UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVO NORDISK INC., *et al.*, Plaintiffs, v. XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services, *et al.*, Defendants.	No. 3:23-cv-20814-ZNQ-JBD

MEMORANDUM OF AMICI CURIAE PUBLIC CITIZEN, PATIENTS FOR AFFORDABLE DRUGS NOW, DOCTORS FOR AMERICA, PROTECT OUR CARE, AND FAMILIES USA IN SUPPORT OF DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND CROSS-MOTION

Wendy Liu (*pro hac vice* pending)
Public Citizen Litigation Group
1600 20th Street NW
Washington, DC 20009
(202) 588-1000

Andrew M. Milz
Jody T. López-Jacobs
FLITTER MILZ, P.C.
1814 East Rt. 70
Suite 350
Cherry Hill, NJ 08003
Phone: 856-878-2854
Fax: 833-775-3450
amilz@consumerslaw.com
jlopez-jacobs@consumerslaw.com

Attorneys for Amici Curiae Public Citizen, et al.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases **Page(s)**

Statutes

Regulations

Other Authorities

INTEREST OF AMICI CURIAE

As detailed in the accompanying motion to file this brief, amici curiae Public Citizen, Patients for Affordable Drugs Now, Doctors for America, Protect Our Care, and Families USA are non-profit organizations with expertise and longstanding interests in expanding patient access to health care. Amici share an interest in the promotion and implementation of policies that make access to medications more accessible to the patients who need them, thereby improving health outcomes, saving lives, and protecting the financial health of individuals and families. Amici believe that the Inflation Reduction Act's drug price negotiation program is an important step towards reining in the high cost of prescription drugs for patients enrolled in Medicare, and they are concerned that the arguments made by plaintiffs, if accepted by this Court, would result in substantial harm to the health and finances of seniors and other Medicare patients.

INTRODUCTION AND SUMMARY OF ARGUMENT

For many years, seniors have struggled to pay the high cost of prescription medications. High prescription drug prices force many seniors to cut back on other expenses—including necessities such as mortgages and groceries—to pay for the drugs they need. Others have had to forgo medications that they cannot afford, risking adverse health effects and premature death.

Enacted in August 2022, the Inflation Reduction Act (IRA) contains several reforms designed to lower the high cost of prescription drugs and make them more accessible to patients, including seniors enrolled in Medicare. *See* Pub. L. No. 117-169, §§ 11001–11003, 136 Stat. 1818, 1833–1861 (codified at 42 U.S.C. §§ 1320f et seq. and 26 U.S.C. § 5000D). One such reform is the IRA's drug price negotiation program, which provides a pathway to lower the prices for a particular set of high-cost drugs—so-called single-source drugs, for which no generic equivalent is currently on the market. The program relies on a process in which the Department of Health and Human Services (HHS), which is responsible for implementing Medicare, and the manufacturer of selected drugs negotiate the prices at which drugs will be made available to Medicare providers and drug plans.

Seeking to protect drug companies' ability to charge Medicare beneficiaries exceedingly high prices for its single-source drugs, plaintiffs Novo Nordisk Inc. and Novo Nordisk Pharma, Inc. (collectively, Novo) have challenged the IRA program on various legal grounds. Among other claims, Novo contends that the program violates the Due Process Clause because it lacks "adequate procedures to 'safeguard against imposition of confiscatory rates' and to ensure that private property owners ultimately receive 'a fair and reasonable return on investment.'" Pls. Mem. in Support of Mot. for Summ. J. 45 (Novo Mem.) (quoting *Michigan Bell Tel. Co. v. Engler*, 257 F.3d 587, 594–96 (6th Cir. 2001)). Underlying this claim is the notion

that the IRA imposes price controls on drug companies akin to rate regulation and that the "market-based price[ ]" of a drug is whatever price drug companies would otherwise charge Medicare participants absent negotiation; anything below that amount, Novo suggests, deprives drug companies of their property interests.

Novo's theory is built on premises that drug companies are obligated to participate in Medicare and that the price they prefer to charge Medicare patients is the "market" price from which any reduction in price under the program must be evaluated. These premises are wrong. And absent any showing that the drug prices negotiated under the IRA program necessarily result in the deprivation of property interests, Novo's due process challenge must be rejected.

ARGUMENT

I. The high cost of prescription drugs harms patients' health and quality of life.

"Medicare is the single largest purchaser of prescription drugs in the [United States], and those drugs account for more than 1 in 4 health care dollars spent by Medicare." Benjamin N. Rome et al., *Simulated Medicare Drug Price Negotiation Under the Inflation Reduction Act of 2022*, JAMA Health Forum, at 2 (2023).[1]

Medicare provides drug coverage to seniors (outside of the inpatient hospital context) through two programs: Part B and Part D. Part B compensates medical

[1] https://jamanetwork.com/journals/jama-health-forum/fullarticle/2800864.

providers for drugs administered by health care professionals in medical facilities and doctor's offices. Ctrs. for Medicare and Medicaid Servs. (CMS), No. 11315-P, *Drug coverage under different parts of Medicare* 1 (2023).[2] HHS does not currently negotiate the prices for drugs covered under Part B. Instead, Medicare reimburses providers based on a statutory formula that typically results in payment of the average sales price plus 6 percent. *See* 42 U.S.C. §§ 1395w-3a(b), (c).

