Will doctors prescribe the first approved US copycat biological drug?

A group of FDA advisers unanimously recommended approval for Novartis' knockoff of a blockbuster Amgen treatment, clearing the way for what would be the first U.S. approval of a copycat biologic medicine.

Novartis' version of filgrastim, marketed as Neupogen, boosts white blood cell production. It's used to prevent infections in bone marrow that develop during chemotherapy.

The FDA is not required to follow the recommendations of its advisers, though it commonly does, and the agency is expected to make a final decision on Novartis' biosimilar in the coming months.

Novartis became the first company to file for a stateside biosimilar approval under the FDA's newly created pathway when it submitted its take on filgrastim over the summer, putting it at the front of the line to tap the U.S. market for cheaper versions of blockbuster biotech treatments. Express Scripts has said the U.S. healthcare system could save roughly ?$250 billion over the next 10 years thanks to the rise of biosimilars, *The New York Times* reported this week.

But although FDA approval is widely expected, the bigger question for all biosimilars is whether physicians will prescribe them interchangeably with their reference products.

Amgen, for its part, is fighting to prolong Neupogen's exclusivity, filing a lawsuit in the fall in hopes of blocking Novartis over an alleged violation of the Biologics Price Competition and Innovation Act.

Read full, original article: Novartis clears an FDA hurdle with its pioneering biosimilar of Amgen's Neupogen