Nos. 24-1820 & 24-1821

UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRISTOL MYERS SQUIBB COMPANY
Plaintiff-Appellant,
v.
XAVIER BECERRA, *ET AL.*,
Defendants-Appellees.

JANSSEN PHARMACEUTICALS, INC.,
Plaintiff-Appellant,
v.

XAVIER BECERRA, *ET AL.,*
Defendants-Appellees.

On Appeal from the United States District Court
for the District of New Jersey, Nos. 3:23-cv-03335 & 3:23-cv-031818

BRIEF OF AMICUS THE BUCKEYE INSTITUTE IN SUPPORT OF APPELLANTS

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CERTIFICATE OF INTERESTED PARTIES

Case Nos. 24-1820 & 24-1821

The undersigned counsel of record for *amicus* The Buckeye Institute certifies that The Buckeye Institute is an Ohio nonprofit organization.[1] Counsel is not aware of any person or entity as described in the fourth sentence of Rule 28.2.1 that have an interest in the outcome of this case other than those listed in the parties' certificates. These representations are made in order that the judges of this court may evaluate possible disqualification or recusal.

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[1] Pursuant to Fed. R. App. 29(a)(4)(E), The Buckeye Institute has authored this brief in whole.

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INTERESTS OF THE *AMICUS CURIAE*

Amicus curiae The Buckeye Institute[2] was founded in 1989 as an independent research and educational institution—a think tank—whose mission is to advance free-market public policy. The staff at The Buckeye Institute accomplishes the organization's mission by performing timely and reliable research on key issues, compiling and synthesizing data, formulating free-market policy solutions, and marketing those policy solutions for implementation in Ohio and replication throughout the country. The Buckeye Institute is a nonpartisan, non-profit, tax-exempt organization as defined by I.R.C. section 501(c)(3). The Buckeye Institute files and joins amicus briefs that are consistent with its mission.

The Buckeye Institute is dedicated to promoting free-market policy solutions and protecting individual liberties, especially those liberties guaranteed by the Constitution of the United States, against government overreach. The Buckeye Institute has long opposed government price controls as antithetical to a free market, and stifling to innovation and supply, which ironically fuels the inflation they were supposed to combat.

[2] Pursuant to Rule 29(a), The Buckeye Institute states that all parties have given consent to file this amicus brief. Further, no counsel for any party has authored this brief in whole or in part and no person other than the amicus has made any monetary contribution to this brief's preparation or submission. The Buckeye Institute has no parent corporation and no publicly held corporation owns 10% or more of its stock.

SUMMARY OF ARGUMENT

Science-fiction author Robert A. Heinlein famously reduced the dismal science of economics to an eight-letter acronym: TANSTAAFL, which served as shorthand for the established economic principle that "there ain't no such thing as a free lunch." Robert A. Heinlein, *The Moon is a Harsh Mistress* 162 (1966); *see Tatro v. Homecomings Financial Network, Inc.,* 2011 WL 240255, *3 (D. Nevada 2021) (noting Heinlein's admonition); *see generally* Dmitry Feofanov, *Luna Law: The Libertarian Vision in Heinlein's the Moon is a Harsh Mistress*, 63 Tenn. L. Rev. 71, 72–73 (1995). While Heinlein popularized the acronym, he was hardly the first—or the last—to recognize that economic truth. Writing in 1977, Nobel Prize-winning economist Milton Friedman explained—with slightly improved grammar—that every economic action, even those which appear to have no cost, comes with an opportunity cost. Milton Friedman, *There's No Such Thing As a Free Lunch* (1975).

In enacting the Inflation Reduction Act ("IRA"), Congress allowed Medicare to "negotiate" the prices of certain drugs with pharmaceutical companies. Rather than allow for a true arms-length negotiation, however, the IRA essentially allowed Medicare to set prices for certain drugs and to impose punitive taxes on drug makers where "negotiation" proved unsuccessful. The IRA's coercive measures not only violate the Fifth and First Amendments, as the Appellants argue, they also fail Economics 101. The economic literature is clear that price controls are a disincentive to innovation, discourage actors from entering a market, and perversely, end up increasing consumer prices.

