HealthHIV
Putting Health First

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January 23, 2013

The Honorable Edward Clere
200 W. Washington St.
Indianapolis, Indiana 46204

Re: HB 1315 on Biosimilar Substitution

Dear Representative Clere,

HealthHIV advances effective prevention, care and support for people living with, or at risk for, HIV/AIDS by providing education, capacity building, health services research, and advocacy to organizations, communities and professionals. We seek to improve the lives of patients and provide them with the best and most effective treatment information, and we support HB 1315 on biosimilar substitution.

I have witnessed the positive effect that biologic medicines can have on patients, and their potential to produce effective treatments for many diseases that currently have no cure. As a member of the Alliance for Safe Biologic Medicines (ASBM), an organization dedicated to ensuring that patients are at the forefront of the biosimilar policy discussion, HealthHIV has been working to guarantee that patient well-being and product safety remain the top priorities as biosimilars are introduced in the United States.

Biologics are highly complex, advanced prescription medicines that, unlike drugs derived from chemicals, are manufactured using a unique process with living cells. No two biologics made from different cell lines are ever identical. Biosimilars, which aim to replicate biologics, are – as the name suggests – similar, but not the same as the innovator drug. Even the smallest difference in the structure of a biologic medicine and its attempted copy can have a significant impact on a patient. Therefore, the issue of substituting a biosimilar for a biologic medicine has created new challenges for policy-makers.

ASBM has been working with both physicians and pharmacists to develop principles to determine the best solutions for these challenges. In May 2012, ASBM convened a working group of our Advisory Board members to discuss the elements of a physician notification policy for interchangeable biosimilars. The policy elements prioritize patient safety and protect the relationship between physicians and their patients, while also respecting the sovereignty of pharmacists as healthcare providers. We released a statement in October 2012 on the key principles that we believe should be included in formal policy recommendations, which also support the measures outlined in HB 1315, specifically your inclusion that:

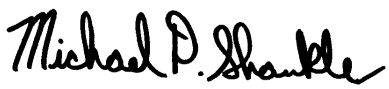
> Sec. 3. A pharmacist may substitute a biosimilar product for a prescribed biological product if the following conditions are met:
>
> (1) The biosimilar product has been determined by the federal Food and Drug Administration to be interchangeable with the prescribed biological product for the specified indicated use.
>
> (2) The prescribing physician has not indicated on the prescription that a substitution is not

permitted.

(4) The pharmacist notifies the physician, in writing or electronically, within twenty-four (24) hours of the substitution.

We would like to take this opportunity to thank you for your leadership to ensure the safety of biosimilars in Indiana and let you know that HealthHIV fully supports HB 1315.

Sincerely,



Michael D. Shankle, MPH
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Mds/EM