IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ASTELLAS PHARMA US, INC.,
2375 Waterview Drive
Northbrook, IL 60062-6111;

Plaintiff,

v.

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

Defendants.

Civil Action No. 1:23-cv-4578

COMPLAINT

Plaintiff Astellas Pharma US, Inc. ("Astellas") brings this action for declaratory and injunctive relief against Defendants 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"), and alleges as follows:

INTRODUCTION

1. In August 2022, Congress enacted the "Drug Price Negotiation Program" ("Program") as part of the Inflation Reduction Act ("IRA").[1] This Program will fundamentally change the pharmaceutical industry in the United States by replacing market-based pricing for innovative, life-saving medicines with prices set by the federal government.

2. The government has attempted to deny that the Program replaces market-based pricing with government-mandated pricing. The IRA purports to create a "negotiation" process through which CMS and a pharmaceutical manufacturer will reach an "agreement" on the "maximum fair price" for a medicine. Invoking these provisions, the President has repeatedly stated that the Program merely "giv[es] Medicare the power to negotiate drug prices." State of the Union Address (Feb. 7, 2023); *see also* Remarks by Pres. Biden on Medicare and the Inflation Reduction Act (Sept. 27, 2022) ("Medicare will finally get the power to negotiate lower prescription drug prices.").

3. But the Program does not allow for "negotiation" in any meaningful sense of that term. It does not provide for the typical arms-length negotiation where the parties can walk away from the negotiation if they cannot reach agreement on mutually beneficial terms. Instead, the

[1] *See* 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.

Program requires a manufacturer to "agree" to whatever prices CMS ultimately determines is the "maximum fair price"—or else lose access to nearly half of the U.S. prescription drug market or pay up to hundreds of millions of dollars per day in penalties.

4. The government has attempted to obfuscate the true nature of the Program to avoid political accountability. The American public supports "allowing the federal government to directly negotiate with drug companies to get a lower price on medications"[2]—likely because reaching agreement on pricing through arms-length negotiations is consistent with the traditional market-based process of determining prices in the United States. In contrast, less than half of Americans support what the Program actually does: "effectively allow[ing] the federal government to set the prices of drugs."[3]

5. There is good reason for such broad opposition to government-mandated pricing: it will stifle innovation and reduce the availability of life-saving medicines to patients. Pharmaceutical innovation is driven by private investments and market-based drug pricing, with revenues from a small fraction of approved drugs funding the research and development of other new drugs—a process that often lasts a decade or more for an FDA-approved drug and, on average, costs $3 billion per new therapy. Government-mandated pricing is estimated to "reduce overall annual cancer R&D spending by about $18.1 billion, or 31.8%."[4]

6. The Program not only is bad policy, it is unconstitutional.

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[2] National Tracking Poll #2109099, Morning Consult (Sept. 2021), at 13.

[3] *Id.* at 17.

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

7. *First*, the Program effects a physical taking of patented pharmaceutical products. The government must provide just compensation to the owner of personal property when it "appropriates for the enjoyment of third parties" the owner's rights, such as the "right to exclude," the "right of access," *Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2072 (2021), or "the rights to possess, use and dispose of" property, *Horne v. Dep't of Agric.*, 576 U.S. 350, 361 (2015) (quoting *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 435 (1982)). Here, through the Program's so-called "agreement," manufacturers will be forced to surrender their property to Medicare beneficiaries, who have been given a "right of access" to that property. And by the Program's design, the compensation that manufacturers will receive is constitutionally insufficient. The Program thus effects an unconstitutional physical taking.

8. *Second*, the Program violates the Due Process Clause. Due process requires, among other things, "a fair opportunity" to be heard "before a neutral decisionmaker." *Hamdi v. Rumsfeld*, 542 U.S. 507, 533 (2004). But the CMS decisionmaker who sets the "maximum fair price" is far from neutral. That official is bound by a statutory directive to "achieve" the "lowest" price; operates as an interested party in an adversarial "negotiation" regarding the drug's price; pre-judges the case by extending an initial pricing "offer"; and unilaterally sets a "maximum fair price" that need not budge from the official's initial offer. Congress compounded the Program's due process problems by shielding critical CMS determinations—including "[t]he determination of a maximum fair price"—from administrative or judicial review. This structure—in which one interested agency official gets the first, second, and *final* word on the "fair" price that will govern hundreds of millions in sales—falls well short of what due process requires.

9. *Third*, the Program violates the First Amendment. The IRA compels a manufacturer to endorse the government's message that the manufacturer has reached an

"agreement" with the government on a "fair" price through a process of "negotiation." None of those things are true. The "agreement" is no agreement because a manufacturer must sign or else face crippling penalties that it cannot pay or withdraw all of its products from one of the largest healthcare markets in the world. The "negotiation" is no negotiation because, for the same reasons, the manufacturer has no ability to walk away from the negotiation—and the process will always end with CMS unilaterally setting the price. And that price will not be "fair" because it will not be the product of the free market (or any market, for that matter). The Program thus unconstitutionally commandeers each manufacturer into a "vehicle for spreading a message with which it disagrees." *Pac. Gas & Elec. Co. v. Pub. Utilities Comm'n of California*, 475 U.S. 1, 17 (1986).

10. Astellas brings this action because it will soon be forced to participate in the Program. By September 1, 2023, CMS must identify ten drugs for the initial round of price "negotiations." Because Astellas's patented drug Xtandi® (enzalutamide)—which is widely used to treat prostate cancer—is among the ten most reimbursed drugs within Medicare Part D, it will be included in the Program. Moreover, depending on how CMS compiles the initial list, Astellas's patented drug Myrbetriq® (mirabegron) may also be included in the Program beginning in September 2023. By October 1, 2023, Astellas will be forced to sign an "agreement" to participate in the Program. When that happens, Astellas's constitutional rights will be violated.

11. Because the Program violates the Takings Clause, the Due Process Clause, and the First Amendment, it is unconstitutional multiple times over. This Court should declare that the Program is unlawful and enjoin its enforcement against Astellas.