In considering the constitutional arguments made by the Appellants, the Court should also consider—given the documented failure of price controls to curb inflation and their pernicious effect on innovation—whether there is even a rational basis to support the policy.

ARGUMENT

I. Price Controls are a Disincentive to Innovation

Economists, journalists, and everyday Americans have recognized the free lunch fallacy for over a century. When Friedman and other economists caution that there is no free lunch, they mean that every economic or policy choice presents a trade-off. As economist Greg Mankiw explains, "[t]o get something that we like, we usually have to give up something else that we also like. Making decisions requires trading off one goal against another." N. Gregory Mankiw, *Principles of Economics* 4 (8th ed.). While the TANSTAAFL principle seems to be simple common sense, policymakers and their constituents are frequently willing to close their eyes to this self-evident truth, particularly when the bill for the "free" lunch comes in the future and is distributed across society.

Policymakers understandably want to deter and punish bad corporate behavior. And there is evidence showing that many Americans believe that pharmaceutical companies have acted unethically. Indeed, "[t]he pharmaceutical industry is now the most loathed sector in America, according to a new poll." *Poll shows Americans are fed up with pharmaceutical industry*, Harvard T.H. Chan School of Public Health, https://www.hsph.harvard.edu/news/hsph-in-the-news/poll-shows-americans-are-fed-up-with-pharmaceutical-industry/ (last visited July 19, 2024). "58% of Americans held negative views of the pharmaceutical industry while only 27% held positive views of it." *Id.* "Gallup noted that high drug prices, the opioid epidemic, and Big Pharma's big lobbying efforts are all factors that likely played into respondents' frustration with the industry." *Id.* And many individuals and politicians complain about Big Pharma for many reasons. *See generally* John LaMatina, *Hiding Data And Other Criticisms Of Big Pharma*, Forbes (Apr. 24, 2017), https://www.forbes.com/sites/johnlamattina/2017/04/24/hiding-data-and-other-criticisms-of-big-pharma/.

Some of these criticisms may be legitimate—others are not. Either way, the laws of economics are real, and a correct economic analysis is critical in evaluating economic policies such as price controls. While Congress has the authority to enact laws that ignore the laws of economics, the chickens of economics will always come home to roost. Amicus informs the Court of the laws of economics and the impact of the improperly promulgated rule. While the Court has an obligation to follow the law, it is also useful for the Court to understand the consequences of the government's misguided action.

When policymakers—or private companies acting at their direction—cap prices on certain products, the trade off comes in the form of lost opportunities to create new drugs or improve on existing ones. It presents not only a cost in hard dollars and cents but in foregone cures and therapies, unnecessary human suffering and even premature death. This was no secret to the lawmakers who enacted the IRA. In its analysis of the IRA, the Congressional Budget Office noted that while the price negotiation provision would reduce the federal deficit by reducing Medicare spending it would result in a decrease of one new drug in the first decade and an additional 12 drugs over the following two decades. Cong. Budget Off., *Estimated Budgetary Effects of Public Law 117-169, to Provide for Reconciliation Pursuant to Title II of S. Con. Res. 14* 15 (2022), www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf.

The Center for Strategic and International Studies ("CSIS") at John Hopkins University analyzed how price controls affected innovation. The first part of understanding the IRA's effect on innovation is to understand some pharmaceutical industry baselines. According to the CSIS study, "[i]n 2021, the U.S. pharmaceutical industry invested over 1.2 billion dollars, or 21.2 percent of total sales, into R & D." Baily Crane, *The Effect of Reference Pricing on Pharmaceutical Innovation*, Ctr. for

Strategic Int'l Stud. (July 12, 2023), https://www.csis.org/blogs/perspectives-innovation/effect-reference-pricing-pharmaceutical-innovation. Second, for pharmaceutical companies to realize any return on that sizable annual investment takes time. "On average, it takes at least ten years and 2.17 billion dollars" to win FDA approval for a new drug. *Id.* And only 10 percent of potential new drugs pass clinical trials and achieve approval. *Id.* While it is easy for politicians to accuse drug-makers of being too profitable, the CSIS analysis explained what, again, should be common sense: Revenue losses incurred in developing new drugs "will not be recovered if prices of successful drugs are capped." *Id.* And "[t]his loss in revenue will lead to a reduction in research and development activities, curtail innovation, and slow advancements in biotechnology." *Id.*

