THE BIOSIMILAR RED TAPE ELIMINATION ACT

MYTH vs FACT

Senate Bill 2035 (S.2035) the "Biosimilar Red Tape Elimination Act" would declare ALL biosimilars "interchangeable" - meaning that insurance companies and pharmacy benefit managers would be able to substitute them without physician approval, inappropriately treating them like generic drugs. Currently, all 50 states limit this "automatic substitution" practice only to "interchangeable" biosimilars- those which have demonstrated to the FDA that switching patients will not impact safety or efficacy.

Proponents say biosimilars are equivalent to generics, that the bill will cut needless bureaucracy in biosimilar approvals, and that it would align U.S. policy with that of European countries. **What are the facts?**

MYTH: BIOSIMILARS ARE GENERICS

Bill Sponsor Sen. Mike Lee:

"The generic equivalent of a biological drug is known as a biosimilar."[1]

MYTH: INTERCHANGEABILITY REQUIRES SWITCHING STUDIES

Bill Sponsor Sen. Mike Lee:

"Under current regulations, acquiring interchangeable status requires the product to undergo switching studies whereby participants must alternate between the biologic and the biosimilar – over and above the initial approval as a biosimilar." [1]

MYTH: DECLARING ALL BIOSIMILARS INTERCHANGEABLE WOULD ALIGN U.S. WITH EUROPEAN POLICY

Bill Sponsor Sen. Mike Lee:

"After examining 15 years of data, the European Medicines Agency (EMA) recently stated that switching studies are unnecessary for biosimilars to obtain interchangeable status." [1]

1 https://www.lee.senate.gov/2023/7/lee-seeks-increased-competition-in-biological-drug-market

2 https://tinyurl.com/USSurv2024

3 FDA Biosimilars Info Sheet, https://www.fda.gov/media/154912/download

4 https://insidehealthpolicy.com/daily-news/fda-drug-center-officials-defend-biosimilar-switching-policy-change

5 https://gabi-journal.net/policy-recommendations-for-a-sustainable-biosimilars-market-lessons-from-europe.html

6 https://tinyurl.com/EMA-IC-Stmt

7 https://tinyurl.com/EUPhysicians2019

8 https://tinyurl.com/USPhys2021

FACT: BIOSIMILARS ARE NOT GENERICS

FACT: While safe and effective, **unlike generics biosimilars are not structurally identical to their reference products. Only 11% of U.S. physicians support treating all biosimilars as interchangeable.[2]**

WHAT FDA SAYS: "Biosimilars are not generics—and important differences exist between them." [3]

FACT: SWITCHING STUDIES ARE NOT REQUIRED FOR APPROVAL AS AN INTERCHANGEABLE BIOSIMILAR

FACT: FDA currently has discretion to determine what data is needed on a case by case basis; the bill would remove this flexibility. **88% of U.S. physicians say switching studies increase their confidence in biosimilars.[3]**

WHAT FDA SAYS: "we were able to approve the majority (9/13) of interchangeable products without the need for a clinical switching study." [4]

FACT: EMA REFERS TO PRESCRIBER SUBSTITUTION, NOT PHARMACY-LEVEL SUBSTITUTION

FACT: Automatic substitution by third parties is rare in Europe, and banned in most advanced European countries.[5] Both European and U.S. physicians can substitute all biosimilars when prescribing. Majorities of both European[6] (76%) and U.S. physicians[7] (59%) are opposed to substitution of biosimilars by someone other than the physician.

WHAT EMA SAYS: "Biosimilars in the EU may be *prescribed interchangeably.* Decisions about dispensing one medicine instead of another medicine without consulting the prescriber, such as automatic substitution at the pharmacy level are not within the remit of EMA and are managed by individual member states."

Learn more at SafeBiologics.org/ICBiosims

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