

February 2, 2016

Representative Mitch Greenlick  
Chair, House Committee on Health Care  
Representative Rob Nosse,  
Vice-Chair, House Committee on Health Care

Dear Representatives,

As the chairman and advisory board chair of the Alliance for Safe Biologic Medicines (ASBM), we are writing to request that you **support House Bill 4105 (HB 4015)** regarding the pharmacy substitution of biosimilar medical products. ASBM is an organization of patients, physicians, pharmacists, manufacturers of both innovative and biosimilar medicines, and others who are working together to ensure patient safety is at the forefront of the biosimilars policy discussion.

As a retired pediatric rheumatologist and a former president of the American Society of Health-system Pharmacists, we are keenly aware of the benefits of biologics in treating serious conditions like cancer, rheumatoid arthritis, diabetes, and MS. “Copies” of these medicines, called “biosimilars” have the potential to provide these therapies at reduced cost. Yet unlike generic versions of chemical drugs biosimilars are not exact duplicates of their reference products. Indeed, the complexity of biologics and their proprietary manufacturing processes mean that these “copies” can only ever be similar, never the same. Even the smallest structural difference between a biologic and its attempted copy can have a significant impact on a patient. Therefore, the issue of interchangeability has been a new challenge for policymakers.

We believe that when interchangeable biosimilar products are substituted, communication between patients, pharmacists, and health care providers is essential to patient care. We fully support HB 4105 and are concerned that patient safety will be compromised if this legislation is not enacted.

Since 2012, ASBM has conducted surveys of physicians in eleven countries, to gather their perspectives on biosimilars. The results of these surveys have since been shared with policymakers in the U.S., Canada, Europe, and the World Health Organization in Geneva, Switzerland.

- **Our survey of 376 U.S. physicians found that 80% of those surveyed called notification in the event of a biosimilar substitution “very important” or “critical”.**
- **Further, 82% of U.S. physicians called the authority to block a substitution by indicating “do not substitute” or “dispense as written” on a prescription “very important” or “critical”.**

These results are consistent with those of physicians around the world, including those surveyed in Canada and Europe, where biosimilars are currently in clinical use. All ASBM surveys are available on our website at [www.safebiologics.org](http://www.safebiologics.org).

It is our view that **HB 4105 appropriately reflects the importance of pharmacist-physician communication** and keeping treatment decisions the purview of the physician and patient, without posing undue or onerous burdens upon the pharmacist:

- It provides that only “interchangeable” biosimilars (those determined by the FDA to produce the same effects in a patient as the reference product without additional risks) or which are “therapeutically equivalent” to their reference products may ever be substituted.
- It provides that the patient be informed of any substitution.
- It allows a physician to prevent a substitution they consider inappropriate for their patient by designating substitution as prohibited on the prescription.

- Finally HB 4105 requires that the pharmacist communicate to the physician within a reasonable time frame (5 days) which biologic the patient actually received – whether that prescribed by the physician, or a substituted biosimilar- so that an accurate patient record can be kept by all parties.

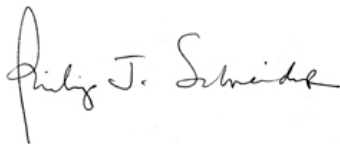
HB 4105 will extend these valuable protections to Oregon's patients while increasing their access to biologic therapies.

**Thank you in advance for taking the necessary steps to keep patient safety a priority in Oregon by supporting House Bill 4105.**

Sincerely,



**Harry Gewanter, MD**  
Chairman, The Alliance for Safe Biologic Medicines



**Philip J. Schneider, MS, FASHP**  
Advisory Board Chair, Alliance for Safe Biologic Medicines  
Professor, University of Arizona College of Pharmacy

**ASBM Steering Committee Members:**

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American Autoimmune Related Diseases Association (AARDA)  
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Colon Cancer Alliance  
Global Colon Cancer Association  
Global Healthy Living Foundation  
Health HIV  
Hepatitis Foundation International  
International Cancer Advocacy Network  
Kidney Cancer Association  
National Psoriasis Foundation  
ZeroCancer

Cc: Members, House Committee on Health Care