Medicare Negotiations for Lower Drug Prices Explained: Enbrel

Thanks to the Biden-Harris administration and Democrats in Congress, Medicare has been negotiating lower prices for the first 10 drugs selected for the Negotiation Program, and will negotiate lower prices for more drugs each year. By 2030, up to 80 drugs will have lower negotiated prices. One of the first ten drugs <u>selected for negotiation</u> is Enbrel, a drug used to treat rheumatoid arthritis, psoriasis, and psoriatic arthritis, manufactured by Amgen. Enbrel has made billions of dollars in revenue, and big drug companies like Amgen are eager to protect their sky-high profits by blocking the Medicare Negotiation so they can continue to charge patients unaffordable prices.

Tens of Thousands of Medicare Beneficiaries Rely on Enbrel.

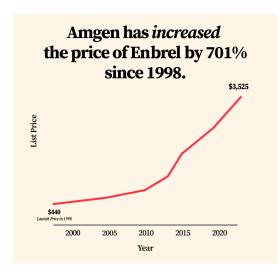
- Nearly 50,000 Medicare Part D beneficiaries rely on Enbrel as of 2022 <1 percent of Medicare Part D enrollees.
- Beneficiaries who are not enrolled in the Extra Help program pay an average of \$921 annually for Enbrel.

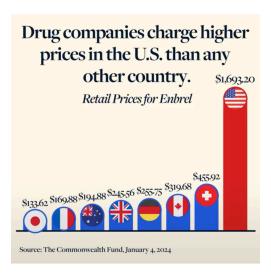
Enbrel Costs Taxpayers Billions.

 Enbrel has cost Medicare over \$21.9 billion as of 2022 – an average of \$56,639 per beneficiary taking Enbrel.

Amgen Price Gouges Americans for Enbrel.

- Enbrel costs significantly more in the U.S. than in other high-income countries. For example, Amgen charges U.S. customers around 4x more than customers in Switzerland, and nearly 13x more to U.S. customers than to customers in Japan.
- According to Analysource, Enbrel has increased in price by <u>701 percent</u> since its launch in <u>1998</u> – 2.3x <u>faster</u> than inflation for prescription drugs and approximately 7.5x <u>faster</u> than inflation overall during the same time frame.





Amgen Rakes In Profits While Rewarding Shareholders and Lobbying.

- Enbrel has generated \$85.8 billion in global revenue since its launch.
- Amgen has spent <u>over \$89 billion</u> on stock buybacks for their investors since launching Enbrel.
- Amgen has spent \$231.4 million on lobbying since launching Enbrel.

Table 1: Enbrel By The Numbers.

Enbrel Quick Facts			
Years on U.S. Market Since Approval	27		
Enbrel List Price Increase Since Launch	701 percent		
Global Revenue Since Enbrel's Launch	\$86 billion		
Lobbying Since Enbrel's Launch	\$231.4 million		
Stock Buybacks Since Enbrel's Launch	\$89 billion		

Enbrel Is Disproportionately Taken by Medicare Enrollees of Color. Relative to their proportion in the population enrolled in Medicare Part D:

- The <u>proportion</u> of American Indian and Alaska Native enrollees taking Enbrel is 3.33 times higher. American Indians and Alaska Natives are <u>more likely</u> to develop arthritis and <u>almost 50 percent more likely</u> to have activity limitations due to the disease than their white counterparts..
- The <u>proportion</u> of Latino enrollees taking Enbrel is 1.39 times higher. Latinos are among the <u>most likely</u> to have activity limitations due to arthritis of any racial/ethnic group.
- The <u>proportion</u> of Black enrollees taking Enbrel is higher. Black Americans are <u>more likely</u> to have activity limitations due to arthritis than their white counterparts.

Table 2: Enbrel Is Disproportionately Taken by Medicare Enrollees of Color

Race/Ethnicity	Medicare Part D Pop.	Enbrel Population	Difference
Black	11 percent	11 percent	1.03 times higher
Latino	10 percent	14 percent	1.39 times higher
American Indian and Alaska Native	0.3 percent	1 percent	3.33 times higher

Enbrel Is Most Expensive In Rural States Like North Dakota. The ten drugs selected for price negotiation by Medicare, with few exceptions, are most expensive in heavily rural states. Enbrel

costs Medicare Part D beneficiaries residing in North Dakota, Minnesota, and Utah the most out-of-pocket.

