PHYSICIAN PERSPECTIVES ON INTERCHANGEABLE BIOSIMILARS

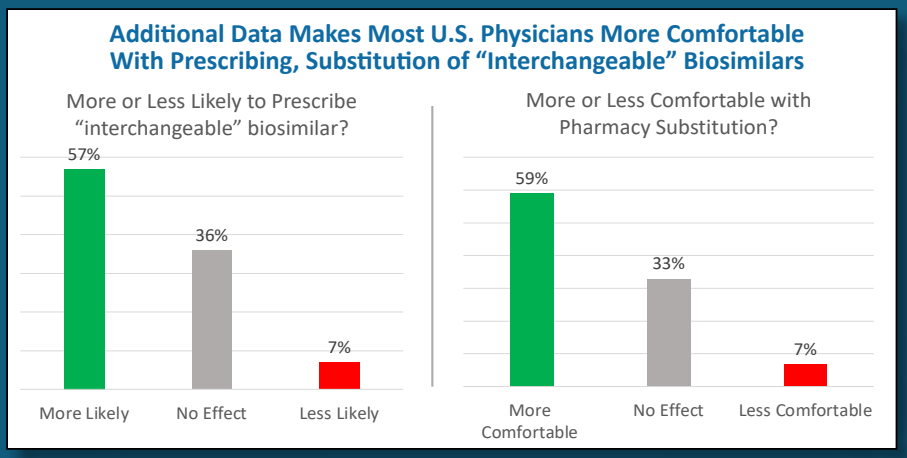
WHAT ARE INTERCHANGEABLE BIOSIMILARS?

Biosimilars are lower-cost copies of 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. While all FDA-approved biosimilars are safe and effective, INTERCHANGEABLE BIOSIMILARS are biosimilars that have provided additional data to the FDA demonstrating that a patient can be switched between the biosimilar and the reference product and still expect the same result without additional risks.

INTERCHANGEABLE BIOSIMILARS BUILD PHYSICIAN CONFIDENCE

Treatment plans are not one-size-fits-all. Patients often try many safe and effective medicines before finding one that works best for them. For this reason, physicians are reluctant to switch patients' medicine unnecessarily.

But the interchangeable biosimilar designation has proven successful in promoting confidence in automatic and third-party substitution among a majority of physicians:



57% said they'd be more likely to prescribe an interchangeable biosimilar; 59% said that an interchangeability designation makes them more comfortable with a pharmacy-level substitution of a biosimilar in place of the originator.[1]

"INTERCHANGEABLE" MEANS "SUBSTITUTABLE BY A PHARMACIST"

Under U.S. state law, **only interchangeable biosimilars can be substituted by a pharmacist without prior physician authorization,** due to the extra confidence the additional data brings to physicians.

AREN'T ALL BIOSIMILARS INTERCHANGEABLE IN EUROPE?

The European Medicines Agency has publicly described all biosimilars it approves as "interchangeable." **However, this refers to substitution by the prescribing physician, not by a pharmacist.** In both Europe and the U.S., all biosimilars may be substituted by the prescribing physician. But while pharmacy substitution is widely accepted with generic small-molecule drugs, it remains controversial with biosimilars and is banned in many countries, including nearly all of Western Europe.

Yet legislation has been proposed in the U.S. that would deem ALL biosimilars to be interchangeable (and thus substitutable at the pharmacy level). This would betray the assurances made to physicians and patients nationwide that only those biosimilars which had provided additional safety and efficacy data would ever be substituted without physician approval.

DOES THE FDA REQUIRE SWITCHING STUDIES FOR AN INTERCHANGEABLE BIOSIMILAR?

No. The FDA has flexibility in determining what data is needed to earn the interchangeable designation. To date, the FDA has approved seven interchangeable biosimilars, in some cases requiring switching studies. But legislation has been proposed which would remove this flexibility from the FDA. This would risk jeopardizing the confidence that physicians have developed in interchangeable biosimilars.

WHERE CAN INTERCHANGEABILITY INFORMATION BE FOUND?

An **interchangeability statement** can be found on a biosimilar's product labeling or package insert. Surveys of physicians (n=400) and pharmacists (n=401) found that **84% of physicians[2] and 87% of pharmacists[3] considered this statement highly important to include on a product's package insert. Despite this, recent FDA Guidance proposes to remove this information and relegate it to the Purple Book, a reference tool used primarily by pharmacists.**

LEARN MORE ABOUT INTERCHANGEABLE BIOSIMILARS AND POTENTIAL POLICY CHANGES:

PHYSICIAN VIDEO

PODCAST DISCUSSION

LETTER TO CONGRESS

SafeBiologics
ALLIANCE for SAFE BIOLOGIC MEDICINES

1 https://safebiologics.org/wp-content/uploads/2023/08/ASBM-2021-US-Biologics-Prescribers-Survey-Specialty-Data.pdf

2 https://safebiologics.wpengine.com/wp-content/uploads/2019/04/US-February-2015-Labeling-Report.pdf

3 https://safebiologics.wpengine.com/wp-content/uploads/2019/04/2015-US-Pharmacists-Report-OCT4.pdf