PARTIES

12. Plaintiff Astellas Pharma US, Inc. ("Astellas") is incorporated in Delaware and has its principal place of business in Northbrook, Illinois. Astellas is an affiliate of Astellas Pharma

Inc. Astellas manufactures and sells enzalutamide, under the trade name Xtandi®. Xtandi® is a prescription medicine used to treat advanced prostate cancer.

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

14. 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 IRA Drug Pricing Program at issue here. Secretary Becerra is sued in his official capacity as the Secretary of HHS.

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

16. Defendant Chiquita Brooks-LaSure is the Administrator of CMS. Administrator Brooks-LaSure is sued in her official capacity as the Administrator of CMS.

JURISDICTION AND VENUE

17. 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.

18. This Court also has subject-matter jurisdiction pursuant to 28 U.S.C. § 1346(a) because 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.

19. 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. *See Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 327 (2015).

20. 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 Astellas's corporate headquarters is located in Northbrook, Illinois.

21. Astellas's patented drug Xtandi® is among the ten most reimbursed drugs within Medicare Part D, meaning that it will be subject to the Program beginning in September 2023. Moreover, depending on how CMS compiles the initial list, Astellas's patented drug Myrbetriq® may also be included in the Program beginning in September 2023.

BACKGROUND

A. The Federal Government Currently Pays Market-Based Prices for Prescription Drugs Covered by Medicare.

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

23. The government pays for prescription drugs under both Part B and Part D of Medicare.

24. Under Part B, Medicare covers various healthcare services for its beneficiaries, including primarily drugs administered by a physician. *See* 42 U.S.C. § 1395k.

25. Congress has long ensured that Part B reimbursements are tied to market-based prices by setting reimbursement rates based on a drug's "average sales price." 42 U.S.C. § 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.

26. People 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 reimburses sponsors of private health insurance plans for a portion of the costs of such drugs. In turn, plan sponsors pay manufacturers for covered drugs.

27. When Congress created Medicare Part D, it included a provision expressly 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).

B. The Program Fundamentally Changes the Prescription Drug Market by Authorizing HHS to Impose Price Controls on Prescription Drugs.

28. Congress passed the IRA by narrow margins (51 to 50 in the Senate and 220 to 207 in the House of Representatives). The bill was signed into law on August 16, 2022.

29. The IRA requires the HHS Secretary to establish what it calls a "Drug Price Negotiation Program," 42 U.S.C. § 1320f(a), for setting Medicare prices for certain drugs. HHS has delegated its authority to administer the Program to CMS. *See* 88 Fed. Reg. 1390 (Jan. 10, 2023).[5]

30. For the first year of the Program, CMS will select ten drugs for "negotiation" of a "maximum fair price." The drugs chosen for negotiation will be the ten highest-reimbursed Part D drugs. The list of drugs selected for negotiation must be published by September 1, 2023. *See* 42 U.S.C. §§ 1320(d)(2)(A), 1320(a)–(b).

31. Once the list of selected drugs is published, each manufacturer of a selected drug is given until October 1, 2023, to sign an "agreement" (hereinafter "Program Agreement") to "negotiate" maximum prices for those drugs. *See id.* §§ 1320(d)(2)(A), 1320(a)–(b), 1320f-2. If

[5] Because the HHS Secretary has delegated his authority to administer the Program to CMS, this Complaint generally refers to "CMS" when discussing the agency's implementation of the Program, even where the statute refers to HHS or the HHS Secretary.

a manufacturer refuses to sign the Program Agreement, it is subject to an "excise tax" penalty on every domestic sale of the selected drug, starting at 186% of the drug's daily revenues and escalating to 1900% of daily revenues. *See* 26 U.S.C. § 5000D(b)(1), (d). The excise tax penalty applies to *each sale* of the subject drug—to any purchaser, not merely government healthcare program sales. *See id.* § 5000D(a). The penalty would begin accruing on October 2, 2023, the day after the signed Program Agreement is due.

32. The excise tax penalty would be debilitating, and would in many instances amount to millions of dollars in penalties every day. As a result, manufacturers will have no practical choice but to sign the Program Agreement.

33. After a manufacturer signs the Program Agreement, it must provide to CMS detailed information, including confidential information that a manufacturer would not ordinarily disclose publicly or share with another market participant or potential contracting counterparty, all "in a form and manner specified" by CMS. 42 U.S.C. § 1320f–2(a)(4). Manufacturers must turn over proprietary and trade secret information, including research and development costs; market data for the drug; patent information; highly sensitive pricing data; and costs of production and distribution. *Id.* § 1320f–2(a)(4)(B), (e)(1). Manufacturers must also "compl[y] with" whatever requirements CMS unilaterally imposes as "necessary for purposes of administering the program and monitoring compliance with the program." *Id.* § 1320f–2(a)(5).

34. If a manufacturer fails to provide the required information or otherwise fails to comply with the requirements that CMS imposes in connection with the "negotiations," the manufacturer "shall be subject to a civil monetary penalty equal to $1,000,000 for each day of such violation." *Id.* § 1320f-6(c).

35. After CMS has a manufacturer's confidential and proprietary information, the "negotiation" takes place. Though labeled a "Negotiation Program," the Program does not involve any "negotiation." During the so-called "negotiation," the agency will make one initial "offer" and a manufacturer may make one "counteroffer." *Id.* § 1320f-3(b)(2)(B)–(D). But these steps are mere formalities. The "negotiation" will always end with CMS setting a price. *See id.* § 1320f-3(b)(2)(E).

36. In a genuine negotiation, Astellas could craft a counteroffer based on any data, factors, or considerations that it deemed relevant. But that is not how the Program's "negotiation" process works. The statute restricts a manufacturer's ability to "counteroffer," permitting a manufacturer to base a "counteroffer" only on a limited set of specified factors, such as research and development costs; current production and distribution costs; prior federal financial support for development; data on pending and approved patent applications; market data and revenue and sales volume data for the drug; and certain evidence regarding alternative treatments. *Id*. §§ 1320f–3(b)(2)(C)(ii), 1320f–3(e).