A similar study by The University of Chicago predicted an even more severe effect on the creation of new drugs. The Chicago study relied on earlier academic literature to conclude that, on average, "a one percent reduction in revenue leads to a 1.5 percent reduction in R&D activity." Tomas J. Philipson & Troy Durie, *Issue Brief: The Impact of HR 5376 on Biopharmaceutical Innovation and Patient Health,* (November 29, 2021). The study's authors found that the IRA would reduce revenues by 12.0 percent through 2039, resulting in an 18.5 percent decrease in R&D spending, amounting to $663 billion. *Id.* This reduction in investment, in turn, would lead to 135 fewer new drugs in the next two decades. *Id.* The academic literature thus predicts an impact on new drugs that is 27 times the amount number of lost drugs anticipated by the CBO. *Id.* The authors predict that this loss in new treatments will "generate a loss of 331.5 million life years in the United States." *Id.* Putting that loss of life in context, the loss of life years lost in the United States from COVID-19 to the date of the study in November 2021, was 10.7 million life years. *Id.*

These predictions are consistent with earlier economic literature on the effect of price controls on drug innovation. For example, in 2005, scholars at the University of Connecticut using industry data from 1952 through 2001 concluded that "drug prices are expected to influence R&D spending directly because of both derived-demand and cash-flow effects." Carmelo Giaccotto, Rexford E. Santerre, & John A. Vernon, *Drug Prices and Research and Development Investment Behavior in the Pharmaceutical Industry*, 48 J.L. & Econ. 195, 212 (2005). The authors' multiple-regression findings suggested that if the federal government "had limited drug price increases to the same rate of growth as the general CPI during the period 1980-2001" the "capitalized value of pharmaceutical R&D spending would have been about 30 percent lower" than it was during that period. *Id.* Put in real terms, the authors estimated that "this drug price control would have resulted in 330–65 fewer new drugs being brought to market during that same time period." *Id.* In stark terms, the hypothetical price controls that the authors posited, and which have become real for certain drugs, would have reduced the creation of new drugs by over a third:

> Using the average of 43 new drugs per year, our simulations suggest that roughly 38 percent of all new drugs would have been lost in the global economy if the U.S. government had implemented the assumed price control regime in 1980.

Id.

Further, because it often takes a decade of research development to bring a new drug to market, like a disease with a long latency period that does not manifest for years, the symptoms of lost R&D will not become apparent until they are irreversible. Indeed, current reductions in venture capital to pharmaceutical companies indicate that the pullback, which will be felt years from now, has already begun. For example, the CSIS study noted that "[s]hortly after implementing the IRA's price controls, pharmaceutical companies began announcing reductions in R& D efforts, with research into rare disorders and cancer treatments. Crane, *supra.* A white paper from the University of Southern California's Shaeffer Center for Health Policy & Economics reports that this pullback in R&D spending is already occurring:

> For example, Alnylam mentioned in its October 2022 earnings report that it had suspended development of a treatment for Stargardt disease as a result of needing to "evaluate the impact of the Inflation Reduction Act." In November 2022, Eli Lilly claimed that the IRA was a key reason it ended investments toward developing a drug for certain blood cancers. A November–December 2022 survey from the Pharmaceutical Research and Manufacturers of America indicated that 78% of its member companies are expecting to cancel some of their early-state development projects, and 63% are expecting to shift R&D investment focus away from small molecules as a result of the IRA.

Dana Goldman et al., *Mitigating the Inflation Reduction Act's Adverse Impacts on* *the Prescription Drug Market*, USC Schaeffer (April 13, 2023), https://healthpolicy.usc.edu/research/mitigating-the-inflation-reduction-acts-potential-adverse-impacts-on-the-prescription-drug-market (internal citations omitted). Like the "free lunch," the cost of these reductions will not be immediately noticeable to most Americans, but they will likely be felt in the decades to come.

