169. The IRA does not provide that the Program shall be implemented through guidance "notwithstanding any other provision of law." There are numerous other instances where Congress, in the Medicare and Medicaid contexts, directed implementation via guidance notwithstanding any other provision of law. *See, e.g.*, 42 U.S.C. § 1320a-7c(a)(6)(J) ("Notwithstanding any other provision of law, the Secretary may implement the partnership established by subparagraph (A) by program instruction or otherwise"); *id.* § 1395cc-7(c) ("Notwithstanding any other

provision of law, the Secretary may implement this section by program instruction or otherwise."); *id.* § 1395g(d)(4) ("Notwithstanding any other provision of law, the Secretary may implement the provisions of this subsection by program instruction or otherwise."). Congress thus knew how to draft a provision making clear that the program instruction or guidance need not comply with notice-and-comment requirements—but did not do so here.

170. *Second*, CMS claimed there was "good cause" to dispense with notice-and-comment requirements because doing so "would be impracticable, unnecessary, and contrary to the public interest, in light of this Congressional direction and in light of the complexity of the preparation that must be undertaken in advance of the publication of the selected drug list by September 1, 2023." Initial Guidance at 2 (citing 5 U.S.C. § 553(b)(B) & (d)(3)).

171. But even "[s]tatutory language imposing strict deadlines, standing alone, does not constitute sufficient good cause under § 553 . . . justifying departure from standard notice and comment." *Asiana Airlines v. FAA*, 134 F.3d 393, 398 (D.C. Cir. 1998). The agency must show there is an "emergency situation" such that "delay could result in serious harm" or that immediate action is required to "stave off an[] immediate threat." *Mack Trucks, Inc. v. EPA*, 682 F.3d 87, 93 (D.C. Cir. 2012) (quotation marks omitted).

172. CMS's conclusory statement that there was not enough time to conduct notice-and-comment rulemaking is insufficient. CMS offered no explanation why, for example, a thirty-day comment period on Section 30 would have interfered with the

agency's ability to publish the selected drug list by September 1, 2023. CMS's cursory explanation is especially deficient given that the agency (1) has had since August 2022 to conduct the necessary proceedings; and (2) "voluntarily" invited comments on most of the Initial Guidance (but not Section 30).

173. Indeed, CMS made revisions to Section 30 in promulgating its Final Guidance, even while reiterating that Section 30 was "final," without a comment solicitation period. Final Guidance at 93; *see also id.* at 97. Those revisions underscore that it was possible for CMS to solicit and consider comments on Section 30.

174. It was arbitrary and capricious for CMS to announce that Section 30 was final and not subject to comment, but then revise that section of the guidance just a few months later. Far from mitigating any error, CMS's about-face further undermines the integrity of the process the agency undertook.

175. BI would have provided detailed and extensive comment on Section 30 had CMS stated that it would accept comments on that section. BI did not file comments in light of CMS's instruction, and in order to use the limited comment period available to focus on the issues on which CMS indicated it would consider comments.

176. CMS's decision to not to follow notice-and-comment requirements is not only unlawful, but will have significant policy consequences that could have been prevented if CMS had lawfully considered and responded to comments.

177. For example, in Section 30, CMS has taken a maximally broad view of what constitutes a single "drug," aggregating products with different dosage forms and strengths merely because they contain the same active moiety or active ingredient and are marketed by the same entity. CMS has thus defined as a single "drug" a wide range of different drug products, including drug products that are marketed pursuant to different new drug applications. *See* Final Guidance at 98–100.

178. As a result, while the IRA calls for ten drugs to be "selected" for "negotiation" in the first year, CMS's redefinition of "drug" to encompass families of multiple distinct products will mean that the Program's price controls apply to a far greater number of drugs. Moreover, CMS will impose price controls on drug products that are not "negotiation-eligible" in their own right—for example, because FDA approved them fewer than seven years ago—by treating those ineligible drugs as being the same drug as a drug that is eligible.

179. CMS also erred in failing to provide for notice and comment on the form Manufacturer Agreement. That Agreement imposes substantive requirements on manufacturers and obligates them to comply with any "guidance" CMS may issue in the future. *See* Manufacturer Agreement §§ II(d), II(e). Moreover, CMS retains authority to unilaterally amend the agreement to reflect any changes in law, regulation, or guidance. *See id.* § IV(b). CMS may not use a form agreement of this nature to implement the program without allowing an opportunity for notice and

comment on the agreement itself. *See, e.g.*, *Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1053–54 (D.C. Cir. 1987).

