

# United States Senate

WASHINGTON, DC 20510

January 24, 2011

Dr. Margaret Hamburg  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Ave  
Silver Spring, MD 20993

Dear Commissioner Hamburg:

As Senators who were actively involved in the debate over the Biologics Price Competition and Innovation Act (BPCIA), we are extremely concerned about possible misinterpretations – whether intended or unintended – that could further delay the availability of generic biologic drugs, restricting access for many Americans and driving up costs for the federal government.

Biologic medicines are a relatively new frontier in patient care – expected to make up half of the sales from the Top 100 medicines by 2014 – and offer great promise for future treatments and therapies for patients. In 2007, Americans spent \$286.5 billion on prescription drugs; \$40.3 billion of which was spent on biologic drugs. A 2009 report by the Federal Trade Commission (FTC) found that a year's worth of a popular biologic treatment for breast cancer can cost \$48,000. Like many Americans, we are concerned that the cost of biologics will continue to be an increasingly significant contributor to healthcare costs for both the nation and the individual consumer.

Under the BPCIA, your agency has new authorities to bring generic biologic medicines to the American consumer. As the Food and Drug Administration (FDA) reviews comments regarding the implementation of the approval pathway for generic biologics, we respectfully request that the agency disregard any interpretation that would result in further delay of the availability of generic biologic drugs.

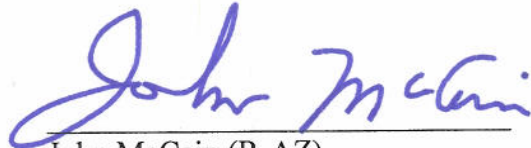
It should be noted that we remain opposed to the 12 years of exclusivity that was granted to protect brand-name biologics from market competition – current law results in limited access for patients who cannot afford these therapies and higher costs for the federal government. It has recently been brought to our attention that the FDA has received suggested statutory interpretations which, if implemented by the FDA, could result in generic competition being delayed well beyond the 12 year exclusivity period in statute. We believe the statute is clear that the FDA can begin reviewing biogeneric applications during the 12 year exclusivity period.

Absent generic competition, biologic drugs will continue to cost patients thousands of dollars for a single dose. Therefore, we strenuously object to any efforts that would further block or delay generic competition at the expense of patients in need. We hope to work with you as your agency develops the generic biologics approval pathway under the BPCIA.

Sincerely,



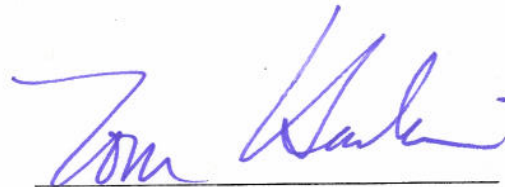
Sherrod Brown (D-OH)



John McCain (R-AZ)



Charles Schumer (D-NY)



Tom Harkin (D-IA)