

# Why Medicare Needs the Power to Negotiate for Lower Drug Costs: Outrageous Prices, Greed, and Patent Exploitation

A Detailed Look At 5 Drugs That Tell The Story

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PROTECT OUR CARE

## REPORT: Why Medicare Needs the Power to Negotiate for Lower Drug Costs: Outrageous Prices, Greed, and Patent Exploitation

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The Inflation Reduction Act, passed by the Biden-Harris administration and Congressional Democrats over unanimous Republican opposition, saves lives, lowers prescription drug costs for seniors, and puts thousands of dollars per year back into Americans' pockets — the greatest health care achievement since the passage of the Affordable Care Act.

The law is already lowering costs for seniors by capping insulin costs at \$35 per month, making vaccinations available without cost sharing, and penalizing pharmaceutical companies for raising drug prices faster than inflation. In 2025, seniors' out-of-pocket costs will be capped at \$2,000 per year. These measures that make prescription drugs more affordable for Medicare beneficiaries are financed in part by savings from a new program to allow Medicare to negotiate with big pharma for lower prescription drug prices.

In enacting the new prescription drug law, Democrats won a decades-long battle against Big Pharma to finally allow Medicare to negotiate lower prescription drug prices. This progress is particularly important for seniors of color and people with disabilities, who experience health disparities in part because they have more <u>limited access</u> to affordable drugs. Seniors who are <u>more likely to live in rural areas</u> and LGBTQI+ seniors who experience <u>greater levels of poverty and worse health outcomes</u> will also benefit from this law.

By early July 2023, the Centers for Medicare & Medicaid Services (CMS) will publish final guidance - the rules of the road - for negotiating lower drug prices. By September 1, 2023, they will select the first ten negotiation-eligible Part D drugs. Those negotiations will culminate in the publication of maximum fair prices for those drugs on September 1, 2024, and those prices will take effect in 2026.

The Inflation Reduction Act specifies that drugs eligible for negotiation must have high Medicare expenditures and be single-source drugs without generic or biosimilar competition. Multiple researchers and analysts have attempted to predict which drugs are most likely to be among the first ten drugs eligible for negotiation using currently

competition. <u>Multiple researchers</u> and <u>analysts</u> have attempted to predict which drugs are most likely to be among the first ten drugs eligible for negotiation using currently available data. (Drugs will be selected based on Medicare expenditures between June 1, 2022, and May 31, 2023, data that is not currently publicly available.) Based on currently available 2021 Medicare spending data and publicly available information about anticipated generic and biosimilar competition, Protect Our Care is profiling the following five drugs for this report, which we believe are likely to meet the criteria for negotiation: AbbVie's Imbruvica, Amgen's Enbrel, Johnson & Johnson's Xarelto, Merck's Januvia, and Pfizer's Ibrance.

Together, the Medicare program incurred total spending of \$16.69 billion in 2021 alone for these five drugs. They cost the seniors who take them thousands of dollars per year in out-of-pocket costs. Cancer drugs Imbruvica and Ibrance cost most Medicare patients an average of \$7,118 and \$6,459 per year in out-of-pocket costs, respectively. Diabetes drug Januvia and blood clot treatment Xarelto cost most Medicare patients an average of more than \$1,300 per year in out-of-pocket costs, and those patients are likely to have three or four chronic conditions that add to their out-of-pocket medication expenses.

These drugs have high list prices and list price increases over time that far exceed inflation. Imbruvica has an annual list price tag of \$197,486; Ibrance is priced at \$181,663 per year. Enbrel's price is \$82,001 per year, which has grown by 346% since 2008.

These prices translate into billions in sales for drugmakers. Merck has made over \$47 billion in global sales of Januvia, with Medicare spending nearly \$28 billion since 2010. Amgen has reported \$80 billion in global sales of Enbrel, with Medicare spending \$15.4 billion since 2010. And Pfizer has raked in \$31 billion from global sales of Ibrance; Medicare has spent \$10 billion on the drug since its launch. AbbVie shares marketing rights for its leukemia and lymphoma drug Imbruvica with drugmaker Johnson & Johnson; the two companies have reported a combined \$50.6 billion in global sales since it launched in 2013. Johnson & Johnson shares marketing rights for its blood thinner Xarelto with Bayer; the two companies have reported \$21.3 billion and €33.1 billion in global sales for Xarelto since it launched in 2011.

To avoid paying their fair share of taxes and boost their value to shareholders, these companies have spent tens of millions on lobbyists. Due to the 2017 Republican tax law, drugmakers' average effective tax rate fell by more than 40 percent in the years after the law was enacted. Amgen has spent over \$200 million on federal lobbying since acquiring Enbrel in 2002. Merck has spent \$114 million on lobbying since gaining approval for Januvia in 2006.