Table 3: States with the Highest Out-of-Pocket Costs for Medicare Part D Enrollees Taking Enbrel

State	Average Out-of-Pocket Costs for Enbrel By State	Difference From National Average*	Rurality
North Dakota	\$2,299	2.50 times higher	39 percent of residents live in rural areas
Minnesota	\$1,795	1.95 times higher	28.1 percent of residents live in rural areas
Utah	\$1,724	1.87 times higher	10.2 percent of residents live in rural areas

^{*}Medicare Part D beneficiaries not in the Extra Help program pay an average of \$921 annually for Enbrel

Amgen Has A Long History of Jacking Up Prices and Exploiting Patents for Enbrel:

- Fierce Pharma: Amgen, Facing Potential Enbrel Price Cap In Colorado, Takes State's New Drug Affordability Board To Court. "Amgen's arthritis blockbuster Enbrel already owns an undesirable spot on the list of 10 drugs eligible for the first round of Medicare pricing negotiations. Now, the company is fighting back against a move in Colorado that aims to cap the med's price at the state level. In a recently filed lawsuit in Colorado federal court, Amgen is challenging a vote from the state's newly created Prescription Drug Affordability Review Board. The board plans to subject the drug to an 'upper payment limit,' local newspaper the Colorado Sun reports. The board has deemed Enbrel's price to be 'unfavorable.' But in its complaint (PDF), Amgen called the board's determination an 'unconstitutional' violation of due process and federal law." [Fierce Pharma, 3/26/24]
- Fierce Pharma: Amgen Stalls Samsung's Enbrel Biosim Until 2029 In 2nd Patent Win Of The Year. "Amgen breathed a sigh of relief this summer when the Supreme Court declined to take up a Sandoz patent dispute challenging its anti-inflammatory blockbuster Enbrel. Now, the California drugmaker has warded off a second would-be rival, securing monopoly sales for many years to come. [...] Enbrel was first approved back in 1998, meaning it will have enjoyed 31 years of U.S. exclusivity by the time Samsung and Sandoz's biosimilars hit the scene..." [Fierce Pharma, 12/1/21]

- Reuters: Amgen Wins U.S. Patent Battle On Arthritis Drug Enbrel, Thwarting Novartis. "A U.S. judge on Friday upheld two patents relating to Amgen Inc's blockbuster rheumatoid arthritis drug Enbrel, denying a challenge by Novartis AG, which is seeking to launch a copycat version. [...] U.S. regulators in recent years have acted to encourage the launch of 'biosimilar' versions of pricey biologic drugs, but drugmakers like Amgen have used litigation to extend patent protections and limit price competition for as long as possible. Biologics are made from living cells and are therefore difficult to copy with precision. The Food and Drug Administration said last year that biologic drugs account for almost 40 percent of U.S. prescription drug spending, and for 70 percent of the growth in drug spending between 2010 and 2015. The United States has lagged behind Europe in use of biosimilars." [Reuters, 8/9/19]
- Public Citizen: Analysis Shows Amgen's Gaming Of Patent System Cost Medicare More Than a Billion in Savings Over Less Than Four Years. "A new analysis by Public Citizen reveals how pharmaceutical company Amgen gamed the patent system and kept Medicare paying high prices for etanercept, sold under the brand name Enbrel and used to treat autoimmune diseases. The analysis estimates that Medicare could have saved \$1,053,023,122 in less than four years on Enbrel if Amgen hadn't circumvented the law to secure additional patent protections after 2019, when biosimilar competitors should have been able to enter the market. Enbrel is one of the 10 drugs chosen by the Biden administration for Medicare drug price negotiations under the Inflation Reduction Act (IRA). By the time a maximum fair price for Enbrel goes into effect under the Inflation Reduction Act in 2026, Medicare will have lost nearly \$2 billion (\$1,891,500,836) because of unwarranted exclusivities protecting Enbrel from competition." [Public Citizen, 10/31/23]

Additional Resources

- <u>Protect Our Care</u>: NEW REPORT: Big Drug Companies Continue to Put Profits Over People
- Protect Our Care: GREED WATCH: Eight Big Drug Companies That Rip Off Patients
 Announce Nearly \$100 Billion in Revenue and Over \$15 Billion in Dividends and Stock

 Buybacks
- <u>Protect Our Care</u>: NEW REPORT: In 2023, Greedy Drug Companies Raked in \$684 Billion and Spent \$106 Billion Rewarding Shareholders
- <u>Protect Our Care</u>: Big Drug Companies Continue To Bring In Hundreds of Billions While Americans Struggle To Afford Skyrocketing Prices
- <u>Protect Our Care</u>: Fact Sheet: American Seniors Will Save As Medicare Negotiates Lower Drug Costs
- <u>Protect Our Care</u>: Big Drug Companies Are in Court to Stop Medicare Negotiation and Protect Their Sky-High Profits

- <u>Protect Our Care</u>: FACT SHEET: How Medicare's New Drug Price Negotiation Power Will Advance Health Equity
- <u>Protect Our Care</u>: By the Numbers: The Ten Costly Drugs That Are Now Eligible to Have Lower Prices Negotiated by Medicare