CLAIMS

Count I
Denial of Due Process in Violation of Fifth Amendment

180. BI re-alleges and incorporates by reference the foregoing paragraphs as if fully set forth herein.

181. The Due Process Clause of the Fifth Amendment provides that "[n]o person shall be deprived of life, liberty, or property, without due process of law." U.S. Const. amend. V.

182. BI has multiple property interests related to Jardiance® that are intruded upon by the IRA and the Program, including: (i) physical doses of Jardiance®, (ii) the patents covering Jardiance® and related intellectual property rights, (iii) the confidential and proprietary data BI will be forced to provide to CMS, and (iv) the enormous financial payments required to satisfy the excise tax and civil monetary penalty provisions.

183. As described above, the Program violates the Due Process Clause of the Fifth Amendment by effectively depriving BI of its property interests without meaningful process.

184. The Program withholds key protections provided under other price control regimes that have withstood constitutional scrutiny.

185. The Act does not require CMS to set a fair and equitable price for selected drugs, or set meaningful parameters as to how a fair and equitable price

would be determined. Instead, the Act gives CMS unfettered discretion to fix prices as low as it likes.

186. CMS is both the arbiter of the "negotiated" price and a party with a pecuniary interest in that price being as low as possible. This type of conflict of interest violates longstanding due process precedent.

187. The Act affords manufacturers no meaningful administrative process to examine and respond to the rationale and data relied upon by CMS in setting an initial and establishing a final "maximum fair price."

188. The Act likewise omits any mechanism to ensure that the price caps established by CMS are not impermissibly confiscatory.

189. In addition, the Act purports to shield CMS's price setting decisions from judicial review.

190. The court should declare that the Program's coercive "negotiation" process violates the Due Process Clause of the Fifth Amendment, and should enjoin Defendants from enforcing the Program against BI.

Count II
Taking of Personal Property in Violation of Fifth Amendment

191. BI re-alleges and incorporates by reference the foregoing paragraphs as if fully set forth herein.

192. The Fifth Amendment prohibits the Government from taking "private property . . . for public use, without just compensation." U.S. Const. amend. V.

193. As detailed above, the Program violates the Takings Clause of the Fifth Amendment by forcing BI to transfer its patented Jardiance® products and appropriating those products for the benefit of third parties.

194. The Program takes BI's personal property by requiring BI, under threat of ruinous penalties or the loss of all Medicare and Medicaid participation, to sign an "agreement" to relinquish its Jardiance® products on terms to which BI would never voluntarily agree. If BI disposes of those products in any way other than that dictated by the Program, the company will be subject to crippling penalties.

195. As explained above, the Act limits the compensation that BI may receive for the Jardiance® products it markets through Medicare to what the Act terms a "maximum fair price"—which must be lower than the statutory price ceiling described in paragraph 59 above, and thus well below the drug's market value. The "maximum fair price" is impermissibly below the threshold for just compensation set by the Constitution. *See Horne*, 576 U.S. at 368 ("The Court has repeatedly held that just compensation normally is to be measured by the market value of the property at the time of the taking." (cleaned up)). Indeed, the whole point of the Program is to *undercompensate* manufacturers like BI.

196. Accordingly, the Program will take BI's property without the just compensation required by the Fifth Amendment.

197. The Court should declare that the IRA unconstitutionally effects a taking of private property without just compensation under the Fifth Amendment.

198. BI seeks only declaratory relief with respect to its physical Takings claim. The Declaratory Judgment Act, 28 U.S.C. § 2201, "allows individuals threatened with a taking to seek a declaration of the constitutionality of the disputed governmental action before potentially uncompensable damages are sustained." *Duke Power Co. v. Carolina Env't Study Grp., Inc.*, 438 U.S. 59, 71 n.15 (1978). In other words, parties may seek declaratory relief when the challenged statute "does not provide advance assurance of adequate compensation in the event of a taking." *Id.*

199. Declaratory relief is appropriate here given the structure of the Program and the irreparable, ongoing, and impossible to quantify harms it causes manufacturers. *See, e.g.*, *Pharm. Rsch., & Mfrs. of Am. v. Williams*, 64 F.4th 932, 944 (8th Cir. 2023); *Di Giovanni v. Camden Fire Ins. Ass'n*, 296 U.S. 64, 70 (1935). *E. Enters. v. Apfel*, 524 U.S. 498, 521 (1998) (plurality op.); *Terrace v. Thompson*, 263 U.S. 197, 214 (1923); Y*oungstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 585 (1952).