Rather than investing in discovering new, innovative medicines and bringing them to market, these companies protect their profits by exploiting the patent system to extend the length of time their drugs are on the market without generic or biosimilar competitors. AbbVie, for example, has filed 195 patent applications for Imbruvica to thwart competition, extending its patent protection for an additional 5.3 years and yielding \$13.8 billion in revenue. Johnson & Johnson has filed dozens of patents to protect Xarelto from competition, extending its patent protection for an additional 4 years and protecting \$9.7 billion in revenue. Amgen has extended patent protections for Enbrel by 13.6 years, protecting \$55 billion in revenue. This abuse of the patent system keeps prices high for seniors and taxpayers.

These companies have systematically exploited the patent system and spent tens of millions on lobbying to protect their high profits, all the while charging seniors outrageous prices for lifesaving medication. Now, pharmaceutical companies, their trade group, and the U.S. Chamber of Commerce are suing the government to prevent the Medicare Drug Price Negotiation Program from going into effect. They want to continue to be able to charge whatever they want.

Drug companies argue the program will harm innovation and lead them to avoid selling their drugs to Medicare patients. The accusation that drug negotiation is anti-innovation is false. The truth is:

- 1. The new prescription drug law is designed to <u>reward truly innovative drugs</u>;
- 2. <u>Business activity</u> since the passage of the IRA demonstrates that pharma investors and executives remain enthusiastic about new drug development; and
- 3. The pharmaceutical industry has been <u>crying wolf</u> about innovation for over half a century.

The public doesn't believe the arguments. Americans overwhelmingly reject drug companies' argument that negotiation threatens innovation. An October 2021 KFF Tracking Poll found that only 6 percent of people think "drug companies need to charge high prices in order to fund the innovative research necessary for developing new drugs." The survey also found that 83 percent of people—including 71 percent of Republicans and 95 percent of Democrats—favor allowing Medicare to negotiate the prices of prescription drugs.

The Inflation Reduction Act and the Medicare Drug Price Negotiation Program are historic steps forward for affordable prescription drugs in America. Medicare will finally be able to negotiate lower drug prices on behalf of seniors and taxpayers, putting in place a long-needed check on unconstrained drug company greed. With Medicare negotiation for prescription drug prices, the era of Big Pharma being in the driver's seat is coming to an end.

#### **Methodology**

To determine which five drugs to include in this report, Protect Our Care identified the 20 drugs with the highest gross Medicare Part D spending in 2021, the most recent year for which public data is available. Protect Our Care then compared that list with drugs that meet eligibility and exclusion criteria for drug negotiation as stated in the Inflation Reduction Act and proposed CMS guidance criteria using the Medicare Price Negotiation tool developed by Marissa B. Reitsma at Stanford University in conjunction with research published in JAMA Internal Medicine in April 2023.

Patent data for Imbruvica and Enbrel can be found in I-MAK's <u>Drug Patent Book</u> <u>database</u>; I-MAK also provided patent data for Xarelto and Januvia, and analysis of expected U.S. revenues during periods between the expiration of the drug's primary patent and expected generic/biosimilar entry.

International price comparison data were found at 46brooklyn's Drug Pricing Down Under Dashboard, a March 2021 GAO Report, Statista.com, and two other studies. Total global revenues and marketing spending were calculated from information available in company annual SEC filings. Lobbying expenditures were calculated using OpenSecrets data, and share repurchase expenditures were calculated using data available through YCharts. The number of Medicare beneficiaries using each drug in 2021 and available beneficiary demographic characteristics were found using CMS data. All other data, unless otherwise noted, is from FDA's Orange Book, Medicare claims files, and SSR health.

#### <u>Acknowledgments</u>

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## **Enbrel (Amgen)**

Arthritis and plaque psoriasis drug marketed without competition for 25 years

#### **IMPACT ON MEDICARE PATIENTS**



Used by **47,739** Medicare beneficiaries in 2021



\$2,455 average annual out-of-pocket cost in 2020



Average user has **2**+ **chronic conditions** 



Populations of note: **women** 

\$82,001

list price for an annual supply in 2022

346%

price increase since 2008



Costs 68% less



Costs 68% less





Costs 87% less

in Switzerland

**\$80.62** Billion

in global sales

Since launching Enbrel, Amgen has spent:

\$6.6+ Billion

\$86 Billion on stock buybacks

\$201.6 Million

on lobbvists

\$15.4 Billion

in total Medicare spending since 2010

#### **EXPLOITING PATENTS, PADDING PROFITS**

Amgen has gamed the patent system to thwart generic competition for Enbrel for an additional **13.6 years**, **protecting an estimated \$55 billion in U.S. revenue.** 

Primary patent expiry: 2015

Last patent expiry: 2039

154 patent applications74 patents granted

## **Enbrel (Amgen)**

#### The New York Times

## For Older Americans, Health Bill Will Bring Savings and 'Peace of Mind.'

"Ms. Armbruster, of Cary, Ill., said she had saved extra insulin from prescriptions filled when she had commercial insurance, enough to keep costs down before a monthly cap kicks in. But her other conditions have caused immense financial strain. By June, she had reached Medicare's threshold for catastrophic coverage after paying more than \$7,000 for Enbrel, a drug she takes for the arthritis; Synthroid, which she takes for Graves' disease; Eliquis, for atrial fibrillation, insulin and her insulin pump."

