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Biosimilar drugs could create billions in health care savings, study finds

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Introducing competing "biosimilar" versions of complex biologic drugs used to treat illnesses such as cancer and rheumatoid arthritis could cut spending on biologics in the United States by $44 billion over the next decade, according to new analysis from the RAND Corporation.

While biologics have advanced medical treatment for many conditions, they often are expensive and patient copays for some biologics can be several thousand dollars per year. In 2011, eight of the top 20 drugs in the United States in terms of sales were biologics and the annual spending on the drugs has grown three times faster than other prescription medications.

The U.S. Food and Drug Administration is developing regulations to govern the approval process for highly similar versions of the already-approved complex, protein-based biologics, which includes drugs such as insulin, monoclonal antibodies and a range of medications to treat other serious conditions.

While expected to produce less-dramatic savings than an earlier generation of less-complex generic drugs, the introduction of biosimilars into the U.S. marketplace is expected to increase competition and drive down prices, resulting in savings for patients, health care payers and taxpayers.

"The emergence of biosimilar drugs has the potential to create significant savings for the nation's health care system," said Andrew

Mulcahy, the report's lead author and a policy researcher at RAND, a nonprofit research organization. "However, the magnitude of savings will depend on a number of factors, including forthcoming decisions from the FDA."

The FDA's approach to regulating small-molecule generic drugs cannot be applied to biologicals, which are complex molecules manufactured in living systems. The federal Affordable Care Act authorized the FDA to develop a regulatory framework for approval of biosimilars.

Draft materials released by the FDA suggest that not all biosimilars will be deemed interchangeable with their original counterparts. In addition, nearly all biosimilars will require at least one head-to-head clinical trial to confirm similarity to the original biologic, a more-strenuous process than required for standard generics.

While there is agreement that biosimilars will lead to health care savings, the magnitude of the savings is not clear. In order to create an estimate of the likely savings from biosimilars, RAND researchers created a framework to predict future use of the drugs, considering issues such as the effect of increased competition and acceptance of biosimilars by physicians, patients and payers.

The effort included examining the experience with biosimilar drugs in the European Union, where an approval process was created a decade ago and several biosimilars already have been approved.

RAND researchers examined 2013 sales information for more than 100 biologics, including all blockbuster biologics with sales of more than $1 billion annually. In total, the drugs had sales of $66.3 billion in 2013 across all distribution channels.

Assuming that biosimilars will penetrate 60 percent of the market,

RAND researchers estimate that savings from biosimilars would be $44.2 billion over 10 years or about 4 percent of the total sales for biologics over the same period.

A number of additional, yet-to-be determined issues ultimately will determine the size of the cost savings from biosimilars and who will benefit, according to RAND researchers.

Among those issues is how much future use of biologics grows as some patients decide to switch to the drugs once biosimilars make such treatment more affordable.

Some cost savings will accrue to patients, but physicians and hospitals also may benefit because biologicals often are purchased by health providers and administered in clinics and other treatment settings.

More information: The RAND perspective, "The Cost Savings Potential of Biosimilar Drugs in the U.S.," is available at www.rand.org.

Provided by RAND Corporation