Remarks to Colorado House Health, Insurance and Environment Committee
R.J. Ours, Colorado Government Relations Director
American Cancer Society Cancer Action Network
Regarding Senate Bill 15-071
Thursday March 5, 2015

Good afternoon Madam Chair and Members of the Committee,

I am R.J. Ours, Colorado Government relations Director for the American Cancer Society Cancer Action Network.

On behalf of the American Cancer Society Cancer Action Network, thank you for your sponsorship of Senate Bill 15-071. ACS CAN is very supportive regarding advancement of these new treatments because of their enormous potential as an effective tool in the fight against cancer, including the potential to lower cancer patient costs and improve their overall quality of life.

Within state policy making deliberations regarding these new disease fighting agents, are the important questions of transparency and notification of prescribing doctors and patients when substitution occurs.

ACS CAN has reviewed Senate Bill 15-071 as it was passed by the Senate, and we are concerned with the words "within a reasonable time" regarding physician notification.

> We would like to see this spelled out with much more specificity and suggest "Within 10 calendar days" or "Within 5 business days".
>
> In several states, we have seen similar bills that have been amended to allow even less time to lapse, but at the very least, we would like to see the above.

I am also providing for the committee copies of ACS CAN's position paper on this matter for your reference. Please let me know if you have any questions or would like to discuss this further. I am available at your convenience. I should also note that yesterday I delivered testimony that was not identical to today's. What I have said here today should be viewed as our official position and that it is consistent with the position we have taken in several other states. I apologize for any confusion.

Thank you Madam Chair.

Cancer Action Network℠ American Cancer Society®

ACS CAN Principles for Biosimilars

ACS CAN Statement on Biosimilars

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. These dual goals will be accomplished by a combination of federal and state policies. Federal policies will primarily be responsible for safety, efficacy, and interchangeability, while state laws will primarily affect access and affordability.

Consent: Physicians should have the ability to withhold or provide consent for biosimilar substitution. Each state varies in how this is done, but physicians can typically mark "Do not substitute" or "Medically necessary" to prevent substitution or conversely "Substitution allowed" to grant consent for substitution. The required consent for biosimilar substitution should be consistent between small molecule drugs and biologics. Patient consent is typically given at the time of dispensing and should mirror state patient consent requirements for generic small molecule drugs.

Notification and Recordkeeping: When there is an interchangeable biosimilar, the prescribing physician should be notified of the actual biologic dispensed, whether an innovator or a biosimilar, to ensure an accurate and enduring patient medical record with longitudinal prescribing history. This notification should be via automated and electronic means that enable effective integration of this information into the patient's electronic medical record in as close to real time after dispensing as feasible. Phone calls, fax or email would only be acceptable means of notification if the appropriate automated means to directly import into the patient's medical record do not exist. Patients should also be informed of the actual drug dispensed at the time of dispensing.

Safety and Interchangeability: Robust evidence is needed to prove sufficient equivalence in terms of safety and efficacy between innovator biologics and those deemed as "interchangeable biosimilars." FDA is the sole entity responsible for ensuring the integrity of this designation. Such a designation should be withheld or removed if evidence shows a clinically meaningful difference in safety or efficacy between products either in isolation, or when products are used sequentially. FDA guidance and analysis of interchangeability should be transparent and utilize the best science and tools available. FDA-deemed interchangeability will be cataloged in the "Purple Book" and this book should be the sole reference for products suitable for interchange.