To: Chair Greenlick and Members of the House Health Care Committee

From: Luis Rodriguez, Oregon Government Relations Director American Cancer Society Cancer Action Network (ACS CAN)



February 3, 2016

Onn behalf of the American Cancer Society Cancer Action Network (ACS CAN), thank you for the opportunity to testify on HB 4105. ACS CAN is the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society. We urge your support of HB 4105, which continues both the prescriber and patient notification requirements for biosimilar substitution.

The development of biologic drugs has provided cancer patients and their physicians with access to improved therapeutic options. As generics have done for small-molecule drugs, interchangeable biosimilars have the potential to increase price competition on older biologic drugs, and result in lower cost burdens for cancer patients.

As biosimilar policies are developed, they must focus on ensuring the safety and efficacy of all biologic drugs, whether innovator or biosimilar, and policies must also ensure access and affordability of biosimilars for cancer patients. The FDA requires robust evidence proving sufficient equivalence in terms of safety and efficacy between innovator biologics and those deemed as "interchangeable biosimilars."

Even so, biologics are manufactured in living organisms, and are therefore much more complex than manufacturing pharmaceutical generics. In addition, biosimilars are not exact replications of their reference biologic product and as such, a patient's response may be different to the substituted product. Given the complexity of treatments for cancer patients, these minor differences could result in significant complications that would not be readily understood if both the patient and prescriber are left uninformed of the biosimilar substitution.

As you can imagine, patients undergoing treatment to fight cancer can be on a variety of both biologic products as well as pharmacological products. In today's health care delivery system patients need to be more actively engaged in their treatments, but can only be as effective as the information provided to them by the providers who are caring for them. Dispensing a biosimilar without the knowledge of the prescriber and patient could jeopardize patient safety in the event of an adverse reaction.

Oregon is a sunset state. Oregon enacted legislation in 2013 permitting substitution of interchangeable biologics. The 2013 legislation required communication with the prescriber, however, that requirement has now sunset. With one biosimilar receiving FDA approval already and the FDA expected to release its rules on interchangeability this year, it's important to reinstate the prescriber communication.

Thank you for your consideration.

Luis Rodriguez, Oregon Government Relations Director

American Cancer Society Cancer Action Network, 0330 SW Curry Street, Portland, OR 97239 503-795-3926