24-2092

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.
Plaintiff-Appellant,

v.

XAVIER BECERRA, U.S. Secretary of Health & Human Services et al.
Defendants-Appellees

On Appeal from the United States District Court
for the District of Connecticut (23-cv-01103), Hon. Michael P. Shea

BRIEF OF *AMICI CURIAE* THE AMERICAN PUBLIC HEALTH ASSOCIATION, THE AMERICAN COLLEGE OF PHYSICIANS, THE SOCIETY OF GENERAL INTERNAL MEDICINE, THE AMERICAN GERIATRICS SOCIETY, AND THE AMERICAN SOCIETY OF HEMATOLOGY IN SUPPORT OF APPELLEES

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INTRODUCTION AND SUMMARY OF ARGUMENT

due to cost."[3] Starting in 2006, older adults and people with certain disabilities could enroll in plans run by private companies that contracted with Medicare. These plans generally require that enrollees pay a premium, occasionally a deductible, and, for prescriptions, co-insurance or a co-payment. Part D benefits have allowed older adults, especially low-income people, to access critical care: "annual out-of-pocket drug costs dropped an average of 49% among those who previously did not have drug coverage."[4] In 2022, 49 million of the 65 million people covered by Medicare were enrolled in Part D plans.[5]

The federal government now accounts for roughly 45% of nationwide drug spending, principally through Medicare and Medicaid. Despite its key role in the

medications. In response to these exponential increases in drug prices, and the attendant concerns for public health, Congress enacted the Program, which gives the Centers for Medicare & Medicaid Services (CMS) authority to directly negotiate with manufacturers of some of the costliest drugs on the market. In so doing, Congress brought the United States' system closer to Germany's, BI's comparator

ARGUMENT

Medicare Part D, which has allowed beneficiaries to afford lifesaving medications and avoid even more expensive hospital visits, has become a vital part of the social safety net and improved older Americans' health outcomes.[6] Unfortunately, those advances are at risk from the never-ending increase in prescription drug prices.

Prescription drug costs have increased at rates far above inflation in recent years,

to Medicare for top-selling name-brand drugs more than doubled again between 2018 and 2021.[9] Even if one considers only the drugs selected for negotiation under the Program, it is clear that their prices have increased far above inflation.[10]

Boehringer Ingelheim's Jardiance, a diabetes and heart failure drug, illustrates this problem. The cumulative rate of retail inflation between 2014 (when Jardiance was approved by the FDA) and the present is approximately 35%, but Jardiance's price went up 97%.[11] It cost Jardiance's developers $2.2 billion dollars to bring it to FDA approval and an additional $1.6 billion to identify additional indications and modes of delivery.[12] Gross Medicare costs for Jardiance from June 2022 to May

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[9] Juliette Cubanski & Tricia Neuman, A Small Number of Drugs Account for a Large Share of Medicare Part D Spending, KFF (July 12, 2023), https://tinyurl.com/ycytf6wm.

[10] See Leigh Purvis, Prices for Top Medicare Part D Drugs Have More Than Tripled Since Entering the Market, AARP Pub. Pol'y Inst. 1 (Aug. 10, 2023), https://tinyurl.com/44by3wpz.

[11] CPI Inflation Calculator, U.S. Bureau Lab. & Stat., https://tinyurl.com/4xdtjs4j; @AARP, Twitter (Sept. 8, 2023, 5:56pm), https://tinyurl.com/3m64hu2x.

[12] ATI Advisory, The First 10 Drugs to be Negotiated by Medicare (Aug. 30, 2023), https://tinyurl.com/294sj44f.

points by summer 2023.[16] And more than a third of older Americans had medical debt recently,[17] a quarter of which is related to their prescriptions.[18]

medication unaffordable, and 2.3 million of them did not take needed prescriptions due to cost.[21] "Black and Latino beneficiaries were 1.5 to 2 times as likely to experience medication-related affordability challenges as White beneficiaries in this age range," showing persistent disparities in US healthcare.[22] These figures would likely be higher still, except that some older people—

and/or extremely costly to treat.[24] Collectively, that leads to greater use of inpatient and emergency medical services by those patients.[25] Indeed, the initiation of Medicare Part D—which reduced CRNA—was itself associated with a drop in hospitalization rates for several conditions.[26] Some analysts have estimated that "high out-of-pocket costs for drugs will cause 1.1 million premature deaths of seniors in the Medicare program and will lead to an additional $177.4 billion in avoidable Medicare medical costs" between 2021 and 2031.[27]

Older adults in other countries do not struggle so mightily. CRNA in the United States is two to four times higher than in other developed countries.[28] And, "[c]ontrolling for age, sex, health status and household income, adults aged 55 and older in the US were approximately six times more likely to report CRNA than adults

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[24] Id. at 5.

[25] Goldman et al., supra note 19, at 65.

[26] Aaron S. Kesselheim et al., Prescription Drug Insurance Coverage and Patient Health Outcomes: A Systematic Review, Am. J. Pub. Health, Feb. 2015, at 19, https://tinyurl.com/3ts9cew5.

