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FDA lays out proposal for naming lower-cost biotech drugs (Update)

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The Food and Drug Administration released its proposal Thursday for naming lower-cost biotech drugs, a critical step in creating a market for the new class of medicines.

These quasi-generic biotech drugs have the potential to save the U.S. health care system billions of dollars in costs. But representatives for the generic drug industry warned that the FDA's proposal could curb those savings by making the drugs more difficult to prescribe.

Biotech drugs are powerful, injected medicines produced in living cells which are typically much more expensive than traditional chemical-based drugs. Many newer biotech drugs cost more than $100,000 per year and together they account for nearly 30 percent of all U.S. drug spending.

For decades, they have not faced generic competition because the FDA lacked a system to approve cheaper versions until 2012. Earlier this year the agency approved the first "biosimilar." That's the industry term for generic biotech drugs, used to indicate that they are not exact copies of the original biologic medicines.

But many questions remain about how the new drugs will be sold and marketed, including whether they can use the same ingredient names as the original products.

Under an FDA proposal, all biotech drugs would be labeled with a four-

letter code to help doctors distinguish them from the original versions.

For example, the original drug might be labeled "drug-cznm" and a biosimilar version could be labeled "drug-hixf." The codes would not have any meaning and would mainly help doctors and pharmacists avoid accidentally switching patients between drugs.

Branded biotech drugmakers have long stressed the safety risks of switching patients to alternate versions of biotech drugs, noting they are not perfect copies of the originals.

The Generic Pharmaceutical Industry Association warned in a statement that the FDA's plan could "erect barriers to patient access to new, more affordable medicines." The group, which represents companies like Teva and Sandoz, said the four-letter code would not increase safety "and in fact would require the health care professional to be armed at all times with a code-breaking reference."

A key factor in the potential cost-savings from biosimilars will depend on how interchangeable they are with the original products.

Currently, U.S. pharmacies and insurers cannot automatically switch patients from a brand-name biologic to a biosimilar, which is allowed for generic versions of traditional drugs.

But if a biosimilar drugmaker applies to the FDA for a designation called "interchangeability," automatic switches by pharmacists and insurers to the cheaper biosimilar drug would be allowed.

The FDA said it is still determining whether biosimilar drugs deemed interchangeable would bear the same four-letter code as the original. The agency is seeking public input on that question and several others for 60 days, before beginning to finalize its proposal.

Next week, Novartis is scheduled to launch its biosimilar version of Neupogen, a blockbuster Amgen drug used to boost blood cells in certain cancer patients. The FDA approved that drug in March but it has been held up by patent litigation between Amgen and Novartis.

Amgen confirmed Thursday it has filed a court petition to reconsider a key aspect of the case, which if granted, could delay the Novartis drugs' launch.

Generic biotech drugs have been available in Europe since 2006, where the European Medicines Agency has approved about 20 products. However, they are still only a small part of the global drug market. Pharmaceutical consulting firm IMS Health estimates low-cost versions of biotech drugs will account for 4 to 10 percent of the global $250 billion market for biologics by 2020.