IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

DAYTON AREA CHAMBER OF COMMERCE, *et al.*,

Plaintiffs,

v.

XAVIER BECERRA, *et al.*,

Defendants.

No. 3:23-cv-00156-TMR-PBS

Judge Thomas M. Rose

Magistrate Judge Peter B. Silvain, Jr.

MEMORANDUM OF LAW 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 A PRELIMINARY INJUNCTION

For many years, seniors have struggled to pay the high cost of prescription medications. The high cost of prescription drugs has forced 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. One such reform is the IRA's drug price negotiation program, which provides 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 process between the Department of Health and Human Services (HHS), which is responsible for implementing Medicare, and the

manufacturers of single-source drugs to determine the prices at which drugs will be made available to Medicare providers and drug plans. Although seniors enrolled in Medicare will not realize the benefits of the negotiation program until 2026, the IRA sets forth a detailed statutory timetable for achieving the 2026 implementation goal, starting with negotiations beginning on October 1, 2023.

In this case, plaintiffs, national and regional Chambers of Commerce, seek a preliminary injunction to halt the negotiation process before it gets started. As HHS explains in its memorandum in opposition to the motion for a preliminary injunction, the motion should be denied because plaintiffs do not satisfy any prong of the preliminary injunction standard. Amici agree with HHS and submit this brief to highlight one of the preliminary injunction factors: the public interest. Although plaintiffs' memorandum gives short shrift to the public interest, enjoining the negotiation process would risk derailing the benefit to seniors that Congress intended them to see in 2026, at the expense of seniors' physical and financial health.

INTEREST OF AMICI CURIAE

As detailed in the motion to file this memorandum submitted concurrently herewith, amici curiae Public Citizen, Patients for Affordable Drugs Now, Doctors for America, Protect Our Care, and Families USA are non-profit organizations with expertise in public health with longstanding interests in patient access to health care, including affordable medicines. Amici share an interest in the promotion and implementation of policies to make access to medications more accessible to the patients who need them, thereby improving health outcomes, saving lives, and protecting individuals and families against the financial harm caused by high medical costs. Amici support the IRA's drug price negotiation program as an important step toward reining in the high cost of drugs for seniors enrolled in Medicare, and they are concerned that a preliminary injunction, if granted by this Court, would result in substantial harm to seniors' health and finances.

ARGUMENT

"To obtain a preliminary injunction, 'a plaintiff must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest.'" *Online Merchants Guild v. Cameron*, 995 F.3d 540, 546 (6th Cir. 2021) (quoting *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008) (cleaned up)). The Sixth Circuit has indicated that the balance-of-equities factor encompasses consideration of "whether the injunction would cause substantial harm to others." *Daunt v. Benson*, 956 F.3d 396, 406 (6th Cir. 2020) (quoting *Bays v. City of Fairborn*, 668 F.3d 814, 818–19 (6th Cir. 2012)). This brief focuses on the third and fourth preliminary injunction factors—substantial harm to others and the public interest—which "merge when the Government is the opposing party." *Wilson v. Williams*, 961 F.3d 829, 844 (6th Cir. 2020) (quoting *Nken v. Holder*, 556 U.S. 418, 435 (2009)).

A preliminary injunction precluding timely implementation of the IRA's drug price negotiation program would harm Medicare enrollees—a group of people who depend on access to physician-administered and prescription medications, but who also are likely to be retired or living on fixed incomes. The IRA establishes detailed timelines for action to ensure that enrollees obtain the benefit of lower prices for up to ten selected drugs beginning in 2026, with additional drugs to be added in each subsequent year. To achieve that goal, the statute builds in lead times for HHS and drug manufacturers to take action: By September 1, 2023, HHS must select ten drugs for inclusion in the program, and HHS and the manufacturers of selected drugs must begin the negotiation process by October 1, 2023, with the goal of setting prices effective in 2026. A preliminary injunction halting the negotiation process on the eve of its commencement would disrupt the IRA's calibrated schedule in a way that likely cannot be rectified if the government later prevails. The brunt of that disruption would be borne by millions of Medicare enrollees, who

would either be forced to use more of their retirement savings to obtain prescription drugs to meet their medical needs, or be forced to go without those drugs.

Plaintiffs' discussion of the public interest ignores altogether enrollees' health and financial interests, but this Court should not. The motion for a preliminary injunction should be denied.