Yet while the free lunch fallacy at least offers the promise of some immediate benefit for some yet-to-be-realized cost, the immediate benefit of the IRA to Medicare recipients or other Americans is not immediately clear. The CBO has projected that while the IRA's drug negotiation provision will reduce the cost of Medicare and achieve an overall reduction of the federal deficit, it would likely increase the cost of Medicaid and provide no immediate benefits to taxpayers. Medicaid already pays decreased costs for pharmaceuticals, but changes in that rebate structure under the IRA will increase Medicaid spending by $15.7 billion over a ten-year period. Elizabeth Williams, *Medicaid and the Inflation Reduction Act of 2022*, KFF (Sept. 22, 2022), https://www.kff.org/policy-watch/medicaid-and-the-inflation-reduction-act-of-2022/. Again, the TANSTAAFL imperative is at work. If drug companies are forced to give deep discounts to one customer, they will make up for them elsewhere.

II. History Shows that Price Controls Do Not Reduce Inflation in the Long Run

The political impulse to use price controls to mitigate inflation is understandable. If prices are rising too quickly, simply decreeing that they rise no more seems an obvious solution. But politicians can no more repeal the law of supply and demand than they can repeal the law of gravity. They can, at best, temporarily shift the effects of the law, but history shows that the bill for the free lunch eventually comes due.

In August of 1971, President Richard Nixon announced a 90-day freeze on all prices and wages in the United States. William Walker, writing in the Wall Street Journal described Nixon's price freezes and subsequent plan for a "Pay Board" and a "Price Commission" as "a watershed moment—a radical program that imposed direct government control over the economy aimed at breaking the cycle of inflationary price and wage hikes." William Walker, *Nixon Taught Us How Not to Fight Inflation*, The Wall Street Journal (Aug. 13, 2021), https://www.wsj.com/articles/nixon-fight-inflation-price-controls-stagflation-gas-shortages-biden-democrats-reconciliation-bill-federal-reserve-11628885071. At the time, economist Milton Friedman warned that the program would end "in utter failure and the emergence into the open of the suppressed inflation." Milton Friedman, *Perspective on Inflation*, Newsweek, June 24, 1974, at 73, *reprinted in* Robert Leeson and Charles G. Palm, The Collected Works of Milton Friedman (2017), https://miltonfriedman.hoover.org/internal/media/dispatcher/214130/full.

Friedman was right. The result was a tightening of supply and a decrease in productivity. Producers lacked an incentive to engage in economic transactions. "Ranchers stopped shipping their cattle to the market, farmers drowned their chickens, and consumers emptied the shelves of supermarkets." Daniel Yergin & Joseph Stanislaw, *The Commanding Heights: The Battle for the World Economy* (1998). Rather than curing inflation, the program "ushered in nearly a decade of so-called stagflation—high inflation coupled with slow growth, which reduced living standard for millions of Americans." Walker, *supra.*

Other economists evaluating the Nixon price controls (coupled paradoxically with the devaluation of the dollar) five decades later describe them as "a poisonous policy stew [ ] doomed to fail horribly." Alan Reynolds, *Nixonomics in Retrospect: Devaluation and Wage-Price Controls, August 15, 1971*, Am. Inst. for Econ. Rsch. (August 18, 2021), https://www.aier.org/article/nixonomics-in-retrospect-devaluation-and-wage-price-controls-august-15-1971/. According to Reynolds, Nixon's efforts failed for the commonsense reason that "[a]rtificially low prices boost demand and discourage supply, resulting in apparent shortages of everything but money." *Id.*; *see also* David R. Henderson, *Price Controls: Still a Bad Idea*, The Hoover Inst. (January 20, 2022), https://www.hoover.org/research/price-controls-still-bad-idea (noting Nixon price controls' effect on gas prices).

