SafeBiologics

ALLIANCE *for* SAFE BIOLOGIC MEDICINES

## Who We Are

The Alliance for Safe Biologic Medicines (ASBM) is an organization composed of diverse healthcare groups and individuals from patients to physicians, innovative medical biotechnology companies, and others who are working together to ensure patient safety is at the forefront of the biosimilars policy discussion.

## Our Mission

It is the mission of ASBM to serve as an authoritative resource center of information for policy makers, the healthcare community and the general public on the issues surrounding biologic medications. We provide information on the safety and quality of biologics, advocate for policies that keep medical decisions between patients and physicians, and seek solutions that ensure affordability and accessibility of biologic medicines while never compromising on patient safety.

## What We Do

Since the organization's founding in 2010, ASBM has emerged as one of the nation's most trusted resource-centers on issues related to the introduction of biosimilars in the United States. We have been actively engaged in the biosimilars policy process.

Ten ASBM member organizations submitted written comments to the U.S. Food and Drug Administration on the biosimilar draft guidance in April 2012, and 9 members and ASBM's Chairman appeared at FDA's May 11, 2012 public hearing to testify on the draft guidance including *Alliance for Patient Access, Amgen, Biotechnology Industry Organization, Colon Cancer Alliance, Genentech, Global Healthy Living Foundation, HealthHIV, National Alliance on Mental Illness,* and *RetireSafe.*

Over the past year ASBM hosted and participated in several educational webinars and forums in Virginia, Pennsylvania, Massachusetts, Washington, D.C. and Toronto, Canada. ASBM distributes a monthly newsletter and maintains a comprehensive website that features relevant news, blogs, and guest commentary.

ASBM members have been featured in a number of widely read publications including *Politico, Inside Health Policy, The Pink Sheet, The Hill, AOL News, Huffington Post, The Buffalo News, The Sacramento Bee.*

### *About Our Chairman, Harry L. Gewanter, MD, FAAP, FACR*

Dr. Gewanter was born in Brooklyn New York and was raised in the same area. He attended Duke University for his undergraduate studies and Wayne State University for his medical training. He attended the University of Rochester/Strong Memorial Hospital for his Pediatric Internship and Residency, performed a fellowship in Pediatric Rheumatology and General Academic Pediatrics, and practiced for 2 years in Rochester, NY before moving to Richmond, VA. He worked at several practices and at Children's Hospital prior to joining Pediatric & Adolescent Health Partners. Dr. Gewanter was the first Walter Bundy, Jr. Professor of Community Pediatrics at VCU from 1999 - 2001.

Dr. Gewanter has special interests in all issues relating to Children and Youth with Special Health Care Needs (CYSHCN), advocating on behalf of all children and people with disabilities. He is known for his untiring advocacy activities at the local, state and national level.

## The Issue

Biologics are advanced prescription medicines to treat cancer, rheumatoid arthritis, and other debilatating diseases. In March of 2010, the Affordable Care Act granted the FDA the authority to establish a pathway for the introduction of biosimilars in the U.S. In November 2010, the FDA began consultation with patient groups, physicians, and industry on how to approve the first biosimilars. As the FDA moves forward in implementing this pathway, ASBM will work to ensure patient safety remains the priority.

## Our Perspective

### *Prioritizing Patient Safety*

In contrast to most medicines that are chemically synthesized and have structures that are known, biologics are complex compounds made from living cells and have highly complex structures that are not easily understood, characterized or replicated. That is why the attempts to replicate biologics are called biosimilar and not generics. Biosimilars are “similar to” but not exact copies of biologics and small differences can have unexpected or harmful clinical outcomes for patients.

The introduction of biosimilars offers great promise to patients through broader access to lifesaving medicines, however patient safety must remain paramount.

### *Leveraging What We Know*

The European Medicines Agency and Health Canada have each established a formal regulatory pathway that led to the introduction of biosimilars in the European Union in 2003 and Canada in 2010. Both regulatory bodies used a patient-centric, scientific approach that can serve as a baseline model for the U.S. By pioneering in this regulatory area, the E.U. and Canada have gathered data which can, at a minimum, help inform our policy makers. ASBM has established a dialogue with both healthcare communities to learn from their experiences.

### *Promoting Pharmacovigilance*

Pharmacovigilance is the surveillance of a drug’s performance, particularly of adverse reactions, after it has been released for marketing. Because biosimilars could be approved on less data than other medicines, pharmacovigilance is particularly important. Before biosimilars are introduced into the U.S. market, a robust traceability system (including distinctive labels, product tracking codes, and a way to report adverse events) must be in place to ensure accurate surveillance.

### *Keeping Doctors Relevant*

The physician-patient relationship and decision-making process must be preserved. Insurers or other third parties must not be empowered to dictate what therapies physicians can prescribe and patients can access. Only physicians have the medical education and understanding of their patients’ individual needs necessary to safely prescribe these powerful therapies.

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