Part D was enacted in 2003 to address seniors' access to outpatient prescription drugs not covered by Part B. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 101, 117 Stat. 2066, 2071 (codified as amended at 42 U.S.C. § 1395w-101 et seq.) (Prescription Drug Act). Under the Part D program, Medicare contracts with private plan sponsors to provide a prescription drug benefit. Prior to the enactment of the IRA, Part D relied on direct negotiations between drug manufacturers and Part D plans to set drug prices; HHS was barred from participating in those negotiations. *See* 42 U.S.C. § 1395w-111(i) (providing that the HHS Secretary "may not interfere with the negotiations between drug manufacturers and pharmacies and [prescription drug plan] sponsors," and "may not require a particular formulary" or "institute a price structure for the

[2] https://www.cms.gov/outreach-and-education/outreach/partnerships/downloads/11315-p.pdf.

reimbursement of covered part D drugs," except as otherwise provided in certain statutory provisions).

Despite the coverage benefits offered under Medicare Parts B and D, Medicare beneficiaries continue to face extremely high drug prices that make access difficult for many consumers, harming their finances, their health, and their ability to enjoy life. Of those adults taking prescription drugs, nearly one in four (24 percent) report difficulty in affording their prescription drugs, and nearly three in ten (29 percent) report not taking their medicines as prescribed because of cost. Ashley Kirzinger et al., *KFF Health Tracking Poll – February 2019: Prescription Drugs*, Kaiser Family Found. (March 1, 2019).[3] Nearly one in ten adults (8 percent) say that their health condition worsened due to not taking their prescription medication as recommended. *Id.*

High drug prices impact seniors in particular. As of 2019, "[n]early nine in ten (89%) adults 65 and older report[ed] they are currently taking any prescription medicine," and "a majority of older adults [had] prescription drug coverage through Medicare Part D." Ashley Kirzinger et al., *Data Note: Prescription Drugs and Older Adults*, Kaiser Family Found. (Aug. 9, 2019).[4] But despite the benefits provided by

[3] https://www.kff.org/health-reform/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/.

[4] https://www.kff.org/health-reform/issue-brief/data-note-prescription-drugs-and-older-adults/.

Part D and other reforms, in 2019, nearly one in four (23 percent) seniors continued to find it "difficult to afford their prescription drugs." *Id.* (emphasis removed).[5] Much of that difficulty is attributed to high levels of price increases in the preceding years. Prescription drug prices rose "faster than prices for overall U.S. goods and services in most years from 2000 to 2020," mainly due to price increases for existing brand-name drugs and adoption of expensive new brand-name drugs. Cong. Research Serv., R44832, *Frequently Asked Questions About Prescription Drug Pricing and Policy* 8–9 (2021).[6] Accordingly, while prior reforms had stabilized consumers' out-of-pocket spending on prescription drugs generally, by the end of the last decade, "the number of consumers with high out-of-pocket costs—such as those with serious conditions or those prescribed specialty drugs—ha[d] increased." *Id.* at 13. According to one study, "Part D enrollees paid $16.1 billion out of pocket in 2019, up 27% over the previous five years." *Id*. at 13 n.43.

These high costs deter seniors from taking the medication they need to maintain or improve their health. According to a 2023 study, "[a]bout 1 in 5 adults

[5] *See also* Anthony W. Olson et al., *Financial hardship from purchasing prescription drugs among older adults in the United States before, during, and after the Medicare Part D "Donut Hole": Findings from 1998, 2001, 2015, and 2021*, 28 J. Managed Care & Specialty Pharm. 508, 509 (May 2022), https://www.jmcp.org/doi/full/10.18553/jmcp.2022.28.5.508 ("Financial hardship from purchasing prescription drugs is still experienced by many older adults after the full implementation of the [2003 law] and [the Affordable Care Act].").

[6] https://crsreports.congress.gov/product/pdf/R/R44832/7.

ages 65 and up either skipped, delayed, took less medication than was prescribed, or took someone else's medication last year because of concerns about cost." Berkeley Lovelace, Jr., *1 in 5 older adults skipped or delayed medications last year because of cost*, NBC News (May 18, 2023)[7] (discussing Stacie B. Dusetzina et al., *Cost-Related Medication Nonadherence and Desire for Medication Cost Information Among Adults Aged 65 Years and Older in the US in 2022*, JAMA Network (May 18, 2023)).[8] A 2022 HHS report similarly found:

> More than 5 million Medicare beneficiaries struggle to afford prescription medications. Among adults 65 and older, Black and Latino beneficiaries are most likely to experience affordability problems. Medicare beneficiaries with lower incomes and those under age 65 also had above-average rates of not taking needed medications due to cost.

Wafa Tarazi et al., HHS, *Prescription Drug Affordability among Medicare Beneficiaries* 1 (Jan. 2022).[9] And a 2020 report estimated that, by 2031, "112,000 seniors each year could die prematurely because drug prices and associated cost-sharing are so high that they cannot afford their medication." Council for Informed Drug Spending Analysis, *High Drug Prices and Patient Costs: Millions of Lives and*

[7] https://www.nbcnews.com/health/health-news/1-5-older-adults-skipped-delayed-medications-last-year-cost-rcna84750.

[8] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2805012.

[9] https://aspe.hhs.gov/sites/default/files/documents/1e2879846aa54939c56feeec9c6f96f0/prescription-drug-affordability.pdf.

