Congress of the United States
Washington, DC 20515

December 21, 2015

Dr. Stephen Ostroff
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

Dear Dr. Ostroff,

As members of the House GOP Doctors Caucus, we write today to express our concerns with the FDA's implementation of the Biologics Price Competition and Innovation Act (BPCIA), and to urge the FDA to solicit and consider physicians' and patients' views in its rulemaking. At a September 17, 2015 congressional hearing, Dr. Janet Woodcock repeatedly emphasized the importance of patient and healthcare provider confidence in biosimilars to the success of this program and identified the agency's responsibility as needing to ensure that the biosimilar scientific framework is "bulletproof." We agree.

The House Doctors Caucus recently held a roundtable discussion with various stakeholders in the biosimilars debate. There was broad agreement among the panelists and the providers present that biosimilars show a great deal of promise in increasing access to treatment and reducing health care costs. The discussion also accentuated, however, that there are many unresolved questions among the patient and physician communities, and that the potential benefits of these products will only be realized when physicians feel comfortable prescribing them and patients feel safe taking them. We believe patient and provider confidence in biosimilars will be enhanced if they have a voice in the development of key policies such as labeling and interchangeability.

We believe physicians want the most accurate information possible so that they can make decisions in the best interest of their patients. Earlier this year the Alliance for Safe Biologic Medicine published a survey of physicians that reflected overwhelming support for the biosimilar label to identify the product as a biosimilar, include data used to determine that it is highly similar to the reference product, and explicitly state which indications were approved for use based on extrapolation. It is also our understanding that the majority of comments that the FDA received from patient and provider advocates in response to its February 2012 draft guidance, "Scientific Considerations in Demonstrating Biosimilarity to a Reference Product," endorsed the requirement that biosimilar labels state that the product is approved as a biosimilar to a reference product for stated indication(s) and indicate the route of administration, as well as whether or not it has been determined by the FDA to be interchangeable. FDA's draft guidance stated that this information was important for providers to have in order to make prescribing decisions. However, when the FDA finalized this guidance this year, these labeling requirements were deleted without any explanation.

Additionally, during the time that the draft "Scientific Considerations" guidance was in effect, the first biosimilar was approved and the label of this product does not include any of this information. Indeed, the labeling of the first biosimilar is virtually the same as the label of the innovator product. This information is important to physicians who will make the decision of whether or not to prescribe or administer biosimilars to their patients. Why did the FDA change the labeling requirements in its "Scientific Considerations" final guidance, in seeming contradiction of both the draft guidance and the strong support from patients and physicians for these aspects of the draft guidance?

Furthermore, during her September 17 testimony, Dr. Woodcock stated that physicians could refer to the FDA's Purple Book to determine whether or not a biosimilar has been determined to be interchangeable. That seems to be contrary to FDA's own labeling regulations, as well as unnecessarily complex. Is it the FDA's expectation that all physicians know that the Purple Book exists, and that they will refer to it every time they consider prescribing a biosimilar product? What is the public health justification for referring physicians to the Purple Book rather than requiring that information on the product label?

We urge the FDA to solicit, consider, and respond to the views of patients and the physicians who care for them. We believe patients and their caregivers deserve an inclusive and transparent process for the development of BPCIA policies.

Sincerely,

Brad Wenstrup, D.P.M.
Member of Congress

David P. Roe, M.D.
Member of Congress

Larry Buschon, M.D.
Member of Congress

Renee Ellmers, R.N.
Member of Congress

Andy Harris, M.D.
Member of Congress

Joe Heck, D.O.
Member of Congress

Tom Price, M.D.
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Ralph Abraham, M.D.
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