SafeBiologics
ALLIANCE *for* SAFE BIOLOGIC MEDICINES

February 27, 2014

Governor Mike Pence
200 West Washington Street, Room 200
Indianapolis, IN 46204

Dear Governor Pence:

As the chairman of the Alliance for Safe Biologic Medicines (ASBM), I am writing to request that you sign SB 262 on the substitution of biosimilar products into law.

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, we fully support SB 262 and are concerned that patient safety will be compromised if this legislation is not enacted.

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.

To help raise education on the issue of these next-generation medicines and the policy challenges they bring with them, 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 safety.

We have been working with physicians and pharmacists since the inception of ASBM nearly three years ago to determine the best solutions on biosimilar interchangeability. ASBM has convened a working group of our Advisory Board members to discuss the elements of a physician notification policy for interchangeable biosimilars that prioritizes patient safety and protects the relationship between physicians and their patients but also respects the sovereignty of pharmacists as healthcare providers. We conducted a physician survey in the U.S. which was first presented at the FDA/DIA Biosimilars Conference in September 2012 and has since been shared with policymakers in the U.S. and also at the World Health Organization in Geneva, Switzerland this past October. The survey found that 86% of the more than 350 physicians who participated, responded that they want to be notified BEFORE a patient is switched to a biologic other than the one prescribed. In addition, in Europe where biosimilars have been available since 2006,

automatic substitution is not allowed. This perspective speaks volumes on the clinical practice of medicine.

Therefore, ASBM has developed key principles that should be included in a formal policy recommendation. We released a statement in October 2012 on the key principles *(http://safebiologics.org/resources/2012/10/asbm-statement-on-automatic-substitution/)* that we believe should be included in formal policy recommendations. We support SB 262 as we find it consistent with our principles, specifically that:

> (1) The biosimilar product has been determined by the United States Food and Drug Administration to be interchangeable with the prescribed product for the indicated use;
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> (2) The practitioner must sign on the line under which the words "May substitute" appear;
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> (3) The pharmacists must inform the customer of the substitution;
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> (4) After dispensing an interchangeable biologic to a patient, the pharmacist must notify the treating physician within 10 days of the exact biologic product by manufacturer in order to attribute any adverse events that may occur; and
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> (5) The pharmacist shall retain a written record of the biosimilar substitution for a period of no less than 2 years.

Thank you for taking the necessary steps to make patient safety a priority in Indiana. We have supported the FDA in its mission to safely bring biosimilars to the U.S. and we support your efforts with SB 262.

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

cc: Sean Keefer, Legislative Director
Brian Neale, Health Policy Director