I. Medicare enrollees pay for the cost of prescription drugs.

A. Medicare provides prescription drug coverage to seniors (outside of the inpatient hospital context) through two programs: Part B and Part D. Part B's drug coverage is the older of the two programs. It compensates medical providers for drugs administered by health care professionals in medical facilities and doctor's offices. Ctrs. for Medicare & Medicaid Servs., *Drug coverage under different parts of Medicare* 1 (Mar. 2023) (CMS Drug Coverage Brochure).[1] This drug coverage is a component of the "medical and other health services" covered by the Part B program. 42 U.S.C. §§ 1395k(a)(1), 1395x(s)(2)(A). Providers are reimbursed for the cost of a drug based on a statutory formula that typically results in payment of the average sales price of the drug plus 6 percent. *See* 42 U.S.C. §§ 1395w-3a(b), (c).

Part B enrollees must pay for drugs out-of-pocket up to Part B's $226 annual deductible (for 2023) applicable to all medical expenses. After the deductible is met, enrollees must pay a coinsurance amount of up to 20 percent for Part B drugs. *See* CMS Drug Coverage Brochure 1. In 2019, a quarter of enrollees who were charged for common Part B drugs—one million beneficiaries—faced cost-sharing expenses of at least $1000, twenty percent faced at least $2000 in cost-sharing expenses, and ten percent at least $5000. Juliette Cubanski *et al.*, *Medicare Part B Drugs: Cost Implications for Beneficiaries in Traditional Medicare and Medicare Advantage*,

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

Kaiser Fam. Found. (Mar. 15, 2022).[2] Enrollees may purchase private supplemental insurance plans to help them bear these cost-sharing requirements, but "roughly 6 million Medicare beneficiaries have no supplemental coverage" and, therefore, "would be responsible for" the full coinsurance amount for any Part B drugs they need. *Id*. Thus, because of deductibles and cost sharing, higher drug prices can harm seniors financially despite the drug coverage that Part B provides.

Congress enacted Part D 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*.). Congress noted that the "typical senior now takes more than 20 prescriptions a year to improve their health or manage their diseases," and "they are often paying the highest prices because about twenty-five percent of seniors have no prescription drug coverage." H.R. Conf. Rep. No. 108-391, at 427 (2003).

The 2003 law allowed Medicare enrollees, beginning in 2006, to purchase optional drug coverage from private drug plans receiving federal subsidies or through their private Medicare Advantage plans (established under Medicare Part C). *See id.* at 428, 431. As initially implemented, the "standard" drug plans consisted of four tiers: (1) a deductible for which the enrollee was solely responsible, (2) an initial coverage tier in which the enrollee paid coinsurance of 25 percent of cost of a drug, (3) a coverage gap in which the enrollee was solely responsible for paying for the drug, and (4) catastrophic coverage, in which the enrollee was responsible for a copayment or 5 percent of the cost of drugs, whichever was greater. *See id.* at 428, 438–39; *see*

[2] https://www.kff.org/medicare/issue-brief/medicare-part-b-drugs-cost-implications-for-beneficiaries-in-traditional-medicare-and-medicare-advantage/.

also 42 U.S.C. § 1395w-102(b). Plans could adjust this design with actuarially equivalent alternatives. *See* H.R. Conf. Rep. No. 108-391, at 428; 42 U.S.C. §§ 1395w-102(a)(1)(B), (c). Low-income individuals who enroll in the program receive additional subsidies. *See* 42 U.S.C. § 1395w-114.

Subsequent reforms have mitigated the burden of the coverage gap on Part D enrollees. In 2010, the Patient Protection and Affordable Care Act reformed Part D by providing that federal subsidies would be available only for drugs whose manufacturers agreed to provide discounts under a Medicare coverage gap program, 42 U.S.C. §§ 1395w-114a, -153, and it used the savings from drug discounts to phase out the coverage gap so that enrollees would be responsible for paying only a 25 percent coinsurance while in that tier. *See generally* Juliette Cubanski & Tricia Neuman, *Closing the Medicare Part D Coverage Gap: Trends, Recent Changes, and What's Ahead*, Kaiser Fam. Found. (Aug. 21, 2018).[3] Starting in 2025, under IRA reforms unchallenged here, enrollees will be responsible only for the deductible and 25 percent of drug costs up to an annual out-of-pocket limit (starting at $2000); Medicare, drug plans, and drug manufacturers (through a replacement discount program that takes effect in 2025, *see* 42 U.S.C. § 1395w-114c) will cover the remainder. *See* Juliette Cubanski *et al.*, *Explaining the Prescription Drug Provisions in the Inflation Reduction Act*, Kaiser Fam. Found. (Jan. 24, 2023).[4]

B. As of 2019, "[n]early nine in ten (89%) adults 65 and older report[ed] they [were] 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*

[3] https://www.kff.org/medicare/issue-brief/closing-the-medicare-part-d-coverage-gap-trends-recent-changes-and-whats-ahead/.

