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

JANSSEN PHARMACEUTICALS, INC.,
1125 Trenton-Harbourton Road
Titusville, NJ 08560

Plaintiff,

v.

XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services,
200 Independence Ave, SW
Washington, DC 20201;

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Ave, SW
Washington, DC 20201;

CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of Centers for Medicare & Medicaid Services,
7500 Security Boulevard
Baltimore, MD 21244; *and*

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

Defendants.

Civil Action No. _____

COMPLAINT

1. Plaintiff Janssen Pharmaceuticals, Inc. ("Janssen") brings this action to stop innovation-damaging congressional overreach that threatens the United States'

primacy in developing transformative therapies and in patients' access to those treatments. Specifically, Janssen seeks relief from the unconstitutional Medicare "Drug Price Negotiation Program" ("Program") established by the Inflation Reduction Act ("IRA" or "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).

2. For decades, federal law has supported a research and development ecosystem that has made the United States the world leader in pharmaceutical innovation. Under that system, drugs that achieve commercial success after extensive scientific development enable the creation of next-generation pioneering medicines that change the way we fight diseases. Janssen has made this patient-driven innovation the cornerstone of its business. It invests tremendous resources in developing transformative medicines that address unmet medical needs and seeking cures to previously untreatable diseases such as cancers, autoimmune conditions, cardiovascular disease, HIV, and depression. Since 2016, Janssen has invested more than $65 billion in research and development, resulting in Food and Drug Administration ("FDA") approvals for eight new medications and 52 expanded indications or new formulations for existing medications.

3. The U.S. innovation ecosystem to which Janssen contributes has two vital components, both of which are severely threatened by the Program. The first is the bargain at the heart of the patent and regulatory laws: when companies invest in and secure FDA approval for new treatments, they receive time-limited and constitutionally safeguarded protections, including the exclusive rights to make and

sell the new treatment. The second is the operation of free-market forces to establish prices for medicines during and after their patent terms. Together, these components strongly encourage risk-taking and innovation to facilitate future breakthroughs. As a result of that system, patients have faster and broader access to pioneering treatments in the United States than in any other country.

4. The Act replaces this self-sustaining cycle with a coercive scheme that, if fully implemented, will deal a fatal blow to both vital components of the innovation ecosystem. That scheme forces manufacturers to relinquish their patented drugs on draconian terms dictated by the Government and retroactively rescinds the bargained-for patent and regulatory exclusivity protections that fuel innovation. The Act also supplants the free-market system with punitive price controls, granting a Government agency nearly unlimited authority to set drug prices at arbitrary amounts untethered to the value of those medications to patients. Those radical changes will impede development of new treatments and result in reduced drug availability and fewer treatment options in the U.S. healthcare market.

5. Tacitly admitting its unconstitutional overreach, Congress cloaked the Program in deceptive terms. According to the Act, manufacturers voluntarily "agree" to "negotiate" so-called "fair" prices for each drug selected for the Program. In truth, those labels are nothing more than rhetorically appealing falsehoods: there is no genuine agreement, no real negotiation, and nothing fair about the price the Government unilaterally dictates.

6. A real negotiation produces a binding contract only when both parties freely agree on its terms—especially price. Yet the Program's "negotiations" result in the Government agency that selects the drugs for the Program unilaterally setting the price it will pay. That price, by statute, must be well below a drug's market value. And the Act both empowers and encourages the Government to lower that automatic price ceiling even further, without any lower limit (all the way down to $0).

7. Nor is participation in the Program voluntary. The Government has gone to great lengths to mislead the public on that point, doubling down on "voluntariness" rhetoric in its final guidance and related statements to generate a carefully crafted smokescreen.

8. Under the Act, a manufacturer may only escape from the Program's mandates and penalties by withdrawing *all* of its products from Medicare and Medicaid—not just the drug selected for the Program. That provision is the legal equivalent of a gun to the head because it would require the manufacturer to give up access to nearly 40% of the U.S. health-care market. That step would immediately deprive the manufacturer of revenues required to fuel research and development of new drugs, while also jeopardizing the manufacturer's ability to innovate, compete, and operate in the future. Even more fundamentally, forcing withdrawal from Medicare and Medicaid would cause millions of patients to lose insurance for and thus access to the manufacturer's drugs they have come to depend on.

9. Manufacturers who remain in Medicare and Medicaid are subject to crippling penalties if they do not submit to the Government's terms: a tax of 186% to

1900% of a selected drug's daily domestic revenues until the manufacturer "agrees" to participate in the supposedly voluntary Program. Those penalties are so coercive that no manufacturer would ever willingly incur them, a point Congress conceded when it projected that the penalty provisions would not raise a single dollar in revenue.

10. The end result is that manufacturers must: (1) submit to the Program's deprivation of constitutionally protected property rights in a selected drug; (2) incur crippling penalties for failing to "agree" with those terms; or (3) withdraw their entire portfolio of treatments from Medicare and Medicaid. That purported choice is no choice at all.

11. The Act's innovation-damaging scheme is unconstitutional as applied to Janssen in at least three ways:

12. *First*, the Program inflicts an uncompensated physical taking of Xarelto®, a widely prescribed medication manufactured and marketed by Janssen that treats blood clots and reduces the risk of stroke. The Program forces Janssen to provide "access" to Xarelto® products on terms set by the Government, and to which Janssen would never voluntarily agree. The Program thus forces a transfer of Janssen's property to third parties, appropriating Janssen's rights to possess and dispose of the medicines it invests billions to develop. This constitutional violation is doubly problematic because the Program targets Xarelto® as a *patented* drug, and those patents confer additional property rights by providing an entitlement to market exclusivity.

13. Stripped of its misleading labels, the Program is a straightforward confiscation of constitutionally protected property. It is akin to the Government taking your car on terms that you would never voluntarily accept and threatening to also take your house if you do not "agree" that the taking was "fair." The Program employs a statutory access requirement rather than a tow truck, but its effect is the same: Janssen has no choice but to surrender its Xarelto® products to Medicare on Government-dictated terms that fail to provide just compensation and undermine Janssen's long-term ability to continue its innovative business of delivering transformational medicines to patients.

14. *Second*, by coercing Janssen to "agree" with the Government that it is "negotiating" a "fair" price, the Program compels Janssen to make false and misleading statements in violation of the First Amendment. Congress passed the Act based upon the false narrative that it created a negotiation process for drug prices. While the Government may choose to deceptively describe the Program as involving an "agreement" to "negotiate" a "fair" price, it cannot force manufacturers to echo its misleading messaging.

15. *Third*, the Act would violate Janssen's constitutional rights even if participation in the Program were voluntary (it is not), by impermissibly conditioning Janssen's overall participation in Medicare and Medicaid on compliance with the Program's terms and the resulting deprivation of Janssen's property and speech rights. That condition is unconstitutional because it is grossly disproportionate to Janssen's total participation in Medicare and Medicaid.

16. The Act's ultimate harm is to patients. It deprives tomorrow's patients of innovative medicines made possible by protected patent rights and market-based pricing, and the future generics enabled solely by today's innovator drugs. And it harms today's patients by threatening access to existing therapies and eviscerating incentives to continually improve those therapies. Janssen brings this action to stop the Act's violation of its property and speech rights and to safeguard its ability to continue developing the pioneering treatments that patients depend on.

PARTIES

17. Plaintiff Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business at 1125 Trenton-Harbourton Road, Titusville, NJ 08560.

