No. 25-751

In the Supreme Court of the United States

BRISTOL MYERS SQUIBB COMPANY,

Petitioner,

v.

ROBERT F. KENNEDY, JR.,
SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

BRIEF OF AMICUS CURIAE PIONEER NEW ENGLAND LEGAL FOUNDATION IN SUPPORT OF PETITIONER

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TABLE OF AUTHORITIES

TABLE OF AUTHORITIES

TABLE OF AUTHORITIES – Continued

Page

TABLE OF AUTHORITIES – Continued

Page

INTEREST OF THE AMICUS CURIAE

PIONEERLEGAL, LLC (PioneerLegal), doing business as Pioneer New England Legal Foundation (the Legal Foundation), is a nonprofit, nonpartisan legal research and litigation entity.[1] PioneerLegal began operating under its new name, the Legal Foundation, after forming a strategic alliance with the New England Legal Foundation (NELF) in May 2025. The Legal Foundation seeks to continue its pre-existing work, as well as NELF's mission.

PioneerLegal was founded by its nonprofit, nonpartisan member, the Pioneer Institute, Inc., in 2022, to promote open and accountable government, economic opportunity, freedom of speech, freedom of association, and education opportunities across the country, through legal action and public education.

NELF has been a nonprofit, public interest law foundation, incorporated in Massachusetts in 1977. NELF's members and supporters have included large and small businesses in New England, other business and nonprofit organizations, law firms, and individuals, all of whom believe in NELF's mission of promoting balanced economic growth in New England, protecting

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[1] Pursuant to Supreme Court Rule 37.2, amicus states that all parties received timely notice of the intent to file this brief. Pursuant to Supreme Court Rule 37.6, amicus states that no counsel for a party authored this brief in whole or in part, and no person or entity other than amicus curiae, its members, or its counsel made a monetary contribution to the preparation or submission of this brief.

the free enterprise system, and defending economic and property rights.

Pioneer NELF supports free market mechanisms as the best solution to most societal problems. Government programs such as the Drug Price Negotiation Program provision of the Inflation Reduction Act which seek to replace the price-setting mechanisms of the free market with mandatory price controls set by the federal government for certain pharmaceuticals are bad policy.

SUMMARY OF ARGUMENT

Pharmaceutical companies provide cutting edge beneficial healthcare to the general public. This includes creating innovative drugs and treatments for diseases and conditions. These treatments and drugs lead to a better quality of life, often significantly extending an individual's life.

The Inflation Reduction Act's Drug Price Negotiation Program (the "Program") is an unwarranted disruption by the federal government of the important process of research and development of new pharmaceutical products. The Program is not a process of negotiation, but instead imposes mandatory price controls dictated by the government on certain pharmaceuticals, with all the negative economic disruptions that mandatory price controls inevitably create.

Price controls are unlikely to be successful in reducing prices long-term because they fail to address the underlying reasons for high pharmaceutical prices. In addition, the price controls in the Program are

creating market distortions which work against the professed goals of the Program to reduce the overall cost and increase the availability of life-saving medications.

There are likely to be a number of unintended negative consequences of the Program's implementation. First, there will be a significant reduction in overall revenue of drug manufacturers, reducing the funds available for groundbreaking research and development. Second, the Program will distort the economic incentives that drive the decision-making by pharmaceutical companies on where to direct their research efforts. Manufacturers will target their research and development efforts towards those classes of drugs that are not subject to the mandatory price controls of the Program.

When the Program was first enacted, many studies predicted the negative unintended consequences of the Program's price controls. Now, a few years later, research is starting to show that those negative unintended consequences are in fact occurring.

This case has enormous implications for the healthcare of the American people. The federal government now accounts for almost half of all spending on prescription drugs—some $200 billion per year. *See Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023). Because of the importance of this case to healthcare in the United States, and the importance of the constitutional issues raised by Petitioner, the Court should grant the petition for certiorari and then reverse the decision of the Third Circuit.

