United States Senate

WASHINGTON, DC 20510

October 9, 2009

The Honorable Harry Reid
Majority Leader
United States Senate
Washington, DC 20510

Dear Majority Leader Reid:

We are writing to express our strong support for including in any health care reform package brought to the Senate floor the Senate Health, Education, Labor, and Pensions (HELP) Committee-passed language creating an approval pathway for biosimilars. This language, which was offered as an amendment when the HELP Committee considered the Affordable Health Choices Act (S. 1679), ensures the parallel and equally important goals of making life-enhancing and life-saving biotechnology products more accessible and more affordable, while also continuing to foster the ongoing search for new cures and treatments through providing 12 years of data exclusivity for innovator biotechnology companies. Importantly, these provisions authorize the Food and Drug Administration to ensure the safety of biosimilar products through appropriate testing and data collection.

This amendment received strong bipartisan support when it was considered, passing the HELP Committee by a vote of 16-7, with support from a majority of both Democrats and Republicans. Nearly identical provisions passed the House Energy & Commerce Committee by a broad, bipartisan vote of 47-11.

Biologic products are at the forefront of medical breakthroughs and include therapies for serious and life-threatening illnesses such as cancer, multiple sclerosis, diabetes, HIV/AIDS, and many serious rare diseases. Additionally, the biotechnology industry has been an area that has consistently supported job creation throughout the country, especially in our current down economy. Because the millions of jobs directly or indirectly created by the biotechnology industry are one of our nation's "strongest economic engines," just recently 10 governors wrote the Senate and House Leadership expressing support for the HELP Committee biosimilars provisions, including at least 12 years of data exclusivity. More than 150 patient groups, research universities, local chambers of commerce, venture capital groups, and innovators have expressed strongly that a base 12 years of data exclusivity is crucial to ensure continued growth in the biotechnology industry and future discoveries that will make a difference in the lives of millions of patients.

We urge you to support the enactment of a pathway for the approval of biosimilars with a base 12-year period of data exclusivity for innovator biotechnology companies, which will bolster the search for new life-saving treatments and cures.

Sincerely,

Orrin G. Hatch

Barbara A. Mikulski

Michael B. Enzi

Kay R. Hagan