New York Times, August 10, 2022

#### **Ibrance (Pfizer)**

Breast cancer drug marketed without competition for 8 years

#### **IMPACT ON MEDICARE PATIENTS**



Used by 18,781 Medicare beneficiaries in 2021



**\$6,459** average annual out-of-pocket cost in 2020



Average user has 3+ chronic conditions



Populations of note: women and Black beneficiaries

\$181,663 list price for an annual

42% price increase supply in 2022 since launch



Costs 64% less in Australia



Costs 66% less



Costs 77% less

\$31 Billion in global sales

Since launching Ibrance, Pfizer has spent:

\$21 Billion on marketing

**\$151.9** Billion on stock buybacks

\$91.5 Million on lobbyists

\$10 Billion

in total Medicare spending since launch

## Ibrance (Pfizer)

#### Los Angeles Times

## Opinion: My wife's life is priceless. But her chemotherapy drugs are too expensive.

"To put this question into perspective, consider the price of Paula's chemotherapy medications. She takes a pill called Ibrance that costs \$10,000 a month. She also receives two monthly injections: Faslodex, at \$5,000 a month, and Xgeva, a veritable bargain at \$2,200 a month. Add it all up, and the annual cost of Paula's chemotherapy is more than \$200,000... I view my wife's life as priceless. But her chemotherapy drugs are too expensive. Congress or private insurers should pursue legislation that requires healthcare prices to reflect health benefits. It's the only way our loved ones can get the healthcare they deserve at a price we can afford."

Los Angeles Times, December 6, 2019

#### Imbruvica (AbbVie\*)

Leukemia and lymphoma drug marketed without competition **for 10 years** 

#### **IMPACT ON MEDICARE PATIENTS**



Used by **26,044** Medicare beneficiaries in 2021



\$7,118 average annual out-of-pocket cost in 2020



Average user has 3+ chronic conditions

\$197,486

list price for an annual supply in 2022

44%

price increase since launch



Costs 34% less in Australia



Costs 50% less



Costs 58% less

in France

\$28.3 Billion\*

in global sales

\*Johnson & Johnson reports an additional \$22.3 billion in global sales from Imbruvica." Since acquiring Imbruvica, AbbVie has spent:

\$10.4 Billion

on marketing

\$31 Billion

on stock buybacks

\$53 Million

on lobbyists

## \$13.6 Billion

in total Medicare spending since 2010

#### **EXPLOITING PATENTS, PADDING PROFITS**

AbbVie has gamed the patent system to thwart generic competition for Imbruvica for an additional **5.3 years**, **protecting an estimated \$13.8 billion in U.S. revenue.** 

Primary patent expiry: 2026

195 patent applications

Last patent expiry: 2036

96 patents granted

\*AbbVie and Johnson & Johnson share a licensing agreement for Imbruvica; AbbVie is responsible for U.S. pricing.

## Imbruvica (AbbVie)

**The List Price Of Imbruvica Has Doubled Since The Drug Was Introduced 10 Years Ago.** "As of January 2023, the wholesale acquisition cost (WAC; that is, list price) of ibrutinib was \$17,018 for a 30-day supply for a standard 420 mg daily dose. The list price has doubled since the drug was first marketed, starting at \$8,200 in 2013. [Health Affairs, 5/2/23]

- AbbVie Has Raised The Price Of Imbruvica At Least Nine Times Since 2013. [Chairman Ron Wyden Letter to AbbVie, 6/2/21]
- HEADLINE: "Ibrutinib Price Tag Keeps Rising, Despite Increased Competition"
   [Medscape, 4/11/23]

After Court Victories, AbbVie Doesn't Expect Generic Competition For Imbruvica Until 2032. "With AbbVie's megablockbuster immunology drug Humira set to face biosimilars next year, the company is counting on Imbruvica to pick up some of the slack along with fast-rising immunology follow-ons Rinvoq and Skyrizi. Imbruvica got a key win in federal court last August when it ruled that two makers of generics infringed four of the drug's patents. AbbVie now doesn't expect generic competition for Imbruvica until March 2032, the company said last year in a securities filing." [Fierce Pharma, 5/31/22]

A Standard Annual Course Of Treatment With Imbruvica Costs Over \$175,000. "Imbruvica is priced between \$181,529 and \$242,039 for a standard annual course of treatment." [House Committee On Oversight And Reform Majority Report on Drug Pricing, December 2021]

## The Washington Post

Science Hinted That Cancer Patients Could Take Less Of A \$148,000-A-Year Drug. Its Maker Tripled The Price Of A Pill.