[4] https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/.

Older Adults, Kaiser Fam. Found. (Aug. 9, 2019).[5] But despite the benefits provided by Part D and other reforms, in 2019, 23 percent of seniors continued to find it "difficult to afford their prescription drugs." Ashley Kirzinger *et al.*, *KFF Health Tracking Poll—February 2019: Prescription Drugs*, Kaiser Fam. Found. (Mar. 1, 2019) (emphasis removed).[6] 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., *Frequently Asked Questions About Prescription Drug Pricing and Policy* 8–9 (updated May 6, 2021) (CRS Report).[7] 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—[had] 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.

In addition to imposing a burden on vulnerable seniors, high drug prices made it more expensive to operate Medicare. In 2019, a House committee considering a predecessor bill to the IRA's drug price negotiation program observed that costs from "the utilization of single-source

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

[6] https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/. *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 (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].").

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

brand drugs that lack generic competition" "accounted for almost three-quarters (72 percent) of total part D spending ($109.3 billion)." H.R. Rep. No. 116-324, pt. 1, at 38 (2019); *see also* H.R. Rep. No. 116-324, pt. 2, at 37 (2019) (a different House committee citing a Congressional Budget Office study concluding that "brand-name specialty drugs accounted for about 30 percent of net spending on prescription drugs under Medicare Part D and Medicaid, but they accounted for only about 1 percent of all prescriptions dispensed in each program"). "In total, 30 percent of Medicare spending went to prescription drug costs." H.R. Rep. No. 116-324, pt. 2, at 37.

Importantly here, high drug prices impose a greater burden on Part D compared to other federal programs such as Medicaid. "Unlike many other industrialized nations, the United States does not operate a single, centralized system for administering government-sponsored drug benefits, procuring pharmaceuticals, or setting drug prices." CRS Report at 16. As a result, different federal programs use different methods for procuring beneficiaries' access to prescription drugs. Since its inception, Part D has relied primarily on direct negotiations between drug manufacturers and Part D plans to set drug prices (subject to the discount program enacted in 2010, *see* 42 U.S.C. § 1395w-114a) and has barred HHS from interfering in those negotiations. *See* 42 U.S.C. § 1395w-111(i). Medicaid, by contrast, requires drug manufacturers to provide rebates as a condition for participating in the program (as well as in Part B). 42 U.S.C. § 1396r-8(a)(1); *see also* CRS Report at 17. According to a Congressional Budget Office report, because of higher manufacturer rebates under Medicaid, the average price of "176 drugs (net of applicable rebates and discounts) … ranged from $118 in Medicaid to $343 in Medicare Part D." CRS Report at 16.

II. The IRA's drug price negotiation program addresses high drug prices.

The IRA's drug price negotiation program was designed to rein in the high cost of drugs for the benefit of Medicare enrollees and the Medicare program. Beginning in 2026, Part D drugs with prices currently set through negotiations between Part D plans and drug manufacturers will

incrementally become subject to direct price negotiations between Medicare and the drug manufacturers, subject to a price ceiling. 42 U.S.C. § 1320f-3. The program expands to include Part B drugs in 2028. 42 U.S.C. § 1320f-1(b)(2).

The program begins with up to ten single-source drugs. HHS must select the drugs from among the most expensive single-source drugs in the Medicare Part D program that have been on the market for at least seven years (or 11 years for biologics, *i.e.*, biologically rather than chemically produced drugs). *See* 42 U.S.C. §§ 1320f-1(b)–(d); *see also* Ctr. for Medicare, HHS, *Medicare Drug Price Negotiation Program: Revised Guidance* § 30.2, at 107 (June 30, 2023).[8] The statute requires HHS to select the drugs for the first year of the program by September 1, 2023, and provides for a negotiation period of October 1, 2023, through August 1, 2024. 42 U.S.C. §§ 1320f(b)(4), (d). If HHS and the manufacturer reach an agreement on price, the drug would become available to Part D plans at the negotiated price beginning in 2026.

The program expands each subsequent year in accordance with a statutorily dictated timetable. For 2027, HHS must repeat the negotiation process for up to 15 of the most expensive single-source drugs in Part D. 42 U.S.C. § 1320f-1(a)(2). For 2028, the program expands to include Part B as well as Part D drugs, and another 15 drugs must be selected for the negotiation program. 42 U.S.C. § 1320f-1(a)(3). Thereafter, up to 20 single-source Part B or Part D drugs are selected each year for price negotiations. 42 U.S.C. § 1320f-1(a)(4). The negotiation periods for 2027 and subsequent years are more compressed than for 2026—generally beginning on February 28 and ending on November 1 of the year that is two years prior to the year when the drugs would become available at the negotiated price. 42 U.S.C. § 1320f(b)(4).