Count III
Compelled Speech in Violation of the First Amendment

200. BI re-alleges and incorporates by reference the foregoing paragraphs as if fully set forth herein.

201. The First Amendment protects the right to speak freely, as well as the right not to speak.

202. The IRA compels BI to proclaim that it will reach an "agreement" with the Government on a "maximum fair" price through a process of "negotiation," 42

U.S.C. § 1320f–2(a), when in fact the prices that will be imposed through the Program are unfair, the "negotiation" process is not a real negotiation, and any "agreement" is entered into under duress.

203. Laws compelling speech are presumptively unconstitutional unless the Government can demonstrate that they are necessary to serve a compelling interest. *See Nat'l Inst. of Fam. & Life Advocates v. Becerra*, 138 S. Ct. 2361, 2371 (2018).

204. The Government has no compelling (or even legitimate) interest in forcing BI to make untruthful statements about the fairness of mandated prices achieved through a price-setting process conducted under duress. *See Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 641 (1994) ("Government action that . . . requires the utterance of a particular message favored by the Government . . pose[s] the inherent risk that the Government seeks not to advance a legitimate regulatory goal, but to . . . manipulate the public debate through coercion rather than persuasion.").

205. Accordingly, the Program violates the First Amendment by compelling BI to "voice ideas with which [it] disagree[s]." *Janus*, 138 S. Ct. at 2464.

206. The Court should declare that the Act's requirements that manufacturers "agree" to "negotiate" "maximum fair prices," 42 U.S.C. § 1320f-2(a)(1), are unconstitutional and enjoin Defendants from enforcing those requirements.

207. Specifically, the Court should enjoin Defendants from forcing BI to sign a "manufacturer agreement" to "negotiate" a "maximum fair price" for Jardiance®,

and likewise should enjoin Defendants from requiring BI to agre[e]" that the maximum prices set by CMS are "fair."

208. An injunction is appropriate because violations of the First Amendment "unquestionably constitute[] irreparable injury." *Elrod v. Burns*, 427 U.S. 347, 373 (1976).

Count IV
Imposition of Excessive Fines in Violation of Eighth Amendment

209. BI re-alleges and incorporates by reference the foregoing paragraphs as if fully set forth herein.

210. The Eighth Amendment prohibits the imposition of "excessive fines." U.S. Const. amend. VIII.

211. As detailed above, the IRA violates the Excessive Fines Clause of the Eighth Amendment by imposing a ruinous penalty to deter BI from refusing to take part in the Program's sham "negotiation" process.

212. That "excise tax" penalty *starts* at 186 percent of the drug's daily domestic revenues and escalates to 1900 percent of those revenues. *See* 26 U.S.C. § 5000D(d). In many instances, that requirement would amount to [tens of millions of dollars] in penalties starting the very first day a manufacturer declines to sign an agreement.

213. The "excise tax" label is irrelevant for constitutional purposes because its "practical characteristics" control. *NFIB*, 567 U.S. at 565. Here, the "excise tax" is not a tax because it imposes an "exceedingly heavy burden" and is not actually expected to raise revenue. *See id.*

214. The IRA's "excise tax" penalty is a "fine" within the meaning of the Excessive Fines Clause because it is punitive and coercive. It serves to deter manufacturers from declining to participate in the Program's compelled-negotiation process, or from declining to accept the CMS-imposed "maximum fair price."

215. The Act's "excise tax" penalty is also "excessive" because it is grossly disproportionate to the punished conduct.

216. The court should declare that the Program's "excise tax" penalty violates the requirements of the Excessive Fines Clause, and should enjoin Defendants from enforcing that penalty against BI.

Count V
Unconstitutional Condition on Medicare and Medicaid Participation

217. BI re-alleges and incorporates by reference the foregoing paragraphs as if fully set forth herein.

218. "[T]he government may not deny a benefit to a person because he exercises a constitutional right." *Koontz*, 570 U.S. at 604 (quoting *Regan v. Taxation With Representation of Wash.*, 461 U.S. 540, 545 (1983)).

219. The Program violates the unconstitutional conditions doctrine by conditioning BI's participation in Medicare and Medicaid on BI's consent to the deprivation of its property rights without due process of law, in violation of the Fifth Amendment. The Program requires the determination by CMS of a so called "maximum fair price" without affording BI a hearing before a neutral adjudicator or any of the other essential characteristics required by longstanding due process precedent.