18. Janssen manufactures and sells Xarelto® (rivaroxaban), a medication that treats and helps prevent blood clots and reduces the risk of stroke. Xarelto® belongs to a category of medications known as direct oral anticoagulants, which represent a significant therapeutic advancement over earlier anticoagulants. Janssen is the exclusive U.S. licensee of the patents that claim rivaroxaban and its use, and has the exclusive right to market Xarelto® products in the United States.

19. Defendant Xavier Becerra is the Secretary of Health and Human Services. Secretary Becerra is charged by statute with administering the Social Security Act, including Medicare, Medicaid, and the Program at issue here. Secretary Becerra is sued in his official capacity.

20. Defendant U.S. Department of Health and Human Services ("HHS") is a cabinet-level department of the United States Government.

21. Defendant Chiquita Brooks-LaSure is the Administrator of the Centers for Medicare and Medicaid Services. Administrator Brooks-LaSure is sued in her official capacity.

22. 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 Program to 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 under 28 U.S.C. § 1346(a) because the United States is a Defendant, and because the United States has waived its sovereign immunity regarding 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 Janssen's corporate headquarters is located in New Jersey.

27. Xarelto® is among the ten most widely reimbursed drugs for Medicare Part D patients, meaning that it will be subject to the Program beginning in September 2023.[1]

FACTUAL ALLEGATIONS

A. The Pharmaceutical Innovation Ecosystem

28. Patented prescription drugs like Xarelto® are the product of a complex innovation ecosystem that involves significant research and investment by Janssen.

29. Janssen invests billions of dollars each year to develop new drugs that help patients live longer, healthier lives. In 2022 alone, Janssen's investment totaled $11.6 billion. Janssen has dedicated more than $65 billion to research and development since 2016.[2]

30. These investments have made it possible for Janssen to provide dozens of medications, including Xarelto®, to Medicare and Medicaid patients. Since 2016, Janssen has secured FDA approval for eight new medications and 52 additional FDA approvals for expanded indications and/or new product formulations—several of which were for innovative forms of Xarelto®.

---

[1] *See* CMS, *Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2026*, § 30.3 (June. 30, 2023), https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf ("*Revised Guidance*") ("CMS *will select* for negotiation the 10 … highest ranked negotiation-eligible drugs remaining on the ranked list for initial price applicability year 2026." (emphasis added)).

[2] *See* Janssen, *U.S. Pricing Transparency Brief* 2 (2022), https://transparencyreport.janssen.com/.

31. The United States healthcare market is the global leader in pharmaceutical development due to an innovation ecosystem that has two key components.

32. The first is a critical bargain at the heart of the patent and regulatory laws: when a manufacturer invests in and secures FDA approval for a new treatment, the manufacturer receives time-limited legal protections for the new treatment. These protections include the exclusive rights to manufacture and market the treatment. *See, e.g.*, *Zenith Radio Corp. v. Hazeltine Rsch., Inc.*, 395 U.S. 100, 135 (1969) ("A patentee has the exclusive right to manufacture, use, and sell his invention."); *Am. Securit Co. v. Shatterproof Glass Co.*, 268 F.2d 769, 777 (3d Cir. 1959) (patents "grant" the owner "the exclusive right to manufacture, use[,] and sell the invention which is disclosed").

33. The second is the operation of the free market to set prices for medicines during and after their patent terms. Under this framework, manufacturers negotiate the prices for their patented drug products with other market participants, such as private insurance plans and their agents. Federal law then bases the amount Medicare and Medicaid pay for the drugs on those free-market negotiations. *See* ¶¶ 51–52, *infra*. This commitment to market-based pricing is so important that when Congress created the Medicare prescription drug benefit program, it expressly *prohibited* federal agencies from "interfer[ing] with the negotiations between drug manufacturers[,] pharmacies[,] and [private health plans]" regarding the prices for covered drugs. 42 U.S.C. § 1395w-111(i).

34. Together, those two components incentivize manufacturers to make the investments necessary to develop transformative new treatments. The end result is a self-sustaining cycle of innovation in which successful drugs generate the revenues necessary to fund next-generation medicines. That incentive structure yields significant benefits for patients: Studies show that new treatments are available much sooner, and much more broadly, in the United States than in other countries.[3] Another critical benefit of this system is that participants in clinical trials gain access to new research treatments before they are widely available and help others by contributing to medical research.

35. These incentives are necessary because developing a new prescription drug is expensive, time-consuming, and rife with failure.

36. The process of developing a new drug and securing FDA approval costs $2.6 *billion* on average, and often takes 10 to 15 years or longer from start to finish.[4]

---

[3] *See, e.g.*, Doug Badger, Galen Inst., *Examination of International Drug Pricing Policies in Selected Countries Shows Prevalent Government Control Over Pricing and Restrictions on Access* 15 (2019), https://galen.org/assets/Badger-Report-March-2019.pdf; Pharmaceutical Research and Manufacturers of America ("PhRMA"), *Global Access to New Medicines Report* 8, 11–26 (2023), https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/A-C/2023-04-20-PhRMA-Global-Access-to-New-Medicines-Report-FINAL-1.pdf.

[4] Tufts Center for the Study of Drug Development, *Cost to Develop and Win Marketing Approval for a New Drug is $2.6 Billion* (Nov. 18, 2014), https://f.hubspotusercontent10.net/hubfs/9468915/TuftsCSDD_June2021/pdf/pr-coststudy.pdf; *see also* Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20 (2016) (similar); PhRMA, *Research & Development Policy Framework* (Sept. 2021), https://phrma.org/en/policy-issues/Research-and-Development-Policy-Framework.

37. The failure rate for new drugs is also exceptionally high. The initial development stage often involves screening hundreds of thousands of investigational compounds. Only 0.5% of drugs that enter preclinical testing are tested in human trials.[5] And as few as 12% of compounds that reach clinical trials ultimately receive FDA approval.[6] The end result is that only 0.02% of drugs that enter preclinical testing will ever reach patients.[7]

38. Even after an approved drug reaches the market, around 20–30% of new drugs recoup the investment necessary to bring them to market.[8]

39. As a result, development of new medicines depends on market-based revenues from the small fraction of clinical compounds that ultimately become commercially successful drugs. As one recent study explained, the small fraction "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."[9]

---

[5] Sandra Kraljevic et al., *Accelerating Drug Discovery*, 5 Eur. Molecular Biology Org. Reps. 837, 837 (2004), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1299137/pdf/5-7400236.pdf.

[6] DiMasi et al., *supra* note 4; Cong. Budget Off., *Research and Development in the Pharmaceutical Industry* 16–17 (2021), https://www.cbo.gov/publication/57126.

[7] Kraljevic et al., *supra* note 5, at 837.

[8] *See* John A. Vernon & Joseph H. Golec, *Pharmaceutical Price Regulation: Public Perceptions, Economic Realities, and Empirical Evidence* 7, 11 (AEI 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), https://pubmed.ncbi.nlm.nih.gov/19655335/ (finding only 20% of new drugs attain revenues that exceed average R&D costs).

[9] Alexander Schuhmacher et al., *Changing R&D Models in Research-Based Pharmaceutical Companies*, 14 J. Translational Med. 1, 4–5 (2016), https://translational-medicine.biomedcentral.com/articles/10.1186/s12967-016-0838-

40. The Act would upend both components of the self-sustaining innovation ecosystem, jeopardizing manufacturers' ability to develop new medicines and improve existing treatments. As described below, the Program supplants the market-based pricing framework with Government-dictated price controls, and also retroactively rescinds the longstanding bargain for patent and regulatory exclusivities by directing CMS to adopt artificially low prices that annihilate the value of manufacturers' exclusive right to market their patented medicines. *See* ¶¶ 70–71, *infra*.

