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March 27, 2009

The Honorable Edward Kennedy
Chairman
Committee on Health, Education, Labor, and Pensions
United States Senate
428 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Chairman Kennedy:

I am writing to express my Administration's support for an important issue that will affect the future of our nation's biotechnology industry and our economic competitiveness here in Massachusetts. The establishment of an abbreviated pathway for the approval of follow-on biologics will have a critical impact on access to safe and innovative treatments for patients with life threatening diseases and the continued growth of the Massachusetts biotechnology sector. I thank you for your leadership on behalf of Massachusetts on this issue and urge your continued support.

Massachusetts remains a leader in the life sciences, with an unparalleled collection of teaching hospitals, universities and industry. Our Administration has been keenly focused on creating new incentives for the continued growth of this field, most recently with the passage of a \$1 billion Life Sciences Initiative that included a collection of capital spending, targeted grants and tax incentives for the industry.

Legislation similar to the compromise bill you and your staff helped author and was reported out of the Senate HELP committee

The Honorable Edward Kennedy
Chairman, Committee on Health, Education, Labor and Pensions
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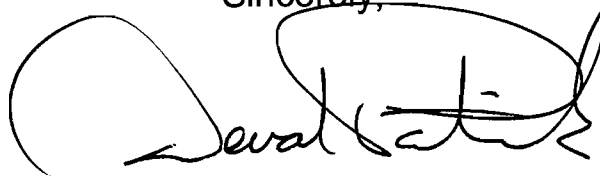
(S. 1695) is likely to reappear in the House during the 111th Congress as it works to extend affordable health care to all Americans. I hope you will continue your leadership on this issue and reintroduce the compromise legislation.

As you know, follow-on biologics – complex protein molecules – pose significant research and development, manufacturing and clinical trial challenges that can drive up their development costs and lengthen their time to market. The biotechnology industry's success is dependent on continued innovation and a strong record of patient safety. I would strongly urge you to include provisions that maintain adequate incentives for innovation and protect patient safety in any legislation put forward.

An adequate period of data exclusivity for innovative products and the timely resolution of patent disputes are also essential to the implementation of an approval pathway for follow-on biologics. A substantial period of data protection is necessary to promote continued innovation and investment in new products.

We are fortunate here in Massachusetts to have your continued leadership and dedicated service on this and countless other issues. As we seek to further the shared goal of extending affordable health care to all Americans, we hope to act as a partner in navigating these very difficult issues.

Sincerely,

A handwritten signature in black ink, appearing to read "Edward Kennedy", written in a cursive style. The signature is positioned below the word "Sincerely,".