United States Senate

WASHINGTON, DC 20510

January 13, 2010

The Honorable Harry Reid
Majority Leader
US Senate
The Capitol, S - 221
Washington, DC 20510

Dear Majority Leader Reid:

As you complete the merger of H.R. 3590, the Patient Protection and Affordable Care Act with H.R. 3962, the Affordable Health Care for America Act, we respectfully request that you preserve 12 years of data exclusivity for any new biologic, as included in both the Senate and House bills, and the patent and naming provisions related to biologics included in the House legislation.

The pathways for the approval of biosimilars included in both the House and the Senate bills will reduce drug costs for millions of Americans while ensuring continued research and development into innovative biologics which will improve countless lives. This bipartisan amendment, which passed the Senate HELP Committee by a vote of 16-7, reflects years of negotiation and compromise. The House amendment also gained bipartisan support and passed the House Energy and Commerce Committee by a vote of 47-11.

There are more than 630 biotechnology medicines currently in development, including 254 for cancer, 162 for infectious diseases, 59 for autoimmune disorders, 25 for cardiovascular disease, and 19 for diabetes. However, the cost of developing a biopharmaceutical and bringing it to market has been estimated at $1.241 billion, and it takes 97.7 months – more than eight years – for a biotech drug to progress through clinical development and FDA review. Furthermore, 90 percent of products fail before even getting to clinical trials, and only 7 percent of the biotech medicines that enter the development stage ever reach the market. According to Duke University Economist Henry Grabowski, it takes about 13 to 16 years of sales for a biopharmaceutical company to break even on new biologics.

Over 150 patient organizations, research universities, venture capital groups, and innovators have stated strongly that 12 years of data exclusivity is crucial for ensuring continued growth and discovery in the biotech industry. Without this limited protection against the use of costly clinical trial data by competitors, pioneering companies would not be able to sustain the current level of R&D investment, patients may not continue to benefit from pioneering advances in biomedicine, and our economy may not benefit from the highly-skilled jobs and business expansion that the industry has the potential to create.

The House biosimilars patent language would put in place a simple, three-step process to facilitate the exchange of patent information between relevant patent owners and biosimilars applicants. Furthermore, it establishes a level playing field for the resolution of patent disputes involving biological products, consistent with existing legal mechanisms for enforcement of patents.

The biopharmaceutical sector is an important source of employment and output in the U.S. economy. Nationwide, there are 3.2 million jobs and $626.6 billion in output tied to this sector. Together, patents and data exclusivity provide a limited period of protection during which an innovative biotech company can attempt to recover the cost of product discovery and development. Without this opportunity, continued investment in developing biotechnology-based medicines would be significantly diminished.

Again, we urge you to support the Senate and House language providing for 12 years of data exclusivity for innovator biotechnology companies, as well as the House-passed patent and naming provisions, which will bolster the ongoing search for life-saving new biologic cures and treatments.

Thank you for your consideration.

Sincerely,

Kay R. Hagan
U.S. Senator

Barbara Mikulski
U.S. Senator

Barbara Boxer
U.S. Senator

Thomas Carper
U.S. Senator

Dianne Feinstein
U.S. Senator

John Kerry
U.S. Senator

Paul G. Kirk, Jr.
U.S. Senator

Jack Reed
U.S. Senator