[27] High Drug Prices and Patient Costs: Millions of Lives and Billions of Dollars Lost, Council for Informed Drug Spending Analysis (Nov. 18, 2020), https://tinyurl.com/yc4tm4vv.

[28] Steven Morgan & Augustine Lee, Cost-Related Non-Adherence to Prescribed Medicines Among Older Adults: A Cross-Sectional Analysis of a Survey in 11 Developed Countries, BMJ Open, Jan. 2017, at 4, https://tinyurl.com/2u8tfn8e.

to be able to afford gas to the appointment, he had reduced how often he took his medication so it would last longer."

- A doctor in North Carolina: "Last week I was talking to an octogenarian

drug prices, but this approach at least allows the government to leverage its purchasing power to reduce Medicare program costs—as any market participant

The United States is one of only two developed countries that allows the drug industry to set its own drug prices independent of government authority.[37] Drug prices in the US are between 2 and 2.5 times higher than in other comparable countries and Medicare's inability to negotiate drug prices, as compared to the ability of other public health systems, is a key reason for higher prices.[38] For example, a government-mandated health insurance association in Germany, BI's corporate home, collectively negotiates drug prices with manufacturers and links prices to drug effectiveness, leading to substantially lower prices

of negotiated drug prices or exit the German market.[40] Drug price negotiation has not caused the sky to fall for German patients. Notably, negotiated drug prices under the IRA price negotiation program remain higher than equivalent prices in Germany.[41] The negotiated price for Jardiance is over four times the average price charged in equivalent countries, and more than twice the price charged in Germany.[42]

Even if prices in the US stay higher than in comparable countries after negotiations, lowered prices under the Program will have substantial benefits for Medicare beneficiaries. KFF has estimated that many older Americans would save over 60% of their out-of-pocket costs under the new standards set by the IRA.[43] Amici who have supported drug companies in companion cases, like the Alliance for Aging Research, misunderstand how Medicare beneficiaries receive care when they

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[40] Id.

[41] Delaney Tevis, How Medicare Negotiated Drug Prices Compare to Other Countries, Peterson-KFF Health Sys. Tracker (Dec. 19, 2024), https://tinyurl.com/5n8hfbm5.

[42] Id.

[43] Juliette Cubanski et al., Explaining the Prescription Drug Provisions in the Inflation Reduction Act, KFF (Jan. 24, 2023), https://tinyurl.com/3adurnbk. Other estimates put the savings at 30% of out-of-pocket costs. CMS Releases 2025 Medicare Part D Bid Information and Announces Premium Stabilization Demonstration, Ctrs. for Medicare & Medicaid Servs. (July 29, 2024), https://tinyurl.com/2mwuzbcc.

manufacturers of generic medicines to keep generic alternatives off the market.[56] These schemes lead to higher costs for consumers and insurers, and higher profits for branded and generic manufacturers, without therapeutic improvements.[57] Following a legal crackdown on Pay for Delay schemes, drug research output increased, especially for more innovative drugs, even when these higher profits were reduced.[58] Indeed, although drug companies and their supportive amici make much of the harm their reduced market exclusivity would cause to innovation, research suggests precisely the opposite: when market exclusivity is reduced, "firms pursue higher-quality innovation."[59]

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[56] See Fed. Trade Comm'n, Pay-for-Delay: When Drug Companies Agree Not to Compete, https://tinyurl.com/9u24eu2k (last visited Sept. 10, 2024).

[57] Notably, generic manufacturer Teva Pharmaceuticals, an amicus in support of drug companies that argues drug price negotiation will hurt the generics industry, has been investigated and fined for colluding with other manufacturers to maintain high prices. See, e.g., Press Release, Fed. Trade Comm'n, FTC Settlement of Cephalon Pay for Delay Case Ensures $1.2 Billion Returned to Consumers (May 28, 2015), https://tinyurl.com/3mucnzfz (regarding Pay for Delay); Press Release, Dep't of Just., Major Generic Drug Companies to Pay Over Quarter of a Billion Dollars (Aug. 21, 2023), https://tinyurl.com/5fe9dkjc (regarding price fixing for a cholesterol drug).

[58] Xuelin Li et al., Paying Off the Competition: Contracting, Market Power, and Innovation Incentives 3 (Nat'l Bureau Econ. Rsch., Working Paper No. 28964, 2024), https://tinyurl.com/2xp7t7sz.

[59] Id. at 4 (emphasis in original).

Even if R&D funding intensity by the biggest drug companies does decline, the evidence still does not suggest that fewer drugs will ultimately be approved by the FDA.[60] Drug development costs vary widely between firms, and "firms rarely disclose verifiable information about the expenses related to individual drug candidates," as they are now required to do to CMS.[61] Much cutting-edge research is done by small pharmaceutical companies rather than major players, which means that blanket claims that lower drug prices necessarily lead to fewer marketable drugs should be viewed with skepticism.