Billions of Dollars Lost (Nov. 18, 2020).[10] This does not have to happen—and does not in other countries: "Seniors in the U.S. have the highest rate among 11 high-income countries (Australia, Canada, France, Germany, the Netherlands, New Zealand, Norway, Sweden, Switzerland, the United Kingdom, and the United States) of not taking prescription drugs because of cost." Christine Ramsay & Reginald D. Williams II, *Medicare Patients Pay More for Drugs Than Older Adults in Other Countries; Congress Has an Opportunity to Move Forward*, The Commonwealth Fund (Sept. 30, 2021).[11]

Beyond the health costs, high drug prices impose financial costs on seniors, who are often retired and living on fixed incomes, and who often struggle to pay for prescription drugs. *See, e.g.*, Matt Sedensky & Carla K. Johnson, *Deal on Capitol Hill could ease seniors' health costs*, Associated Press, July 28, 2022.[12] And paying for drugs often requires sacrificing other essential needs. A 2022 survey of 2000 seniors, for instance, found that "35 percent have cut down on costs in other aspects of their life in order to have enough money to afford their healthcare needs," and about 20 percent have "cut down on paying for necessities like the rent or mortgage

[10] https://www.cidsa.org/publications/xcenda-summary.

[11] https://www.commonwealthfund.org/blog/2021/medicare-patients-pay-more-drugs-older-adults-other-countries-congress-has-opportunity.

[12] https://apnews.com/article/health-seniors-medicare-prescription-drug-costs-drugs-8aaa8fd3959c1da5fba5b5a352b6afb0.

payments … and groceries … in order to pay for medical costs." Chris Melore, *Healthcare hell: 1 in 5 seniors skip paying rent, buying groceries to afford their cocktail of prescription meds*, StudyFinds (Nov. 15, 2022).[13] The high prices have a particularly damaging impact on the many seniors of limited means who must "decid[e] whether they will buy groceries or pay for a prescription." Andrea Baer, *Why are seniors struggling to afford their medications?*, Pan Foundation (July 2, 2019).[14]

II. Prices negotiated under the IRA Program do not result in the deprivation of a property interest.

To address the high cost of prescription drugs, and the concomitant high cost in terms of patient health and quality of life, Congress created a pathway to lower the prices of a particular set of high-cost drugs—so-called single-source drugs. The program relies on a negotiation between HHS and drug manufacturers to determine the prices at which some of those drugs will be made available to Medicare providers and drug plans.

Novo's due process claim rests on the flawed premise that the IRA's price-negotiation program necessarily results in the deprivation of drug manufacturers' property interests. *See* Novo Mem. 3 (arguing that the IRA lacks "adequate

[13] https://studyfinds.org/healthcare-hell-seniors-prescription-medication/.

[14] https://www.panfoundation.org/why-are-seniors-struggling-to-afford-their-medications/.

procedures to protect against unfair and confiscatory pricing"). The IRA program, however, applies only to drug companies that elect to participate in Medicare (and Medicaid). It imposes no legal duty on any company to participate in these programs, and it does not prevent drug companies that do not participate from selling their drugs at whatever price they wish. Novo is therefore wrong to analogize the IRA program to laws that regulate public utilities, which typically both require utilities to sell their services to the public and regulate the prices at which those services must be provided. That the government here is leveraging its buying power to lower prices does not transform the IRA program into a price-setting scheme that deprives drug companies of property interests. Indeed, the government often negotiates significant purchases,[15] and drug companies negotiate prices with other government entities, both in the United States and abroad.

Finally, any reduction as compared to current prices charged by drug companies through Medicare does not "threaten[ ] Novo's rights to sell its product at market-based prices." *See* Novo Mem. 44. The prices that brand-name drugs can currently command within the Medicare system do not represent a benchmark against which a market price can be measured. Thus, outside of Medicare, brand-name drug companies charge different amounts to different buyers. Novo's

[15] *See, e.g.*, 48 C.F.R. § 15.405 (price negotiation for contracts under the Federal Acquisition Regulation).

argument that the IRA program results in the deprivation of a property interest thus does not reflect the dynamics that inform pricing in the market for brand-name prescription drugs. And without a showing that the IRA program deprives drug companies of a property interest, Novo's procedural due process claim fails at the first step. *Abbott v. Latshaw*, 164 F.3d 141, 146 (3d Cir. 1998) ("It is elementary that procedural due process is implicated only where someone has claimed that there has been a taking or deprivation of a legally protected liberty or property interest.").

A. The IRA does not prevent drug companies from selling drugs outside of the Medicare program.

The pharmaceutical supply chain for brand-name drugs in the United States is complex, but it generally involves three steps: First, a drug company manufactures a drug; second, the manufacturer sells the drug to wholesalers or distributers; and third, the wholesaler or distributer sells the drug to retail pharmacies or provider facilities, such as hospitals and physician offices. *See* Andrew W. Mulcahy and Vishnupriya Kareddy, Rand Corporation, *Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships* 4–5, 22 (2021).[16] Typically, the pharmacy benefit managers of insured patients negotiate rebates for retail drugs with drug manufacturers and negotiate prices with pharmacies. *Id*. at 4–5. For drugs administered to patients in a provider setting, the patient (or her insurer) pays the

[16] https://aspe.hhs.gov/reports/prescription-drug-supply-chains.

provider. *Id*. at 22–24. Through this supply chain, any brand-name prescription drug manufacturer can sell its product at any price, subject to the requirement that a physician authorize the patient's use of the drug and the patient's ability and willingness to pay. *See id*. at 20.