41. The Program undermines the innovation ecosystem in other ways as well. For example, the Program strongly disincentivizes continued investment in development of new indications for and formulations of medicines following their initial FDA approval. Post-approval development, which can result in treatments becoming available to new patient populations, has created a substantial benefit for cancer patients and pediatric patients, among others.[10] But the Program will sharply curtail development of new indications for and formulations of existing medicines because these innovations will often immediately become subject to the Program's

4; *see also* Joe Kennedy, Info. Tech. & Innovation Found., *The Link Between Drug Prices and Research on the Next Generation of Cures* 6 (2019), https://www2.itif.org/2019-drug-prices-cures.pdf.

[10] *See, e.g.*, Partnership for Health Analytic Research, *Implications of the Inflation Reduction Act Price Setting Provisions on Post-approval Indications for Small Molecule Medicines* 12 (2023), https://www.pharllc.com/publication/implications-of-the-ira-price-setting-provisions-on-post-approval-indications-for-small-molecule-medicines/ (finding that 61% of small-molecule oncology medicines approved between 2006 and 2012 received at least one post-approval indication, and that nearly half of those post-approval indications were awarded more than seven years after initial approval).

automatic price ceilings. Manufacturers are thus left with no time to recoup the investments necessary to develop them.[11]

42. Xarelto® demonstrates the impact of post-approval innovations that will be lost in the future due to the Program's restrictive scheme. FDA first approved Xarelto® in 2011. Janssen's subsequent research and development have resulted in multiple additional FDA approvals for Xarelto® since 2018. These post-approval innovations include: a lower 2.5 mg strength to treat patients with chronic coronary artery disease or peripheral artery disease in 2018; a new indication to help prevent blood clots in acutely ill medical patients in 2019; an expanded peripheral artery disease indication in 2021; and two new pediatric indications and a new oral suspension formulation in 2021. But the Program's aggregation methodology—in which CMS treats all medicines with the same active moiety as a single drug—subjects these recently approved medicines to the Program's price controls now because a different Xarelto® product was first approved more than seven years ago.

43. Drug manufacturers have already begun to shift R&D investment priorities, portfolios, and budgets in response to the Program's limits on

[11] This disincentive results from (1) the statutory rule that a drug becomes eligible for the Program seven years after it is first approved, and (2) CMS's decision to aggregate "all dosage forms and strengths of [a] drug with the same active moiety and the same holder of a New Drug Application" when determining which drugs are subject to the Program. *See Revised Guidance*, *supra*, § 30.1 ("CMS will identify a potential qualifying single source drug [for drug products] using … all dosage forms and strengths of the drug with the same active moiety and the same holder of a New Drug Application (NDA), inclusive of products that are marketed pursuant to different NDAs." (citations omitted)).

manufacturers' ability to benefit from the innovation they create.[12] For example, one study estimates that Government-dictated price caps will "reduce overall annual cancer R&D spending by about $18.1 billion, or 31.8%."[13]

44. By undermining constitutionally protected property rights and incentives to develop new drugs, the Program will eventually result in fewer new treatment options for doctors and patients.

45. And because today's branded pharmaceuticals become tomorrow's generics, the Program also threatens to limit generic entry, and therefore patient access to reduced cost generics and biosimilars, in the future. Nine out of every ten prescriptions dispensed in the United States are for generic versions of branded

---

[12] *See, e.g.*, Josh Nathan-Kazis, *Novartis CEO: Some Cancer Drugs Dropped From Pipeline Because of Medicare Price Negotiations*, Barron's (May 19, 2023), https://www.barrons.com/articles/novartis-stock-price-ceo-cancer-drug-medicare-e9b0fcb7; James Waldron, *Bristol Myers CEO Already Reassessing Portfolio in Wake of US Pricing Law: Report*, Fierce Biotech (Nov. 21, 2022), https://www.fiercebiotech.com/biotech/bristol-myers-already-reassessing-portfolio-wake-ira-ceo-tells-ft (Act will result in cancellation of some development programs and adversely affect "investment in clinical research, especially in areas like oncology that require significant investment following initial FDA approval"); Max Gelman, *Updated: Eli Lilly Blames Biden's IRA for Cancer Drug Discontinuation as the New Pharma Playbook Takes Shape*, Endpoint News (Nov. 1, 2022), https://endpts.com/eli-lilly-rolls-snake-eyes-as-it-axes-two-early-stage-drugs-including-a-40m-cancer-therapy-from-fosun/ (identifying two drug-development programs cancelled in light of Act's restrictive terms).

[13] Tomas J. Philipson et al., *Policy Brief: The Impact of Recent White House Proposals on Cancer Research* 1 (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; *see also* Stephen J. Ubi, *Biden Promised a "War on Cancer"—But Declared War on the Cure Instead*, STAT (July 6, 2023), https://www.statnews.com/2023/07/06/biden-cancer-moonshot-ira-intellectual-property/.

drugs,[14] meaning that 10% of prescriptions for innovative medicines drive the entire pharmaceutical industry. By sharply curtailing the incentives to develop new innovative treatments, the Program will create unmet healthcare needs rather than reduce them.

B. Statutory and Regulatory Background

Medicare and Medicaid Dominate the U.S. Health Care Industry

46. The Program directly governs Medicare drug pricing, but it will also have significant effects on drug pricing and patient access for participants in Medicaid, the 340B Drug Pricing Program, and private plans.

47. 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*.

48. Medicaid provides health insurance coverage for low-income Americans. *See id.* §§ 1396–1396w-7.

49. The 340B drug pricing program requires manufacturers to provide discounts for covered outpatient drugs for qualifying health care organizations that care for uninsured and low-income patients. *See id.* § 256b.

50. In 2021, Medicare accounted for 21% of total U.S. health-care expenditures, while Medicaid accounted for another 17%.[15]

---

[14] Association for Accessible Medicines, *The U.S. Generic & Biosimilar Medicines Savings Report* (2021), https://accessiblemeds.org/sites/default/files/2021-10/AAM-2021-US-Generic-Biosimilar-Medicines-Savings-Report-web.pdf.

[15] CMS, *NHE Fact Sheet*, https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet (updated June 14, 2023).

51. Medicare Part B provides health-insurance benefits for physician-administered drugs, among other things. Under Medicare Part B, the Federal Government reimburses providers for a portion of the costs of those medications, using an "average sales price" model that incorporates the discounts negotiated by private health plans and other market participants.

52. Medicare Part D provides health-insurance benefits for self-administered prescription drugs. Under Medicare 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. Historically, the Government under Medicare Part D has received the benefit of drug prices negotiated in the free market, based on rebates provided by drug manufacturers.

53. Under the Medicaid prescription drug rebate program, manufacturers enter into rebate agreements with the Secretary of HHS.

54. As explained below, the Act radically changes Medicare's long-established public-private partnership model, with significant spillover implications for Medicaid, the 340B program, and the private payer market. *See, e.g.*, 42 U.S.C. § 1396r-8(c)(1) (tying rebates under the Medicaid drug rebate program to the average price paid by wholesalers and retail pharmacies, which will in turn be influenced by the maximum price dictated under the Program).[16]

[16] *See also, 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

55. Moreover, there will be additional spillover effects in the commercial market, given that the "maximum fair price" will be publicly released and therefore available to be leveraged by plans in commercial market negotiations with manufacturers. Previously, pricing information in certain government programs has been protected as proprietary and highly confidential.

