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FDA approves first cheaper version of J&J's top drug Remicade

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Federal health officials have approved a cheaper version of Johnson & Johnson's blockbuster drug, Remicade, a pricey biotech medicine for inflammatory diseases.

The approval of Inflectra Tuesday is only the second time that the Food and Drug Administration has approved a quasi-generic biotech drug for the U.S. market. These so-called biosimilar drugs, already available in Europe, have the potential to generate billions of dollars in savings for insurers, doctors and patients in coming years.

Inflectra, from drugmakers Celltrion and Pfizer, is approved for a half-dozen uses, including psoriasis and five other conditions in which the immune system attacks the body's tissue. The drug helps reduce inflammation and control the immune system, which helps slow these diseases.

Remicade, first approved in 1998, is J&J's top-selling medicine with sales of $6.56 billion last year.

Biotech drugs are powerful, injected medicines produced in living cells which are typically much more expensive than traditional, chemical-based drugs. In 2014, the latest year data is available, six of the 10 best-selling medicines globally were biologics, with about $49 billion in combined sales.

For decades, biotech drugs lacked generic competition because the FDA

had no system to approve cheaper versions. That changed in 2012 and the agency approved the first biosimilar drug last March—a cheaper version of the blockbuster Amgen drug Neupogen. Biosimilar is the industry term for generic biotech drugs, used to indicate that they are not exact copies of the original biologic medicines.

"Biosimilars can provide access to important treatment options for patients who need them," said Janet Woodcock, the FDA's director for drugs.

Remicade sales slipped 4 percent in 2015 due to overseas competition from biosimilar versions already made by Pfizer and Celltrion Inc., which is based in Korea.

A key factor in U.S. uptake of the new drug will depend on whether it is reserved for first-time patients or whether patients already on Remicade are switched to the cheaper medication. Many states are still deciding whether pharmacists can substitute a biosimilar for the original biologic drug without the prescribing doctor's permission, as usually happens with generic pills.

Other blockbuster biotech drugs expected to face U.S. competition in coming years include AbbVie's anti-inflammatory drug Humira, which is from the same family as Remicade. Humira was the best-selling drug in the world last year with sales of $14 billion.