Within the Medicare program, Medicare Parts B and D are designed to subsidize the cost of drugs administered by providers and the cost of prescription drugs for beneficiaries. Part B reimburses providers that administer drugs to patients, *see* 42 U.S.C. §§ 1395w-3a(b), (c), while Part D subsidizes prescription drug plans, 42 U.S.C. § 1395w-115(a). These payments to providers and drug plans make drugs covered by the Medicare program more affordable for enrollees and, in that way, make it more likely that seniors will have access to needed medications. This increased utilization, in turn, generates profits for drug companies. But neither program provides subsidies directly to drug companies.[17] Moreover, drug companies are not directly regulated by either program. Rather, to be eligible for payments under Parts B and D, drug companies enter into voluntary agreements with HHS; and companies may opt out of those agreements for any reason. A company that

[17] Indeed, drug companies historically did not need to opt in to Medicare to have their drugs covered under Parts B or D: Both programs define covered drugs without regard to whether a drug company has agreed to participate in Medicare. See 42 U.S.C. §§ 1395x(t) (defining "drugs" and "biologicals" for purposes of Part B); 1395w-102(e) (defining "covered Part D drug").

does not participate, including by opting out, is not precluded from selling drugs to providers and patients at any price they wish to set.

Specifically with respect to Part B, the 2003 Prescription Drug Act (which enacted Part D) provides that drug manufacturers seeking the benefits of Part B coverage must enter into rebate agreements designed to make drugs more affordable under *Medicaid*. *See* Prescription Drug Act, § 303(i)(4)(A), 117 Stat. at 2254 (amending 42 U.S.C. § 1396r-8(a)). Under the Medicaid Drug Rebate Program (MDRP), such manufacturers agree to "rebate a specified portion of the Medicaid payment for the drug," and "[i]n exchange, Medicaid programs cover nearly all of the manufacturer's FDA-approved drugs, and the drugs are eligible for federal matching funds." Rachel Dolan, *Understanding the Medicaid Prescription Drug Rebate Program,* Kaiser Family Found. (Nov. 12, 2019).[18]

With respect to Part D, a 2010 amendment conditioned drug companies' access to Part D coverage for their drugs on participation in the Coverage Gap Discount Program. *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 3301, 124 Stat. 119, 461–67 (2010), *codified at* 42 U.S.C. §§ 1395w-114(a), 1395w-153(a). The Coverage Gap Discount Program assists seniors that fall within the "coverage gap" of standard Part D plans, which arises after a certain level of Part

[18] https://www.kff.org/medicaid/issue-brief/understanding-the-medicaid-prescription-drug-rebate-program/.

D benefits have been utilized. *See* H.R. Conf. Rep. No. 108-391, at 428, 438–39 (2003). Under the program, manufacturers must provide seniors in the coverage gap with "a 50 percent discount on the price that Part D plan sponsors negotiate for brand-name drugs." Gov't Accountability Off. (GAO), GAO-12-914, *Medicare Part D Coverage Gap: Discount Program Effects and Brand-Name Drug Price Trends* 2 (2012) (footnote reference omitted).[19]

Drug companies that opt into either Part B (by participating in the MDRP) or Part D (by participating in the Coverage Gap Discount Program) may opt out "for any reason." 42 U.S.C. § 1396r-8(b)(4)(B)(ii) (addressing termination of Medicaid rebate agreement); *id*. at § 1395w-114a(b)(4)(B)(ii) (addressing termination of agreement to participate in the Coverage Gap Discount Program). Termination of a Medicaid rebate agreement is effective on "the calendar quarter beginning at least 60 days after the date the manufacturer provides notice" of termination. 42 U.S.C. §§ 1396r-8(b)(4)(B)(ii). Termination of participation in the Coverage Gap Discount Program is effective at the end of a plan year or, if terminated after January 30, of the succeeding plan year. 42 U.S.C. § 1395w-114a(b)(4)(B)(ii). Termination of either agreement does not preclude a drug manufacturer from selling drugs to

[19] https://www.gao.gov/assets/gao-12-914.pdf.

providers or patients at any price; it only precludes Medicare or Medicaid funds from being used to subsidize the cost of those drugs.

B. The IRA does not transform Medicare into a coercive program.

Novo does not contend that drug companies are forced to participate in Medicare Part B or D. It argues, however, that the IRA drug price negotiation program changed Medicare from a voluntary program for drug companies into a "coercive" one, Novo Mem. 55, and that, as a result, the IRA must "safeguard against imposition of confiscatory rates" and ensure "a fair and reasonable return on investment," *id*. at 45 (quoting *Michigan Bell* , 257 F.3d at 593); *see also* 51–53 (discussing price-control statutes). Novo contends that the IRA program therefore unconstitutionally deprives drug companies of their property without due process of law. *Id*. at 44.