37. In a genuine negotiation, if CMS did not want to accept Astellas's "counteroffer," it could convey a further counteroffer that Astellas, in turn, would be free to accept or to reject in favor of a further counteroffer (or walk away). Again, that is not how the Program's "negotiation" process works. After CMS receives the manufacturer's "counteroffer," there are no further offers or counteroffers under the statute. CMS simply "respond[s] in writing," *id*. § 1320f-3(b)(D), and then proceeds to set the "maximum fair price," *id*. §§ 1320f(d)(5)–(6), 1320f-4(a)(1). That final "maximum fair price" could very well be identical to or even lower than CMS's initial "offer."

38. The IRA gives the agency broad discretion in setting the "maximum fair price," while instructing it to exercise that authority "to achieve the lowest maximum fair price for each

selected drug." *Id*. § 1320f-3(b)(1). Consistent with that goal, the IRA imposes a statutory ceiling on the "maximum fair price," but no floor.

39. The maximum fair price must be at least 25 percent below the actual market value of the drug. *Id.* § 1320f-3(c)(3)(A). For "long-monopoly" drugs that have been FDA-approved for at least 16 years, the maximum fair price must be at least 60 percent lower than the market price. *Id.* § 1320f-3(c)(3)(C), (5). In contrast, aside from an exception not relevant here, there is no minimum for the price CMS may dictate as the "lowest" achievable price under the IRA. *See id.* § 1320f-3(c)(4) (carving out a "[t]emporary floor for small biotech drugs"). Nothing in the statute prevents CMS from setting the price of a drug at a penny, and if it did, the manufacturer would have no recourse but to accept it.

40. The "negotiation" process for the initial price applicability year must conclude by August 1, 2024. If a manufacturer refuses to "agree" to CMS's chosen "maximum fair price" by the end of the negotiation period, the manufacturer must pay an "excise tax" penalty on every domestic sale of the selected drug, starting at 186% of the drug's daily revenues and escalating to 1900% of daily revenues. *See* 26 U.S.C. § 5000D(b)(2), (d). The excise tax penalty applies beginning August 2, 2024—*i.e.*, the day after the "negotiation" process concludes. *See id.* § 5000D(b)(2).

41. By September 1, 2024, the Secretary must publish the so-called "maximum fair price" for each of the ten selected drugs for the 2026 initial price applicability year. 42 U.S.C. §§ 1320f(d)(6), 1320f-4.

42. The Secretary will then publish an "explanation" for those prices no later than March 1, 2025. *Id.* § 1320f-4(a)(2).

43. The government-dictated prices for the first 10 drugs selected for the Program will become effective on January 1, 2026.

44. After the price is set, the IRA mandates that manufacturers provide "access" to the drug at the "maximum fair price" to "maximum fair price eligible individuals." *Id.* §§ 1320f–2(a), 1320f–3(a), 1320f(c)(2).

45. These include all eligible individuals enrolled under Medicare Parts B and D (and enrollees in certain Medicare Advantage plans) and hospitals, physicians, pharmacies, mail order services, and other dispensers with respect to maximum fair price eligible individuals. *Id.* § 1320f–2(a)(1)(A)–(B); *see id.* § 1320f(c)(2).

46. Manufacturers are obligated to grant eligible beneficiaries this "access" until the agency determines otherwise. *Id.* §§ 1320f-2(a)–(b).

47. Manufacturers that fail to provide access to CMS's "maximum fair price" are subject to a civil monetary penalty of *ten times* the difference between the price charged and the "maximum fair price," multiplied by the total number of units sold. *Id.* § 1320f–6(a).

48. Because the statute imposes no lower limit on the "maximum fair price" that CMS can select, that penalty could easily amount to several multiples of the fair market price of the drug, for every drug unit sold at that fair market price.

49. Finally, many of CMS's decisions under the Program are insulated from "administrative or judicial review." *Id.* § 1320f-7. For example, the IRA states that there shall be "no administrative or judicial review of" the "determination of negotiation-eligible drugs" nor the "determination of a maximum fair price." *Id.* § 1320f-7(1)–(4).

C. The IRA's Government-Mandated Pricing Will Stifle Innovation

50. Xtandi® is the first and only novel hormone therapy approved by the FDA to treat three types of advanced prostate cancer. In these three types of advanced prostate cancer, data have shown Xtandi® significantly reduced the risk of disease progression or death.

51. Prescription drugs like Xtandi® are the product of years and sometimes decades of research, development, hard work, and investment.

52. There are extraordinary costs associated with the development of groundbreaking drugs like Xtandi®. On average, a manufacturer spends $2.6 billion developing just one new medicine.[6]

53. Globally, Astellas entities spent approximately $1.9 billion on research and development costs in Fiscal Year 2022.

54. Astellas—in collaboration with Medivation, Inc. and Pfizer Inc.—invested more than $2.3 billion to develop Xtandi®, which obtained FDA approval in 2012. Astellas alone invested nearly $1.5 billion to research and further develop Xtandi® to make it available to more patients with advanced prostate cancer.

55. Additional research and development on Xtandi® led to FDA approval of further indications in 2014, 2018, and 2019. Astellas continues to invest in research to support FDA approval of additional indications for Xtandi®.

56. The drug development process is also time-consuming. It now takes an average of 10 to 15 years to develop a new drug.[7]

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[6] *See* Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20, 25–26 (2016), https://bit.ly/30UAIdg.

[7] *Id.* at 25–26.

57. Manufacturers working to develop drugs face challenging odds. Only one compound in 5,000 that enters preclinical testing will achieve FDA approval—a success rate of 0.02%.[8] And just 12 percent of compounds that make it into a Phase I clinical trial ultimately receive FDA approval.[9]

58. Although thousands of compounds are initially investigated as potential drugs, and hundreds proceed to clinical trials, FDA approved an average of only 38 drugs annually between 2010 and 2019 (a miniscule percentage that was still an increase over the previous decade). *See* Congressional Budget Office, Research and Development in the Pharmaceutical Industry, at 1 (Apr. 2021).

59. The revenues from this tiny fraction of drugs that receive FDA approval and become marketable are necessary to subsidize investments in the future research and development of other drug compounds or biologics, and to further explore additional uses of already-marketed drug compounds or biologics. In other words, the development of new, life-saving treatments is highly dependent on revenues from a handful of successful therapies.