Nixon's experiment with price controls, which ended in 1974, was hardly the first time that leaders—like King Canute ordering the tide to recede—sought to repeal the economic law of supply and demand. In their 1979 book *Forty Centuries of Wage and Price Controls: How Not to Fight Inflation*, economists Robert Schuettinger and Eamonn F. Butler, relate the history of government attempts to cure inflation by fiat from Ancient Egypt to the Carter administration. They note, for example, that the Code of Hammurabi contained price and wage restrictions. Historians have recorded a Babylonian recession coming quick on the heels of these laws and the decrease in market participants:

> Prominent and wealthy tmukaru (merchants) were no longer found in Hammurabi's reign. Moreover, only a few tmnkaru are known from Hammurabi's time and afterwards . . . all . . . evidently minor tradesmen and money-lenders.
>
> In other words, it appears that the very people who were supposed to benefit from the Hammurabi wage and price restrictions were driven out of the market by those and other statutes.

Robert Schuettinger & Eamonn F. Butler, *Forty Centuries of Wage and Price Controls: How Not to Fight Inflation* 12 (1979) (citing Irving S. Olds, *The Price of Price Controls* 4 (1952)).

Similarly, in A.D. 301, Emperor Diocletian, struggling with runaway inflation caused largely by the excess coining of new money, announced a comprehensive edict fixing prices on goods such as beef, grain, eggs, and clothing. Those selling in excess of the prescribed prices were subject to the death penalty. *Id*. at 23. Ancient contemporaries recorded the predictable results:

> There was much blood shed upon very slight and trifling accounts; and the people brought provisions no more to markets, since they could not get a reasonable price for them and this increased the dearth so much, that at last after many had died by it, the law itself was set aside.

Id. at 24 (citing L.C.F. Lactantius, *A Relation of the Death of the Primitive Persecutors* 67–68 (Amsterdam, 1697), translated by Gilbert Burnet).[3]

For all of their knowledge of the classical world, our founding generation fell victim to the same fallacy that plagued Diocletian. During the winter of 1777, while Washington's troops were quartered at Valley Forge, "[t]he legislature of [Pennsylvania] decided to try a period of price control limited to those commodities needed for use by the army" under the theory that "this policy would reduce the expense of supplying the army and lighten the burden of the war upon the population." *Id.* at 41. The result was that "[t]he prices of uncontrolled goods, mostly imported, rose to record heights" and "[m]ost farmers kept back their produce, refusing to sell at what they regarded as an unfair price." *Id.*

The following year, the Continental Congress recognized the error of this policy and resolved:

> Whereas . . . it hath been found by experience that limitations upon the prices of commodities are not only ineffectual for the purposes proposed, but likewise productive of very evil consequences to the great detriment of the

[3] Incidentally, Diocletian, like Nixon, resigned.

> public service and grievous oppression of individuals . . . resolved, that it be recommended to the several states to repeal or suspend all laws or resolution within the said states respectively limiting, regulating or restraining the Price of any Article, Manufacture or Commodity.

Id. (citing 21 *Journal of the Continental Congress* 569 (New York, 1908)).

The Federal Reserve Bank of St. Louis recently summed up the economic consensus regarding price controls as a remedy for current inflation, writing, "[e]conomists generally oppose most price controls, believing that they produce costly shortages and gluts" and that "[m]ost economists do not believe that 1970s-style price controls could successfully limit U.S. inflation over a 12-month horizon, and many of those economists cite high costs of controls." Christopher J. Neely, *Why Price Controls Should Stay in the History Books*, Federal Reserve Bank of St. Louis (Mar. 24, 2022), https://www.stlouisfed.org/publications/regional-economist/2022/mar/why-price-controls-should-stay-history-books. The St. Louis Fed concludes, "[p]rice controls have a long but no very successful history. Although economists accept that there are certain limited circumstances in which price controls can improve outcomes, economic theory and analysis of history show that broad price controls would be costly and of limited effectiveness." *Id.*

CONCLUSION

As Justice Holmes observed, "[e]xperience is the lifeblood of the law." Oliver Wendell Holmes, *The Common Law* 1 (1881). In evaluating this case, the Court should consider how—far from providing the proverbial free lunch—the IRA's price controls on certain drugs may stifle innovation and fail to reduce the inflation they were enacted to remedy. For the foregoing reasons, the Court should reverse the district court's decision.

Respectfully submitted,

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July 19, 2024

CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing Amicus Brief was served on all counsel of record via the Court's electronic filing system this 19th day of July 2024.

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