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

III. A preliminary injunction would harm Medicare enrollees.

A preliminary injunction would preclude HHS from complying with the congressionally prescribed timetable, under which Medicare Part D enrollees would pay lower prices starting in 2026. Delay, however, would impose severe—and irreparable—costs on seniors' health and their finances, and Medicare enrollees would not be able to recover later the adverse health and financial losses suffered because of the delay in bringing down drug prices.

The high cost of drugs has significant adverse effects on enrollees. To start, high cost deters seniors from taking the medication they need to maintain or improve their health. According to a 2023 study, "[a]bout 1 in 5 adults 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)[9] (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)).[10] A 2022 HHS report similarly found that: "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.*, *Prescription Drug Affordability among Medicare Beneficiaries*, Off. of the Ass't Sec'y for

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

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

Planning and Eval., HHS 1 (Jan. 2022).[11] 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 Billions of Dollars Lost* (Nov. 18, 2020).[12] 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." Christina 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).[13] If implementation of the IRA is delayed, the harms to seniors' health caused by high drug costs will necessarily continue, with no possibility of redress if the drug price negotiation program is later upheld.

In addition to the health costs, high drug prices impose financial costs on seniors, who are often retired and living on fixed incomes. Articles are replete with examples of seniors struggling 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.[14] And paying for drugs often requires sacrificing other essential needs. A 2022 survey of 2000 seniors, for instance, found that

[11] https://aspe.hhs.gov/sites/default/files/documents/1e2879846aa54939c56efeec9c6f96f0/prescription-drug-affordability.pdf.

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

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

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

"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 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).[15] Although the lower prices envisioned by the IRA will benefit all enrollees in these plans, it is of particular importance to 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).[16] Again, if implementation of the drug price negotiation program is delayed, seniors will have no means to recover these financial costs.

The costs involved are substantial. The Congressional Budget Office estimates that "average drug prices in 2031 will be 9 percent lower in Part B and 8 percent lower in Part D (net of rebates and discounts) because of negotiation." Cong. Budget Off., *How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act* 11 (Feb. 2023) (CBO Analysis).[17] For Part B, these savings translate to $9 billion in lower federal spending on drugs. *Id*. Because Part B enrollees pay up to 20 percent coinsurance on Part B drugs, they will also enjoy the benefits of lower Part B drug prices. *Cf.* Memorandum from Off. of the Actuary, Ctrs. for Medicare & Medicaid Servs., *Updated Financial Impacts of Titles I and II of H.R. 3, "Lower Drug Costs Now Act of 2019"* 11 (Nov. 8, 2019) (estimating Part B beneficiary impacts

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

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

[17] https://www.cbo.gov/system/files/2023-02/58850-IRA-Drug-Provs.pdf.

of earlier bill requiring drug price negotiations).[18] For Part D, the Congressional Budget Office estimates that the drug price negotiation program saves $14 billion in federal Part D spending and $7 billion in Part D enrollee costs. CBO Analysis at 35–36.

These savings will have positive health impacts. "With lower drug prices, Medicare enrollees, who pay a portion of drug costs, will probably use more prescription drugs…. At the same time, they will probably use fewer medical services covered under Medicare Parts A [covering hospitalizations and other inpatient care] and B." CBO Analysis at 11. Indeed, the Congressional Budget Office estimates that increased affordability of Part D drugs will engender another $5 billion in savings from decreased utilization of other medical services under Parts A and B. *Id.* at 31. Enrollees will also have greater access to medications because the IRA requires Part D drug plans to include price-negotiated drugs in their formularies. 42 U.S.C. § 1395w-104(b)(3)(I).

In short, high prices make access difficult for many, harming their finances, their health, and their ability to enjoy life. A preliminary injunction would extend these concrete, irreparable harms by severely disrupting the statutory timetable and process for achieving lower prices, and thus create a substantial risk that Congress's 2026 deadline for implementation of the program will not be met. In marked contrast, because manufacturers of drugs selected for negotiation in the first year of the program do not have to make drugs available at the negotiated price *until 2026*, plaintiffs' claim could be remedied after final judgment, if plaintiffs were to prevail, without risk of irreparable harm. The equities and the public interest thus strongly favor allowing the drug price negotiation program to move forward while plaintiffs' lawsuit is pending.

[18] https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/HR3-Titles-I-II.pdf.

CONCLUSION

Plaintiffs' motion for a preliminary injunction should be denied.

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Respectfully submitted,

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