



February 1, 2016

Chairman Mitch Greenlick
House Committee on Health Care
900 Court St. NE, H-493
Salem, OR 97301

Re: Oregon House Bill – 4105 An Act relating to biological products

Dear Mr. Chairman:

On behalf of the Lupus and Allied Diseases Association and the millions of Arizona residents struggling to manage autoimmune conditions like lupus and other diseases of unmet need who eagerly await access to affordable, appropriate and safe therapies, I passionately urge you to support HB 4105. This landmark legislation creates a new pathway for biologic substitution where none currently exists in Oregon, while at the same time enhancing patient access to new and potentially less costly medications.

The Lupus and Allied Diseases Association, Inc., is a passion driven, all-volunteer patient advocacy organization dedicated to improving quality of life for those impacted by lupus and allied diseases and conditions of unmet need by fostering collaboration among all stakeholders and promoting innovative advocacy, awareness and biomedical research program initiatives.

As patient stakeholders who represent patients and loved ones dealing with serious chronic medical conditions on a daily basis, we support HB 4105 as it promotes patient safety and collaboration among all members of the patient's health care team by facilitating consumer knowledge and communication between pharmacists and prescribing physicians when biosimilars designated as "interchangeable" are substituted for a prescribed biologic. It also gives the pharmacist authorization to select an alternative biological product if it is interchangeable and the prescriber does not indicate an intent to prevent substitution.

Furthermore, the proposed legislation ensures that the treating physician is aware of the exact biologic, indicated by manufacturer, given to a patient in order to facilitate patient care and accurate attribution of any adverse events that may occur. Pharmacist-Prescriber communication is paramount in identifying exactly which medicine was received if an adverse event occurs since biologics and biosimilars in reality will be administered to patients suffering from serious, life-threatening diseases who usually take several concomitant medications and are not participating in a controlled clinical study.

Unlike small molecules, biologics are extremely complex large molecules patterned after human tissue and cells that have the ability to target the underlying cause of some diseases. They have advanced with each generation; evolving from proteins that are naturally-occurring to monoclonal, and eventually to polyclonal and fusion proteins. Biosimilar drugs hold tremendous promise and therapeutic advantages for lupus and autoimmune patients just as biologic medicines have for millions of individuals living with life-

threatening and life-diminishing diseases. As more biosimilars become available in the United States we want to ensure they are safe, efficacious, accessible, and affordable. We must remain vigilant in protecting patient safety while promoting unfettered access to vital and effective treatments.

HB 4105 outlines the parameters for substitution of interchangeable biologics, guaranteeing patients have access to high quality, safe, and efficacious biologic medicines. Substitution should only occur when the FDA has designated a biologic product as interchangeable and proper patient protections are upheld including Pharmacist-Patient communication to ensure complete transparency. Pharmacist-Prescriber communication regarding the dispensed product must occur within five business days and be conveyed by making an entry that can be electronically accessed by the prescriber. Communicating through an electronic-record keeping system guarantees that the patient has a longitudinal health record and given that many patients have comorbidities requiring treatment by multiple health care providers, an accurate medical record is essential.

For the above reasons we ask you to please facilitate communication between patients, pharmacists, and healthcare providers by supporting HB 4105. This legislation is especially important given the FDA's approval of the first biosimilar last March, the second one to be reviewed in February and additional products in the pipeline. It is imperative that these safeguards are put in place to ensure that healthcare professionals continue to be empowered to provide the best medical care possible and that patients have access to lifesaving and life-enhancing therapies.

Please feel free to contact me at 315-264-9101 if you have any questions. Thank you.

Sincerely-



Kathleen A. Arntsen
President/CEO

Cc: Representative Cedric Hayden, Vice Chairman
Representative Rob Nosse, Vice Chairman
Representative Brian L. Clem
Representative Knute Buehler
Representative Bill Kennemer
Representative Alissa Keny-Guyer
Representative John Lively
Representative Jim Weidner