March 3, 2015

The Honorable Laurie Monnes Anderson
Chair, Committee on Health Care and Human Services
Oregon Senate
900 Court St. NE, S-413
Salem, Oregon 97301

Dear Chairperson Monnes Anderson,

On behalf of the 13,500 members of the American Academy of Dermatology Association (Academy) and Oregon Dermatology Society (ODS), we encourage you to amend Senate Bill 147, which would change the physician communication requirements in existing law governing biosimilar substitution in Oregon. We strongly recommend that physician communication be retained and the language in the legislation be amended from "within a reasonable amount of time" to "by the time of dispensing" in order to ensure 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 and ODS are 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. An undefined "reasonable" amount of time, presumably days after the drug has been dispensed, could jeopardize patient safety. 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 of the pharmacy are not justified as most biologics are delivered via shipping to patients through specialty

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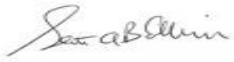
pharmacies and are not picked up at the pharmacy in the same way as more traditional medications.

In order to protect our patients, the Academy and ODS urge you to amend SB 147 to require physician communication by the time of dispensing. We look forward to working with 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 of State Policy, at lalbany@aad.org or (202) 842-3555 should you require any additional information or clarification.

Sincerely,

Brett M. Coldiron, MD, FAAD
President
American Academy of Dermatology Association



Scott Collins, MD, FAAD
Legislative Affairs Director
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