National Kidney Foundation™

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February 3, 2016

The Honorable Mitch Greenlick
Chairman, House Committee on Health Care
900 Court Street NE
H-493
Salem, Oregon 97301

RE: Support House Bill 4105

Dear Chairman Greenlick,

The National Kidney Foundation (NKF) supports HB 4105, which was introduced in the Oregon State Senate to regulate the substitution of biosimilars for certain prescribed products with prescriber notification.

According to the legislation, Oregon pharmacists will be required to communicate – to a patient's prescribing physician – any and all dispensations of a substitute biosimilar for a biologic drug. NKF supports the expanded access that biosimilars will offer for patients, and as biosimilars enter the market, the substitution of a biosimilar must include communication between the pharmacist and the prescriber to ensure patient safety. NKF also supports patient choice in the decision making and believes patients should be notified of substitutions.

NKF is America's largest and oldest health organization dedicated to the awareness, prevention, and treatment of kidney disease for hundreds of thousands of healthcare professionals, millions of patients and their families, and tens of millions of people at risk. In addition, NKF has provided evidence-based clinical practice guidelines for all stages of chronic kidney disease (CKD), including transplantation since 1997 through the NKF Kidney Disease Outcomes Quality Initiative (NKF KDOQI). We also provide professional and patient education, patient support services, and community health programs. We work with volunteers to offer the scientific, clinical and kidney patient perspective on what needs to be done to prevent kidney disease, delay progression, and better treat kidney disease and kidney failure. NKF has local division and affiliate offices serving our constituents in all 50 states, including Oregon.

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With biologics, we know that individual patients can respond differently to even seemingly insignificant changes in drug formulation, manufacturing process, packaging, storage, or handling. These unintended consequences could be life threatening. Since biosimilars are produced without access to the innovator's proprietary manufacturing processes, differences in composition compared to the original innovator product are likely to occur.

A decade ago the Food and Drug Administration (FDA) collected information on 82 patients worldwide who had developed pure red-cell aplasia as a result of changes in the manufacture and/or packaging of a reference biological product used by kidney patients. Most recently a synthetic erythropoietin stimulating agent – peginesatide – was approved by FDA in March of 2012 and nearly a year later pulled from the market due to an allergic reaction not seen in patients during the clinical trial. Because of that experience, the kidney community has been especially cautious regarding the possibility of substituting or alternating between reference drugs and biosimilars or between biosimilars.

In conclusion: NKF asks you, in order to protect Oregon's patients, to support HB 4105, which includes prescriber and patient communication and pharmacist record keeping requirements. To monitor for adverse events, it is vital that patients and physicians know, which medication was dispensed.

We respectfully encourage you to pass HB 4105.

Sincerely,

Tonya L. Saffer

Tonya L. Saffer, MPH