Drug manufacturer

lead to innovative drug development resulting in measurable increases in patient health outcomes.[62] Between 1988 and 2005, federal research funding contributed to 45% of all drugs approved by the FDA and to 65% of drugs that received priority review.[63] From 2010 through 2019, every one of the 356 new drugs approved by the FDA was the result of research funded by the National Institutes of Health (NIH).[64] Major innovative drugs have been discovered in public universities funded through grants from the NIH.[65]

In fact, government funding supported research led to most of the drugs currently subject to negotiation.[66] Insulin is a great example of this kind of process. It was developed in a non-commercial laboratory in the early 20th century and its

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[62] See Kerstin N. Vokinger et al., Therapeutic Value of First Versus Supplemental Indications of Drugs in US and Europe (2010-20): Retrospective Cohort Study, BMJ Open, July 2023, https://tinyurl.com/5xfs593m (using French data on effectiveness, as collection of US data on effectiveness is inconsistent).

[63] Daniel, supra note 37, at 60.

[64] Joel Lexchin, Therapeutic Benefit from New Drugs from Pharmaceutical Companies, 184 JAMA Internal Med. 52 (2023).

[65] Ensuring Equitable Access, supra note 2, at 2. Between 6 and 10% of "new molecular entities" (new innovative drugs) were first patented by public sector or academic institutions and up to 40% of new molecular entities were first

patent was sold to the University of Toronto for $3, which in turn allowed manufacturers to license it royalty-free.[67] Despite being the product of public and academic research a century ago, insulin prices have skyrocketed in recent years. Amongst the most expensive of these insulin-based treatments are Fiasp and Novolog, which accounted for $2.6 billion in total Medicare Part D spending between June 2022 and May 2023, despite being built on a base of publicly supported research.[68] Similarly, the active compound in Jardiance, empagliflozin, has been studied by university-affiliated scientists and foundational research was sponsored by the NIH.[69]

When so much funding for research comes from public programs—a fact drug companies and their supporting amici ignore—there is little reason to believe

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[67] Hilary Daniel et al., Policy Recommendations to Promote Prescription Drug

reduction in prices charged by big pharma companies will result in substantially reduced effective innovation. Instead, the Program will spare U.S. taxpayers from paying exorbitant prices through government health programs for pharmaceutical

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of so-called ‘me-too’ drugs.[72] And recent studies suggest that more than 60% of R&D spending is post-approval research into additional indications for approved drugs, rather than into new drugs.[73] These additional indications—which drug companies claim are uniquely at risk under the Program—have on average substantially lower therapeutic value than new drugs.[74]

The current market thus has limited incentives for breakthrough research. Indeed, some research has shown a progressive decrease in industry commitment and investment in basic research and development over the last several decades.[75] Even if it were to lead to less research funds for ‘me-too’ drugs, since CMS now requires manufacturers to provide data on therapeutic value during the negotiation

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[72] *See* Lexchin, *supra* note 64;

process, the Program may divert funding towards more innovative drug development through value-based pricing.[76]

Amici are unaware of any peer-reviewed or rigorous independent research undergirding claims, like those in the Alliance for Aging Research *amicus* brief, that the Program will lead to dozens of fewer drugs or hundreds of millions of life years lost in the US.[77] Many briefs criticizing the drug price negotiation program cite, directly or indirectly, a series of seemingly independent studies by a single lead researcher, Professor Tomas Philipson at the University of Chicago.[78] Yet, much of

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[76] Rachel Sachs et al., *A Holistic View of Innovation Incentives and Pharmaceutical Policy Reform*, Health Affs. Scholar, July 2023, at 2, https://tinyurl.com/36hamdfr.

[77] *See* Alliance Br. at 14.

[78] *See, e.g.*, Alliance Br. at 14. Other briefs that cite Professor Philipson include those by Daniel E. Troy, ECF No. 119-1 at 12, and the Pioneer Public Interest Law Center, ECF No. 81-1 at 5-7 (citing a news article discussing Professor Philipson's work). These briefs and the one from Teva Pharmaceuticals, ECF No. 64 at 11, 16, occasionally cite to a study from USC's Shaeffer Institute: Dana Goldman et al., *Mitigating the Inflation Reduction Act's Adverse Impacts on the Prescription Drug Market*, USC Shaeffer Ctr. for Health Pol'y & Econ. (Apr. 13, 2023), https://tinyurl.com/msefpyfj, and one from the Center for Strategic and International Studies: Baily Crane, *The Effect of Reference Pricing on Pharmaceutical Innovation*, Ctr. for Strategic & Int'l Studs. (July 12, 2023), https://tinyurl.com/ym6ty78n. Those studies themselves rely on Professor Philipson's work for the impact of the IRA on drugs and life years lost.

this research was funded by industry and none appears to be peer-

pharmaceutical companies and their allies as independent academic analyses without disclosing that funding.

There is little reason to credit Plaintiff's claim that the Program will cause the sky to fall. The federal government can use its purchasing power, like other market participants, to command a better price for the goods it purchases without threatening pharmaceutical innovation. In turn, those reduced prices may bolster public and individual health outcomes and help maintain the viability of the public health safety net for older Americans.

CONCLUSION

For the foregoing reasons, Public Health amici respectfully request that the Court affirm the District Court in this case.

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Respectfully submitted,

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