The Inflation Reduction Act's Sham "Negotiation" Program for Prescription Drugs

56. The Act directs the Secretary of HHS to implement what the Act deceptively describes as a "Drug Price Negotiation Program." *Id.* § 1320f(a).

57. According to the Act, the Program involves three basic steps: (1) CMS selects a group of drugs each year for participation in the Program, (2) each manufacturer of a selected drug must then sign an "agreement" to "negotiate" with CMS regarding the price Medicare will pay for the drug, and (3) the negotiations will result in CMS adopting a "maximum fair price" for the drug. *See id.* §§ 1320f-1(a), 1320f-2(a)(1)-(3), 1320f-3(a)(1), 1320f-4(a).

58. CMS has doubled down on Congress's deceptive labels, repeatedly stating in a recent guidance document that CMS will "negotiate with" manufacturers to select a "maximum fair price" for each selected drug, and likewise repeatedly characterizing that process as "voluntary."[17] CMS similarly asserted in a press release that the Program allows the Government "to directly negotiate the prices of

changes to Medicare drug prices "could have implications for Medicaid rebates and ultimately Medicaid drug spending by changing drug list prices").

[17] *E.g.*, *Revised Guidance*, *supra*, §§ 40.1, 40.6.

covered prescription drugs" with manufacturers.[18] CMS Administrator Brooks-LaSure likewise told a news outlet that "this is a voluntary process for manufacturers to negotiate with us directly."[19]

59. In reality, the Program is far from a "negotiation."

60. In the first year of the Program, CMS must select ten of the highest-reimbursed Part D drugs for participation in the Program by September 1, 2023. *See* 42 U.S.C. §§ 1320f(d)(1), 1320f-1(a)(1). Once CMS selects a drug, its manufacturer then has until October 1, 2023, to sign an "agreement" to "negotiate" with CMS regarding the maximum price Medicare will pay for the drug. *Id.* §§ 1320(a), (b), (d)(2)(A), 1320f-2. CMS unilaterally dictates the terms of this purported agreement, which it has presented to manufacturers on a take-it-or-leave-it basis.[20]

61. Contrary to the Act's false labels, the Program does not rest on a genuine agreement to participate, because the Government has given manufacturers no real choice but to sign the Manufacturer Agreement and shoulder the obligations associated with it. If a manufacturer refuses to sign this "agreement" to "negotiate," it must pay an excise tax penalty on *every* domestic sale of the selected drug, starting

---

[18] CMS, *CMS Releases Revised Guidance for Historic Medicare Drug Price Negotiation Program* (June 30, 2023), https://www.cms.gov/newsroom/press-releases/cms-releases-revised-guidance-historic-medicare-drug-price-negotiation-program.

[19] Michael Erman & Patrick Wingrove, *U.S. Will Allow Drugmakers to Discuss Medicare Drug Price Negotiations*, Reuters (June 30, 2023), https://www.reuters.com/business/healthcare-pharmaceuticals/us-issues-revised-guidance-medicare-drug-price-negotiation-2023-06-30/.

[20] *See* CMS, *Medicare Drug Price Negotiation Program Agreement* (July 3, 2023) ("Manufacturer Agreement"), https://www.cms.gov/files/document/inflation-reduction-act-manufacturer-agreement-template.pdf.

at 186% of the drug's daily U.S. revenues and escalating to 1900% of those revenues. *See* 26 U.S.C. § 5000D(d).[21] In many instances, that requirement would amount to millions of dollars in penalties starting the *very next day* after a manufacturer fails to sign an agreement.

62. Those penalties are so draconian that no manufacturer would ever willingly incur them. Indeed, Congress recognized that manufacturers have no choice but to comply when it estimated that nearly identical penalty provisions in a precursor bill to the IRA would generate "no revenue."[22]

63. The only way a manufacturer can avoid this penalty (aside from acquiescing to the Government's demands) is if the manufacturer withdraws its products from both Medicare and Medicaid. The required withdrawal is not limited to the product selected for "negotiation," but extends to *all* of the manufacturer's products, including those not chosen for "negotiation" and those excluded from "negotiation" by statute. *See* 26 U.S.C. § 5000D(c). Not only is this punishment wholly unconnected and disproportionate to a manufacturer's decision to not "negotiate" over a single Medicare drug, but it would result in the manufacturer

---

[21] *See also* Cong. Rsch. Serv., *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).

[22] 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,' As Passed by The House of Representatives: Fiscal Years 2022–2031*, at 8 (Nov. 19, 2021), https://www.jct.gov/publications/2021/jcx-46-21/; *see also* Cong. Budget Off., *How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act*, at 10 (2023), https://www.cbo.gov/system/files/2023-02/58850-IRA-Drug-Provs.pdf ("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.").

losing access to nearly 40% of the U.S. health-care market. As the Third Circuit recently observed, "[t]he federal government dominates the healthcare market," "pay[ing] 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) (citing Cong. Budget Off., *Prescription Drugs: Spending, Use, and Prices* 8 (2022)).

64. By withdrawing, a manufacturer would immediately lose access to critical revenue needed to research and develop new treatments, and the economic effects of this withdrawal would compound over time, jeopardizing the manufacturer's ability to innovate, compete, or successfully operate over the long term. Critically, withdrawal would also harm the vulnerable patient populations who have come to rely on the manufacturer's medicines through Medicare and Medicaid.

65. That all-or-nothing approach has far-reaching effects because manufacturers often provide many products to patients through Medicare and Medicaid. Janssen alone has Medicare Part D and Medicaid agreements for dozens of products, including treatments for autoimmune conditions (such as rheumatoid arthritis), cancer, cardiovascular disease, depression, and HIV. As a result, Janssen could not avoid the Act's penalties without depriving Medicare and Medicaid patients of access to these medications.

66. In short, when the Government selects a manufacturer's drug for the Program, the manufacturer faces the following purported alternatives: (1) sign the Manufacturer Agreement to negotiate, which as explained below will deprive the manufacturer of constitutionally-protected property rights and market-based pricing

for the selected drug; (2) incur crippling penalties for failing to "agree" to that deprivation; or (3) withdraw its portfolio of treatments from Medicare and Medicaid entirely. The Government has persisted in telling the public that manufacturers have the "optio[n]" of choosing among these crippling outcomes, and that participation in the Program is "voluntary." *Revised Guidance*, *supra*, § 40.1. But it is clear that the Program was specifically designed with only one outcome in mind: forced participation in the Program on terms a manufacturer cannot refuse.

67. After a manufacturer is forced to sign the Manufacturer Agreement, the coercion continues. For example, manufacturers of drugs selected for 2026 must submit detailed and highly sensitive confidential business information to CMS by October 2, 2023. 42 U.S.C. §§ 1320f(d)(5)(A), 1320f-2(a)(4), 1320f-3(b)(2)(A). In addition, manufacturers must "compl[y] with" any other "requirements determined by the Secretary to be necessary for purposes of administering the [P]rogram and monitoring compliance with the [P]rogram," with no apparent limit on what those obligations could be. *Id.* §§ 1320f-2(a)(5). The Act imposes a civil monetary penalty of $1 million "for each day" a manufacturer fails to comply with these mandates. *Id.* § 1320f-6(c); *see also Revised Guidance*, *supra*, § 100.2.