ARGUMENT

I. The Prices Set by the Drug Price Negotiation Program Are Price Controls Dictated by the Government, with All the Negative Economic Disruptions That Mandatory Price Controls Inevitably Create.

The Drug Price Negotiation Program (the "Program") provisions of the Inflation Reduction Act, 42 U.S.C. § 1320f, are described in the Act as a negotiation process, but that really is not the case. As Judge Hardiman of the Third Circuit persuasively argues in his dissent in this case, there was no real negotiation. "Congress compelled manufacturers to subject themselves to prices set by CMS. The byzantine scheme established by the Act forced BMS and Janssen to turn over Eliquis and Xarelto at prices set by CMS while requiring the Companies to misrepresent that they agreed to such prices. That scheme violates the Companies' First and Fifth Amendment rights." *Bristol Myers Squibb Co. v. Secretary*, 155 F.4th 245, 289 (3rd Cir. 2025) (Hardiman, J., dissenting).

The Program provides only the illusion of negotiation, not the real back and forth between market participants that characterize a true negotiation. Instead, as Judge Hardiman noted, "The Act sets a price ceiling for selected drugs . . . " *Id.*, 155 F.4th at 271 (Hardiman, J., dissenting). The Program thus represents another in a long line of legislative efforts to impose price controls on some aspect of American economic life. *See generally*, Joint Economic Committee

Republicans, *The Economics of Price Controls* (September 2022), pp. 4-7, https://www.jec.senate.gov/public/_cache/files/7171cb80-ef0d-4058-b3e6-f20fe608745f/the-economics-of-price-controls-final-092122.pdf.

There is no doubt that Congress has the power to impose price controls. *Yakus v. United States*, 321 U.S. 414, 422-423, 64 S.Ct. 660, 667, 88 L.Ed. 834 (1944). However, it is equally clear that price controls are generally ineffective in the long run, because they fail to address the underlying causes of high prices. In addition, price controls generally have negative economic consequences, by distorting and obscuring the important information that prices provide, and by creating incentives for market participants to act in ways they would not otherwise act, but for the existence of price controls.

In the context of the price controls imposed by Drug Price Negotiation Program, the Joint Economic Committee Republicans summarized their concerns on the price controls of the Program as follows:

> Concerningly, the Inflation Reduction Act of 2022 has a provision that allows Medicare to "negotiate" the prices of certain prescription drugs. Instead of a fair and open negotiation, the government caps the maximum price that can be attained by the firm in the negotiation, effectively acting as a price control. The loss in research and development expenditures will likely be substantial, leading to estimates of 15 fewer pharmaceutical drugs over the next 30 years, a significant harm to the health of future Americans. Applying the estimates from Santerre and Vernon, this policy could result in a cost between $0.6

> trillion and $1.9 trillion, due to the loss of between 6 million and 19 million life-years over the next 30 years.

Joint Economic Committee Republicans, *supra*, pp. 9-10.

A. The Price Controls Imposed by the Program Fail to Address the Underlying Cause of High Pharmaceutical Costs.

The price controls imposed by the Program fail to address the fundamental cause of high prescription drug prices – the enormous cost of developing new drugs. One study estimated that the average research and development cost of new drugs was $1.1 billion per drug, based on a review of the cost of developing over sixty new therapeutic drugs and biologic agents approved by the US Food and Drug Administration between 2009 and 2018, including expenditures on failed trials. Wouters, Olivier J., et al., *Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018*, JAMA, March 3, 2020, https://jamanetwork.com/journals/jama/fullarticle/2762311.

The price controls established by the Program will do nothing to reduce the costs incurred by manufacturers to develop new pharmaceuticals. Instead, it hinders the efforts of manufacturers to recover their massive investments in researching and developing new drugs. As a result, a rational manufacturer will be inclined to redirect its research efforts away from those drugs or classes of drugs that are subject to price controls, in favor of those drugs or classes of drugs that are not subject to or are less affected by the price controls.

