November 13, 2013

Margret A. Hamburg, M.D., Commissioner
Food and Drug Administration
15B-31 Parklawn Building
5600 Fishers Lane
Rockville, Maryland 20857-0001

Dear Dr. Hamburg,

We are writing to you in regard to the Biologics Price Competition and Innovation Act (BPCIA), legislation which was signed into law in 2010 to create a new pathway at FDA for the approval of biosimilars.

As authors and champions of this historic legislation, representing both houses and both parties, we worked hard to create this new pathway which will, for the first time in our country's history, allow biosimilars to compete with innovative biologics to increase competition and lower prices for patients.

We also understand the importance of carefully considered, science-based guidance that will allow BPCIA to be fully implemented. That's why we want to assure you that it was the intent of Congress to provide the FDA with the flexibility to establish a science-based policy for non-proprietary naming of drug substances, and not to encourage the FDA to adopt a policy of either identical or differentiated naming. It is not the role of Congress to predetermine decisions that should be based on scientific evidence.

We appreciate your attention to this important issue of "naming" in light of the new biosimilars pathway. Patient safety depends on accurate, scientifically-based descriptors for life-saving biologics and we look forward to working with your agency to achieve that.

Sincerely,

Orrin G. Hatch
United States Senator

Anna G. Eshoo
Member of Congress

Lamar Alexander
United States Senator

Joe Barton
Member of Congress

Michael B. Enzi
United States Senator

Kay R. Hagan
United States Senator