Docket No. 24-2510

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

NOVO NORDISK INC.; NOVO NORDISK PHARMA, INC.
Plaintiffs-Appellants,

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 New Jersey (3:23-cv-20814), Hon. Zahid N. Quraishi

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BRIEF OF 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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STATEMENT OF INTEREST OF [1]

Amici 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 (the "Public Health *amici*") are some of the world's largest public health organizations, representing hundreds of thousands of doctors (and other clinicians), public health officials, and health professional trainees (including medical students) who have managed care for millions of Americans. They have been active for decades in tracking the effects of high prescription drug prices on public health and patient outcomes. They explain below why the Inflation Reduction Act (IRA) Drug Price Negotiation Program (the "Program") is vital to maintaining and strengthening patient care and the Medicare program. *Amici* also explain why assertions by Plaintiffs-Appellants Novo Nordisk Inc. and Novo Nordisk Pharma, Inc. ("Novo Nordisk" or "Plaintiff") regarding the negative effects of the Program are

due to cost."[3]

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 (

drugs that account for billions of dollars in revenue to their manufacturers. From 2009-2018, the average price of these brand-name drugs "more than doubled in the Medicare Part D program and increased by 50 percent in Medicaid."[9] And the cost to Medicare for top-selling name-brand drugs more than doubled again between 2018 and 2021.[10] Even if one considers only the drugs selected for negotiation under the Program, it is clear that their prices have increased far above inflation.[11]

Novo Nordisk's Novolog and Fiasp illustrate this issue. Since Novolog was first approved in 2000, its price has increased a shocking 628%; cumulative retail

eight times more in the US than it did in peer countries.[13] In Denmark, similar products cost roughly 12% of US prices.[14]

B. AMERICANS, ESPECIALLY OLDER ADULTS, CANNOT SUSTAIN THESE PRICES.

Although most high-priced medication costs are borne by American taxpayers through Medicare, a significant portion is also borne directly by older Americans and individuals with disabilities, whose cost-sharing can include burdensome monthly premiums and other costs, which are unaffordable for some.[15] In 2022, 20% of all older Americans reported having difficulty affording their prescription drugs, even with Medicare Part D.[16] That figure had increased by 5 percentage

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[13] Evan D. Gumas et al., *How Prices for the First 10 Drugs Up for U.S. Medicare Price Negotiations Compare Internationally*, Commonwealth Fund, at ex. 3 (Jan. 4, 2024), http://tinyurl.com/u2cszvub.

[14] *Compare* Danish Meds. Agency, *Medicinpricer.dk* (last visited Dec. 13, 2024), http://tinyurl.com/ysxexw7w (under "Extended search," search with "insulin aspart" in "Active substance" and "novo" in "Company") (per unit price for NovoMix FlexPen is roughly €4.50, or $5) *with* Gumas et al., *supra* note 13, at ex. 2 ($39.72/unit for Novolog FlexPen in 2021).

[15] *See An Overview of the Medicare Part D Prescription Drug Benefit*, *supra* note 5. For the standard framework for Medicare Part D plans after the Inflation Reduction Act, *see Part D Payment System*, MedPAC, https://tinyurl.com/37c87543 (last revised Oct. 2022).

[16] Alex Montero et al., *Americans' Challenges with Health Care Costs*, KFF (July 14, 2022), https://tinyurl.com/yck7juez.

points by summer 2023.[17] And more than a third of older Americans had medical debt recently,[18] a quarter of which is related to their prescriptions.[19]

The most predictable and poignant effect of American's expensive prescription drug delivery system is cost-related nonadherence ("CRNA") to medications, where patients stop taking prescription drugs because of rising prices, even when those drugs are essential to their health.[20] In 2022, roughly a quarter of adults reported that they or someone in their family had "not filled a prescription, cut pills in half, or skipped doses of medicine in the last year because of the cost."[21]

Although Americans covered by Medicare are insulated from some of the challenges faced by uninsured Americans under 65, they are not immune. A recent analysis by the Office of Health Policy using the National Health Interview Survey reported that 6.6% of all adults over 65 (a total of 3.5 million people) found

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[17] Ashley Kirzinger et al., *Public Opinion on Prescription Drugs and Their Prices*, KFF (Aug. 21, 2023), https://tinyurl.com/hun2y8bn.

[18] Noam N. Levey,

older in the USA were approximately six times more likely to report CRNA than

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 patient on a fixed income. . . . She admitted she had started 'stretching' her supply [of Eliquis], skipping a few days each month, to make her supply last longer, and wanted my advice on how many days per month she could skip without putting herself at serious risk for a stroke. I had to tell her I wasn't really sure, and discouraged her from doing this, but I also tried to counsel her realistically, knowing that she might continue doing this and [should] at least [be] spacing out her skipped days."
- A doctor in Delaware: "Patients consistently resist trying to get us to change them from Lisinopril to Entresto despite what the data shows when it comes to readmissions and quality of life. It is the same issue with Jardiance. If we convince them, it often means they are giving up something else in their life given many are on a limited income."

