WE WORK FOR HEALTH

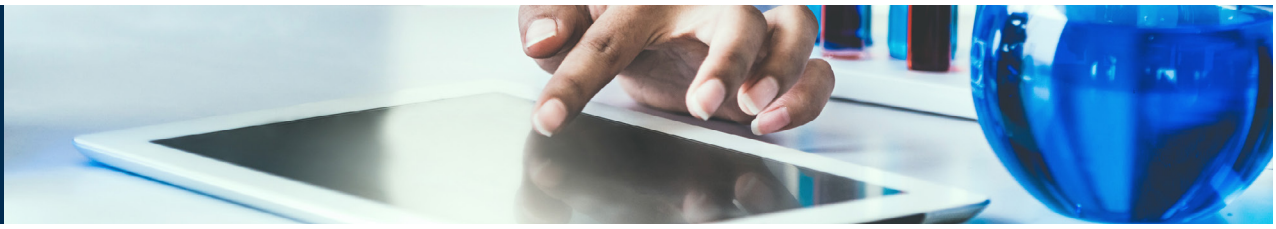
POLICY BRIEF:

PRESERVE BIOSIMILAR COMPETITION AND SAVINGS FOR AMERICAN PATIENTS

Since the U.S. Food and Drug Administration approved the first biosimilar in 2015, biosimilars have played a critical role in increasing treatment options for patients and enhancing the sustainability of the U.S. healthcare system. A biosimilar is a biological product that has no clinically meaningful difference in safety, purity and potency from existing FDA-approved reference products. Biosimilars expand treatment options and competition, effectively lowering costs for treatment and generating significant savings for Medicare, employers, patients and other healthcare stakeholders.

Over the last decade, the FDA has approved **59** biosimilars for **17** reference products – with dozens more expected to launch in the coming years.[1] Biosimilars have produced a total of **$36 billion** in savings since 2015, including **$12.4 billion** last year alone.[2]

WE WORK FOR HEALTH



Unfortunately, provisions in the Inflation Reduction Act (IRA) threaten biosimilar development and jeopardize the cost savings and health benefits they provide.

Under the IRA, biologics can qualify for price setting 11 years after FDA approval as long as no biosimilar is marketed. CMS's 2026-2027 guidance adds the requirement that the biosimilar must be "bona fide marketed." The IRA's 11-year timeline conflicts with the Biologics Price Competition and Innovation Act (BPCIA), which prevents FDA approval of a biosimilar until at least 12 years after the reference biologic's licensure. To account for this, the IRA includes a "Special Rule" that may delay price setting to allow time for biosimilar market entry.

Under the "Special Rule," manufacturers of potential biosimilars must submit an Initial Delay Request before the selected drug list is published. If CMS determines a biosimilar is "highly likely" to be marketed within two years of the selection date, the biologic's price setting can be delayed by one year, with a possible extension. However, the IRA and CMS's interpretation offer limited certainty for biosimilar manufacturers, who face development costs of $100-250 million spent over 7-8 years of research.[3] Once the price of a biologic is artificially reduced under the IRA, biosimilars will not be able to compete as well on price to gain market share and a return on investment.

Congress recognized the need to balance incentives for innovation with robust competition from biosimilars when it passed the BPCIA in 2010. The U.S. biosimilars market has demonstrated its ability to deliver on that framework, providing lower-cost options for patients and significant savings to the healthcare system. To continue realizing these benefits, it's critical that policymakers fix the "Special Rule" provisions in the IRA through the following changes:

1. Simplify the process for application of the "Special Rule" by automatically granting a two-year pause if biosimilar manufacturers meet specific criteria, with an option to request a pause outside the automatic process. Additionally, eliminate the restriction that limits pause eligibility to drugs having FDA approval for more than 12 years.

2. Allow selected drugs to exit the price-setting program once a biosimilar is approved and marketed before the Initial Price Applicability Year (IPAY). Additionally, prevent the publication or application of a Maximum Fair Price (MFP) if a biosimilar is approved and marketed after the "negotiation period" but before the IPAY begins.

3. Clarify that "marketing" of a biosimilar biological product means its introduction or delivery for introduction into interstate commerce, not the "bona fide marketing" concept invented by CMS.

FOR MORE INFORMATION ABOUT THE IRA AND BIOSIMILARS, VISIT WEWORKFORHEALTH.ORG

1. https://www.amerisourcebergen.com/-/media/assets/cencora-biosimilars-usmarketlandscape-11mar24/cencora-biosimilars-usmarketlandscape-may24/cencora-biosimilars-usmarketlandscape-jun24/cencora-biosimilars-usmarketlandscape-jul24.pdf
2. https://accessiblemeds.org/sites/default/files/2024-09/AAM-2024-Generic-Biosimilar-Medicines-Savings-Report.pdf
3. https://pubmed.ncbi.nlm.nih.gov/24991376/