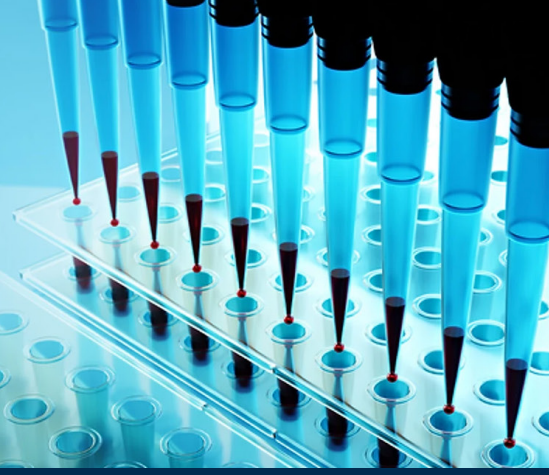
WE WORK FOR HEALTH

Price Setting Will Have a Chilling Effect on Biosimilar Innovators and Manufacturers



Biosimilars are a vital, and growing, part of the prescription drug ecosystem. As a highly similar version of a complex, biologic drug with no clinically meaningful differences, biosimilar therapies exist for a wide variety of illnesses such as autoimmune conditions, arthritis, diabetes, kidney conditions, macular degeneration and some cancers. They are also critical to lowering healthcare costs and promoting competition in the market for prescription drugs.

42

The number of biosimilar products that have been approved by the FDA as of November 1, 2023.[1]

$7 billion

Total savings to the U.S. healthcare system as a result of biosimilar competition.[2]

THE IRA'S PRICE SETTING PROGRAM WILL REPRESENT A MAJOR DISRUPTION IN THE MARKET FOR BIOSIMILARS.

Because of the timelines set by the IRA, most biologics will be eligible for price setting before potential biosimilar competitors are legally or feasibly able to enter the market. Though the IRA includes a "pause" in the process to allow time for a biosimilar to launch, the policy as well as CMS' interpretation of the provisions are deeply flawed, making the "pause" largely ineffective. As a result, biosimilars may be entering a market where they must compete against a biologic competitor with a substantially lower price. Consequently, the incentive for manufacturers to develop a biosimilar competitor **decreases** and some companies could **exit the market altogether**.

Ultimately, the impact of the IRA on the biosimilars market raises questions and concerns around how development of, and access to, biologic drugs will evolve and what the role of biosimilar competition will be in driving **patient access** in the future**.**

We Work For Health is advocating for a number of **policy objectives** to help address these concerns and protect the biosimilars market.

1 Require CMS to grant an automatic two-year pause in the selection of drugs if certain defined criteria are met.

2 Broaden the pause eligibility to all approved biologics, not just extended-monopoly drugs.

3 Extend the eligibility to biosimilar products that have been licensed ≤ years since licensure without marketing.

4 Ensure the definition CMS is using for "marketing" for a product is consistent with the FDA's definition, rather than empowering CMS to create a new definition and further confusion.

5 Fix the restrictions on timing of generic and biosimilar approval to allow faster exit from the Medicare Drug Price Negotiation program.

TO LEARN MORE ABOUT THE IMPACT OF PRESCRIPTION DRUG PRICE SETTING, VISIT WWW.WEWORKFORHEALTH.ORG.

1. Biehn, Brian & Nell, Connor. U.S. Biosimilars Report. September 1, 2023. Cencora. https://biopharmaservices.amerisourcebergen.com/l/168232/2023-02-16/5jzybg/168232/1688587836qO7Kh4MF/SGS_Biosimilars_USMarketLandscape_070123.pdf
2. Association for Accessible Medicines. 2022 U.S. Generic and Biosimilar Medicines Savings Report. https://accessiblemeds.org/resources/reports/2022-savings-report