220. The IRA violates the unconstitutional conditions doctrine by conditioning BI's participation in Medicare and Medicaid on BI's acquiescence in the Government's uncompensated taking of BI's Jardiance® products. If BI wishes to continue participating in Medicare and Medicaid, it must agree to relinquish those products on Government-dictated terms, including a statutory right of "access" for the benefit of third parties, that do not afford BI just compensation.

221. The IRA violates the unconstitutional conditions doctrine by conditioning BI's ability to sell its medications through the Medicare and Medicaid programs on BI promoting a misleading Government message with which BI disagrees. If BI wishes to continue selling its medications through Medicare and Medicaid, it must agree to promote the Government's message that it has agreed to sell Jardiance® at a "maximum fair price" established through "negotiation."

222. These conditions lack a nexus to the Government's interests in maintaining the Medicare and Medicaid programs. In addition, the Act's conditions fail the proportionality prong of the test, for example because the Government's interest in future pricing for a single Medicare drug is significantly outweighed by a rule requiring manufacturers to withdraw *all* of their products—not just the selected drug—from Medicare *and* Medicaid. *See Dolan v. City of Tigard*, 512 U.S. 374, 391 (1994).

223. The Court should declare that the IRA imposes an unconstitutional condition on Medicare and Medicaid participation, and enjoin Defendants from enforcing that condition or imposing penalties for non-compliance.

Count VI
Implementation of the Program in Violation of the APA and Medicare Statute

224. BI re-alleges and incorporates by reference the foregoing paragraphs as if fully set forth herein.

225. As detailed above, CMS violated the APA and Medicare Statute by promulgating Section 30 of the Guidance without undertaking notice and comment rulemaking procedures.

226. Under the APA, agency action that "purports to impose legally binding obligations or prohibitions on regulated parties—and that would be the basis for an enforcement action for violations of those obligations or requirements" is a "legislative rule" that must be promulgated using notice and comment procedures. *Nat'l Mining Ass'n*, 758 F.3d at 251. The Medicare statute imposes additional notice and comment requirements. *See Allina*, 139 S. Ct. at 1812–13.

227. The Guidance, including Section 30, is a legislative rule that requires notice and comment under the APA and Medicare statute because it imposes legally binding obligations that are enforced through the imposition of "excise tax" penalties and civil monetary penalties.

228. Despite the APA and Medicare statute's notice-and-comment requirements, CMS declared that Section 30 of the Guidance would be "final, without a comment solicitation" period. Final Guidance at 96–97.

229. The Court should declare that Section 30 is a legislative rule, and enjoin CMS from proceeding to implement the Program in accordance with the provisions of Section 30.

230. CMS issued the Manufacturer Agreement without providing for notice and comment as required by law. Because the Manufacturer Agreement imposes substantive obligations on manufacturers, obligates manufacturers to comply with any "guidance" CMS may issue in the future, and authorizes CMS to unilaterally amend the Manufacturer Agreement in the future to reflect changes in law, regulation, or guidance, the Manufacturer Agreement is subject to the notice-and-comment requirements in 5 U.S.C. § 553, as well as the APA's broader requirements for agency action.

231. The Court should therefore declare that the Manufacturer Agreement is arbitrary and capricious, and was issued without observance of the procedure required by law, and enjoin CMS from enforcing the Manufacturer Agreement's terms.

PRAYER FOR RELIEF

WHEREFORE, BI respectfully requests that the Court issue judgment in its favor and against Defendants and grant the following relief:

A. Declare that the Program violates the Fifth Amendment by taking BI's property without due process of law.

B. Declare that the Program violates the Fifth Amendment by physically taking BI's property without just compensation.

C. Declare that the Program violates the First Amendment by compelling BI's speech.

D. Declare that the Program imposes excessive fines in violation of the Eighth Amendment.

E. Declare that the Program unconstitutionally conditions BI's participation in Medicare and Medicaid on the relinquishment of BI's constitutional rights.

F. Declare that the Program, including the Guidance and the Manufacturer Agreement, violates the Administrative Procedure Act and the Medicare statute.

G. Enjoin Defendants from forcing BI to sign the Manufacturer Agreement, enforcing the Manufacturer Agreement, and imposing penalties for non-compliance with the Program and the Manufacturer Agreement.

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

I. Grant such other and further relief as the Court deems just and proper.

Dated: August 18, 2023

Respectfully submitted,

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