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# Biosimilars and the Future of Patient Access

You may have heard the term "biosimilars," but how much do you know about this pioneering and vital aspect of today's prescription drug ecosystem? A biosimilar is exactly as its name implies – a biologic that is highly similar to – and has no clinically meaningful differences in safety, purity or potency from – the original biologic.

So what are biologics? Biologics are medicines that are made from living organisms, often involving complex manufacturer processes. These medicines are used to treat a wide range of illnesses, including autoimmune conditions, arthritis, diabetes, kidney conditions, macular degeneration and some cancers.

Since Congress enacted the Biologics Price Competition and Innovation Act (BPCIA) in 2010, biosimilars have bolstered competition and increased access to lower-cost treatment options for patients. Biosimilars today compete against a wide range of brand biologic products.

## HOW DO BIOSIMILARS LOWER HEALTHCARE COSTS AND PROMOTE PATIENT ACCESS?

Increased biosimilar launches and competition have led to:

**$238 million**
**in out-of-pocket cost savings for patients in Medicare and employer plans in 2020 alone.[I]**

**$23.6 billion**
**in cumulative savings to the U.S. healthcare system since 2015.[II]**

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The future holds promise for increased patient access to lower-cost treatment options with:

**100** **biosimilar products in development.[III]**

**$180 billion**
**in projected savings over the next five years, a more than four-fold increase from the previous five years.[IV]**

## Why is the Future of Biosimilars at Risk?

**While biosimilars are increasingly driving competition and savings, challenges remain that impede the biosimilar marketplace from realizing its full potential.**

Too often perverse incentives lead middlemen corporations, known as pharmacy benefit managers (PBMs), to favor products with higher list prices and rebates that increase PBM profits over low-cost alternatives that could save patients money. This may result in PBMs putting biosimilars on less favorable cost sharing tiers or leaving them off formularies altogether. In 2022, 14 biosimilars were excluded from the formulary of at least one of the three largest PBMs.[v]

And now price setting policies enacted as part of the Inflation Reduction Act create uncertainty and threaten the sustainability of the biosimilar marketplace by discouraging the development of these medicines.[vi] The requirement that a branded biologic medicine must have a biosimilar with 'bona fide marketing' available by 11 years after licensure to avoid potential selection for price setting is at odds with other laws governing when biosimilars can be approved. As a result, the IRA completely upends existing incentives for biosimilars to come to market.

The lack of incentives for robust biosimilar development and misaligned incentives for adoption have raised questions and concerns about the ability to bring more biosimilar products to market, the role of biosimilar competition in lowering costs, and the ability for patients to access low-cost treatment options in the future.

**FOR MORE INFORMATION ABOUT THE FUTURE OF BIOSIMILARS, VISIT WWW.WEWORKFORHEALTH.ORG**


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