January 15, 2013

Delegate Robert D. Orrock, Sr.
Chairman, Health, Welfare and Institutions Committee
General Assembly Building, Room 411
Capitol Square
Richmond, VA 23219
Sent electronically to DelBOrrock@house.virginia.gov

**RE: House Bill 1422 – dispensing of interchangeable biosimilars**

Dear Chairman Orrock:

On behalf of the more than 12,600 members of the American Academy of Dermatology Association (Academy), I commend members of the Virginia House Health, Welfare and Institutions Committee for considering biosimilar legislation during this legislative session. 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. The availability of biosimilars is such a concern that the Academy's Board of Directors recently released a position statement regarding generic therapeutic and biosimilar substitution. To this end, we are pleased that HB 1422 largely reflects the Academy's position on dispensing of biosimilar products and recommends as a friendly amendment that the Committee amend the legislation to shorten the notification from five days to 24 hours prior to dispensing in order to ensure patient safety.

As you know, biosimilars are not exact replications of their reference biologic products; therefore, due to their variability, a patient's response to a biosimilar may not always mirror the response to the reference drug. For this reason, patient substitution decisions for biosimilars should be carefully considered. The Academy cautions that authorizing a five-day notification period after the drug has been dispensed could jeopardize patient safety. Reducing the notification period to 24-hours prior to the substitution as outlined in the Academy's position statement could prevent adverse outcomes by requiring the approval of the physician before the medication is dispensed to the patient. Concerns raised that pre-notification would impede access to medication are not justified as most 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.

We look forward to working with the Committee to ensure biosimilars are dispensed in a safe manner and without impeding access to patients of such medications. Please contact Lisa Albany, JD, Assistant Director of State Policy, at lalbany@aad.org or (202) 842-3555 should you require any additional information or clarification.

Sincerely,

Daniel M. Siegel, MD, FAAD
President, American Academy of Dermatology Association

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