60. The Program's unprecedented new mandates present an existential threat to this virtuous cycle of innovation by blocking manufacturers' ability to develop innovative medicines and improve on existing treatments by recouping costs through the pharmaceutical markets.

61. By imposing below-market price caps on existing drugs, the Program weakens the incentive to develop new medicines. *See* Congressional Budget Office, *Research and Development in the Pharmaceutical Industry*, at 1 (Apr. 2021) (explaining that investment

[8] Sandra Kraljevic et. al., *Accelerating Drug Discovery*, 5 Eur. Molecular Biology Org. Reps., no. 9, 2004, at 837, https://bit.ly/2Y2gwEK.

[9] *See, e.g.*, DiMasi et al., *supra* n.6, at 23.

amounts are a function of anticipated revenues). The result will be "fewer new drugs," because there will be "less incentive for companies to spend on [research and development]." *Id.* at 12.

62. Indeed, several leading biopharmaceutical companies and small biotech companies have already started shifting their research-and-development investment priorities, portfolios, and budgets in response to the Program's enactment.

63. For example, one study estimates that the Program's government-determined prices will "reduce overall annual cancer R&D spending by about $18.1 billion, or 31.8%."[10]

64. By undermining intellectual property rights and incentives to develop new drugs, the Program's pricing regime will eventually result in fewer new treatment options, for both doctors and patients.

65. The Program will have such debilitating effects on R&D because it will soon impact the pricing for all prescription drugs that are not exempt from the "Negotiation" Program.

66. Specifically, although the Program will set prices for only ten drugs in the first year, that number will increase in subsequent years with fifteen additional Medicare Part D drugs selected for 2027, fifteen additional Medicare Part D and Medicare Part B drugs selected for 2028, and twenty additional Medicare Part D and Medicare Part B drugs selected for 2029 and each year thereafter. 42 U.S.C. § 1320f–1(a)(1)–(4).

67. The Program's drug-selection process is also cumulative: Once a drug is selected, it remains selected until CMS determines that a generic or biosimilar version of the drug is approved or licensed and marketed pursuant to that approval. *Id.* § 1320f–1(c)(1). The number of

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

drugs subject to the Program thus snowballs over time—within ten years, it is expected that half of all Medicare drug spending will be for drugs subject to the Program's price controls.

68. Government-mandated pricing for Medicare patients will also have spill-over effects for Medicaid. Federal law expressly links rebates under the Medicaid Drug Rebate Program to the average price paid to manufacturers by wholesalers and retail pharmacies. *See id*. § 1396r-8(c)(1). Given that Medicare accounted for 21 percent of total national healthcare expenditures in 2021,[11] the Medicare drug prices dictated by the Program will necessarily influence that average.[12]

69. Once the government-mandated pricing for Medicare has spilled over to Medicaid, it will also impact the private payer market. Together, Medicare and Medicaid were responsible for nearly 40% of U.S. healthcare expenditures in 2021,[13] and Medicare and Medicaid accounted for more than half of Astellas's total U.S. revenue in that same year. The prices paid by roughly half of the market will necessarily impact the prices paid by the other half.

70. For Xtandi®, a significantly higher percentage of sales come from Medicare and Medicaid, and the Program will have a correspondingly larger impact on Xtandi®'s pricing both within Medicare and Medicaid and without.

71. That is especially true given that the IRA announces that the CMS-mandated Medicare price is the "maximum fair price." Once a manufacturer has ostensibly "agreed" that

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[11] CMS, *NHE Fact Sheet*, https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.

[12] *See, e.g.*, Rachel Dolan, *Understanding the Medicaid Prescription Drug Rebate Program*, KFF (Nov. 12, 2019), https://www.kff.org/medicaid/issue-brief/understanding-the-medicaid-prescription-drug-rebate-program/ (observing that changes to Medicare drug prices "could have implications for Medicaid rebates and ultimately Medicaid drug spending by changing drug list prices").

[13] CMS, *NHE Fact Sheet*, https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.

the Medicare price is the "maximum fair price," any attempt to negotiate a higher price for a private payer would suggest that the manufacturer was attempting to charge a price that is unfairly high.

D. Astellas Will Be Required to Participate in the Program This Year.

72. The IRA requires the Secretary to select ten "negotiation-eligible" drugs for the 2026 "initial price applicability year" of the Program by September 1, 2023. 42 U.S.C. § 1320f-1(a)(1).

73. 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).

74. 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 various exceptions not relevant here. *Id.* § 1320f-1(e)(1)(A); *see also* 21 U.S.C. § 355.

75. Based on these criteria, Astellas's highly effective, and therefore highly successful, prostate cancer drug Xtandi® will be "negotiation eligible" for the 2026 initial price applicability year.

76. According to CMS's guidance concerning implementation of the Program, the agency will select the top 10 drugs that account for the highest Medicare spending. 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 30.3 (June 30, 2023) ("CMS Guidance").

77. Xtandi® falls within this group and thus will be selected for the 2026 initial price applicability year. *See* S. Dickson & I. Hernandez, *Drugs Likely Subject to Medicare Negotiation*, 2026-2028, 29 JMCP 229 (Mar. 2023), https://www.jmcp.org/doi/epdf/10.18553/jmcp.2023.29.3.229?role=tab.

78. As a result, Astellas will be forced to sign a false Program Agreement to "negotiate" a "maximum fair price" for Xtandi® no later than October 1, 2023. 42 U.S.C. §§ 1320f(d)(1), 1320f(d)(2)(A), 1320f-2.

E. The IRA's Government-Mandated Pricing Violates Astellas's Constitutional Rights.

1. The Program Effects a Taking and Denies Just Compensation.

79. The Fifth Amendment prohibits the government from "tak[ing]" "private property … for public use, without just compensation." U.S. Const. amend. V.

80. This protection exists "to preserve freedom and [to] empower[] persons to shape and to plan their own destiny in a world where governments are always eager to do so for them." *Cedar Point Nursery*, 141 S. Ct. at 2071 (cleaned up). "[P]eople … do not expect their property, real or personal, to be actually occupied or taken away" without being compensated for it. *Horne*, 576 U.S. at 361.