68. CMS has taken this authority a step further, asserting that it *also* has the right to unilaterally "amend" those obligations as it deems "necessary" at any time *after* the manufacturer signs the agreement.[23] In other words, CMS will force manufacturers to not only submit to its terms, but to also concede that CMS can

[23] Manufacturer Agreement, *supra*, §§ II(e), IV(b).

change those terms whenever it chooses. To call that one-sided process an "agreement" strains the English language past the breaking point.

69. Nor does the Program involve an actual negotiation. The Act uses this terminology, with CMS making an initial so-called "offer" and the manufacturer making a "counteroffer." 42 U.S.C. § 1320f-3(b)(2)(B)–(D). But behind these empty words looms the coercive reality: a manufacturer that does not agree to the price CMS imposes must either shoulder the excise tax penalty or withdraw *all* its products from Medicare and Medicaid entirely. *See* 26 U.S.C. § 5000D(a); *see also Revised Guidance*, *supra*, § 60.4.4. Like the supposedly voluntary Manufacturer Agreement, this "negotiation" is designed to end only one way: with the Government unilaterally dictating a price. *See* 42 U.S.C. § 1320f-3(b)(2)(E).

70. According to the Act, the Program's "negotiations" are also supposed to yield a "maximum fair price" for the selected drug. Yet the Program intentionally jettisons market forces and drives the price well below what is objectively fair. For example, the Act requires the price to be *at least* 25% below the average price paid by non-federal wholesalers and retail pharmacies. *Id.* § 1320f-3(c)(3)(A). That automatic discount increases to 35% for "extended monopoly" drugs that have been approved for 12 to 16 years, and 60% for "long monopoly" drugs that have been approved for more than 16 years. *Id.* § 1320f-3(c)(3)(C), (c)(4)–(5).

71. The Act further exacerbates that departure from market-based pricing by directing CMS—the same agency that pays for the drugs—to "achieve the lowest maximum fair price for each selected drug" below those statutory ceilings. *Id.*

§ 1320f-3(b)(1). The Act empowers CMS to drive the prices down, without limit, based on CMS's own vested interest in obtaining artificially low prices. Indeed, because the Act does not prescribe a pricing floor (with one exception not relevant here), CMS could seek to adopt a $0 price for a selected drug, regardless of the drug's market value or entitlement to market exclusivity under the patent laws and related statutes and regulations.

72. Once CMS has picked its price, it must publish the so-called "maximum fair price" for the drug, along with an "explanation" for that price. *Id.* §§ 1320f(d)(6), 1320f-4(a). This price ceiling will then become effective on January 1, 2026.

73. After this price goes into effect, the manufacturer is obligated—under threats of additional civil monetary penalties *ten times* the difference between the price charged and the Government-dictated price, *id.* § 1320f-6d(a)—to grant hospitals, physicians, and other Medicare participants "access" to the selected drug on the Act's one-sided terms. *Id.* §§ 1320f-2(a). That access obligation continues indefinitely, and can thus remain in place for years, until "the Secretary determines" that a generic version of the drug is "approved" and "marketed." *Id.* § 1320f-1(c)(1).

The Imminent Selection of Xarelto® for the Program

74. The Act requires the Secretary to select ten "negotiation-eligible" drugs by September 1, 2023. *Id.* § 1320f-1(a)(1).

75. The Act 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(d)(1)(A).

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

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

78. According to CMS's implementing guidance, the agency will select the top 10 drugs that account for the highest Medicare spending.[24]

79. Xarelto® falls within this group and thus will be selected for the 2026 initial price applicability year.[25]

80. Because Xarelto® was first approved by FDA in 2011, it will be classified as a "short monopoly" drug under the Program, with CMS required by statute to select a "maximum fair price" that is *at least* 25% below market value. *See* 42 U.S.C. § 1320f-3(c)(3)–(5).[26] Together with the other provisions described above, this requirement rescinds the bargain at the heart of the patent and regulatory laws and replaces it with a radical new price-control scheme that deprives Janssen of its constitutionally protected speech rights and property rights in Xarelto® products.

---

[24] *Revised Guidance*, *supra*, § 30.3.

[25] *See also* Sean Dickson & Inmaculada Hernandez, *Drugs Likely Subject to Medicare Negotiation, 2026-2028*, 29 J. Mgmt. Care Spec. Pharm. 229, 229 (Mar. 2023), https://www.jmcp.org/doi/epdf/10.18553/jmcp.2023.29.3.229?role=tab (stating that Xarelto® is "expected to be" selected for initial price applicability year 2026).

81. CMS has admonished manufacturers to begin taking action now, before the agency publishes the list of selected drugs, given the extensive requirements associated with participation in the Program. For example, the *Revised Guidance* issued on June 30, 2023 states that "manufacturers need to take a number of actions well in advance of September 1, 2023, to prepare for the possibility that a drug that they manufacture will be included on the selected drug list."[27]

C. The Act Violates Janssen's Constitutional Rights

82. The Program violates Janssen's constitutional rights in at least three respects.

83. *First*, the Program will appropriate Janssen's patented Xarelto® products for third-party use without providing adequate compensation, a clear physical taking in violation of the Fifth Amendment.

84. *Second*, the Program will violate the First Amendment by compelling Janssen to make false and misleading statements through the Manufacturer Agreement, including that the Program will involve "negotiating" a "fair" price for Xarelto® products.

85. *Third*, the Act would violate Janssen's constitutional rights even if participation in the Program were voluntary (it is not), by impermissibly conditioning Janssen's ability to participate in Medicare and Medicaid on Janssen's relinquishing its speech and property rights.

[27] *Revised Guidance*, *supra*, at 9.

The Program Effects a Physical Taking of Janssen's Patented Xarelto® Products

86. The Fifth Amendment prohibits the Government from taking private property without compensating the owner for the full and fair value of that property.

87. This protection "preserve[s] freedom and empowers 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 v. Hassid*, 141 S. Ct. 2063, 2071 (2021) (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 v. Dep't of Agric.*, 576 U.S. 350, 361 (2015).

88. The Government has a categorical duty to compensate the owner of personal property when it "appropriates" the owner's rights in that property "for the enjoyment of third parties." *Cedar Point Nursery*, 141 S. Ct. at 2072. Rights protected by this principle include the "right to exclude," *id.*, the "right of access," *id.*, and "the rights to possess, use and dispose of" the property, *Horne*, 576 U.S. at 361–62 (quoting *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 435 (1982) (cleaned up)).

89. For example, a physical taking occurs when a law or regulation "requires physical surrender" of personal property, with "the [owner] los[ing] any right to control [its] disposition." *Id.* at 364.

90. Janssen's Xarelto® products are personal property protected by the Fifth Amendment's Takings Clause. *See Horne*, 576 U.S. at 358. As a result, the Government may not take those products without providing just compensation.

91. Janssen's property rights are reinforced by the Xarelto® patents, which confer an additional "right to exclude others from making, using or vending [the] invention." *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* 35 U.S.C. § 154(a)(1).

92. Federal law further protects Janssen's Xarelto® products by granting additional and distinct regulatory exclusivity rights. These protections apply in a variety of circumstances, including when a drug receives initial or supplemental FDA approval (e.g., for a new pediatric use studied at the Government's request). *See* 21 U.S.C. §§ 355(c)(3)(E), 355(j)(5)(F), 355A. These provisions afford additional periods of market exclusivity for approved Xarelto® products, creating a key incentive for Janssen to pursue additional innovations that enhance patient outcomes.