B. A Widespread Decline in Revenue Will Inevitably Lead to a Dramatic Reduction in Research and Development, Stifling Innovation.

There is no real question that the price reductions of the Program will reduce revenues for the pharmaceutical industry – that was the whole point of the Program. Questions remain as to the magnitude of the reduction in revenue, and how that reduction in revenue will affect research and development decisions.

Initial estimates of the size of the loss of revenue were startling. In 2022, the healthcare consulting firm Avalere Health projected a reduction in the revenues of pharmaceutical manufacturers of $300-$450 billion as a result of the IRA. Avalere Health, *Drug Pricing Bill Could Reduce Manufacturer Revenue by Over $450B*, July 27, 2022, https://advisory.avalerehealth.com/insights/drug-pricing-bill-could-reduce-manufacturer-revenue.

It is still too early to know with certainty the full extent of the industry's losses. However, recent research suggests that manufacturers are already experiencing cutbacks in research and development spending. Research by the Council for Affordable Health Coverage, an advocacy group, suggests that since the IRA was passed, two dozen companies have announced that they are reducing or stopping research and development new drugs and secondary uses for existing medication. Council for Affordable Health Coverage, *IRA Gambles with Cancer Patients' Lives*, April 14, 2025, https://cahc.net/ira-gambles-with-cancer-patients-lives/.

Another study suggests that it is not just pharmaceutical manufacturers who will see a reduction in

revenue as a result of the Program. There will also be negative impacts on physicians, who derive revenue from administering certain drugs under Medicare Part B. This study estimated that that physicians could lose at least $25 billion in add-on payments for 10 Part B drugs expected to be negotiated by CMS, with oncology products accounting for at least $12 billion of that loss. *See* Avalere Health, *Commercial Spillover Impact of Part B Negotiations on Physicians*, September 16, 2024, https://advisory.avalerehealth.com/insights/commercial-spillover-impact-of-part-b-negotiations-on-physicians.

C. The IRA Will Have a Disproportionately Negative Impact on Seniors.

The IRA threatens to impose disproportionate harms on seniors, who rely most heavily on access to innovative and flexible treatment options. Because seniors are the primary users of prescription drugs and healthcare services, any policy that constrains drug development or limits therapeutic choice will affect them first and most severely.

Seniors often require a range of treatment options because they may develop resistance to one therapy, they may experience side effects to a determined therapy, or they may have co-occurring conditions that rule out a particular therapy. *See* Longo, Nicole, *IRA Threatens Seniors' Access to Robust Treatment Options*, PhRMA BLOG (Sept. 23, 2023), https://phrma.org/Blog/IRA-threatens-seniors-access-to-robust-treatment-options. Simply put, any pricing restrictions that result in a reduction in new drug innovation will disproportionately affect seniors because they are the predominant participants in the healthcare system.

Moreover, studies already confirm the existence of the economic distortion that results from the fact that the Program targets those drugs that are most likely to be used by the Medicare/Medicaid population. Manufacturers have begun to devote more research and development to medications not targeted to the Medicare/Medicaid population, thereby diverting research and development resources away from pharmaceuticals that would be most helpful to the elderly. This diversion of resources tends to undermine one of the fundamental goals of the Program, the goal of increasing the availability of pharmaceuticals that are likely to benefit the Medicare/Medicaid population.

One study has found a 74% decline in the median size of aggregate investments into indications targeting the Medicare-aged population. Schulthess, D.G., et al., *The Inflation Reduction Act's Impact Upon Early-Stage Venture Capital Investments*, THERAPEUTIC INNOVATION & REGULATORY SCIENCE 59:769–780 (April 13, 2025) at 779, https://doi.org/10.1007/s43441-025-00773-3.

