

United States Senate

WASHINGTON, DC 20510

October 23, 2009

The Honorable Harry Reid
Majority Leader
United States Senate
The Capitol, S - 221
Washington, D.C. 20510

Dear Leader Reid:

Please support the establishment of a responsible pathway for the approval of follow-on biologic treatments, or "biosimilars," that ensures patient safety and includes 12 years of data exclusivity.

Establishing a pathway to bring biosimilars to market is an historic and crucial effort, the policy ramifications of which cannot be taken lightly. The bipartisan vote this past summer by the Health, Education, Labor, and Pension (HELP) Committee to provide 12 years of data exclusivity for innovator biotechnology companies will help ensure the twin goals of making life-changing and life-saving biologic treatments more accessible and affordable, while continuing to foster the ongoing search for new cures and treatments.

The biotechnology industry advances medical science and supports job-creation all over the country. The future of both biotech medicines for patients and biotech jobs for our economy depends on preserving incentives for innovation. A sustainable and equitable cycle of investment, return on investment, and reinvestment in research and development is essential to ensure that these advances continue. For many patients facing life-threatening diseases without effective treatment – or any treatment at all – biotech discovery offers their best hope. Therefore, lengthy and costly research and development must be coupled with an adequate period of data exclusivity for the innovator to ensure the future of new life-saving biotech discoveries.

As the Senate considers establishing a regulatory pathway for the U.S. Food and Drug Administration to approve biosimilars, more than 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 protection for intellectual property assets, 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.

With these thoughts in mind, and noting the strong bipartisan vote in the Senate HELP Committee, we urge you, this year, to support the enactment of 12 years of data exclusivity for innovator biotechnology companies, which will bolster the ongoing search for life-saving new biologic cures and treatments.

Respectfully,

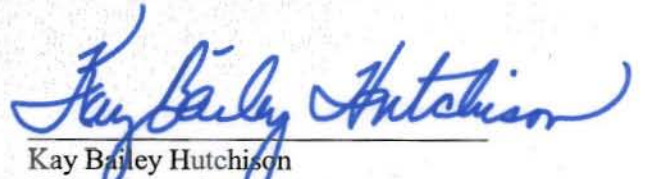


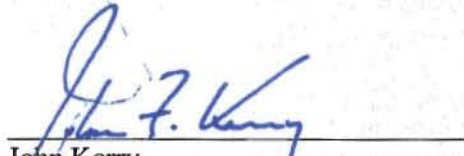
Mark Udall
United States Senator

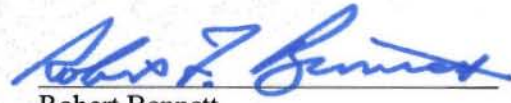


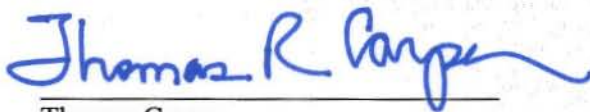
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Robert Bennett
United States Senator

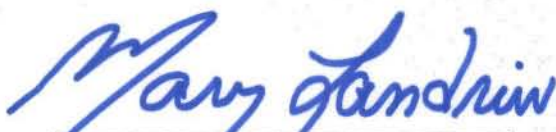

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