The Biosimilar Access and Affordability Act

Increasing Cost Savings for Americans and saving the Medicare program billions

Biosimilars Have the Potential to Save American Taxpayers Billions

Biologics play a critical role in the treatment of many serious illnesses, ranging from cancers to gastrointestinal disease to genetic disorders. Since the biosimilars pathway was established in the Biologics Price Competition and Innovation Act of 2009,[1] biosimilars have brought enhanced competition to the U.S. market, expanding patient access to high-quality treatment options while reducing costs. Since the first biosimilar was approved ten years ago, these safe and effective medicines have generated substantial savings: biosimilars cost on average 50% to 85% less than the originator products they reference and have the potential to save hundreds of billions of dollars. **If all products with a patent expiring in the next 10 years were to have a biosimilar in the pipeline, the U.S. healthcare system could save an additional $189 billion**.[2]

Despite Savings, the Biosimilars Market Faces Persistent Challenges

Biosimilar competition is crucial to lowering healthcare costs and maintaining a robust marketplace. Yet as a new segment of the market, biosimilars face obstacles to growth, including high costs of production and high regulatory burdens. A typical biosimilar costs from $100 million to $300 million and takes six to nine years to develop.[3] This cost and duration leaves the nascent biosimilar market particularly vulnerable to negative impacts from additional costs.

There is a troubling Biosimilar Void looming in the future. Currently, *only 10 percent* of the 118 biologics expected to lose patent protection in the next decade have biosimilars in development.[4]

The Inflation Reduction Acts (IRA) Creates Additional Challenges for Biosimilars

Adding to the challenges that already exist in the market, the Inflation Reduction Act ("IRA") creates a price-setting framework for certain "selected" drug and biological products[5] that make it more difficult for biosimilar manufacturers to recoup their investments, undermining the development pipeline for the next generation of cost-saving biosimilar medicines.

Biosimilar producers must have sufficient incentives to bring these cost-saving medicines to the market, and sufficient clarity and transparency to plan development pipelines.

In enacting the IRA, Congress recognized that biosimilar competition is crucial to lowering healthcare costs and maintaining a robust marketplace, and that imposing price controls on biological reference products had the potential to disincentivize biosimilar development. For this reason Congress included a "special rule" for biosimilars in the Medicare negotiation program, which was intended to preclude CMS from selecting a drug for negotiation that has an approved and marketed biosimilar or one that will be imminently approved and marketed.

Unfortunately, CMS's implementation of the **Special Rule has not maintained that intention and has added additional undue challenges** to the biosimilars market.

The Biosimilars Access and Affordability Act (S.5459) Fixes these Challenges

S. 5449 provides the clarity required in the implementation of the IRA Biosimilar Special Rule, removing the current ambiguity being used by CMS and replacing it with objective processes and decision-making requirements, as well as strengthening the requirement that a biosimilar must be marketed within the required timeframe in order for the reference product to avoid negotiation. This bill will provide greater assurances to this important source of lowering healthcare costs for Americans through the advancement of strong free-market biosimilar competition.

The Biosimilars Access and Affordability Act (S.5459)

- **Removes any subjectivity** on the part of CMS in granting a biosimilar delay by creating an "Automatic Delay" if certain well-defined requirements are met by the biosimilar.
- **Requires the biosimilar developer to certify** that the biosimilar will be launched and marketed within the two-year delay, ensuring that competition will begin.
- **Removes the current subjective use of the CMS ill-defined "bona fide marketing" standard** and replaces it with long-standing statutory definition of "marketed" in the US.
- **Requires CMS to comply** with the dates reflected in the original IRA Biosimilars Special Rule.
- **Maintains all rebate and penalty provisions** for the reference product if the biosimilar is not marketed within the 2-year delay period.

[1] 42 U.S.C. § 262(k).
[2] IQVIA Assessing the Biosimilar Void in the U.S. (Feb. 3, 2025), available at: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/assessing-the-biosimilar-void-in-the-us.
[3] McKinsey & Company, Three imperatives for R&D in biosimilars (Aug. 19, 2022), available at: https://www.mckinsey.com/industries/life-sciences/our-insights/three-imperatives-for-r-and-d-in-biosimilars.
[4] IQVIA Assessing the Biosimilar Void in the U.S. (Feb. 3, 2025), available at: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/assessing-the-biosimilar-void-in-the-us.
[5] Pub. L. No. 117-169, §§ 11001–11003, 136 Stat. 1818, 1833–62 (2022).