SafeBiologics
ALLIANCE *for* SAFE BIOLOGIC MEDICINES

January 23, 2013

Representative Edward Clere
200 W. Washington St.
Indianapolis, Indiana 46204

HB 1315

Dear Representative Clere,

As the chairman of the Alliance for Safe Biologic Medicines (ASBM), I would like to express to you our support for HB 1315 on biosimilar biological products. Our organization is dedicated to ensuring that patients are at the forefront of the biosimilar policy discussion and we have been working with patients, physicians, pharmacists, innovative medical biotechnology companies and others for over two years to make sure this happens. Since the FDA was given the authority to bring biosimilars to patients in the U.S., we have supported their efforts in introducing an approval pathway and we support your legislation promoting patient safety.

As a practicing endocrinologist, I have personally been very involved in working with physicians, pharmacists and patients across the country to raise awareness on these next-generation biologic medicines that are treating cancer, rheumatoid arthritis, diabetes, MS, infertility and many other debilitating diseases.

Biologics are highly complex, advanced prescription medicines that, unlike drugs derived from chemicals, are manufactured using a unique process with living cells. No two biologics made from different cell lines are ever identical. Biosimilars, which aim to replicate biologics, are – as the name suggests – similar, but not the same as the innovator drug. 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 substituting a biosimilar for a biologic medicine has created new challenges for policy-makers.

We have been working with both physicians and pharmacists to develop principles to determine the best solutions for these challenges. 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. We released a statement in October 2012 on the key principles that we believe should be included in formal policy recommendations, which also support the measures outlined in HB 1315, specifically your inclusion that:

> Sec. 3. A pharmacist may substitute a biosimilar product for a prescribed biological product if the following conditions are met:

(1) The biosimilar product has been determined by the federal Food and Drug Administration to be interchangeable with the prescribed biological product for the specified indicated use.
(2) The prescribing physician has not indicated on the prescription that a substitution is not permitted.
(4) The pharmacist notifies the physician, in writing or electronically, within twenty-four (24) hours of the substitution.

As an organization dedicated to patient safety, we commend you for taking the necessary steps to ensure that patients are the top priority as biosimilars are introduced in the U.S. and substituted for biologics in Indiana.

Sincerely,

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

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