This study also found that between 2021-2023, the time of the IRA's introduction, small and mid-size biotech companies saw a 35% reduction in early-stage phase I and II therapies under development. *Id.* at 774, Figure 1. The average phase II and III clinical development time is roughly 40 months each. Therefore, the data indicates that there will be a considerable reduction in FDA approvals targeting the Medicare-aged population in 5 to 6 years. *Id.* at 777-778.

D. The Program Incentivizes Companies to Shift Their Research and Development Priorities.

The Program distorts pharmaceutical research and development incentives by favoring biologic drugs over small-molecule therapies. By encouraging investment in higher-cost, more complex medications while discouraging development of affordable and widely accessible treatments, the Program undermines innovation patterns that have historically benefited patients.

There are two main types of drugs: small molecule drugs and biologics. Ninety percent of all pharmaceuticals, such as antibiotics and blood pressure medications, are small molecule drugs. They are synthetic medications obtained from natural products. Biologics, such as vaccines, are derived from living organisms or their products. Biologics are more time consuming, challenging, and expensive to develop. Biologics are also more difficult and expensive to administer, because biologics generally must be injected, while small molecule drugs can be administered in pill form. Small-molecule drugs are generally easy and cheap to reproduce as non-branded generics once the original drug patent expires, increasing availability to patients. *See generally* Council for Affordable Health Coverage, *The Inflation Reduction Act & the Small Molecule Penalty* (Jan. 12, 2023), https://cahc.net/the-inflation-reduction-act-the-small-molecule-penalty/.

Even though biologics typically have a much larger price tag than small molecule drugs, the Program incentivizes companies to produce biologics. The price controls for biologics will be implemented thirteen years after approval, while the price controls for small-molecule drugs will be implemented after only

nine years. *Id.* The fact that biologics enjoy an extra four years of exemption for the price controls of the Program can be a major boost to the profitability of biologics relative to small-molecule drugs.

Research to date shows that pharmaceutical manufacturers are in fact shifting their research and development to favor biologics. The study by Schulthess, et al., discussed above on the impact of the IRA on research and development and investor behavior also found a significant impact on small molecule research. The study found that aggregate small molecule investments dropped by 68% since the IRA was introduced. The study also found that with respect to investments targeting the Medicare-aged population, there was a greater decrease in investments in small molecules compared to large molecules. Overall, this study is clear that the IRA disincentivizes the development of small molecule medicines, which account for more than 90% of all prescriptions. Schulthess, D.G., et al, *supra*, p. 779.

Another innovative study recognized that direct measurement of the impact of the Program on investment decisions is difficult at this early stage of the Program. Canestaro, William J., et al, *Inflation Reduction Act Impact on Pharmaceutical Investment: Insights from Investor Interviews*, HEALTH AFFAIRS SCHOLAR, 2025, 3(9) (August 7, 2025), https://doi.org/10.1093/haschl/qxaf156. The authors of this study performed a series of interviews with life science investors and decision-makers. Interview questions were in three categories: awareness of the IRA and Program; influence of the Program on product development strategies; and changes to overall strategy. *Id.*, p. 2. This study yielded the following results:

1. 87% of respondents said that the IRA was making it more challenging to bring innovative new products to market. *Id.*, p. 4.
2. 77% of respondents said that the IRA had created a disincentive away from investing in small molecules. *Id.*
3. All but one respondent said that they had shifted their focus towards drugs with the largest potential patient population. *Id.*
4. The shift towards drugs with the largest potential patient population makes it harder for smaller biotech companies to compete with the larger firms. *Id.*, pp. 4-5.

These shifts in the direction of pharmaceutical research and development are disrupting the direction of research and development that would exist without the price controls imposed by the Program. In the long run, these disruptions may have the unintended consequence of increasing overall drug costs by shifting research and development towards more expensive drugs which target large patient populations, instead of reducing costs and increasing the availability of new medications.

CONCLUSION

For the reasons stated above, the Legal Foundation respectfully requests that this Court grant certiorari and ultimately reverse the decision of the Third Circuit.

Respectfully submitted,

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