American Autoimmune
Related Diseases Association, Inc.
www.aarda.org

A nonprofit association bringing a national focus to autoimmunity, the major cause of chronic disease

Dear Representative Greenlick: 2/3/2016

On behalf of the American Autoimmune Related Diseases Association (AARDA), a national not for profit health organization, we are writing to request that you **support HB 4015 HD1** regarding the pharmacy substitution of biosimilar medical products. As patient advocates, we are often the first place newly diagnosed patients come for help and information. Until one decade ago, the treatment choice for most autoimmune diseases was cortical steroids which had significant side effects for the patient. The use of biologics have made a significant impact on improving the lives of patients with serious and life threatening autoimmune diseases such as Crohn's disease, lupus, multiple sclerosis and rheumatoid arthritis. Biosimilars hold much promise in expanding access to better treatments.

"Copies" of these medicines, called "biosimilars" have the potential to provide these therapies at a reduced cost. Yet unlike generic versions of chemical drugs, biosimilars are not exact duplicates of their reference products. Indeed, the complexity of biologics and their proprietary manufacturing processes mean that these "copies" can only ever be similar, never the same. Even the smallest structural difference between a biologic and its attempted copy can have a significant impact on a patient. Therefore, the issue of interchangeability has been a new challenge for policymakers.

AARDA believes that when interchangeable biosimilar products are substituted, communication between patients, pharmacists, and health care providers is essential to patient care. We fully support HB 254 HD1 and are concerned that patient safety will be compromised if this legislation is not enacted. It is our view that this bill appropriately reflects the importance of pharmacist-physician communication and keeping treatment decisions the purview of the physician and patient, without posing undue or onerous burdens upon the pharmacist:

a. It provides that only "interchangeable" biosimilars (those determined by the FDA to produce the same effects in a patient as the reference product without additional risks) or which are "therapeutically equivalent" to their reference products may ever be substituted.

b. It allows a physician to prevent a substitution they consider inappropriate for their patient by writing "do not substitute" on the prescription.

c. Finally HB 4015 HD1 requires that the pharmacist communicate to the physician within a reasonable time frame which biologic the patient actually received – whether that prescribed by the physician or a substituted biosimilar- so that an accurate patient record can be kept by all parties.

HB 4015 HD1 will extend these valuable protections to Oregon's patients while increasing their access to biologic therapies.

Thank you in advance for taking support the necessary steps to keep patient safety a priority in Oregon by supporting HB 4015 HD1.

Sincerely,

Virginia Ladd
President

22100 Gratiot Avenue - Eastpointe, MI 48021-2227 - Phone (586) 776-3900 - Fax (586) 776-3903 - E-mail: aarda@aarda.org