The Washington Post, April 18, 2018

### Januvia (Merck)

Type 2 diabetes drug marketed without competition for 17 years

#### **IMPACT ON MEDICARE PATIENTS**



Used by **934,542** Medicare beneficiaries in 2021



\$1,316 average annual out-of-pocket cost in 2020



Average user has 3+ chronic conditions



Populations of note **Black beneficiaries** 

\$6,346 list price for an annual supply in 2022

231% price increase since launch



Costs 87% less in Australia



Costs 82% less



Costs 66% less

\$49.9 Billion
in global sales

\$27.7 Billion
in total Medicare spending
since 2010

Since launching Januvia, Merck has spent:

\$27.3 Billion on marketing since 2011

\$197.8 Billion on stock buybacks

\$114 Million on lobbyists

#### **EXPLOITING PATENTS, PADDING PROFITS**

Merck has gamed the patent system to thwart generic competition for Januvia for an additional 3.3 years, protecting an estimated \$3.5 billion in U.S. revenue.

Primary patent expiry: 2023 Last patent expiry: 2038 48 patent applications 26 patents granted

## Januvia (Merck)

#### **POLITICO**

#### Merck Sues HHS Over Drug Negotiation, Claims Program 'Tantamount To Extortion'

"Pharmaceutical giant Merck sued the federal government on Tuesday to block Medicare drug price negotiations, calling the program unconstitutional. The complaint, filed against the Department of Health and Human Services and the Centers for Medicare and Medicaid Services, argued that Medicare's efforts to negotiate certain drug prices is "political Kabuki theater" that is "tantamount to extortion."

Politico, June 6, 2023

Merck Lobbied Against Drug Negotiation, Arguing It Would Slash Research & Development Funding "By Almost Half." Ken Frazier, the executive chairman of Merck, which is helping fund the ads, conceded in a recent call with reporters that the companies were fighting the proposal so hard because they believed it would slash their revenue. But he also portrayed the lobbying push as altruistic, arguing that a decline in profit would lead to less money for research and development into new treatments and cures for diseases. 'We have looked at what this would be,' Mr. Frazier said. 'We have modeled it, and our ability to fund R & D inside Merck will be reduced by almost half."

New York Times, October 4, 2021

## Xarelto (Johnson & Johnson\*)

Blood thinner drug marketed without competition for 12 years

#### **IMPACT ON MEDICARE PATIENTS**



Used by **1,258,010** Medicare beneficiaries in 2021



\$1,340 average annual out-of-pocket cost in 2020



Average user has **3+ chronic** conditions

\$6,240 list price for an annual supply in 2022

126% price increase since 2012



Costs 80% less in Australia



Costs 83% less



Costs 50% less

in France

\$21.3 Billion\*

in global sales

\*Bayer reports an additional €33.1 billion in sales from Xarelto.

Since launching Xarelto, Johnson & Johnson has spent:

\$29.1 Billion

on marketing

**\$71.9 Billion** 

on stock buybacks

\$75.8 Million

on lobbyists

## **\$25.17** Billion

in total Medicare spending since launch

#### **EXPLOITING PATENTS, PADDING PROFITS**

J&J has gamed the patent system to thwart generic competition for Xarelto for an additional 4 years, protecting an estimated \$9.7 billion in U.S. revenue.

Primary patent expiry: 2020

Last patent expiry: 2034

43 patent applications

23 patents granted

\*Johnson & Johnson and Bayer share a licensing agreement for Xarelto; J&J is responsible for U.S. pricing.

## Xarelto (Johnson & Johnson)

#### **NXIOS**

## Medicare blockbusters' list prices more than doubled since launch

"Two blood thinners that Medicare spent a collective \$46 billion on between 2015 and 2020 have more than doubled their list prices since entering the market, according to a new analysis by Patients for Affordable Drugs."

Axios, April 6,2022

### **HEALTHCARE FINANCE**

#### Price of Two Expensive Drugs Has Cost Medicare Part D \$46 Billion Since 2015

"Eliquis and Xarelto, two blood-thinning medications that are already among Medicare's costliest, have seen their list prices more than double since entering the market, finds a new report by Patients for Affordable Drugs. Both drugs promise less risk than warfarin, a blood thinner that is inexpensive but also carries a high risk of bleeding and requires frequent lab tests to monitor the bleeding risk. Both Eliquis and Xarelto carried a price of more than \$200 for a month's supply, a marked increase from the \$10 for the cost of a month's supply of warfarin."

Healthcare Finance, April 7,2022