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## Why price of Humira keeps rising despite FDA approval of generic competition

Humira, the world's biggest-selling drug, is used to treat rheumatoid arthritis, psoriasis and Crohn's disease.

By Christopher Rowland January 8, 2020

[https://www.washingtonpost.com/business/economy/why-humiras-price-keeps-rising-despite-fda-approval-of-generic-competition/2020/01/07/549ed0ce-2e3a-11ea-bcb3-ac6482c4a92f\\_story.html](https://www.washingtonpost.com/business/economy/why-humiras-price-keeps-rising-despite-fda-approval-of-generic-competition/2020/01/07/549ed0ce-2e3a-11ea-bcb3-ac6482c4a92f_story.html)

The Food and Drug Administration has approved five generic versions of Humira – the world's biggest-selling drug, with global revenue of \$20 billion – and two of them have come within the past six months.

But so far the generic biologic drugs (called "biosimilars" in industry parlance) have failed to lower costs and make the therapies more accessible to patients.

AbbVie, Humira's manufacturer, kicked off 2020 with a price increase in excess of 7% on its mega-blockbuster brand-name treatment, which is used to treat rheumatoid arthritis, psoriasis and Crohn's disease.

The increase followed total Humira price hikes of 19% during 2017 and 2018, according to a survey by the nonprofit Institute for Clinical and Economic Review, which deemed the increases unjustified.

Drugmakers introduced price increases on more than 400 drugs to start the year, in what has become a semiannual ritual, Reuters reported last week. Most of the increases were in the range of 5%, which is lower than some previous years as manufacturers react to intense, bipartisan political pressure to hold prices down.

There is evidence, however, that drug companies took shallower increases on a larger number of drugs. Rx Savings Solutions, a company that helps clients navigate drug prices, said Monday that the number of drugs subject to increases in the early going of 2020 is 50% more than the initial days of 2019.

Humira was among a handful of drugs with the highest jumps. The cost of Humira, which is injected via syringe, was more than \$72,000 a year on prescription drug websites this week and is not expected to come down until at least 2023.

Humira's price has defied gravity – and been ensconced as a frequent rhetorical target on Capitol Hill – through AbbVie's aggressive use of patents and deals with generic manufacturers to forestall competition. (Industry and regulators call generic biologic drugs biosimilars because, while the FDA's standard for their approval requires there be no meaningful clinical difference, they are not replicas.)

Eli Lilly promised cheaper insulin in 2019. The result has some senators steamed.

Humira was approved by the FDA in 2002 and its core patents expired in 2016, according to the Biosimilars Council, a division of the Association for Accessible Medicines, which represents generic manufacturers. But AbbVie won dozens of additional patents – what critics call a “patent thicket” – that extended the exclusive market for the drug to as late as 2034, the council said.

“Biosimilars have so much to offer for America's patients, but the potential savings that they can bring is being squashed by burdensome patent thickets in the name of profits,” said Christine Simmon, senior vice president at the Biosimilars Council. “Patent thicketing, and Humira is the poster child for this, builds a patent fortress around their product to protect their ability to continue their monopoly pricing.”

Rather than fight through the thicket via risky patent litigation, however, the generic makers, which include traditional brand manufacturers such as Pfizer and Amgen, have chosen to settle.

Congress showers health-care industry with multibillion-dollar victory after wagging finger for much of 2019.

The trade group supports deals between AbbVie and makers of generic biologic drugs that have drawn bipartisan fire from senators as “pay for delay.”

“Humira currently has 100% of market share for its primary therapy area because the alternatives haven't launched yet,” said Michael Kleinrock, senior director of the IQVIA Institute for Human Data Science, which tracks prescription drug data and health outcomes. “There is little precedent in biosimilar patent litigation, and while it is possible to launch at risk, biosimilar companies have agreed to the settlement that sets the launch date as January 2023.”

With no competition, AbbVie has a free hand to boost prices in the United States for another three years. That potentially allows it to make up for slower sales in Europe, where generic competition is taking a bite out of Humira sales.

European countries have a more robust generic market for biologic drugs as well as state-sponsored price controls.

In the United States, Humira sales increased 11% in 2018, compared with just 1% internationally, AbbVie said in its last annual report. Year-end figures for 2019 were not yet available. More than two-thirds of Humira sales are in the United States, the company said.

Asked about the increase in its list price, AbbVie did not respond directly. In a statement, it chose to focus on its "net price," the amount paid by insurance companies.

"This is an increase in list price and represents a net price increase that is in line with the projected rate of inflation," the company said.

Michael Rea, chief executive of Rx Savings Solutions, which tracks prices and market trends, says the drug companies' lack of transparency and their emphasis on net pricing is one of the factors making it difficult for consumers to anticipate what they will pay at the pharmacy counter.

"If list price didn't matter, then no one would increase list price," Rea said. "But the reality is it does matter. It is used as a benchmark in the calculation that ends up being what people pay."

A bipartisan bill that would have cracked down on companies that deploy patent thickets failed in the Senate in 2019 as drug companies successfully fought off the most aggressive efforts on Capitol Hill to rein in drug pricing.

Class-action lawsuits have been filed by unions and other large-scale health-care purchasers against AbbVie and generic manufacturers, alleging that their agreements violate antitrust statutes. The defendants argue that their agreements are legal.