SafeBiologics
ALLIANCE *for* SAFE BIOLOGIC MEDICINES

February 26, 2013

Senator Laurie Monnes Anderson
900 Court St, NE S-413
Salem, OR, 97301

Senator Jackie Winters
900 Court St. NE, S-301
Salem, OR 97301

Dear Senator Monnes Anderson and Senator Winters,

As the chairman of the Alliance for Safe Biologic Medicines (ASBM) and a practicing physician who prescribes biologics, I would like to express to you our support for Senate Bill 460 on the substitution of interchangeable biosimilar biological products. Our organization was formed in December 2010 after the FDA was given the authority to bring biosimilars to the U.S. and since then we have been working with patients, physicians, pharmacists, innovative medical biotechnology companies and others to ensure that patient safety is at the forefront of the biosimilars policy discussion. We have supported the FDA for over two years in its mission to safely bring biosimilars to patients in the U.S. and we support your efforts to safely bring biosimilars to patients in the Beaver State.

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.

We believe it is absolutely critical that when substituting biosimilars for biologics there needs to be clear communication between physicians, pharmacists and patients and we have been very focused on bringing these stakeholders 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. ASBM agrees

with SB 460 that a pharmacy or pharmacist filling a prescription order for a biological product may not substitute a biosimilar product for the prescribed biological product unless:

1. The biosimilar product has been determined by the United States Food and Drug Administration to be interchangeable with the biological product for the use for which the prescribing practitioner prescribed the biological product;
2. The prescribing practitioner has not designated on the prescription that substitution is prohibited;
3. The patient for whom the biological product is prescribed is informed of the substitution prior to dispensing the biosimilar product;
4. The pharmacy or pharmacist provides written, electronic or telephonic notification of the substitution to the prescribing practitioner or the prescribing practitioner's staff within three business days of dispensing the biosimilar product; and
5. The prescribing practitioner, and the pharmacy or pharmacist, retain a record of the substitution for a period of not less than three years.

Thank you for taking the necessary steps to ensure patient safety in Oregon. I've included a fact sheet that demonstrates broad support for physician notification when interchangeable biosimilars are automatically substituted. I hope 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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