National Kidney Foundation™

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March 16, 2015

Chairman Mitch Greenlick
House Health Care Committee
900 Court St. NE, H-493,
Salem, Oregon 9730
email: Rep.MitchGreenlick@state.or.us

Subject: Oppose HB 2026

Dear Chairman Greenlick,

The National Kidney Foundation (NKF) opposes HB 2026, which was introduced in the Oregon State House and would require substitution of any biologic with a lower cost alternative without notifying prescribers. While we support patients being informed about lower-cost alternatives, substitution by pharmacists of biologics should only occur when the product has been deemed as an interchangeable biosimilar by the FDA and prescribers and patients should be notified of such substitution as a measure to protect patients' safety.

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.

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

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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.

As a result NKF opposes HB2026. To monitor for adverse events, it is vital that physicians know, which medication was dispensed.

Sincerely,

Tonya L. Saffer

Tonya L. Saffer, MPH