The IRA, however, is not a price-control statute like the one at issue in *Michigan Bell* and the other statutes on which Novo relies. A price-control statute, by definition, controls the prices that a business may charge. The Michigan law at issue there "prohibit[ed] any rate increase for every 'telecommunication service' offered to subscribers" during a specified period. 257 F.3d at 593. In addition, "[c]ompanies providing telephone service have traditionally been regulated as monopolistic public utilities," *Verizon Commc'ns, Inc. v. FCC*, 535 U.S. 467, 477 (2002), which are, in turn, are *legally obligated* to serve the public, *see*, *e.g.*,

Duquesne Light Co. v. Barasch, 488 U.S. 299, 307 (1989) ("As public utilities, both Duquesne and Penn Power are under a state statutory duty to serve the public."); *FCC v. Fla. Power Corp.*, 480 U.S. 245, 253 (1987) (discussing "regulation of rates chargeable from the employment of private property devoted to public uses"). The telecommunication carriers subject to the Michigan law thus could not lawfully offer their services to customers at the price they wished to charge. In that circumstance, this Court held, "the Constitution protects utilities from being limited to a charge for their property serving the public which is so unjust as to be confiscatory." 257 F.3d at 593 (quoting *Duquesne Light Co.*, 488 U.S. at 307 (internal quotation marks omitted)).

"Cases concerning public utilities are inapposite, however, because the present case simply does not involve a forced taking of property by the [government]": Drug companies, "unlike public utilities, have freedom to decide whether to remain in business and thus subject themselves voluntarily to the limits imposed" on them as a result of their "voluntary participation" in a federal program. *Minn. Ass'n of Health Care Facilities, Inc. v. Minn. Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984) (addressing Medicaid). Brand-name drug manufacturers have no legal obligation to "serv[e] the public" or participate in Medicare. *See, e.g.*, *Garelick v. Sullivan*, 987 F.2d 913, 916–17 (2d Cir. 1993) (distinguishing between utilities "compelled to employ their property to provide services to the public" and

situations "where a service provider voluntarily participates in a price-regulated program or activity" for purposes of determining whether an amendment to Part B resulted in a taking); *Blocktree Properties, LLC v. Pub. Util. Dist. No. 2*, 447 F. Supp. 3d 1030, 1038 (E.D. Wash. 2020) (same), *aff'd sub nom Cytline, LLC v. Pub. Util. Dist. No. 2*, 849 F. App'x 656, 658 (9th Cir. 2021). To the extent that drug companies participating in Medicare are subject to federal limits on drug prices—i.e., the MDRP and the Coverage Gap Discount Program—it is because those companies voluntarily agreed to accept those limits in exchange for the financial benefits they receive from having customers receive Medicare and Medicaid dollars for using their products.

Moreover, drug companies may withdraw from Medicare (or Medicaid) should their assessment of financial costs and benefits change. As noted above, a drug company may withdraw from the MDRP (and Part B) within approximately two quarters of terminating the rebate agreement, and from the Coverage Gap Discount Program (and Part D) by the end of a current or subsequent plan year. Indeed, the IRA sunsets the Coverage Gap Discount Program at the end of 2024, *see* 42 U.S.C. § 1395w-114a(h), and replaces it with the Manufacturer Discount Program beginning in 2025, 42 U.S.C. § 1395w-114c. Drug companies that do not wish to be subject to the conditions that Medicare imposes on Part D pricing can thus decline to enter into the new program. *See Dayton Area Chamber of Com. v.*

Becerra, No. 3:23-CV-156, 2023 WL 6378423, at *11 (S.D. Ohio Sept. 29, 2023) ("[P]harmaceutical manufacturers who do not wish to participate in [Medicare] have the ability—practical or not—to opt out of Medicare entirely."). The ability to opt out distinguishes brand-name drug companies from businesses subject to compulsory price controls.

Ignoring Part B, Novo argues that drug companies could not have withdrawn from Part D before the drug negotiation program begins because of an "11 to 23" month transition period. Novo Mem. 56. Negotiated prices, however, are not "confiscatory" because the drug companies have the ability to withdraw from Medicare and Medicaid well before the negotiated prices take effect in 2026. 42 U.S.C. § 1320f-1(a). Thus, contrary to Novo's contention (Novo Mem. 45), "the risks of an erroneous deprivation" of Novo's property are non-existent.

Novo also argues that the government cannot "require the surrender of constitutional rights in return for a government benefit." Novo Mem. 58. But the IRA does not require drug companies to surrender their right to avoid supposedly confiscatory price controls because the statute preserves drug companies' ability to withdraw from Medicare and Medicaid and sell their drugs at whatever price they wish. Withdrawing from Medicare and Medicaid, moreover, would not deny drug manufacturers' access to any market. *See* Novo Mem. 55. Drug companies that withdraw may still offer drugs for sale to providers or patients; they simply must do

so without the cost support that federal funding provides to their customers. "[P]articipation in Medicare, no matter how vital it may be to a business model, is a completely voluntary choice." *Dayton Area Chamber of Com.*, 2023 WL 6378423, at *11; *see also Baker Cnty. Med. Servs., Inc. v. U.S. Atty. Gen.*, 763 F.3d 1274, 1280 (11th Cir. 2014) ("Although the Hospital contends that opting out of Medicare would amount to a grave financial setback, 'economic hardship is not equivalent to legal compulsion for purposes of takings analysis.'" (quoting *Garelick*, 987 F.2d at 916)).

