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# United States Senate

COMMITTEE ON HEALTH, EDUCATION,  
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WASHINGTON, DC 20510-6300

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August 1, 2014

The Honorable Sylvia Burwell  
Secretary  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Secretary Burwell:

We write today with concerns about the implementation of the Biologics Price Competition and Innovation Act (BPCIA), bipartisan legislation enacted in 2010 to provide the U.S. Food and Drug Administration (FDA) with a framework to review and approve biosimilars. The FDA has not yet issued guidance on some of the key scientific policy questions related to biosimilars, such as naming, labeling, indication extrapolation, and interchangeability.

In November, some members of the Health, Education, Labor, and Pensions Committee along with other authors of BPCIA, wrote a letter to Commissioner Hamburg outlining congressional intent that FDA should use science-based policy for the implementation of the biosimilar pathway. However, we still have seen no draft proposal on the naming issue, or guidance on demonstrating interchangeability. We have heard there is some difference of opinion on these matters, making it even more important that these policies, which are integral to the success of the biosimilar pathway, be released in draft form as soon as possible. The public needs to have time to comment and FDA needs time to revise the policies set forth in this draft guidance if necessary.

On July 24, 2014, Sandoz issued a press release announcing that the FDA has accepted its 351(k) biosimilar application. We assume that FDA and Sandoz had conversations about key issues such as those listed above, and that the FDA is engaged in conversations with other manufacturers who intend to file biosimilar applications in the future. These meetings should not be the only or primary means by which BPCIA implementation policies are developed. Does the FDA intend to approve the first biosimilar before policies on these key scientific questions are publicly released?

It is our understanding that FDA has forwarded the naming guidance to the Department of Health and Human Services (HHS), and this guidance is awaiting HHS' clearance so it can be released for stakeholder comment. In order to ensure the success of the biosimilar pathway, it is imperative that the scientific experts at FDA maintain the autonomy to implement the pathway as intended in a manner that puts the safety of patients first.

We urge you and those within your Department to immediately release guidance pending within the HHS related to the implementation of the biosimilar pathway. We expect that FDA's Good Guidance Practices will be followed on any guidance related to biosimilar naming, labeling, indication extrapolation, interchangeability, and other important BPCIA implementation topics. Only in this way will FDA's policies be informed by patients, healthcare professionals, policy makers, and others. Their participation is necessary before settling on final policies.

Thank you for your consideration on this urgent matter, and we hope to continue to work with you to implement the biosimilar pathway in a way that benefits the public health.

Sincerely,



Lamar Alexander  
Ranking Member



Orrin G. Hatch  
U.S. Senator



Michael B. Enzi  
U.S. Senator



Richard Burr  
U.S. Senator



Pat Roberts  
U.S. Senator