81. The government has a categorical duty to fully compensate the owner of personal property when it "appropriates for the enjoyment of third parties" the owner's rights, such as the "right to exclude," the "right of access," *Cedar Point Nursery*, 141 S. Ct. at 2072, or "the rights to possess, use and dispose of" property, *Horne*, 576 U.S. at 361 (quoting *Loretto*, 458 U.S. at 435).

82. For example, a physical taking occurs when a law or regulation "compel[s]" or "requires physical surrender" of personal property, with "the [owner] los[ing] any right to control [its] disposition." *Horne*, 576 U.S. at 364.

83. The Takings Clause protects Astellas's property rights in its patented products like Xtandi® because those products are personal property. *See Horne*, 576 U.S. at 358.

84. The rights to possess, control, and prevent third-party access to those products are especially strong given the additional protections provided by patent law. Because of Xtandi®'s

patents, Astellas's property rights include "the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States." 35 U.S.C. § 154(a)(1). The Takings Clause also protects this additional right. *See Horne*, 576 U.S. at 359–60.

85. The Program effects a physical taking of Astellas's patented Xtandi® products because it appropriates for eligible beneficiaries a right to access these products. In doing so, the Program compels Astellas to surrender its property, over its objections, to eligible beneficiaries and strips Astellas of its ability to control the disposition of these products.

86. This physical taking arises from the Program Agreement, which sets the terms of the Program. *See* 42 U.S.C. § 1320f-2. By statute, the Program Agreement says that manufacturers, including Astellas, "shall" give eligible beneficiaries (and their hospitals, doctors, providers, and suppliers) "access" to their selected drugs, such as Xtandi®. *Id*. § 1320f-2(a)(3). The government then promises compensation in exchange for the beneficiaries' right of access, but on heavily discounted terms Astellas would never voluntarily accept. *Id.*

87. This obligation, which binds Astellas before the so-called "negotiations" even begin, thus appropriates Astellas's property rights in Xtandi® by foreclosing any future attempts to possess, use, or dispose of its product as Astellas sees fit. *See Cedar Point Nursery*, 141 S. Ct. at 2072; *Horne*, 576 U.S. at 361–62.

88. Because Astellas will be forced to surrender its property to third parties who have been given "right of access" from the government, the Program effects a physical taking of Astellas's patented drugs.

89. The IRA's promise that Astellas can receive a highly discounted maximum price in exchange for the government's appropriation of Astellas's property rights does not change 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). Instead, "any payment from the Government in connection with that action goes, at most, to the question of just compensation." *Id.* at 364.

90. Thus, the "maximum fair price" affects the amount of just compensation due, not the threshold question whether the Program inflicts a taking of Astellas's property. And it is clear that the CMS-mandated "maximum fair price"—which by statute must be at least 25%–60% below the drug's market value, *see* 42 U.S.C. § 1320f-3(c)(3)(A)—is not "just compensation" under the Takings Clause.

91. As applied to Astellas, the Program effects a physical taking. Astellas will be required to sign a Program Agreement under threat of a massive daily penalty on every domestic sale of a selected drug or the total loss of its Medicare and Medicaid revenues. That Program Agreement by statute will then force Astellas, over its objection and under the threat of additional civil monetary penalties, to grant Medicare beneficiaries unlimited access to its patented drug product, Xtandi®. Through these coercive obligations, the government appropriates for those beneficiaries Astellas's right to possess, use, and dispose of its personal patented property.

2. The Program Violates Astellas's Due Process Rights.

92. 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. When CMS establishes the "maximum fair price" for the drugs it selects under the Program, it deprives the manufacturer of property interests that are entitled to due process protections.

93. "The fundamental requirement of due process is the opportunity to be heard 'at a meaningful time and in a meaningful manner.'" *Mathews v. Eldridge*, 424 U.S. 319, 333 (1976) (quoting *Armstrong v. Manzo*, 380 U.S. 545, 552 (1965)). For a hearing to be "meaningful," as due process requires, it must at a minimum take place before a "neutral and detached judge."

Concrete Pipe & Products of Cal., Inc. v. Construction Laborers Pension Trust for Southern Cal., 508 U.S. 602, 617 (1993) (quoting *Ward v. Monroeville,* 409 U.S. 57, 61–62 (1972)); *see also Hamdi*, 542 U.S. at 533 (due process requires "a fair opportunity to rebut the Government's factual assertions before a neutral decisionmaker").

94. The Program is structured to systematically deprive manufacturers of property without ever affording them a hearing before a neutral adjudicator, as due process requires.

95. For example, when CMS unilaterally imposes a final "maximum fair price," CMS is not a neutral decisionmaker because, among other things:

a. CMS operates under a statutory mandate "to *achieve* the *lowest* maximum fair price for each selected drug," *id.* § 1320f–3(b)(1) (emphasis added);

b. CMS, as the instrument of a government insurer and payer, has a direct financial and pecuniary interest in attaining the lowest possible price on the drugs that it purchases;

c. CMS engages in the Program's sham "negotiation" process as an adversary of the manufacturer, and so cannot be "detached" when the time comes to determine the "maximum fair price";

d. CMS pre-judges the determination by making an initial "offer" that indicates an early judgment regarding the appropriate "maximum fair price."

96. Regardless of the final price set by CMS as an interested and final arbiter, Astellas must "agree" that CMS has imposed the "maximum fair price" on pain of ruinous "excise tax" penalties or the loss of more than half of Astellas's U.S. revenues. *See* 26 U.S.C. § 5000D(b)(2), (d). Astellas must provide "access" to Xtandi® at that price to "maximum fair price eligible individuals." 42 U.S.C. §§ 1320f–2(a), 1320f–3(a), 1320f(c)(2).

97. For a hearing to be "meaningful" as due process requires, it must also be conducted in accordance with administrable, substantive standards that are applied consistently across cases. The Program sets no clear standards governing how CMS is supposed to set the "maximum fair price." Aside from an exception not relevant here, there is no floor to the price that CMS may dictate under the Program—only a ceiling.