Novo invokes *National Federation of Independent Business v. Sebelius*, 567 U.S. 519 (2012) (*NFIB*), in which a plurality concluded that Congress may not withhold Medicaid funds from states to incentivize states to expand Medicaid. *See* Novo Mem. 59. *NFIB*, however, rested on federalism concerns not presented here. *See* 567 U.S. at 578 ("Permitting the Federal Government to force the States to implement a federal program would threaten the political accountability key to our federal system."). Moreover, unlike in *NFIB*, the drug price negotiation program is not a "new health care program." 567 U.S. at 584 (plurality op.). It simply seeks to lower the cost of an input into existing Medicare programs as "a means to safeguard the Federal Government's own treasury." *Id*. at 579 (plurality op.) (cleaned up). Nothing in *NFIB* suggests that the IRA transformed Medicare from a voluntary program into a price-control statute.

C. The IRA program does not result in below-market pricing.

Novo's due-process argument also rests on its assertion that negotiated prices "threatens Novo's rights to sell its products at market-based prices." *See* Nov. Mem. 44. The implicit assumption in Novo's argument is that the prices that drug companies prefer to charge represent a benchmark against which prices under the IRA program should be evaluated. In fact, there is no single market price for the brand-name drugs to which the IRA program applies. Rather, drug prices are influenced by a host of factors and can differ for different buyers in different markets. Accordingly, there is no basis for Novo's suggestion that companies are deprived of a property interest because the negotiated price under the program may be less than the price that they prefer to charge.

1. The products at issue under the IRA program are brand-name prescription drugs currently on the market without generic alternatives. Because of the power afforded by market exclusivity of these products, combined with mandates requiring coverage of such drugs in federal programs, the manufacturers of those drugs have, to date, been able to set prices with minimal constraints.

Two forms of market exclusivity—a period of time when a brand-name drug is protected from generic drug competition—apply to brand-name prescription drugs: First, a company that has a patent on its drug generally has the exclusive right to make or sell the drug for 20 years after the filing date of the patent application.

See 35 U.S.C. § 154(a).[20] A patent is awarded by the U.S. Patent and Trademark Office, *see* 35 U.S.C. §§ 101–103, and can be sought by a company at any time during the development of a drug, FDA, *Frequently Asked Questions on Patents and Exclusivity*.[21] Second, after a drug company receives FDA approval of a new drug application, allowing a company to market the product for specified uses, the company is entitled by statute to an exclusivity period. *See id.* As the FDA has explained, "[s]ome drugs have both patent and exclusivity protection while others have just one or neither. Patents and exclusivity may or may not run concurrently and may or may not cover the same aspects of the drug product." FDA, *Frequently Asked Questions*, *supra*.

---

[20] In addition, drug companies sometimes use "patenting practices" that extend the exclusivity period. Cong. Research Serv., R46679, *Drug Prices: The Role of Patents and Regulatory Exclusivities* 5 (2021), https://crsreports.congress.gov/product/pdf/R/R46679. These practices include: (1) "evergreening," which refers to the practice of "obtain[ing] new patents to cover a product as older patents expire to extend the period of exclusivity without significant benefits for consumers"; (2) "attempting to switch or 'hop' the market to a slightly different product covered by a later-expiring patent when the patent covering a current product is close to expiration"; (3) "acquir[ing] many overlapping patents on a single product, creating so-called 'patent thickets'"; and (4) "'pay-for-delay' or 'reverse payment' settlements, where companies 'settle litigation that results when a generic seeks to compete with a patented branded product' by 'transfer[ing] value from the brand to the generic in return for the generic delaying its market entry.'" *Id.* at 5–6 (citations omitted).

[21] https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity.

The pricing power afforded by market exclusivity is amplified by laws requiring coverage of many prescription drugs. For example, Medicare Part D plans are generally required to cover "at least two Part D drugs that are not therapeutically equivalent and bioequivalent" within each therapeutic category and class of Part D drugs. 42 C.F.R. § 423.120(b)(2)(i); *see also* 42 U.S.C. § 1395w-104(b)(3)(G). In addition, Part D plans are required to cover all FDA-approved "[a]nticonvulsants," "[a]ntidepressants," "[a]ntineoplastics" (cancer-treatment drugs), "[a]ntipsychotics," "[a]ntiretrovirals" (HIV-treatment drugs), and "[i]mmunosuppressants for the treatment of transplant rejection." 42 U.S.C. § 1395w-104(b)(3)(G)(iv)(I)–(V). Although the federal government does not mandate prescription drug coverage by state Medicaid programs, state Medicaid programs receiving federal rebates for prescription drugs are required to cover all FDA-approved drugs, subject to certain exceptions. *See* Rachel E. Sachs, *Delinking Reimbursement*, 102 Minn. L. Rev. 2307, 2316–17 (2018) (discussing public payer coverage requirements for prescription drugs); *see also* 42 U.S.C. § 1396r-8(k)(2).

For these reasons, drug companies during the exclusivity period can impose prices that are orders of magnitude higher than the marginal cost of producing the drug. Indeed, the pre-IRA Medicare Part D purchasing scheme, which barred negotiations by HHS, illustrates these unrestrained monopoly price-setting dynamics. Although other countries have similar patent laws and regulatory

exclusivity periods comparable to those in the United States—for example, the exclusivity period in the European Union can run up to 11 years[22]—the U.S. "practice is distinct from that of other high-income countries, which to differing degrees have government-affiliated organizations that negotiate a price based on evaluation of the drug's clinical and cost-effectiveness," resulting in "most brand-name drugs cost[ing] far more in the United States than in other comparable settings around the world." Aaron S. Kesselheim et al., *Pharmaceutical Policy in the United States in 2019: An Overview of the Landscape and Avenues for Improvement*, 30 Stan. L. & Pol'y Rev. 421, 453 (2019).

