

**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.

**MOTION OF PUBLIC CITIZEN, PATIENTS FOR AFFORDABLE DRUGS NOW,
DOCTORS FOR AMERICA, PROTECT OUR CARE, AND FAMILIES USA
FOR LEAVE TO FILE A MEMORANDUM AS AMICI CURIAE IN SUPPORT OF
DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION
FOR A PRELIMINARY INJUNCTION**

Public Citizen, Patients for Affordable Drugs Now, Doctors for America, Protect Our Care, and Families USA respectfully move for leave to file a memorandum as amici curiae in support of the defendants' opposition to the plaintiffs' motion for a preliminary injunction. Counsel for amici has conferred with counsel for the plaintiffs and the defendants. The plaintiffs take no position on this motion. Defendants do not oppose grant of this motion.

A. Movants are five non-profit organizations with expertise in public health and with longstanding interests in patients' access to health care, including affordable medicines.

Public Citizen is a non-profit consumer advocacy organization with members and supporters in all 50 states. Public Citizen advocates before Congress, administrative agencies, and courts on a wide range of issues, including ensuring that patients' and consumers' interests are protected in the resolution of the many legal and regulatory issues posed by prescription drugs and

medical devices. A central concern of Public Citizen is protecting and expanding access to affordable medicines for consumers, both domestically and globally. As part of its longstanding commitment to protecting access to medications, Public Citizen has advocated for enforcement of the antitrust laws against brand-name drug manufacturers that seek to exclude generic competition. And through its Access to Medicines program, Public Citizen works with partners worldwide to improve health outcomes and save lives by advancing policies to lower pharmaceutical prices. Public Citizen has provided technical assistance concerning patent rules and access to medicines to dozens of governments as well as to international organizations.

Patients For Affordable Drugs Now (P4ADNow) is the only national patient advocacy organization focused exclusively on lowering prescription drug prices. P4ADNow is bipartisan, independent, and does not accept funding from any organizations that profit from the development or distribution of prescription drugs. Since its founding, P4ADNow has advocated to empower Medicare to negotiate prices directly with pharmaceutical companies for a better deal for both patients and taxpayers in the United States. P4ADNow is pleased to sign an amicus memorandum to protect the Inflation Reduction Act's drug price negotiation program—an historic measure which will strengthen the health, well-being, and financial security of individuals and families across the country.

Doctors for America mobilizes doctors and medical students to be leaders in putting patients over politics on the pressing issues of the day to improve the health of its patients, communities, and nation. Doctors for America is one of the only non-partisan, non-profit, non-trade organizations of medical professionals working on patients' behalf. It is continuously working to improve access to equitable, affordable, high-quality health care for patients across the country. For this reason, Doctors for America has a longstanding history of working to improve

drug affordability by advocating for legislative, regulatory, and judicial changes to ensure patients can access their life sustaining treatments.

Protect Our Care, a fiscally sponsored project of the New Venture Fund, is dedicated to making high-quality, affordable, and equitable health care a right, and not a privilege, for everyone in America. Protect Our Care educates the public, influences policy, supports health care champions, and holds lawmakers accountable. Protect Our Care supported the development and enactment of the Inflation Reduction Act's provisions to make prescription drugs more affordable, including the Medicare drug price negotiation program. Protect Our Care is committed to the successful implementation of the law, including by defeating legal attacks, to ensure seniors and taxpayers benefit from more affordable prescription drugs.

Families USA is a non-partisan voice for health care consumers and is dedicated to achieving high-quality, affordable health care and improved health for all. On behalf of health care consumers, working people, and patients, Families USA has advocated for decades for legislation and rulemaking that improves the accessibility and affordability of prescription drugs. Since the creation of Medicare Part D, Families USA has believed that ensuring drug affordability should be a key part of the program and has urged policymakers to explore the root causes of high and irrational drug prices and to tackle the complex network of abusive practices that underpin the American pharmaceutical market.

B. The plaintiffs' motion for a preliminary injunction seeks to enjoin the Department of Health and Human Services (HHS) from implementing the drug price negotiation program, 42 U.S.C. § 1320f *et seq.*, enacted as part of the Inflation Reduction Act of 2022, Pub. L. No. 117-169, 136 Stat. 1818. The program seeks to lower the high cost of prescription drugs made available to seniors enrolled in Medicare by providing a mechanism for the federal government and drug

manufacturers to negotiate drug prices available to enrollees beginning in 2026. To meet the 2026 implementation goal, the statute requires HHS to begin the negotiation process on October 1, 2023, for an initial set of up to 10 drugs. Plaintiffs' motion, if granted, would prevent HHS from moving forward with the statutory schedule and, therefore, would create a risk of failing to meet the 2026 start for the program.

The proposed amicus memorandum addresses an important component of the preliminary-injunction analysis: the substantial harm to others and to the public interest that would arise if the drug price negotiation program could not move forward as scheduled. The proposed memorandum traces Congress's prior efforts to improve Medicare enrollees' access to provider-administered medications and prescription drugs and explains how those efforts have not been sufficient to prevent significant increases in the drug prices that have left many seniors unable to afford their out-of-pocket payments. As the proposed memorandum explains, many Medicare enrollees consequently forgo medications that they cannot afford or sacrifice other essential needs in order to pay for their medications. The drug price negotiation program addresses affordability by providing a means for negotiating lower drug prices and thereby improving seniors' access to Medicare-covered drugs. Because millions of seniors rely on Medicare coverage to help them pay for the medications, any delay in the program's 2026 start date will necessarily cause widespread harm to Medicare enrollees. In these circumstances, where the public interest considerations of the preliminary-injunction standard point to significant public harm, the information and arguments set out in the proposed amicus memorandum by organizations focused on the public interest and with expertise on this topic will assist this Court in resolving the pending motion.

The proposed memorandum is attached to this motion as Exhibit A. A proposed order is also attached.

CONCLUSION

The Court should grant this motion for leave to file an amicus curiae memorandum.

August 14, 2023

Respectfully submitted,

/s/ Daniel R. Karon

Daniel R. Karon (0069304)

Trial Attorney

Karon LLC

700 W. St. Clair Ave., Suite 200

Cleveland, OH 44113

(216) 622-1851

dkaron@karonllc.com