Medicare Negotiations for Lower Drug Prices Explained: *Entresto*

Thanks to President Biden and Democrats in Congress, Medicare is currently 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 selected for negotiation is Entresto, a drug used to treat heart failure, manufactured by Novartis. Entresto has made billions of dollars in revenue, and big drug companies like Novartis 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 Entresto.

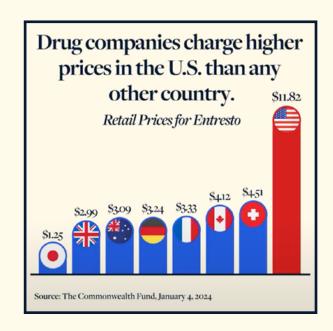
- <u>521,000</u> Medicare Part D beneficiaries rely on Entresto as of 2022 <u>around 1 percent of</u> Medicare Part D enrollees.
- Beneficiaries who are not enrolled in the Extra Help program pay an average of \$357 annually for Entresto.

Entresto Costs Taxpayers Billions.

• Entresto has cost Medicare <u>just under \$7 billion</u> as of 2022 – an average of \$4,780 per beneficiary taking Entresto.

Novartis Price Gouges Americans for Entresto.

- Entresto costs significantly more in the U.S. than in other high-income countries. For example, Novartis charges U.S. customers <u>nearly 3x</u> more than customers in Switzerland, and 9.5x more to U.S. customers than to customers in Japan.
- Entresto has increased in price by <u>78</u>
 percent since its launch in 2015.





Novartis Rakes In Profits While Rewarding Shareholders and Lobbying.

- Entresto has generated over \$18.5 billion in global revenue since its launch.
- Novartis has spent \$44.3 billion on stock buybacks for their investors since launching Entresto.
- Novartis has spent \$58.2 million on lobbying since launching Entresto.

Table 1: Entresto By The Numbers.

| Entresto Quick Facts | | |
|---|----------------|--|
| Years on U.S. Market Since Approval | 9 | |
| Entresto List Price Increase Since Launch | 78 percent | |
| Global Revenue Since Entresto's Launch | \$18.5 billion | |
| Lobbying Since Entresto's Launch | \$58.2 million | |
| Stock Buybacks Since Entresto's Launch | \$44.3 billion | |

Entresto Is Disproportionately Taken by Black Medicare Enrollees. Relative to their proportion in the population enrolled in Medicare Part D, the proportion of Black enrollees taking Entresto is 1.68 times higher – 18 percent, compared to 11 percent overall. Black Americans are 30 percent more likely to die from heart disease and 30 percent more likely to have high blood pressure than their White counterparts. Black Medicare beneficiaries have more than twice the emergency care rates for heart failure than their White counterparts.

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

Table 2: States with the Highest Out-of-Pocket Costs for Medicare Part D Enrollees Taking Entresto

| State | Average Out-of-Pocket Costs for Entresto By State | Difference From National Average* | Rurality |
|--------------|---|--------------------------------------|---|
| North Dakota | <u>\$656</u> | 1.84 times higher | 39 percent of residents live in rural areas |
| South Dakota | \$601 | 1.68 times higher | 42.8 percent of residents live in rural areas |
| Wyoming | <u>\$589</u> | 1.65 times higher | 38 percent of residents live in rural areas |

^{*}Medicare Part D beneficiaries not in the Extra Help program pay an average of \$357 annually for Entresto



Novartis Has A Long History of Jacking Up Prices and Exploiting Patents for Entresto:

- Fierce Pharma: Aiming To Block Entresto Generics, Novartis Sues Mylan, Alembic And Others For Patent Infringement. "In its latest effort to defend against forthcoming Entresto copycats, Novartis is taking to U.S. federal court to allege infringement against several generics players. [...] It's not Novartis's first attempt to defend Entresto. Last December, the company filed a lawsuit against Torrent Pharma, alleging patent infringement when Torrent submitted its generic application. The company argued that if Torrent were to move forward with production, it would be doing so knowing its actions constitute patent infringement, which would be 'substantially and irreparably' damaging to Novartis. Meanwhile, last month, the company petitioned the FDA to not approve generics of the drug until the end of its three-year exclusivity period that lasts until February 2024. That move followed a similar but unsuccessful appeal last November. Last year, Entresto garnered nearly \$3.55 billion in global sales. The company has maintained that the drug could deliver peak sales of \$5 billion." [Fierce Pharma, 10/26/22]
- Pharmaceutical Technology: Novartis Plans Appeal To Ward Off Entresto Generics. "Swiss-based Novartis announced that the US District Court for the District of Delaware has invalidated the patent covering its cardiac drug Entresto, which expires on 15 July 2025 with the associated paediatric exclusivity. The company said it will now appeal to the US Court of Appeals for the Federal Circuit (CAFC) to further pursue the efforts to validate the combination patent around Entresto. [...] Novartis has also been involved in patent infringement litigation with multiple abbreviated new drug application (ANDA) filers over Entresto, since October 2019. As a result, the company has settled with some manufacturers to launch Entresto generics at a certain date. Novartis reaffirmed that it would counteract any breach of its intellectual property rights relating to Entresto, the combination treatment, and the multiple patents covering additional innovations. Adding that later litigation may be carried out on any commercial launch of a generic Entresto product prior to the outcome of Novartis' appeal, or ongoing infringement litigations involving other patents." [Pharmaceutical Technology, 7/10/23]

Additional Resources

- <u>Protect Our Care</u>: Big Drug Companies Continue To Bring In Hundreds of Billions While Americans Struggle To Afford Skyrocketing Prices
- Protect Our Care: Fact Sheet: American Seniors Will Save As Medicare Negotiates Lower Drug Costs
- Protect Our Care: 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

