Medicare Negotiations for Lower Drug Prices Explained: Januvia

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 Januvia, a drug used to treat type 2 diabetes, manufactured by Merck. Januvia has made billions of dollars in revenue, and big drug companies like Merck are eager to protect their sky-high profits by blocking the Medicare Negotiation so they can continue to charge patients unaffordable prices.

Hundreds of Thousands of Medicare Beneficiaries Rely on Januvia.

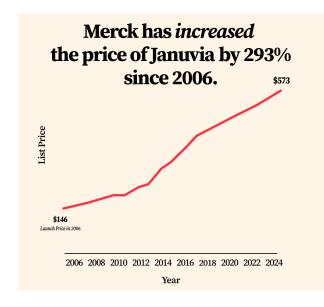
- 885,000 Medicare Part D beneficiaries rely on Januvia as of 2022 1.7 percent of Medicare Part D enrollees.
- Beneficiaries who are not enrolled in the Extra Help program pay an average of \$270 annually for Januvia.

Januvia Costs Taxpayers Billions.

 Januvia has cost Medicare <u>around \$32.2 billion</u> as of 2022 – an average of \$4,631 per beneficiary taking Januvia.

Merck Price Gouges Americans for Januvia.

- Januvia costs significantly more in the U.S. than in other high-income countries. For example, Merck charges U.S. customers <u>5.5x</u> more than customers in Canada, and over 20x more to U.S. customers than to customers in Germany.
- According to Analysource, Januvia has increased in price by 293 percent since its launch in <u>2006</u> – over 5 times <u>faster</u> than inflation for most prescription drugs and greater than 5 times faster than inflation overall.





Merck Rakes In Profits While Rewarding Shareholders and Lobbying.

- Januvia has generated \$54.3 billion in global revenue since its launch.
- Merck has spent \$53.6 billion on stock buybacks for their investors since launching Januvia.
- Merck has spent <u>nearly \$132 million</u> on lobbying since launching Januvia.

Table 1: Januvia By The Numbers.

Januvia Quick Facts			
Years on U.S. Market Since Approval	19		
Januvia List Price Increase Since Launch	275 percent		
Global Revenue Since Januvia's Launch	\$54.3 billion		
Lobbying Since Januvia's Launch	\$132 million		
Stock Buybacks Since Januvia's Launch	\$53.6 billion		

Januvia 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 Asian American, Native Hawaiian, and Pacific Islander beneficiaries taking Januvia is 1.89 times higher. Asian Americans are 40 percent more likely to be diagnosed with diabetes. Native Hawaiians/Pacific Islanders are 2.5 times more likely to be diagnosed with diabetes and 2.5 times more likely to die from diabetes.
- The proportion of Latino enrollees taking Januvia is 1.58 times higher. Latinos are 70 percent more likely to be diagnosed with diabetes and 1.3 times more likely to die from diabetes when compared to their non-Hispanic white counterparts. Latinos are more likely to have higher levels of disability-related diabetes compared to their non-Hispanic white counterparts.
- The <u>proportion</u> of Black enrollees taking Januvia is 1.5 times higher. Black Americans are 60 percent more likely to be diagnosed with diabetes and twice as likely to die from the disease when compared to their white counterparts. Black Americans are 2.5 times as likely to be hospitalized for complications of diabetes and have nearly three times higher rates of emergency department visits for the disease than their white counterparts.

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

Race/Ethnicity	Medicare Part D Pop.	Januvia Population	Difference
Black	11 percent	16 percent	1.5 times higher
Latino	10 percent	16 percent	1.58 times higher

Asian American,	4 percent	7 percent	1.89 times higher
Native Hawaiian, and Pacific Islander			

Januvia 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. Januvia costs Medicare Part D beneficiaries residing in North Dakota, South Dakota, and Nebraska the most out-of-pocket.

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

State	Average Out-of-Pocket Costs for Januvia By State	Difference From National Average*	Rurality
North Dakota	\$653	2.42 times higher	39 percent of residents live in rural areas
South Dakota	<u>\$576</u>	2.13 times higher	42.8 percent of residents live in rural areas
Nebraska	\$502	1.86 times higher	27 percent of residents live in rural areas

^{*}Medicare Part D beneficiaries not in the Extra Help program pay an average of \$270 annually for Januvia

Merck Has A Long History of Jacking Up Prices and Exploiting Patents for Januvia:

• The Philadelphia Inquirer: How Merck Extended Its Monopoly On A Blockbuster

Diabetes Drug. "Merck's monopoly on a blockbuster diabetes drug that has generated about \$50 billion in global sales seemed like it might be coming to an end over the past couple years. The pharmaceutical giant's key U.S. intellectual property on the active ingredient in Januvia was set to expire in early 2023, and rivals started gearing up to launch low-cost copies — an outcome that would almost certainly drive down the drug's price and offer consumers more choices. But, as happens so often in the pharmaceutical industry, the owner of the brand-name drug was able to stave off the competition with the help of a secondary patent. That additional legal protection helped Merck prevail in a high-stakes court fight last year. Separately, the company has reached 26 settlement agreements with generic manufacturers that have sought to market their own versions of Januvia and Janumet, another Merck drug that uses the same key ingredient. As a

result, Merck, the biggest employer in Montgomery County, has told investors it expects to maintain U.S. market exclusivity on Januvia until about May 2026, even as regulators in Europe and China have approved less-expensive copies known as generic drugs. That three years of extra protection for Merck could mean an additional \$3.5 billion in U.S. revenue, according to one estimate. Research shows a drug's price can drop as much as 20% when the first generic hits the market — and as much as 85% after multiple alternatives are approved." [The Philadelphia Inquirer, 12/20/23]

• Fierce Pharma: Merck, Defending Its Blockbuster Januvia, Prevails In High-Stakes Patent Lawsuit Against Viatris. "Merck & Co., after settling with nearly two dozen drugmakers aiming to launch generics of its blockbuster Type 2 diabetes med Januvia, has successfully parried a Viatris patent assault in court. [...] Earlier this year, Merck said Januvia was set to lose U.S. exclusivity in January 2023. But Merck cautioned that if its 2027 'salt/polymorph patent' is upheld, that 'would preclude generic manufacturers from making sitagliptin phosphate salt and polymorphic forms until 2027.' That means with the latest decision, Merck could have secured itself several more years of lucrative exclusivity for the medicine, subject to any appeals. Whenever the Merck diabetes drugs lose exclusivity, the drugmaker expects sales to drop 'substantially' following generic launches." [Fierce Pharma, 9/22/22]

Additional Resources

- <u>Protect Our Care</u>: NEW REPORT: Big Drug Companies Continue to Put Profits Over People
- <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