February 3, 2016

The Honorable Mitch Greenlick
Chair, House Committee on Health Care
900 Court St. NE, H-493
Salem, Oregon 97301

The Honorable Rob Nosse
Vice Chair, House Committee on Health Care
900 Court St. NE, H-472
Salem, Oregon 97301

Dear Chairman Greenlick and Vice-Chairman Nosse:

On behalf of the 13,500 members of the American Academy of Dermatology Association (Academy), we write in support of HB 4105, and seek a friendly amendment. While we strongly support communication between a pharmacist and physician concerning the substitution, such communication should occur by the time of dispensing. Authorizing that a substitution has occurred "within five days following the dispensing" could jeopardize patient safety.

Dermatologists who treat severe psoriasis call the advent of biologic therapies a revolution. U.S. patents for these therapies expire in the next ten years, which will open the pathway for biosimilars. Manufacturing a biosimilar is much more complex than manufacturing generics for small molecule drugs. Because biologics are manufactured in living organisms, biosimilars are not exact replications of their reference biologic products. Due to this variability, a patient's response to a biosimilar may not always mirror the response to the reference drug. Even minor changes in the manufacturing process can significantly affect the efficacy of the biosimilar. The treating physician must know of a biosimilar substitution in order to appropriately assess the patient's experience and further treatment options. For these reasons, patient substitution decisions for biosimilars should be carefully considered and should include a physician's medical judgment.

While the Academy is pleased that the language retains a communication requirement between the pharmacist and provider, the legislation lacks any assurance that the communication will occur prior to an adverse reaction occurring. Amending the legislation to require pharmacists to notify a physician by the time of dispensing ensures that a physician's medical judgment is involved in the patient's care. The prescribing physician, who has a thorough knowledge of the patient's medical history, could identify potential adverse outcomes among multiple biosimilar medications before the medication is dispensed to the patient. Further, concerns raised that notification by the time of dispensing would impede access or increase the administrative burden for the pharmacy are not justified as most dermatology biologics are delivered via shipping to patients through specialty pharmacies and are not picked up at the pharmacy in the same way as more traditional medications.

In order to protect our patients, the Academy urges you to amend HB 4105 to require physician communication by the time of dispensing. We look forward to working with

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you to ensure biosimilars are dispensed in a safe manner and without impeding access to patients of such medications. Please contact Lisa Albany, JD, associate director, state policy, at lalbany@aad.org or (202) 842-3555 should you require any additional information or clarification.

Sincerely,

Mark Lebwohl, MD, FAAD
President
American Academy of Dermatology Association

CC: Members of the Committee on Health Care