SafeBiologics
ALLIANCE for SAFE BIOLOGIC MEDICINES

ABOUT ASBM

The Alliance for Safe Biologic Medicines

ASBM is an organization of physicians, patient advocates, pharmacists, researchers, and others who share the common goals of improving patient access to biologic therapies, promoting high safety and quality standards, and keeping physicians and patients in charge of making treatment decisions. As of 2017, ASBM has more than 60 members spread across five continents. The overwhelming majority of these are patient groups.

What ASBM Does

ASBM works to educate lawmakers and regulators as they craft biosimilar policy at the state, federal, and international level by providing them the perspectives of the physicians who prescribe them every day, and the patients who count on them being safe and effective. To date ASBM has gathered data from biologic prescribers in twelve countries, and partners with patient organizations worldwide to ensure patient voices are heard by policymakers.

Since 2010, ASBM has presented research findings and patient testimony to regulators around the word, including forums in: Australia, Belgium, Brazil, Canada, Italy, Germany, Spain, and the United States. Regulatory bodies include the World Health Organization (WHO), the European Union, the International Conference of Drug Regulatory Authorities, Australia's Therapeutic Goods Administration (TGA), as well as the U.S. Food and Drug Administration (FDA) and numerous state legislatures in the U.S.

ASBM Chair

Madelaine Feldman MD, FACR is a practicing rheumatologist in New Orleans, Louisiana and current chair of ASBM. She is a founding member and past president of the Rheumatology Alliance of Louisiana, and vice-president of the Coalition of State Rheumatology Organization where she is board liaison to the Association of Women in Rheumatology. She also recently served on the insurance subcommittee for the American College of Rheumatology.

She received her training from Tulane University School of Medicine, where she also completed her internal medicine residency and rheumatology fellowship. Dr. Feldman continues her devotion to Tulane University School of Medicine serving as a Clinical Associate Professor of Medicine.

What are Biologics and Biosimilars?

Biologic medicines are used to treat cancer, rheumatoid arthritis, psoriasis and other serious conditions. Attempts to copy these therapies bring patients new treatment options at reduced cost. But unlike with chemical drugs, the complexity of biologics and the process by which they are created in living cells means that a copy can only ever be "similar" to its reference product, hence these are referred to as "biosimilars." Even seemingly minor differences between similar biologics can produce unexpected effects in patients, including unwanted and harmful immune reponses.

How similar is "similar enough" to be therapeutically interchangeable is a question regulators are in the process of determining.

Biosimilar Policy Issues

Biosimilars can bring great benefits to patients worldwide. In order to bring these benefits to patients, policymakers must address numerous regulatory challenges. ASBM supports policies that will increase physician and patient confidence in biosimilars such as: clear product identification, transparent and informative labeling, and keeping treatment decisions between a patient and his or her physician.

Some key policy questions on which ASBM engages include:

Approval
ASBM supports strong approval standards for biosimilars. The burden must be on the manufacturer to demonstrate that their product is as safe and effective as the product it aims to replicate. Approval to treat one disease of the reference product should not automatically translate into approval to treat all diseases. Approval granted based on extrapolation across diseases should be done cautiously with biosimilarity having been demonstrated in the indications, and populations, most sensitive to adverse events such as immunogenic responses.

Naming
ASBM supports proposals by the U.S. Food and Drug Administration (FDA) and World Health Organization (WHO) to ensure clear naming of all biologics (including biosimilars) by means of a four-letter suffix. It is ASBM's position that these suffixes should be meaningful and memorable (reflective a manufacturer's names, for example, rather than random letters) as these are easier for healthcare providers to recognize and remember.

Labeling
ASBM supports product labeling which clearly identifies a biosimilar as such; this serves as a flag to physicians that the biosimilar may not have been evaluated in, or approved for all indications of its reference product. In order for physicians to make informed treatment decisions, the biosimilar should specify whether or not it was approved to treat a disease based on clinical biosimilarity data or on extrapolation from biosimilarity data demonstrated in another disease.

Substitution
ASBM believes that treatment decisions, including whether to prescribe or switch to a biosimilar should remain with the patient and physican, rather than a third-party payer. The decision to switch should only be made for medical reasons, rather than any potential savings to an insurer or government. The prescribing physican must always be informed in the event a biosimilar is substituted at the pharmacy, in order that he or she can accurately monitor a patient's response to treatment.

Global Standards
ASBM supports the establishment of global standards for approval, naming, labeling, and substitution. Safe, effective biosimilars should not be a luxury reserved for wealthy countries. High standards will protect patients worldwide, and patients should be able to expect safe, effective biosimilars in whichever country they recieve treatment.

Learn More at SafeBiologics.org

To learn more about biologics, explore ASBM's physician surveys, and our global advocacy on behalf of patients who want safe, effective biosimilars, please visit **www.SafeBiologics.org.**

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