Patients and physicians want doctors involved in treatment decisions. **Notification after substitution of interchangeable biologics is common sense.**

WHAT PATIENTS SAY

The decision to utilize a biologic or a biosimilar should be overseen by the physician with the consent of his or her patient. Physicians are in the best place to make medical decisions because they know a patient's history and can prescribe treatments accordingly. **Third parties like pharmacists and insurers should not interfere with this role.**

-American Association of People with Disabilities
(FDA Testimony, 5/12/12)

"In addition to unique names for all biologic therapies and transparent product labels, **physicians should be consulted prior to a patient's medicine being switched from one product to another** to ensure proper adverse event reporting."

-National Alliance on Mental Illness
(FDA Testimony, 5/12/12)

"For the patient community, a determination of product interchangeability could **take the decision-making process out of the hands of patients and doctors** and put it into the hands of the pharmacists or insurers through states' automatic substitution policies. **We believe that the choice of product should be decided only by patients and physicians,** who are ultimately responsible for patient care and have the full spectrum of a patient's medical history."

-Colon Cancer Alliance
(FDA Testimony, 5/12/12)

"Biosimilars' are aptly named because they are *similar* - but not identical - to the original reference product. [This] creates a complex risk/benefit assessment that **can only be made safely by the patient's physician. The prescriber and patient should always be involved** in decisions regarding selection of the biological product a patient receives. **Automatic retail substitution of biotech medicines is not appropriate.**"

-Immune Deficiency Foundation
(FDA Testimony, 5/12/12)

The following physician groups have spoken out publicly about the need to prevent substitution of biologic medicines without the prescribing physician's knowledge:

American Association of Clinical Endrocrinologists
American Academy of Dermatology Association
American Association of Neurological Surgeons
American Association of Orthopaedic Surgeons
American College of Emergency Physicians
American College of Obstetricians & Gynecologists
American College of Rheumatology
American Gastroenterological Association
American Society for Therapeutic Radiology & Oncology
American Society of Cataract & Refractive Surgery
American Urological Association
Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons
Heart Rhythm Society
National Association of Spine Specialists
Medical Society of New Jersey

Biosimilar Policy in Europe:

No Interchangability
No Automatic Substitution
Physician-approved Substitution Only

Opponents of physician notification consistently cite the European Union as an example of good biosimilars policy.

Yet automatic substitution by a pharmacist of a biosimilar for a reference biopharmaceutical medicine is **not allowed in any European country**[1] and is **not recommended** by the World Health Organization or by medical societies.[2-4]

The European Medicines Agency advises that **the physician should be in charge of the decision** to switch between the reference and biosimilar, or vice versa[5].

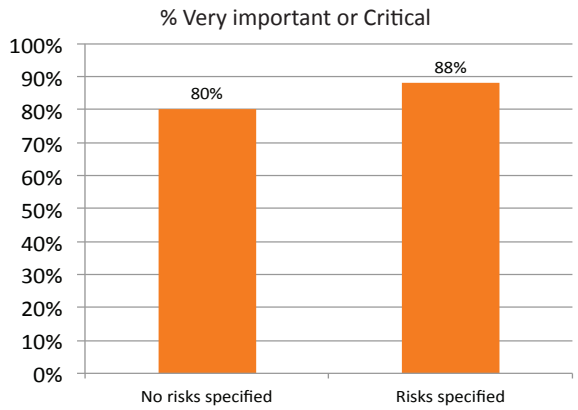
Countries with the most experience with biosimilars don't allow automatic substitution due to concerns about patient safety.

We do not oppose automatic substitution, provided that a physician is notified AFTER a substitution has occurred.

The patient community in the US shares the concerns of the EU and the WHO. **They deserve, at a minimum, physician notification if a biosimilar is automatically substituted in the US.**

1. *European Generic Medicines Association. Biosimilars Handbook, 2nd ed. Brussels: European Generic Medicines Association; 2011.*
2. *Hodgson J. WHO guidelines presage US biosimilars legislation, Nat Biotechnol. 2009;27:963–965.*
3. *Holmes DR Jr, Becker JA, Granger CB, et al. ACCF/AHA 2011 Health Policy Statement on Therapeutic Interchange and Substitution: a report of the American College of Cardiology Foundation Clinical Quality Committee. Circulation. 2011;124:1290–1310.*
4. *Jelkmann W. Biosimilar epoetins and other "follow-on" biologics: update on the European experiences. Am J Hematol. 2010;85:771–780.*
5. *European Medicines Agency. Questions and Answers on Biosimilar Medicines (Similar Biological Medicinal Products). London: European Medicines Agency; 2012. Available from: http://www.ema.europa.eu/docs/en_GB/document_library/Medicine_QA/2009/12/WC500020062.pdf. Accessed November 6, 2012.*

WHAT PHYSICIANS SAY



In a recent survey of 376 prescribing physicians, Over 80% of Physicians say **it is "very important or critical" that they be notified** of medication switiching by a third party such as a pharmacist or insurer- even if there are no *known* risks.

Source: Alliance for Safe Biologic Medicines, Prescriber Survey August 31, 2012

Insurers or other third parties must not be empowered to dictate what therapies physicians can prescribe and patients can access. Only physicians, not insurers or other third parties, have the medical **education and understanding of their patient's individual needs necessary to safely prescribe these powerful therapies.**

- Dr. Robert Yapundich, Alliance for Patient Access (FDA Testimony, 5/12/12)

"Therefore, in the interest of our patients relying on biologic products I urge the FDA to foreclose this avenue until the science advances in this area. **Anything short of barring interchangeability at this time would be detrimental to patient safety** and would erode physician confidence in prescribing these medications"

-Coalition of State Rheumatology Organizations (FDA Testimony, 5/12/12)

The Alliance for Safe Biologic Medicines (ASBM) is a 501C (4) organization of diverse healthcare groups and individuals from patients, physicians and pharmacists, biotechnology companies that develop biologics and biosimilars medicines, and others who are working together to ensure patient safety is at the forefront of the biosimilars policy discussion. ASBM supports the efforts of FDA in introducing an approval pathway focused on patient safety and is dedicated to educating stakeholders on these next-generation medicines.

SafeBiologics
ALLIANCE *for* SAFE BIOLOGIC MEDICINES