93. The Program effects a physical taking of Janssen's Xarelto® products because it strips Janssen of its rights to possess and control the disposition of those products and forces their transfer to third parties on the Government's terms, over Janssen's objection. *See Horne*, 576 U.S. at 2429; *Cedar Point Nursery*, 141 S. Ct. at 2072.

94. This physical taking stems from the Act's statutory "access" requirement and the so-called Manufacturer Agreement that implements the access requirement. *See* 42 U.S.C. § 1320f-2. Specifically, the Act requires manufacturers, as part of their "agreement" with the Government, to "provid[e]" eligible beneficiaries

(and their hospitals, doctors, providers, and suppliers) "access to" drugs selected for participation in the Program. *Id.* § 1320f-2(a)(3).

95. This obligation, which binds Janssen before the sham "negotiations" even begin, appropriates Janssen's property rights in its Xarelto® products by transferring Janssen's rights to possess and dispose of these products to third parties—thus effecting a physical taking. *See Cedar Point Nursery*, 141 S. Ct. at 2072; *Horne*, 576 U.S. at 361–62.

96. The Act's promise that Janssen can receive a highly discounted, Government-dictated price in exchange for the appropriated property 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; *accord Cedar Point Nursery*, 141 S. Ct. at 2074. Thus, the "maximum fair price" bears on the amount of compensation due, not the threshold question whether the Program inflicts a taking.

97. At most, an arbitrary and artificially low price cap is simply a limitation on third parties' right of access. A limitation restricting access "for up to four 30-day periods in one calendar year" did not call into question the physical taking in *Cedar Point Nursery*. *See* 141 S. Ct. at 2069, 2074–75. The same principle applies here. That the Act "authorizes only limited … access" (here, access on terms unilaterally

imposed by the Government) "does not transform [the Program] from a physical taking into a use restriction." *Id.* at 2075.

98. The Manufacturer Agreement, with its property-stripping obligations, is not the result of Janssen "voluntarily participat[ing] in a price-regulated program or activity." *Garelick v. Sullivan*, 987 F.2d 913, 916 (2d Cir. 1993). Rather, the Program compels Janssen to sign the agreement to avoid crushing tax penalties, and then coerces continued compliance with the agreement's terms under threat of additional monetary penalties.

99. After Xarelto® is selected in September 2023 for the 2026 initial price applicability year, Janssen must sign the Manufacturer Agreement by October 1, 2023, and thus give up core property rights in its Xarelto® products. Failing to do so would make Janssen liable for a penalty on *every* domestic sale of Xarelto® (including sales outside Medicare and Medicaid), starting at 186% of each sale and ballooning to as much as 1900% until Janssen relinquishes its property rights. *See* 26 U.S.C. § 5000D. Given the widespread use of Xarelto® in the market, this penalty would quickly reach extraordinary levels.

100. The statute purports to offer a third option, but it is illusory. Specifically, the Act suggests that manufacturers can avoid the penalties described above by withdrawing their entire product portfolio *not just* from Medicare but also from Medicaid as well. *Id.* § 5000D(c). But that is not a viable option for several reasons.

101. *First*, no rational manufacturer can pull out of a market that accounts for "almost half the annual nationwide spending on prescription drugs." *Sanofi Aventis*, 58 F.4th at 699. Doing so would deprive the manufacturer of funds needed for research and development of new medications in the near term, and would eventually prevent the manufacturer from competing successfully in the marketplace in the long-term. More fundamentally, Medicaid and Medicare patients would suffer the loss of access to critical medicines they rely upon today.

102. *Second*, even if Janssen could terminate all of its existing Medicare and Medicaid agreements and forgo access to nearly half of the Nation's health-care market to the detriment of millions of patients, the Act delays a manufacturer's withdrawal such that the manufacturer would *still* be subjected to the Act's penalties. *See, e.g.*, 42 U.S.C. § 1395w-114a(b)(4)(B)(ii). CMS has sought to circumvent this doubling up of adverse consequences by adopting, through guidance, an expedited protocol for termination of a manufacturer's Medicare and Medicaid agreements. *See Revised Guidance*, *supra*, §§ 40.1, 40.6. That protocol seeks to treat withdrawals initiated by manufacturers, which are subject to a statutory 11- to 23-month delay before taking effect, as withdrawals 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). CMS does not explain how its protocol complies with these statutory requirements, and no explanation is apparent. Even if CMS has authority to manipulate the statutory text in that fashion, CMS's attempt to reverse course tacitly acknowledges

the weakness in the Government's position and makes the agency's gamesmanship readily apparent.

103. The Act, by design, dictates one and only one outcome: the forced transfer of a drug manufacturer's property on the Government's terms. Janssen's supposed alternatives are a crushing penalty on every domestic sale of Xarelto® or a loss of access to nearly half of the U.S. health-care market for all of the company's products. This impossible situation amounts to a "gun to the head" that gives Janssen no choice "but to acquiesce" and sign away its rights. *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 581–82 (2012) ("*NFIB*"); *see also Union Pac. R. Co. v. Pub. Serv. Comm'n of Mo.*, 248 U.S. 67, 70 (1918) (government cannot "impose an unconstitutional burden" on private parties "by the threat of penalties … and then … declare the acceptance [of that burden] voluntary").

104. Should a manufacturer acquiesce, additional civil monetary penalties compel continued compliance with the Program's terms. The Program imposes these penalties at ten times the amount a manufacturer charges over the "maximum fair price." 42 U.S.C. § 1320f-6(a). This is yet another "gun to the head" to cement the forced transfer of property to and appropriated right of access for third parties. *NFIB*, 567 U.S. at 581.

The Program Compels Speech in Violation of the First Amendment

105. The Act compels manufacturers like Janssen to endorse the false narrative that they "agre[e]" to a "negotiat[ion]" that results in a "fair" price. 42 U.S.C. § 1320f-2(a), (a)(1).

106. More specifically, the Act requires the manufacturer of a selected drug to enter into an "agreement" with the Secretary, under which the manufacturer will be statutorily bound to "negotiate" what the Act refers to as a "fair" price for the selected drug. *Id.* Moreover, due to the structure of the Program, a manufacturer must "agree" to accept the Government-dictated price before the "negotiation" has even begun, at a time when the manufacturer does not know what price the Government will impose. As CMS has made clear, by signing the Manufacturer Agreement and accompanying addendum, "the Manufacturer agrees" that it will "negotiate to determine … a maximum fair price," that it later will "have engaged in negotiation," that the resulting price was "negotiated," and that it "agree[s]" the price is "fair."[28]

107. Those statements are speech governed by the First Amendment.

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

109. The Manufacturer Agreement to participate in the Program is not voluntary, but instead consists of Government-dictated terms that manufacturers have no real choice but to accept. Opting out of the Program is not, in fact, an option given the grossly disproportionate impact of doing so on a manufacturer's entire drug portfolio or the crushing tax penalties that would apply—penalties so onerous that Congress acknowledged no company would willingly endure them.

110. Similarly, the process that follows after a manufacturer signs the Manufacturer Agreement is not a "negotiation" because the Government has

[28] Manufacturer Agreement, *supra*, § V, add.

authority to unilaterally pick the price it will pay. The manufacturer must accept the Government's decision or else shoulder immense penalties for failing to acquiesce.