II. THE PROGRAM IS A VITAL FIRST STEP IN ENSURING OLDER AMERICANS CAN AFFORD THEIR MEDICATION.

The Program is a measured attempt to bolster public health and ensure care for all of us as we age, by permitting the federal government to negotiate prices for the drugs it covers. *Amici* are under no illusions that negotiation alone will rein in

drug prices, but this approach at least allows the government to leverage its purchasing power to reduce Medicare program costs—as any market participant would—while also allowing plan sponsors (insurance companies) to maintain the power to negotiate for most drugs covered by Part D. Moreover, the government routinely negotiates prices on goods it purchases from private companies—including for products for which it is the sole or primary purchaser, such as defense equipment[31]—and it already

analyzed, the VHA paid less than half the price per unit Medicare paid; for 106 drugs, the VHA paid less than 25% of what Medicare paid.[33]

Similarly, the Department of Defense (DoD) uniform drug formulary, which

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] Indeed, Denmark, Novo Nordisk's corporate home, negotiates drug prices, lists them publicly, and is collaborating with other Nordic countries to negotiate drug prices collectively, to increase "price pressure" by leveraging a larger market share.[39] Drug price negotiation has not caused the sky to fall for Danish patients.

Lower prices under the Program will

of their out-of-

does not apply to new drugs and continues to grant drug companies almost unfettered discretion to price these drugs at exorbitant rates. Indeed, the limited scope of the Program—affecting a handful of drugs from the biggest companies in the world—means that it does not interfere with the sites of greatest innovation: novel interventions from government-funded academic research and small pharmaceutical companies. Plaintiff and *amici* supporting drug companies speculate that lower prices will trigger lost profits, drug shortages, and reduced drug research funding, with consequent adverse public health outcomes. But they cannot substantiate their dire predictions with credible evidence.

drug prices, an association between the 2 variables would be found," but it was not.[47]

For one thing, we now

R&D.[52] Drug companies would likely be able to offset reduced revenue from lower prices by reducing non-R&D spending like advertising and shareholder payouts.

Further, a large part of drug cost increases is not driven by innovative R&D but by the manipulation of patents and other anticompetitive activities by large drug companies to protect their market dominance. For example, under so-called

reduced.[55] Indeed, although drug companies and their supportive *amici* make much of the harm their reduced market exclusivity would cause to

(NIH).[61] Major innovative drugs have been discovered in public universities funded through grants from the NIH.[62]

In fact, government funding supported research led to most of the drugs currently subject to negotiation.[63] Insulin is illustrative. It was developed in a non-commercial laboratory in the early 20th century and its patent was sold to the University of Toronto for $3, which in turn allowed manufacturers to license it royalty-free.[64] Novo Nordisk used that free license to start producing insulin in 1923, and now controls 52% of the global market for insulin by volume, and 41% of market share by revenue.[65] Its insulin aspart products—Fiasp and Novolog—

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

[62] *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 synthesized or purified in academic institutions. *See* Ekaterina Galkina Cleary et al., *Contribution of NIH Funding to New Drug Approvals 2010–2016*, Proc. Nat'l Acad. Scis., Mar. 2018, at 2332.

[63] *See* Tarazi et al., *supra* note 22, at 1.

[64] Hilary Daniel et al., *Policy Recommendations to Promote Prescription Drug Competition: A Position Paper from the American College of Physicians,* Annals Internal Med., Sept. 2020, at 1006, https://tinyurl.com/y56byn7y.

[65] *See* Ryan Knox,

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.

benefit of new and expensive treatments over longstanding alternatives. Privately funded drug R&D often focuses on differentiating similar drugs, instead of higher risk research into new scientific paradigms that could reduce morbidity and mortality.[68] Simply put, the majority of new drugs approved provide little additional clinical value compared to already approved alternatives, leading to the proliferation of so-called 'me-too' drugs.[69] 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.[70] These additional indications—which drug companies like Novo Nordisk claim are uniquely at risk under the Program, *see* ECF No. 18, at 30-31—have on average substantially lower therapeutic value than new drugs.[71]

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.[72] 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 process, the Program may divert funding towards more innovative drug development through value-based pricing.[73]

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.[74] 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.[75] Yet, much of

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[72] *See* Ashish Arora et al., *Killing the Golden Goose? The Decline of Science in Corporate R&D* (Nat'l Bureau Econ. Rsch., Working Paper No.( )l.3 (ch)no(n)8]3zehep lling 51

this research was funded by industry and none appears to be peer-reviewed.[76] Indeed, Professor Philipson's IRA-specific papers are often not even new research, but rather rely on his own earlier non-peer reviewed studies or drug company statements. This fits a pattern of pharma-friendly briefs in these cases relying on industry or industry-hired consultants' statements to come up with the number of

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(*Bristol Myers Squibb v. Becerra* (24-1820), ECF No. 62, at 6) (citing a news article discussing Professor Philipson's work). These briefs and the one from Teva Pharmaceuticals (*Bristol Myers Squibb v. Becerra* (24-1820), ECF No. 69, 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 Stud. (July 12, 2023), https://tinyurl.c -0c /j

CONCLUSION

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

Dated: December 17, 2024

Respectfully submitted,

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CERTIFICATES OF COMPLIANCE

1. In accordance with Third Circuit Rules 28.3(d) and 46.1(e), I certify that I am a member in good standing of the bar of the United States Court of Appeals for the Third Circuit.

2. In accordance with Third Circuit Rule 31.1(c), I certify that the texts of the

CERTIFICATE OF SERVICE

I hereby certify that the foregoing brief was filed with the Clerk of the Court for the United States Court of Appeals for the Third Circuit through the appellate CM/ECF system on December 17, 2024, which will serve a notice of electronic filing to all registered counsel of record. I also certify that ten paper copies of the foregoing brief will be sent to the Clerk's Office via overnight delivery.

Dated: December 17, 2024

/s/ *Ananda V. Burra*
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