To be sure, enabling drug companies to charge above marginal-cost prices is the reason for an exclusivity period—so that the companies can recoup the substantial costs of research and development, including the cost of clinical trials and other costs incurred to bring a drug to market. *See* Cong. Research Serv., *Drug Prices*, *supra*; *see also* Richard G. Frank & Paul B. Ginsburg, *Pharmaceutical Industry Profits and Research and Development*, Health Affairs Blog (Nov. 13, 2017); Aaron S. Kesselheim et al., *The High Cost of Prescription Drugs in the*

[22] Lisa Diependaele et al., *Raising the Barriers to Access to Medicines in the Developing World – The Relentless Push for Data Exclusivity*, 17 Developing World Bioethics, no. 1, 2017, at 13, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5347964/pdf/DEWB-17-11.pdf (discussing the European Union's data exclusivity period).

United States: Origins and Prospects for Reform, 316 JAMA, no. 8, 2016, at 863.[23] But that federal policy—as well as federal mandates requiring drug coverage—necessarily affects the pharmaceutical "market" and, consequently, the price at which drug companies can command for their brand-name products. Novo's suggestion that the pre-IRA Medicare price for brand-name drugs represents a benchmark "market-based price[ ]" from which any reduction in price should be measured gives no weight to these important considerations.

2. That a brand-name manufacturer's preferred Medicare price is not properly deemed the "market" price of the drug is further confirmed by the fact that manufacturers do not generally set a uniform price for the "market"; they negotiate different prices with different buyers. In this regard, the Medicare program, lacking the ability to negotiate, has been an outlier, and the prices charged to Medicare have not been reflective of market value. The IRA program, by requiring negotiation, will bring prices more in line with those paid by other large-scale buyers. For example, for drugs with no therapeutic alternatives or where the price of the alternative is above the statutory ceiling under the IRA program, CMS will use "the maximum price a drug manufacturer is allowed to charge the 'Big Four' federal agencies, which are the Department of Veterans Affairs (VA), Department of Defense (DoD),

[23] https://jamanetwork.com/journals/jama/article-abstract/2545691.

the Public Health Service, and the Coast Guard" as its starting point to determine its initial offer for the price negotiation. 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 147 (2023).[24]

Other government agencies and programs responsible for purchasing and reimbursing the cost of prescription drugs do not simply accept prices dictated by the manufacturer. For example, the Department of Veteran Affairs (VA), unlike Medicare, determines which drugs it will cover and can negotiate prices with manufacturers. *See* Gov't Accountability Office, GAO-21-111, *Prescription Drugs: Department of Veteran Affairs Paid About Half as Much as Medicare Part D for Selected Drugs in 2017* (2020)[25]; *see also* Health Affairs, *Prescription Drug Pricing: Veterans Health Administration* 2 (2017).[26] Because of this, prices paid by the VA are substantially lower than those paid under Medicare Part D for the same drug. For example, the VA "paid, on average, 54 percent less per unit for a sample of 399 brand-name and generic prescription drugs in 2017 as did Medicare Part D, even after accounting for applicable rebates and price concessions in the Part D

[24] https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf.

[25] https://www.gao.gov/assets/gao-21-111.pdf.

[26] https://www.healthaffairs.org/do/10.1377/hpb20171008.000174/full/healthpolicybrief_174-1525355141023.pdf

program." GAO, *Prescription Drugs*, *supra*.[27] The GAO also reported that "233 of the 399 drugs in the sample were at least 50 percent cheaper in VA than in Medicare, and 106 drugs were at least 75 percent cheaper." *Id.* The VA achieves these lower prices through a combination of statutory fixed discounts (including the Federal Ceiling Price, which, like the IRA Program, is based on percentages of the non-federal average manufacturer price, *see* 38 U.S.C. § 8126(b)) and bulk negotiating power. *Id.* at 9–10.[28]

Likewise, manufacturers do not set prices under the MDRP, which requires prescription drug manufacturers to provide a discount of at least 23.1 percent of the average manufacturer price, or a greater discount to match the best price available

[27] https://www.gao.gov/assets/gao-21-111.pdf.

[28] Moreover, within Medicare, fee-for-services prices paid to hospitals and physicians are set by statute and regulations—not by the provider—and are generally updated annually by regulation. *See* Cong. Research Serv., R46797, *Finding Medicare Fee-For-Service (FFS) Payment System Rules: Schedules and Resources* (2023), https://crsreports.congress.gov/product/pdf/R/R46797 (collecting statutory and regulatory requirements for different fee-for-service payment systems); *see also* CMS, *Medicare Fee-for-Service Payment Regulations*, https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Policies/Medicare-Fee-for-Service-Payment-Regulations (collecting all Fee-for-Service payment regulations by provider type). CMS determines rates for physician reimbursement under Medicare Part B according to "the Resource Based Relative Value Scale," which "weight[s] services according to the resources used in delivering the service": the physician work required to provide the service, the expenses related to the practice, and malpractice insurance expenses. HHS, No. 04-008, *Determinants of Increases in Medicare Expenditures for Physicians' Services* 79 (2003), https://www.ncbi.nlm.nih.gov/books/NBK43879/pdf/Bookshelf_NBK43879.pdf.