111. Compounding these problems, the "maximum fair price[s]" established under the Program bear none of the traditional hallmarks of fairness. The prices are not set through proceedings before a neutral arbiter, but rather are imposed by the same agency that pays for the selected drugs. CMS has also claimed authority to unilaterally alter the terms of the negotiation and subject manufacturers to a daily $1,000,000 penalty for noncompliance with any new or modified requirements it chooses to impose.[29] Further, while courts have long held that "fair market value" is the proper metric for determining the value of property protected by the Fifth Amendment (such as patented drug products), *Horne*, 576 U.S. at 368–70, the Act disregards market forces and instead mandates that the Government-dictated prices be at least 25% below the average price paid by non-federal wholesalers and retail pharmacies.

112. For those reasons, Janssen strongly *disagrees* that the "maximum fair price[s]" are "fair" and the result of "negotiation."

113. By coercing manufacturers to signal their "agreement" with the Government's preferred rhetoric, the Act improperly turns Janssen into a "vehicle for spreading a message with which it disagrees." *Pac. Gas & Elec. Co. v. Pub. Utils. Comm'n*, 475 U.S. 1, 17 (1986).

[29] Manufacturer Agreement, *supra*, §§ II(e), IV(b).

114. As the Supreme Court has recognized, requiring private entities to follow "a [G]overnment-drafted script" necessarily "'alters the content'" of constitutionally protected speech. *Nat'l Inst. of Fam. & Life Advocs. v. Becerra*, 138 S. Ct. 2361, 2371 (2018) (quoting *Riley v. Nat'l Fed'n of Blind, Inc.*, 487 U.S. 781, 795, (1988)). The Government may choose to deceptively describe the Program as involving an "agreement" to "negotiate" a "fair" price, but it cannot force manufacturers to be its messengers.

115. CMS has attempted to fend off First Amendment challenges through sleight of hand by including a disclaimer in the Manufacturer Agreement. According to CMS, a manufacturer signing the Agreement "does not make any statement regarding or endorsement of CMS' views."[30] This obscure provision buried in the fourth section of the agreement cannot overcome the singular message communicated by the Act and every other provision in the Manufacturer Agreement. Regardless of what CMS's self-serving disclaimer says, a manufacturer's signature will convey that the manufacturer has "agree[d]" to "negotiate" a "fair" price. Indeed, this disclaimer provision—which CMS alone has drafted and will present to manufacturers on a take-it-or-leave-it basis—is nothing more than another exercise of CMS's coercive powers to compel additional speech, using the same threat of immense penalties and economic loss to force a manufacturer to "agree" with the Government's litigating position.

[30] Manufacturer Agreement, *supra*, § IV(f).

116. Based on the selection criteria for "negotiation-eligible" drugs, Janssen will be compelled to sign the Manufacturer Agreement by October 1, 2023, creating an obligation for Janssen to "negotiate" a "maximum fair price" for Xarelto®. Under that Agreement, the Government will establish the price by August 1, 2024, and require Janssen to provide access to its Xarelto® products at that price beginning in 2026.

The Program Unconstitutionally Conditions Participation in Medicare and Medicaid on Janssen's Relinquishment of Constitutional Rights

117. The Government cannot shield the Program from constitutional scrutiny by asserting that participation is voluntary. The Act was specifically designed to force manufacturers' compliance without true alternatives. But even if that were not the case, the Act would still violate Janssen's rights by imposing an unconstitutional condition on Janssen's participation in Medicare and Medicaid.

118. "[T]he unconstitutional conditions doctrine … vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up." *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013). Accordingly, "the government may not deny a benefit to a person because he exercises a constitutional right." *Id.* (quoting *Regan v. Taxation With Representation of Wash.*, 461 U.S. 540, 545 (1983)).

119. That doctrine applies even when a person has no right to participate in a Government-sponsored program. *See Perry v. Sindermann*, 408 U.S. 593, 597 (1972). Were it otherwise, the Government would be able to "penaliz[e] and inhibi[t]"

the "exercise of [constitutional] freedoms," "produc[ing] a result which it could not command directly." *Id.* at 597 (cleaned up).

120. In the property-rights context, conditioning participation in a government program is unconstitutional if (1) directly imposing the condition would result in a taking, and (2) there is no "nexus" or "rough proportionality" between the condition and the program participation sought. *Koontz*, 570 U.S. at 605–06; *Dolan v. City of Tigard*, 512 U.S. 374, 386 (1994); *Loretto*, 458 U.S. at 439 n.17 (right to use one's own "property may not be conditioned on [the owner] forfeiting the right to compensation for a physical occupation").

121. In the speech context, "freedom of speech prohibits the government from telling people what they must say." *Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.*, 570 U.S. 205, 213 (2013) (cleaned up). The Government therefore cannot "compel" parties who wish to participate in a program "to adopt a particular belief as a condition of" doing so. *Id.* at 218–19; *see also W. Va. State Bd. of Educ. v. Barnette*, 319 U.S. 624, 641–42 (1943).

122. To the extent the Program is voluntary (it is not), compliance with the Program is a condition of Janssen's participation not just in Medicare but also Medicaid: to continue to market *any* of its products through Medicare and Medicaid without incurring massive tax penalties, Janssen must comply with the Program's requirements for the single product being "negotiated." *See* 26 U.S.C. § 5000D(c).

123. That condition is unconstitutional: The Program coerces Janssen into relinquishing its property rights, and it imposes a condition on both Medicare and

Medicaid participation that is grossly disproportionate to the Government's interest in lowering the price of a single Medicare drug.

124. *First*, the Program effectuates a physical taking of Janssen's patented Xarelto® products, as alleged above. *See* ¶¶ 86–104, *supra*.

125. *Second*, the Program achieves its goals through coercive means. *See Koontz*, 570 U.S. at 604; ¶¶ 56–73, *supra*. If Janssen does not comply with the Program's requirements, the Government will impose a daily penalty starting at 186% of every domestic sale. To avoid that penalty, Janssen would have to forgo access to nearly half of the U.S. health-care market. No rational drug manufacturer would take that step given the serious adverse effect it would have on the manufacturer's long-term ability to innovate and compete, and the harm Medicare and Medicaid patients would experience. Both of those approaches amount to "economic dragooning that leav[e] [Janssen] with no real option but to acquiesce" to the Program's property-stripping demands. *NFIB*, 567 U.S. at 582.

126. The condition is even more coercive because, as explained above, Janssen's revenues from Medicare and Medicaid are integral to its research and development efforts to develop the lifesaving drugs of tomorrow.

127. *Third*, the Program's all-or-nothing approach is grossly disproportionate. *See Dolan*, 512 U.S. at 386. Had the Program's punitive terms extended only to Janssen's ability to market Xarelto® through Medicare, proportionality would have been a closer question. But under the Act, Janssen will not be able to provide *any* of its products through Medicare or Medicaid unless it

relinquishes core property rights in *one* selected drug for the Medicare program. And the Program's adverse impact on *existing* Medicare and Medicaid agreements despite its purported focus on *future* drug prices only exacerbates this imbalance.

128. The condition imposed by the Program is also unconstitutional because it forces manufacturers to give up their free-speech rights by "agreeing" to endorse the fiction that the Program involves a "negotiation" to establish a "fair" price. *See Agency for Int'l Dev.*, 570 U.S. at 218–19. The Government cannot "deman[d] that [manufacturers] adopt—as their own—the Government's view" of the Program as a condition of participating in Medicare and Medicaid. *Id.* at 218.

