SafeBiologics
ALLIANCE *for* SAFE BIOLOGIC MEDICINES

February 19, 2013

Senator Kelli Ward
1700 W. Washington
Room 304
Phoenix, AZ 85007

Senator Nancy Barto
1700 W. Washington
Room 307
Phoenix, AZ 85007

Dear Senator Ward and Senator Barto,

As the chairman of the Alliance for Safe Biologic Medicines (ASBM) and a local practicing endocrinologist, I would like to express to you our support for SB 1438 on substituting biosimilar medicines. 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.

I have personally been very involved in working with physicians, pharmacists and patients across the country to raise awareness on these next-generation medicines. In September 2012, ASBM, the International Cancer Advocacy Network (ICAN) and AZBio hosted "Biosimilars Policy Forum: Ensuring Patient Safety" here in Phoenix, to discuss the complex challenges we face as a regulatory pathway is established and biosimilars are made available to patients.

Biologics are highly complex, advanced prescription medicines used to treat diabetes, cancer, rheumatoid arthritis, MS, infertility 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 policy-makers.

ASBM has been very focused on bringing both physicians and pharmacists together to determine the best solutions on biosimilar interchangeability. In May 2012, we 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. In September, I presented findings from a physician survey we conducted at the FDA/DIA Biosimilars Conference that found that 86% of the 350 physicians who participated, responded they want to be notified BEFORE a patient is switched to a biologic other than the one prescribed EVEN IF there are no known concerns associated with the product.

In October 2012, ASBM released key principles that should be included in a formal policy recommendation. We believe that building policy around these common sense recommendations will help ensure safety without delaying the introduction of biosimilars to patients and for this reason, we support the measures in SB 1438, especially that a substitution can occur if:

1. The FDA has determined the biosimilar product is interchangeable with the prescribed biological product.
2. The medical practitioner has not indicated that the pharmacist may not substitute the specific biologic product prescribed by the practitioner.
3. Pharmacy personnel have notified the patient of the substitution of the interchangeable biosimilar product in writing and orally.
4. The pharmacist notifies the medical practitioner of the substitution in writing or electronically within seventy-two hours.

We strongly believe that when interchangeable biosimilar products are substituted, communication among patients, pharmacists, and health care providers is essential to patient care and we thank you for taking the steps to ensure communication and patient safety are priorities here in Arizona.

Sincerely,

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

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