

Kidney ~~Cancer~~ Association

January 14, 2013

Delegate Robert D. Orrock, Sr.
Chairman
Health, Welfare and Institutions Committee
General Assembly Building, Room 411
Capitol Square
Richmond, Virginia 23219

Dear Chairman Orrock,

As the president of the [Kidney Cancer Association](#), I would like to express to you our support for House Bill 1422 on the dispensing of interchangeable biosimilar biological products. The Kidney Cancer Association is an active member of the [Alliance for Safe Biologic Medicines](#) (ASBM) that has been working for the past two years to ensure that patient safety is at the forefront of the biosimilars policy discussion. ASBM and the Kidney Cancer Association have been very supportive of the FDA in its mission to safely bring biosimilars to patients in the U.S.

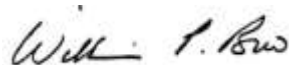
Biologics are highly complex, advanced prescription medicines used to treat cancer, rheumatoid arthritis, diabetes, MS, infertility and many other debilitating diseases. Unlike drugs derived from chemicals, biologics are manufactured using a unique process with living cells and for this reason no two biologics made from different cell lines are ever identical. When attempting to replicate biologics, their “copies,” known as biosimilars, are similar to, but not exact versions of the biologic they aim to replicate and are often mistakenly referred to as “generics.” Even the smallest difference in the structure of a biologic medicine and its attempted copy can have a significant impact on a patient and therefore, the issue of interchangeability has been a new challenge for policy-makers.

To overcome and work through the policy challenges, ASBM has collaborated with both physicians and pharmacists to determine the best solutions on biosimilar interchangeability. In May 2012, ASBM Advisory Board members discussed the elements of a physician notification policy for interchangeable biosimilars that prioritizes patient safety and protects the relationship between physicians and their patients but also respects 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 a formal policy recommendations and we find HB 1422 to be in direct alignment with ASBM principles, which included:

- (1) Physicians have the authority to specify “do not substitute” for biological products and that specification overrides any policy – e.g. by payers or state law – that would have substitution be the standard or default practice;
- (2) Physicians and pharmacists should work collaboratively to ensure that the treating physician is aware of the exact biologic – by manufacturer – given to a patient in order to facilitate patient care and accurate attribution of any adverse events that may occur;
- (3) The timing of the notification process must not impose an undue burden on the pharmacist and need not be in advance of a substitution being made but must be timely enough to facilitate accurate record keeping and attribution of adverse events by the physician.

As part of an organization dedicated to patient safety, I commend you for taking the necessary steps to ensure that patients are the top priority as biosimilars are introduced in the U.S. and substituted for biologics in the Commonwealth of Virginia.

Sincerely,

A handwritten signature in cursive script that reads "William P. Bro".

William P. Bro
President, Kidney Cancer Association