



Massachusetts Biotechnology Council

One Cambridge Center
Cambridge, MA 02142
tel: 674-5100
www.massbio.org

March 2, 2009

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

Dear Chairman Kennedy,

We the undersigned, representing companies and institutions based in Massachusetts or that otherwise have a strong business presence in the Commonwealth, and all of whom are members of the Massachusetts Biotechnology Council (MBC), commend you for your work during the 110th Congress to advance S. 1695, the Biologics Price Competition and Innovation Act. The MBC asks that you reintroduce this consensus, bipartisan legislation as soon as possible, move it quickly through the HELP Committee, and then help guide it to final passage.

In this effort, we commit to working with you to ensure patient access to safe and affordable medicine, while protecting and sustaining continued biomedical innovation. In our view, the very future of biotechnology and continued medical breakthroughs rests with initiatives like S. 1695 which protect and promote both innovation and the best interests of patients.

The Massachusetts biotechnology community believes there are three key principles that Congress should incorporate into any legislation, principles that are outlined and articulated in Senate 1695:

- Assuring that follow-on biologics are safe and effective;
- Providing adequate incentives for investment in research and development of new biotechnology medicines as well as for investment in existing products, to improve their safety or effectiveness or to expand their benefits to new patient populations through new indications for use; and
- Establishing a clearly defined and efficient pathway for approval of follow-on biologics after appropriate periods of data protection have expired.

The incentive most needed to sustain biotechnology innovation is the assurance of an adequate period of data protection for the innovators. S. 1695 would have provided a period sufficient to encourage innovators to undertake the very expensive and risky discovery and development activities needed to bring new biologics to patients and physicians today. We greatly appreciate the role you have played in building support among your colleagues for adequate data protection for innovator biologics.

We understand the pressure of ever-increasing health care costs on businesses and those families dealing with a serious illness, particularly in today's difficult economic times. We are committed to working with you and our colleagues in the life sciences sector to develop a system that makes health care, including biologics, more affordable to patients while nurturing our globally competitive life sciences sector in Massachusetts and across the United States.

As you know, the field of biotechnology barely existed a quarter-century ago. Since then, Massachusetts has become a global force in discovering new cures for diseases, bringing hope to millions of people suffering from serious and life-threatening diseases such as cancer, heart disease and multiple sclerosis. Massachusetts' early-stage and established biotechnology companies, unified across the entire life sciences chain of discovery with our state's academic research centers and venture capital firms, have become a dynamic economic engine that attracts new investment, construction, research, business, and thousands of new jobs.

The benefits of the biotechnology industry in Massachusetts alone are impressive:

- The biotechnology industry employed 44,005 people in Massachusetts in 2006, and the biotech and pharmaceutical industry generated \$3.9 billion in payroll.
- While statewide employment only grew by 0.7 percent from 2002-2006, employment growth for the biotechnology industry was 30.4 percent.
- 10.4 percent of the global biotechnology drug development pipeline is based in Massachusetts.
- The life sciences industry generated \$7.6 billion in exports from Massachusetts in 2008, or 27 percent of all Massachusetts exports.
- Massachusetts-based biologic and pharmaceutical drug manufacturers generated \$9.5 billion in sales for 2007, excluding sales of biotechnology research products.
- Massachusetts is also proud to be a model for other states in developing similar clusters of biotechnology excellence across the country.

We must not take our leadership for granted, however. We need to ensure that Massachusetts and the nation remain at the forefront of this breathtaking new era of discovery in the life sciences. Our industry's success is dependent on continued innovation and a strong record of patient safety. But this simply won't be possible if Congress creates a pathway for follow-on biologics – including exciting new therapies emanating from embryonic stem cell research - that erodes patient safety protections or fails to secure adequate incentives for innovation.

We greatly appreciate all the time you and your staff have spent working with us on this important issue. We look forward to continuing this critical work and ensuring that the resulting legislation protects patient safety, preserves biotech innovation, and maintains Massachusetts' and America's world leadership in the life sciences in the 21st century.

Sincerely yours,

cc: The Honorable Michael B. Enzi
Ranking Member
Committee on Health, Education, Labor and Pensions
United States Senate
379A Senate Russell Office Building