March 16, 2015

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

Subject: Oppose House Bill 2026 regarding biosimilar substitution

Dear Chairman Greenlick:

On behalf of the more than 13,500 members of the American Academy of Dermatology Association ("Academy") and Oregon Dermatology Society, we write in opposition to House Bill 2026 regarding biosimilar substitution. In accordance with the proposal, pharmacists would be authorized to substitute biosimilars for biologic drugs without notification to the physician prescriber. While we applaud the cost benefits that might occur from biosimilars, substituting a biosimilar absent the medical judgment of the patient's prescribing physician could be detrimental to patient safety. According to the Academy's *Position Statement on Generic Therapeutic and Biosimilar Substitution*, such communication should occur by the time of dispensing (see attached).

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.

A proposal that lacks physician notification of the substitution implies that the risks associated with biosimilars are minimal. 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, the concern that notification would impede a patient's access to medication is not justified as most biologics are

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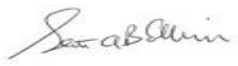
delivered via shipping to patients through specialty pharmacies as opposed to traditional medications that are purchased at a patient's local pharmacy.

In order to protect our patients, the Academy and ODS strongly oppose House Bill 2026, which would eliminate the physician's role and medical judgment from patient care. We would welcome an opportunity to work with Oregon policymakers to ensure that biosimilars are dispensed in a safe manner and that does not impede patient access. 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
Oregon Dermatology Society

Enclosure
cc: Members of the House Committee on Health Care