PATIENT HEALTH ISN'T 'RED TAPE'

WHY PHYSICIANS AND PATIENTS OPPOSE THE BIOSIMILAR RED TAPE ELIMINATION ACT

The Biosimilar Red Tape Elimination Act (S.2035) would inappropriately eliminate the FDA safeguards now required for the pharmacy substitution of biosimilars. This would undermine physician confidence, risk treatment stability for millions of patients, and give PBMs and insurance companies control of treatment decisions that should be made by physicians and patients.

BIOSIMILARS: SAFE AND EFFECTIVE...BUT NOT GENERICS

Biosimilars are lower-cost copies of off-patent biologic medicines used to treat conditions like rheumatoid arthritis, psoriasis, and cancer. **Unlike generic copies of small-molecule drugs, biosimilars are not identical copies of their reference products**, For this reason, it is illegal for a pharmacy to substitute them "automatically" (without prior physician approval) as is widely accepted with generics.

ONLY INTERCHANGEABLE BIOSIMILARS MAY BE SUBSTITUTED BY A PHARMACY

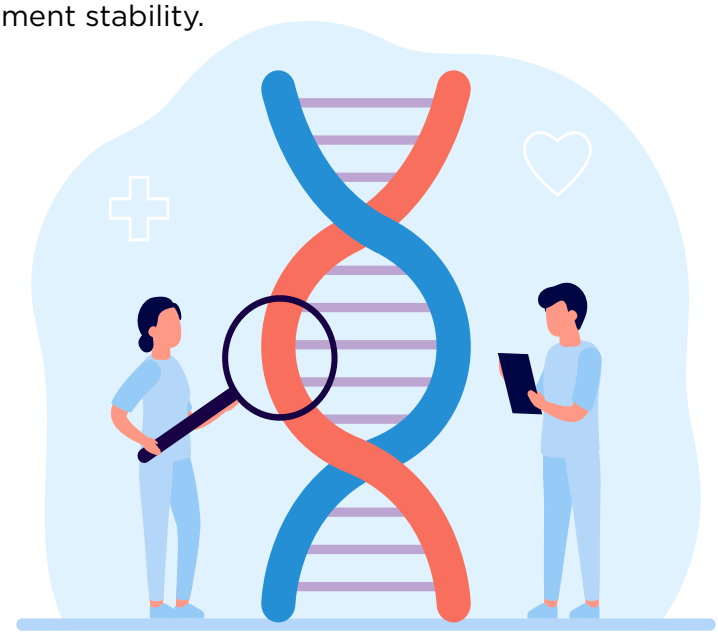
These biosimilars are backed by additional data provided to the FDA - including switching studies when needed- to demonstrate that a patient can be switched between the biosimilar and the reference product and still expect the same safety and efficacy without additional risks.

U.S. PHYSICIANS STRONGLY OPPOSE PHARMACY SUBSTITUTION OF NON-INTERCHANGEABLE BIOSIMILARS

While 89% of U.S. physicians[1] are confident in the safety and efficacy of biosimilars, **69% also say the physician and patient should determine which biologic to use, not a third-party such as a pharmacy or insurance company.** That's because treatment plans aren't one-size-fits-all. Each is uniquely tailored, and patients frequently try several products before finding one that best stabilizes their condition. Physicians need to be confident that a substitution by a pharmacy or insurance company won't disrupt the patient's treatment stability.

The interchangeable standard's data requirements provide that assurance, making a majority (59%) of U.S. physicians more comfortable with a pharmacy-level substitution.

From 2013-2021 all 50 state legislatures passed laws restricting automatic pharmacy substitution of biosimilars ONLY to interchangeable biosimilars. These laws were passed with the support of state medical societies and patient organizations, conditional on these limits. **S.2305 would betray these assurances made to physicians and patients.**



S.2305 Undermines Physician Confidence and Risks Patient Health

S.2305 would classify ALL biosimilars as interchangeable-inappropriately permitting generic-style pharmacy substitution by insurance companies and pharmacy benefit managers, without the safety and efficacy data now needed. This would jeopardize treatment stability for millions of patients and betray the assurances made to physicians and patients nationwide that only biosimilars which had provided additional safety and efficacy data would ever be substituted without physician approval.

It would also restrict what data FDA can ask for to approve an interchangeable biosimilar, requiring the HHS Secretary to hold a private briefing with the chairs and ranking members of the Senate HELP and House Energy and Commerce Committees to justify asking for a study demonstrating switching won't reduce safety of efficacy in patients.

ASBM WHITEPAPER: MISINFORMATION ABOUT INTERCHANGEABLE BIOSIMILARS UNDERMINES US HEALTH POLICY, PHYSICIAN CONFIDENCE, AND PATIENT HEALTH

- CONFUSION ABOUT EUROPEAN SUBSTITUTION POLICY: Others confuse European Medicines Agency's use of the term "interchangeable" (meaning physician-substitutable) with the U.S. definition (meaning pharmacist-substitutable) and incorrectly believe eliminating the distinction would bring the U.S. in line with Europe. **In fact, pharmacy substitution of biosimilars is rare in Europe and frequently banned by EU member states.**[2] **Like their U.S. counterparts, European physicians (73%) strongly oppose pharmacy substitution of biosimilars.**[3]

- MISCONCEPTIONS ABOUT DATA REQUIREMENTS: Some supporters of weakening FDA data requirements incorrectly believe switching studies are mandated by the FDA for a biosimilar to be deemed interchangeable. In fact, **the FDA has flexibility and approved several without these studies. S. 2305 removes that flexibility.**

READ THE PAPER[4]

THE FDA'S INTERCHANGEABLE BIOSIMILAR STANDARD IS WORKING AS INTENDED: BUILDING CONFIDENCE IN SAFE SUBSTITUTION. DON'T UNDERMINE THIS SUCCESS.

Biosimilars have saved the U.S. health system $23 billion to date.[5] 53 have been approved, 13 of them interchangeable. U.S. uptake rates match those seen in Europe[2]: filgrastim, trastuzumab, and bevacizumab biosimilars have an uptake rate of 80%; Rituximab biosimilars; 60% and infliximab, pegfilgrastim, and erythropoietin-stimulating agent biosimilars have 40% market share.[6] Adalimumab biosimilars, after a slow uptake in their first year, recently achieved 36% market share.[7]

JOIN PHYSICIANS AND PATIENTS IN OPPOSING THESE HARMFUL CHANGES TO THE U.S. BIOSIMILAR PROGRAM.

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