98. Similarly, the IRA directs the Secretary to "consider" certain information provided by the manufacturer, including research and development costs, unit costs, prior federal financial support, data on pending and approved patent applications, market data and revenue and sales volume data, and information about alternative treatments. *Id.* § 1320f–3(e). But the statute does not provide guidance on *how* CMS is supposed to consider or otherwise weigh that information to arrive at a "maximum fair price," or provide any mechanism for ensuring that the final price reflects such consideration.

99. Congress compounded the Program's due process deficiencies by specifically prohibiting *any* "administrative or judicial review" of various CMS determinations, including drug selection and "[t]he determination of a maximum fair price." *Id.* § 1320f-7. Because the IRA prohibits any administrative or judicial review of CMS's determination of the "maximum fair price" (among other key CMS decisions under the Program), CMS acts under the Program *both* as an interested adversary *and* as the final adjudicator in selecting covered drugs and determining the "maximum fair price" that will apply to those drugs.

100. In sum, under the Program's administrative scheme, CMS makes unchallengeable decisions about drug selection; operates as an interested party in an adversarial "negotiation" regarding the drug's price; extends an initial pricing "offer" that is unconstrained by any statutory standard; and subsequently decides the reasonableness of that same "offer" by setting a "maximum

fair price" (that could be the same as the initial offer or even lower)—a decision that is unreviewable, since the "maximum fair price" determination is insulated from administrative and judicial review. That structure is unconstitutional because it denies manufacturers "a fair opportunity" to be heard "before a neutral decisionmaker," as due process requires. *Hamdi*, 542 U.S. at 533.

3. The Program Compels Astellas to Speak in Violation of the First Amendment.

101. The First Amendment provides that "Congress shall make no law . . . abridging the freedom of speech." U.S. Const. amend. I. The First Amendment protects not only the right to speak, but also the right to refrain from speech. *See Nat'l Inst. of Fam. & Life Advocs. v. Becerra*, 138 S. Ct. 2361, 2371 (2018).

102. The IRA violates the First Amendment by compelling Astellas and other manufacturers to endorse a message that they do not believe. Astellas must state that it will reach "agreement" with the government on a "fair" price through a process of "negotiation," 42 U.S.C. § 1320f–2(a), when in fact Astellas believes that the price caps imposed through the Program are unfair, the negotiation is a sham, and the agreement is compelled.

103. More specifically, the IRA requires CMS and the manufacturer of a selected drug to enter a Program Agreement, under which manufacturers will be statutorily bound to "agree" to "negotiate" a "fair" price for the selected drug. *Id*.

104. By signing a Program Agreement, Astellas conveys that it will "agree" with the government on a "fair" price through a process of "negotiation."

105. Those statements are compelled, false, and misleading.

106. In a real arms-length negotiation, both sides are free to walk away from the table. And in a free market economy, the law of supply and demand—not a unilateral government edict—

determines what prices are "fair." Indeed, courts have long held that "market value" is the proper metric for determining the value of property protected by the Fifth Amendment, such as patented drug products. *See Horne*, 576 U.S. at 368–70; *see also United States v. Reynolds*, 397 U.S. 14, 15–16 (1970) (explaining that "'just compensation' means the full monetary equivalent of the property taken," which means "the owner is entitled to the fair market value of the property at the time of the taking").

107. But as explained above, no manufacturer can walk away from the table due to the IRA's crushing penalties and the coercive weight of Medicare and Medicaid in the U.S. health insurance market. *See* 42 U.S.C. § 1320f-6; 26 U.S.C. § 5000D.

108. Moreover, Astellas strongly *disagrees* that a government-dictated price is "fair" and the result of "negotiation."

109. In the wake of litigation challenging the Program, Members of Congress who supported the IRA's enactment have sought to defend the Program by asserting that it merely authorizes CMS to leverage its "bargaining power" to "buy in bulk" and save money. *See, e.g.*, Statement of Sen. Jack Reed (June 21, 2023) ("Anyone who has ever shopped at a wholesalers like BJ's or Costco understands that when you buy in bulk you can save money.");[14] Statement of Sen. Ron Wyden (June 21, 2023) (urging the Administration to "vigorously defend Medicare's bargaining power so seniors will see the lower drug prices they expect");[15] Statement of Rep.

[14] *Available at* https://www.reed.senate.gov/news/releases/reed-blasts-phrmas-lawsuit-seeking-to-block-medicare-from-negotiating-for-lower-rx-drug-prices.

[15] *Available at* https://www.finance.senate.gov/chairmans-news/wyden-statement-on-phrma-lawsuit-to-ban-medicare-prescription-drug-negotiation.

Richard E. Neal (June 21, 2023) (the Program "open[ed] the door to Medicare negotiation" and will "put[] money back in Americans' pockets").[16]

110. But those characterizations are false. The significance of the Medicare and Medicaid markets backed by the statutory authority to impose crippling excise tax penalties is not "bargaining power" or a standard feature of "bulk" purchasing. To borrow an analogy cited in the preceding paragraph, "BJ's or Costco" can decline to buy or sell products to other market participants if the offered price is undesirable, but neither company can threaten to impose millions of dollars in daily penalties to extract a favorable "bargain." That is a coercive feature of the Program that forces manufacturers to accept whatever price CMS unilaterally dictates.

111. By forcing manufacturers to signal their "agreement" to participate in a sham "negotiation" that will result in the government unilaterally setting what it deems to be a "fair price," the IRA turns Astellas into a "vehicle for spreading a message with which it disagrees." *Pac. Gas & Elec.*, 475 U.S. at 17. The statute thus violates the First Amendment.

F. The Government Cannot Save the Program by Claiming That Astellas's Participation in the Program Is Voluntary.

112. The IRA will violate Astellas's constitutional rights for the reasons discussed above, and it is irrelevant that Astellas could *in theory* avoid that result *in part* by exiting the Medicare and Medicaid programs, perhaps months after the IRA's ruinous penalties begin to accrue.

