SafeBiologics
ALLIANCE *for* SAFE BIOLOGIC MEDICINES

March 1, 2013

Representative Matt Hudson
222 The Capitol
402 South Monroe Street
Tallahassee, FL 32399-1300

Dear Representative Hudson,

As the chairman of the Alliance for Safe Biologic Medicines (ASBM) and as a practicing endocrinologist, I would like to express to you our support for HB 365, on the substitution of 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. We agree that when interchangeable biosimilar products are substituted, communication among patients, pharmacists, and health care providers is essential to patient care.

Biologics are highly complex, advanced prescription medicines used to treat cancer, rheumatoid arthritis, diabetes, MS, infertility and many other debilitating diseases in Florida and around the world. 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.

To help raise awareness on the issue of these next-generation medicines and the policy challenges they bring with them, ASBM has been holding educational forums across the country and working with stakeholders to discuss the need for stringent standards when manufacturing biosimilars to ensure safety.

Over the past year, we have been very focused on the issue of interchangeability and the need for physician notification when biosimilars are substituted for biologics. 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. We support HB 365 because we agree that a pharmacist may only dispense a substitute biological product for the prescribed biological product if:

(1) The United States Food and Drug Administration has determined that the substitute biological product is biosimilar to and interchangeable for the specified indicated use of the prescribed biological product.

(2) The prescribing health care provider does not express a preference against substitution in writing, verbally, or electronically.

(3) The pharmacist, within 5 business days after dispensing the substitute biological product in lieu of the prescribed biological product, notifies the prescribing healthcare provider of the substitution by facsimile, telephone, voicemail, email, electronic medical record, or other electronic means.

(4) The pharmacist and the prescribing health care provider each retain a written record of the substitution for at least 4 years.

Thank you for your leadership on this issue and fighting for patient safety in Florida. I have included a fact sheet that demonstrates broad support for physician notification when interchangeable biosimilars are automatically substituted that I hope you find helpful. Please let me know if ASBM can be a resource for you moving forward.

Sincerely,

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

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