



July 25, 2014

Mark Johnston, R. Ph
Executive Director
Idaho Board of Pharmacy
P.O. Box 83720
Boise, ID 83720-0067

Dear Mr. Johnston:

As the chairman of the Alliance for Safe Biologic Medicines (ASBM), I am writing to you in regards to the Idaho Board of Pharmacy's proposed regulations and upcoming hearing on the substitution of biosimilar products.

ASBM is an organization of patients, physicians, pharmacists, biotechnology companies that develop innovative and biosimilar medicines and others, who are working together to ensure patient safety is at the forefront of the biosimilars policy discussion. We believe that when interchangeable biosimilar products are substituted, communication among patients, pharmacists, and health care providers is essential to patient care and therefore, as a result patient safety would be enhanced in Idaho by regulations that consider the unique nature of biologics medicines.

As you know, biologics are highly complex, advanced prescription medicines used to treat cancer, rheumatoid arthritis, diabetes, MS and many other debilitating diseases. Unlike drugs derived from chemicals, biologics are manufactured using a unique process with living cells and for this reason no two biologics made from different cell lines are ever identical. When attempting to replicate biologics, their "copies," known as biosimilars, are similar to, but not exact versions of the biologic they aim to replicate and are often mistakenly referred to as "generics." Even the smallest difference in the structure of a biologic medicine and its attempted copy can have a significant impact on a patient and therefore, the issue of interchangeability has been a new challenge for policymakers.

Since the inception of ASBM nearly four years ago, ASBM has been working with physicians and pharmacists to determine the best solutions on biosimilar interchangeability. To help raise education on the issue of these next-generation medicines and the policy challenges they bring, ASBM has been holding forums across the country with policymakers, patient advocates, physicians, pharmacists and other stakeholders to discuss the need for stringent standards when manufacturing biosimilars to ensure patient well being. In 2012, ASBM convened a working group of our Advisory Board members to discuss what are the important considerations in crafting biosimilars policies and developed key principles that we believe should be included in any formal policy recommendation regarding biosimilars. These principles can be found on our website. (<http://safebiologics.org/resources/2012/10/asbm-statement-on-automatic-substitution/>).

Specifically, ASBM believes regulations are needed to ensure doctors have a complete knowledge of what medicines are administered to their patients. Physicians and pharmacists should work collaboratively to ensure the well being of patients remains the top priority. Therefore, we believe it is necessary for physicians to be informed of the exact biologic – by manufacturer – given to a patient in order to accurately attribute any adverse events that may occur. Communication between pharmacists and physicians enhance the safety and efficacy of biologic products, while also advancing more treatment options to patients.

This year alone the states of Indiana, Delaware and Massachusetts have all updated their pharmacy regulations to pave the way for biosimilars and just recently the Food and Drug Administration accepted their first biosimilars application for review. ASBM supported the measures in those states and we continue to work with the FDA and other regulatory bodies around the world on biosimilars policies. We support the future use of biosimilars in the United States, and we look forward to working with Idaho’s Board of Pharmacy as it moves forward in crafting biosimilars regulations.

Sincerely,



Richard Dolinar, M.D.
Chairman, The Alliance for Safe Biologic Medicines

ASBM STEERING COMMITTEE:
American Academy of Dermatology
Association of Clinical Research Organizations
Global Colon Cancer Association
Health HIV
Kidney Cancer Association
National Psoriasis Foundation

Alliance for Patient Access
American Autoimmune Related Diseases Association
Colon Cancer Alliance
Global Healthy Living Foundation
International Cancer Advocacy Network
National Hispanic Medical Association
ZERO-The End of Prostate Cancer