113. The IRA restricts a manufacturer from immediately withdrawing all of its products from Medicare and Medicaid. *See* 42 U.S.C. § 1395w-114a(b)(4)(B)(ii) ("Any such termination shall be effective, with respect to a plan year— (I) if the termination occurs before January 30 of

[16] *Available at* https://democrats-waysandmeans.house.gov/media-center/press-releases/neal-statement-phrma-lawsuit-over-lifesaving-drug-price-negotiation.

a plan year, as of the day after the end of the plan year; and (II) if the termination occurs on or after January 30 of a plan year, as of the day after the end of the succeeding plan year.").

114. Given these delayed effective dates, a manufacturer could not exercise its statutory right to terminate its Medicare and Medicaid agreements in time to avoid the "excise tax."

115. For example, had Astellas begun the withdrawal process in August 2022 when the IRA was enacted, various statutory provisions would have foreclosed any suspension of the penalties until January 2024—*i.e.*, delaying the termination of those agreements by at least 16 months. *See id*. With the excise tax penalty starting on October 2, 2023, Astellas would have been forced to pay nearly 200 percent of every domestic sale of Xtandi® in penalties for the last quarter of 2023. *See* 26 U.S.C. § 5000D.

116. Alternatively, if Astellas were to attempt to withdraw now, the statute would delay Astellas's withdrawal until January 2025, such that every domestic sale of the drug would be penalized for at least 15 months. Penalties would reach 1900 percent of every domestic sale during the last 6 months of that period.

117. Given the constitutional problems exacerbated by Congress's decision to delay a manufacturer's exit from the Medicare and Medicaid programs, CMS has proposed an end-run around this statutory requirement. In the Final Guidance, CMS has instructed manufacturers that instead of terminating the agreements themselves, CMS will terminate the manufacturers' agreements upon request. Under this approach, CMS would treat terminations initiated by manufacturers, which are subject to a statutory 11- to 23-month delay before taking effect, as terminations by the government, which are subject to a 30- or 60-day delay. *See id.*; 42 U.S.C. §§ 1395w-114a(b)(4)(B)(i)-(ii); 1396r–8(b)(4)(B)(i). But manufacturers have reason to doubt that CMS will follow through on that promise. CMS has already taken the position that it can change

its Guidance without notice or an opportunity to comment, and there is good reason to question whether CMS has statutory authority to treat a manufacturer-initiated termination as if it were a government-initiated termination.

118. If there were any doubt about whether a manufacturer could afford to withdraw all of its products from the Medicare and Medicaid programs and pay any penalties that would accrue before the withdrawal would take effect, the government's revenue estimates resolve it. Congress projected that virtually identical penalty provisions in a precursor bill to the IRA would generate "no revenue" for the government.[17]

119. But even if Astellas could withdraw from Medicare and Medicaid to avoid paying massive penalties, it does not abandon its constitutional rights by remaining in those programs. As a practical matter, no reasonable manufacturer could afford to exit Medicare and Medicaid entirely. And these markets are even more important to Astellas than the average drug manufacturer. Under the "unconstitutional conditions" doctrine, the government may condition a benefit on forfeiture of a constitutional right only if it substantially advances a purpose related to that benefit, and is "rough[ly] proportiona[l]" to it. *Dolan v. City of Tigard*, 512 U.S. 374, 391 (1994).

120. Forcing a manufacturer to withdraw entirely from Medicare and Medicaid if it will not sell one of its products at a significantly reduced price does not substantially advance any legitimate purpose related to those programs. Instead, it will harm the many Medicare and Medicaid patients who have a need for those other products, but may not be able to obtain them if they are no longer covered by Medicare and Medicaid.

[17] 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-46-21/.

121. Nor are the Program's penalty provisions "rough[ly] proportiona[l]" to the purpose it purportedly serves. *Dolan*, 512 U.S. at 391. To the contrary, the prospect of an enormous and perpetual penalty or a permanent loss of access to nearly half of the U.S. health-care market (and the imposition of penalties nonetheless) amounts to a "gun to the head" that gives Astellas no real choice "but to acquiesce" and sign away its constitutional rights. *Nat'l Fed'n of Indep. Bus. ("NFIB") v. Sebelius*, 567 U.S. 519, 582 (2012).

CLAIMS

Count I
Physical Taking of Personal Property in Violation of Fifth Amendment

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

123. The Fifth Amendment prohibits the government from "tak[ing]" "private property … for public use, without just compensation." U.S. Const. amend. V.

124. Astellas's patented Xtandi® products are personal property protected by the Fifth Amendment.

125. The Program effects a physical taking of Xtandi® products. Under the Program, Astellas will be forced, over its objection and under the threat of ruinous monetary penalties, to provide access to its Xtandi® products. Through these coercive obligations, the government appropriates for Medicare beneficiaries Astellas's right to possess, use, and dispose of its personal property.

126. The government-mandated "maximum fair price" is not "just compensation" under the Takings Clause. By the IRA's express terms, the price set under the Program must be significantly below the drug's market value, which precludes it from satisfying the government's constitutional duty.

127. Astellas seeks only declaratory relief with respect to its physical takings claim. Such relief is appropriate here because it would "avoid[] . . . the burden of numerous suits at law between the same . . . parties, [and] where the issues are substantially the same." *PhRMA v. Williams*, 64 F.4th 932, 943 (8th Cir. 2023) (citation omitted). Moreover, without declaratory relief, Astellas "would be bound to litigate a multiplicity of suits to be compensated" in a manner that would not be "complete, practical, and efficient." *Id.* at 945. Declaratory relief is also appropriate because suits for damages "would entail an utterly pointless" back-and-forth, where "every dollar" taken from Astellas would "generate a dollar of … compensation." *E. Enterprises v. Apfel*, 524 U.S. 498, 521 (1998) (plurality opinion).

128. The Court should grant declaratory relief because Astellas's injuries cannot be adequately compensated through a legal remedy. Patented drug products, including Xtandi®, play a crucial role in the cycle of innovation that is impossible to quantify, replace, or replicate, and the Program's effects will spill over into non-Medicare and Medicaid markets in ways that are equally significant and impossible to quantify. *See supra* section C.