to the manufacturer's most favored commercial customer, subject to certain exceptions. *See* 42 U.S.C. § 1396r-8(c)(1). If price increases outpace inflation, the statute requires an additional rebate. *Id.* § 1396r–8(c)(2). In addition to statutory discounts, state Medicaid programs negotiate supplementary rebates, sometimes through purchasing pools where states join together for greater negotiating leverage. *See* Kathleen Gifford et al., Kaiser Family Found., *How State Medicaid Programs are Managing Prescription Drug Costs: Results from a State Medicaid Pharmacy Survey for State Fiscal Years 2019 and 2020* (April 29, 2020)[29]; *see also* Sachs, *supra*, at 2317 (stating that "states are empowered to seek additional rebates on top of" the ones required by statute). For top-selling drugs, the statutory discounts and negotiations have resulted in average net prices in Medicaid that are 35 percent of the average net price in Medicare Part D. Cong. Budget Office, *A Comparison of Brand-Name Drug Prices Among Selected Federal Programs* 18 (2021).[30]

Moreover, manufacturers charge substantially lower prices to peer countries than they charge for the same drugs in the United States. For example, a RAND study found that U.S. prices for drugs in 2018 were 256 percent of those in 32 comparison countries combined. Andrew W. Mulcahy et al., *International*

[29] https://www.kff.org/report-section/how-state-medicaid-programs-are-managing-prescription-drug-costs-payment-supplemental-rebates-and-rebate-management/.

[30] https://www.cbo.gov/system/files/2021-02/56978-Drug-Prices.pdf.

Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies, RAND Research Report 36 (2021).[31] For brand-name drugs, U.S. prices were even higher than those in comparison countries, with U.S. prices at 344 percent of those in comparison countries. *Id.* Other studies similarly have found that U.S. prices for brand-name drugs "were more than two to four times higher" than prices in other peer countries. GAO, GAO-21-282, *Prescription Drugs: U.S. Prices for Selected Brand Drugs Were Higher on Average than Prices in Australia, Canada, and France* (2021) (comparing 2020 drug prices in the U.S. against those in Australia, Canada, and France)[32]; *see also* H.R. Comm. on Ways & Means, *A Painful Pill to Swallow: U.S. vs. Int'l Prescription Drug Prices* 4 (2019) [hereafter, *Painful Pill*] (comparing 2017 and 2018 drug prices in the U.S. against those in 11 other countries and finding that "U.S. drug prices were nearly four times higher than average prices compared to similar countries").[33] A House report analyzing 2017 and 2018 prices found that "[t]he greatest disparity was with

[31] https://www.rand.org/pubs/research_reports/RR2956.html. The 32 comparison countries are Australia, Austria, Belgium, Canada, Chile, Czech Republic, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Japan, Latvia, Lithuania, Luxembourg, Mexico, Netherlands, New Zealand, Norway, Poland, Portugal, Slovakia, Slovenia, South Korea, Spain, Sweden, Switzerland, Turkey, and the United Kingdom. *Id.* at 17.

[32] https://www.gao.gov/assets/gao-21-282.pdf.

[33] These 11 countries are the United Kingdom, Japan, Ontario, Australia, Portugal, France, the Netherlands, Germany, Denmark, Sweden, and Switzerland.

Japan, where the average drug price was only 15 percent that of the U.S., meaning that the U.S. on average spends seven times what Japan pays for the same drugs." *Id*. at 4.

With drug companies charging different customers domestically and abroad widely different prices for the same drug confirms that there is no one "market" for brand-name drugs and, thus, no one market price from which any reduction in price can be evaluated. Therefore, Novo's contention that the drug price negotiation program necessarily precludes "market-based prices" rests on assumptions that do not withstand scrutiny.

* * *

Novo does not contest that drug companies want to sell brand-name drugs to Medicare participants and beneficiaries. It does not contest that they will be paid for purchases of their drugs. It argues, however, that Medicare will pay less than the average amount that drug companies *prefer* to charge in the United States—although not necessarily less than the amount that they charge other buyers in the United States and internationally. But Novo is wrong that its desire to impose a high price on Medicare, the world's largest drug purchaser, means that purchase below that price necessarily deprives it of its property interests. Novo's procedural due process claim thus fails to take account of the pricing dynamics in the market for brand-name prescription drugs and should be rejected.

CONCLUSION

Plaintiffs' motion for summary judgment should be denied and defendants' motion for summary judgment should be granted.

January 31, 2024

Respectfully submitted,

/s/ Andrew M. Milz

Andrew M. Milz
Jody T. López-Jacobs
FLITTER MILZ, P.C.
1814 East Rt. 70
Suite 350
Cherry Hill, NJ 08003
Phone: 856-878-2854
Fax: 833-775-3450
amilz@consumerslaw.com
jlopez-jacobs@consumerslaw.com

Wendy Liu (*pro hac vice* pending)
Public Citizen Litigation Group
1600 20th Street NW
Washington, DC 20009
(202) 588-1000
wliu@citizen.org

CERTIFICATE OF SERVICE

I hereby certify that on January 31, 2024, I caused the foregoing to be filed with the Clerk of the Court through the Court's ECF system, which will serve notice of the filing on all filers registered in the case.

/s/ *Andrew M. Milz*
Andrew M. Milz