Biosimilar Red Tape Elimination Act

Biologic drugs make up approximately 46% of U.S. prescription drug spending, despite only making up 0.4% of prescriptions.[1] Biologics are more expensive than small molecule drugs because their complexity requires greater testing prior to FDA approval. These tests are meant to ensure safety, but they also pose a barrier to market access.

Historically, prices among small molecule drugs have decreased thanks to competition from generics.[2] Biologics, on the other hand, have not faced similar competition because their generics – known as biosimilars – must undergo more strenuous testing. Bringing a new biosimilar to market costs as much as $250 million and can take as long as 8 years.[3]

To gain approval, biosimilars are required to undergo studies to show there is no clinical difference in health outcomes compared to the reference biologic.[4] Yet those studies are not enough to guarantee market access. Many state laws prohibit pharmacists from filling prescriptions for biologics with an FDA-approved biosimilar unless the FDA declares the biosimilar is interchangeable. To gain interchangeable status, federal law requires that biosimilars undergo what are known as switching studies.[5] In these studies, which can cost millions of dollars and further delay market access, participants must alternate back and forth between the reference biologic and the biosimilar.

While switching studies are meant to act as another layer of safety, more than a decade of data reveals that they are largely unnecessary.[6] The European Medicines Agency (EMA) does not require switching studies. In 2019, the EMA analyzed more than ten years of data and found no difference in "nature, severity or frequency of adverse effects between biosimilars and their reference medicines."[7] In September 2022, the EMA reaffirmed its position, stating: "systematic switch studies are not required to support the interchangeability at prescriber level."[8]

Right now, biosimilars are booming. A recent RAND Corporation study estimates that biosimilars could save $38.4 billion over five years.[9] Repealing the switching studies requirement could accelerate this trend by helping biosimilars get to market faster.[10] With strong evidence suggesting switching studies are unnecessary for biosimilar safety, Congress should repeal this red tape that keeps patients from accessing life-saving drugs.

Bill Summary:

- Would prohibit the FDA from requiring that biosimilars undergo switching studies to receive an "interchangeable" designation.

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[1] Avik Roy, "The Growing Power of Biotech Monopolies Threatens Affordable Care," Foundation for Research on Equal Opportunity, September 15, 2020.
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[4] U.S. Food and Drug Administration, "Data Requirements for Biosimilars," *YouTube.com*, May 22, 2018.
[5] U.S. Food and Drug Administration, "The Concept of Interchangeability," *YouTube.com*, May 22, 2018.
[6] Niazi, SK. No two classes of biosimilars: Urgent advice to the US Congress and the FDA. *J Clin Pharm Ther*. 2022; 47(9): 1352- 1361. doi:10.1111/jcpt.13743
[7] European Medicines Agency, European Commission, *"Biosimilars in the EU: Information guide for healthcare professionals,"* *European Medicines Agency*, (2019).
[8] European Medicines Agency and Heads of Medicines' Agencies (HMA) Biosimilar Working Group, "Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU," *European Medicines Agency*, (September 19, 2022).
[9] Andrew W. Mulcahy, "Biosimilar Drugs Could Generate $38.4 Billion in Savings over Five Years," *RAND Corporation*, January 10, 2022.
[10] Stanton Mehr, "How Did Kaiser Permanente Reach 95%+ Utilization of Biosimilar Herceptin and Avastin so Quickly?," *Biosimilars Review & Report*, November 2019.