CLAIMS

Count I
Physical Taking of Personal Property (Fifth Amendment)

129. Janssen re-alleges and incorporates by reference paragraphs 1 through 128 as if fully set forth herein.

130. The Fifth Amendment prohibits the Government from taking personal property without just compensation.

131. Janssen's Xarelto® products are personal property protected by the Fifth Amendment.

132. As applied to Janssen, the Program effects a physical taking of the company's Xarelto® products. Janssen will be required, under threat of a massive penalty on every domestic sale of a Xarelto® product or a total loss of both Medicare and Medicaid participation, to sign the Manufacturer Agreement. That Agreement by statute will then force Janssen, over its objection and under the threat of

additional civil monetary penalties, to provide Medicare participants access to its Xarelto® products. Through these coercive obligations, the Government forces Janssen to transfer its products to third parties and appropriates Janssen's rights to possess and dispose of its personal property.

133. The Program provides for a Government-dictated "maximum fair price" in return for this coerced right of access—a price that by statute must be significantly below the drug's market value, and therefore by definition cannot satisfy the Government's constitutional duty to provide just compensation.

134. Janssen seeks only declaratory relief with respect to its physical takings claim. Such relief is appropriate here because it would "avoi[d] … the burden of numerous suits at law between" Janssen and the Government regarding each instance of a taking of a Xarelto® product, which would present issues that "are substantially the same." *PhRMA v. Williams*, 64 F.4th 932, 943 (8th Cir. 2023) (citation, alteration, and quotation marks omitted); *Di Giovanni v. Camden Fire Ins. Ass'n*, 296 U.S. 64, 70 (1935).

135. Without declaratory relief, Janssen "would be bound to litigate a multiplicity of suits to be compensated" in a manner that would not provide "complete, practical and efficient" relief. *Williams*, 64 F.4th at 945 (citation and quotation marks omitted); *see also Terrace v. Thompson*, 263 U.S. 197, 214 (1923). Instead, declaratory relief would "(1) clarify and settle legal relations in issue and (2) terminate and afford greater relief from the uncertainty, insecurity, and controversy

giving rise to present action." *Gruntal & Co. v. Steinberg*, 854 F. Supp. 324, 333 (D.N.J. 1994) (cleaned up).

136. Declaratory relief is also appropriate because repeated inverse condemnation suits "would entail an utterly pointless" back-and-forth, where "every dollar" taken from Janssen would "generate a dollar of … compensation." *E. Enters. v. Apfel*, 524 U.S. 498, 521 (1998) (plurality opinion).

137. Most fundamentally, the Court should grant declaratory relief because Janssen's injuries cannot be adequately compensated through a legal remedy. Patented drug products, including Xarelto®, play a crucial role in Janssen's innovation ecosystem that is impossible to quantify, replace, or replicate, and the Program's effects will spill over into non-Medicare markets in ways that are equally significant and impossible to quantify. It follows that the physical taking of Janssen's Xarelto® products is "bound to result in many present and future damages of such nature as to be difficult, if not incapable of, measurement." *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 585 (1952).

138. Xarelto® is a unique drug with no competing generics, patented precisely because it is useful, novel, and nonobvious. *See* 35 U.S.C. §§ 102–03. Those unique characteristics "mak[e] damages an inadequate remedy" because no dollar amount can fully compensate for what is, in reality, irreplaceable. *Ramirez de Arellano v. Weinberger*, 745 F.2d 1500, 1527–28 (D.C. Cir. 1984), *vacated on other grounds*, 471 U.S. 1113 (1985).

139. The Court should therefore declare that the Program effects a physical taking of Janssen's Xarelto® products.

Count II
Compelled Speech (First Amendment)

140. Janssen re-alleges and incorporates by reference paragraphs 1 through 139 as if fully set forth herein.

141. The First Amendment protects the right to refrain from speaking. *Becerra*, 138 S. Ct. at 2371.

142. The Act compels Janssen to state in writing 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 the prices imposed through the Program are unfair, the negotiation is a sham, and the agreement is coerced.

143. Laws compelling speech are presumptively unconstitutional unless the Government can demonstrate that they are necessary to serve a compelling interest. *Becerra*, 138 S. Ct. at 2371.

144. The Government has no legitimate interest in forcing Janssen to convey its misleading message regarding the nature of the Program and its sham "negotiations." As a result, the Act violates Janssen's First Amendment rights.

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

146. 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.

147. More specifically, the Court should enjoin Defendants from forcing Janssen to sign the Manufacturer Agreement to "negotiate" a "maximum fair price" for Xarelto®.

148. The Court should also enjoin Defendants from requiring Janssen to "agree" that the Government-dictated price is "fair."

149. If the Government unconstitutionally coerces Janssen into signing the Manufacturer Agreement before the Court has an opportunity to rule on the merits of this suit, the Court should declare that the Agreement is unlawful and enjoin the Government from enforcing its terms, including any penalties provided for under the Act.

Count III
Unconstitutional Condition on Medicare and Medicaid Participation
(First and Fifth Amendments)

150. Janssen re-alleges and incorporates by reference paragraphs 1 through 149 as if fully set forth herein.

151. The Government cannot condition a benefit on the relinquishment of constitutional rights.

152. The Act's coercive structure makes clear that there is no way manufacturers can avoid the Program's requirements. But the Act would violate Janssen's constitutional rights even if the Program were voluntary, by impermissibly conditioning Janssen's participation in Medicare and Medicaid on compliance with the Program's terms. The Government may not force Janssen to surrender core

property rights in its Xarelto® products in order to continue participating in Medicare and Medicaid.

153. This condition is coercive because its acceptance is compelled by a massive penalty on every domestic sale of a Xarelto® product or complete withdrawal from both Medicare and Medicaid. The condition is also disproportionate because it makes Janssen's ability to provide *all* of its pharmaceutical products' through Medicare and Medicaid—not just the selected drug—contingent on the price for a single drug, and because it applies to existing agreements despite a goal of lowering future prices.

154. The Act also unconstitutionally conditions participation in Medicare and Medicaid on Janssen endorsing the false narrative that it "agrees" to "negotiate" Government-dictated prices, and that such prices are "fair."

155. To the extent the Court concludes that the Program is voluntary, the Court should declare that the Act imposes an unconstitutional condition on Medicare and Medicaid participation, and enjoin Defendants from enforcing that condition and imposing penalties for noncompliance therewith.

PRAYER FOR RELIEF

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

A. Declare that the Program effects an uncompensated physical taking in violation of the Fifth Amendment.

B. Declare that the Program compels speech in violation of the First Amendment.

C. Declare that the Act unconstitutionally conditions participation in Medicare and Medicaid on the relinquishment of Janssen's property and free-speech rights.

D. Declare that any agreements Janssen may have been forced to sign in connection with the Program are null and void.

E. Enjoin Defendants from forcing Janssen to sign the Manufacturer Agreement, imposing penalties for non-compliance with the Program's requirements, and enforcing any further agreements Janssen may have been forced to sign in connection with the Program.

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

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

Respectfully submitted,

/s/ David A. Luttinger, Jr.

David A. Luttinger, Jr.
S. Conrad Scott (*pro hac vice* application forthcoming)
COVINGTON & BURLING LLP
The New York Times Building
620 Eighth Avenue
New York, NY 10018-1405
(212) 841-1134
dluttinger@cov.com
cscott@cov.com

Robert A. Long, Jr. (*pro hac vice* application forthcoming)
Kevin F. King (*pro hac vice* application forthcoming)
COVINGTON & BURLING LLP
850 Tenth Street, NW
Washington, DC 20001-4956
(202) 662-6000
rlong@cov.com
kking@cov.com

Counsel for Plaintiff

July 18, 2023