United States Senate
WASHINGTON, DC 20510

October 23, 2013

Dear Commissioner Hamburg,

We are writing in regard to the U.S. Food and Drug Administration's (FDA), implementation of the Biologic Price Competition and Innovation Act (BPCIA). Specifically, we write to share our concerns on the issue of naming biosimilars.

The name that will be given to the active ingredient for these biosimilar medications- a drug's International Nonproprietary Name (INN)- has significant implications for both patients and providers. If biosimilars are unable to share the same active ingredient name as the brand originator product, we believe the Congressional intent behind the BPCIA would be undermined as would the safety and accessibility of affordable biosimilars.

The INN is the official generic name given to a pharmaceutical's active ingredient, not the product itself, by the World Health Organization (WHO). In September 2006, the FDA issued a public statement, specifically supporting WHO's use of the INN system. This system serves to advise health care professionals worldwide as to the active ingredients in medicines. In that statement, the FDA concluded that "INNS should not be used to differentiate products with the same active ingredient(s) when credible scientific data demonstrate that no pharmacologically relevant differences exist."

We believe the BPCIA prohibits the FDA from approving a biosimilar with pharmacologically relevant differences from the brand product, thus no unique name should be required for a FDA-approved biosimilar. Moreover, there is already a precedent for shared names (e.g., erythropoietins, somatropin, interferon), which has not resulted in any known issues.

During consideration of BPCIA, Congress ultimately rejected a statutory requirement that biosimilars must be given unique INNs. First and foremost, we believe that a unique name could lead to patient and prescriber confusion, increasing the possibility of medication errors. Moreover, we are concerned that applying a unique name to biosimilars would effectively separate the biosimilar product from the existing safety data on the brand biologic, placing this important information beyond easy reference.

Secondly, we feel it is essential to not interfere with the many state laws on generic substitution. While not all biosimilars will be designated as interchangeable, it is essential that, once a biosimilar has such a designation, a unique name does not stand in the way of otherwise appropriate substitution. Mandatory generic substitution is a common cost savings tool for public and private benefit providers and payers that we cannot afford to lose.

Lastly, unique INNs would make U.S. product names different than those in the rest of the world, contrary to the policy of the WHO naming system. We also believe unique names for biosimilars would inhibit the efforts of U.S. manufacturers of these products to extend their reach abroad. With biologics set to account for 75% of all U.S. drug spending by 2020, we cannot overstate the importance of this concern to both health care access and the overall U.S. economy.

In crafting the BPCIA, the intent of Congress was to create a safe and competitive marketplace for biosimilars, akin to the marketplace for generic drugs. The hope was that, by allowing for market competition, prices would come down, giving consumers more affordable access to these important medicines and reducing prescription drug costs for the health system as a whole.

It was brought to our attention that the FDA has removed its 2006 statement on naming from its website. Does the removal of this statement indicate that the FDA is considering a change to its position on naming? If so, we ask that the FDA provide a briefing for our staff on this topic in advance of any changes. In particular, we would like to know what factors led to the agency's decision to reevaluate this policy and what outreach the FDA has done to consumers, pharmacists and others to inform its assessment.

Sincerely,

John D. Rockefeller IV
United States Senator

Tom Harkin
United States Senator

John McCain
United States Senator

Bill Nelson
United States Senator

Charles E. Schumer
United States Senator

Ron Wyden
United States Senator