129. Moreover, Xtandi® is a unique drug with no competing generics, patented precisely because of its novelty and nonobviousness. *See* 35 U.S.C. §§ 102–03. Those unique characteristics "mak[e] damages an inadequate remedy." *See Ramirez de Arellano v. Weinberger*, 745 F.2d 1500, 1527–28 (D.C. Cir. 1984), *vacated on other grounds*, 471 U.S. 1113 (1985).

130. The Court should declare that the Program effects a physical taking of Astellas's patented drug products.

Count II
Deprivation of Property Without Due Process of Law

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

132. 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.

133. Astellas has constitutionally protected property interests in its patented Xtandi® product. When the government unilaterally subjects Astellas to the Program and establishes a "maximum fair price" for Xtandi® under the Program, it deprives Astellas of those interests without due process of law.

134. Due process entitles Astellas to an "opportunity to be heard at a meaningful time and in a meaningful manner." *Mathews*, 424 U.S. at 333 (cleaned up). That right entitles Astellas to various procedural safeguards, including a neutral decisionmaker. *Hamdi*, 542 U.S. at 533.

135. From beginning to end, the Program is structured to deny due process to Astellas. Under the IRA, CMS makes final drug selection decisions without ever providing manufacturers a meaningful hearing. And far from appointing a neutral arbiter to set a "maximum fair price," the IRA directs that CMS must: "*achieve* the *lowest* maximum fair price"; engage in the Program's sham "negotiation" process as an adversary of the manufacturer; and pre-judge the price by making an initial "offer" that indicates an early judgment regarding the appropriate "maximum fair price."

136. These features—particularly when combined with CMS's pecuniary interest as both government insurer and payer—ensure that CMS will be far from impartial when it makes drug selection decisions and sets the "maximum fair price."

137. The IRA aggravates the due process harm by barring administrative and judicial review of various CMS determinations, including CMS's chosen price.

138. The IRA thus ensures that the CMS official is an interested adversary and the sole decisionmaker. That structure is unconstitutional because it systematically deprives Astellas of its property interests without due process.

139. Because the Program is unconstitutionally structured, it subjects Astellas and other manufacturers to a "here-and-now injury" that warrants immediate relief. *See Axon Enter., Inc. v. Fed. Trade Comm'n*, 143 S. Ct. 890, 897, 904 (2023) (explaining that being "subject[ed] to an unconstitutionally structured decisionmaking process" due to the "combination of prosecutorial and adjudicatory functions" in a single agency is a "here-and-now injury" that cannot be remedied through subsequent judicial proceedings).

140. Nor can the Program be salvaged because manufacturers enter into nominal "agreements" to the Program's unconstitutional terms. An "agreement" executed with a "gun to the head"—in the form of ruinous penalties and exit from nearly half the U.S. healthcare market—is no agreement at all. *NFIB*, 567 U.S. at 582; *see also Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013) ("[T]he government may not deny a benefit to a person because he exercises a constitutional right.").

141. If Defendants unconstitutionally coerce Astellas into signing any Program Agreement before this case is adjudicated, the Court should declare such agreements unlawful and enjoin Defendants from enforcing them.

142. This Court should declare that the Program's structure violates the requirements of the Due Process Clause, and should enjoin Defendants from enforcing the Program.

Count III
Compelled Speech in Violation of First Amendment

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

144. The IRA violates Astellas's First Amendment rights by compelling it to engage in speech with which it disagrees.

145. The IRA requires CMS and Astellas to enter an "agreement," under which Astellas will be statutorily forced to commit to "negotiate" a "fair" price for Xtandi®. The IRA then compels Astellas to endorse the false message that it reached an "agreement" to sell Xtandi® at below-market prices through a "negotiation" process, because that new, lower price is the "maximum fair price" for Xtandi®. 42 U.S.C. § 1320f–2(a), (a)(1). In other words, the higher prices that purchasers of Xtandi® have previously paid were necessarily unfair.

146. Astellas does not want to make any of those statements because it believes they are all false and misleading. Astellas strongly *disagrees* that it has charged anyone an unfair price for Xtandi®, or that the IRA-dictated "negotiation" will result in a price that is "fair."

147. By forcing manufacturers to signal their "agreement" with the government-mandated "fair price," the IRA turns Astellas into a "vehicle for spreading a message with which [they] disagree[]." *Pac. Gas & Elec.*, 475 U.S. at 17.

148. Based on the selection criteria for "negotiation-eligible" drugs, Astellas will be compelled to sign an "agreement" by October 1, 2023 to "negotiate" a "maximum fair price" for Xtandi®. Under that Program Agreement, the government will unilaterally establish the price by August 1, 2024, publish that price by September 1, 2024, and require Astellas to grant beneficiaries access to Xtandi® products at that price beginning in January 2026.

149. Because these violations of the First Amendment "unquestionably constitute[] irreparable injury," an injunction is warranted. *Elrod v. Burns*, 427 U.S. 347, 373 (1976).

150. The Court should declare that the IRA's requirements that manufacturers "agree" to "maximum fair prices" are unconstitutional.

151. The Court should also enjoin Defendants from enforcing the Program Agreements. More specifically, the Court should enjoin Defendants from forcing Astellas to sign an initial

"manufacturer agreement" to "negotiate," *see* 42 U.S.C. § 1320f-2(a)(1), and from requiring Astellas to "agree" that CMS's price is "fair," *see id*. § 1320f-2(a)(2).

152. If Defendants unconstitutionally coerce Astellas into signing any Program Agreement before this case is adjudicated, the Court should declare such agreements unlawful and enjoin Defendants from enforcing them.

PRAYER FOR RELIEF

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

A. Declare that the Program effects a physical taking in violation of the Fifth Amendment by forcing Astellas to provide third parties with access to its personal property without just compensation;

B. Declare that the Program's structure violates the requirements of the Due Process Clause by depriving Astellas of property interests without the opportunity to be heard before a neutral decisionmaker;

C. Declare that the Program compels speech in violation of the First Amendment by forcing Astellas to sign a Program Agreement that endorses statements with which it does not agree;

D. Enjoin Defendants from forcing Astellas to sign a Program Agreement and imposing penalties for non-compliance with the Program;

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

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

Dated: July 14, 2023

Respectfully submitted,

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