NEBA
NEW ENGLAND BIOTECH ASSOCIATION

September 21, 2009

To the Honorable New England delegation of the United States Senate and United States House of Representatives:

We, the undersigned join the New England Biotech Association in support of legislation to create a pathway for biosimilar biologic products. There is perhaps no issue of greater importance to the future viability of New England's biotech community than a legislative pathway for biosimilars that protects patient safety and preserves future innovation. As Congress considers this issue in the context of health care reform, it is critical the legislation ensures the highest standards for patient safety, expands competition, lowers costs, increases access to cutting-edge medicines, and preserves the incentives necessary to bring forth new biologic medicines.

New biologic medicines represent the greatest hope for treating diseases such as cancer, asthma, Parkinson's, and Alzheimers. It is crucial that biosimilars legislation preserve the incentives necessary for biotech researchers to develop the next breakthrough medical treatments. These incentives should include an appropriate period of 12-years of data exclusivity to allow New England's biotech companies to attract and protect the massive investment necessary to develop a biologic. Data exclusivity is important because - unlike patent protection - it allows manufacturers of innovative biologics to protect the extensive proprietary data they create for the purpose of developing and securing regulatory approval of their products.

During its recent consideration of health care reform legislation, both the Senate Health, Education, Labor and Pensions (HELP) Committee and the House Energy and Commerce Committee adopted bipartisan amendments that provide a safe, effective and reasonable pathway for the approval of biosimilars. These amendments, approved by overwhelmingly bipartisan votes, strike the right balance between expanding competition to lower costs for consumers and preserving incentives for continued biomedical innovation by providing a 12-year period of data exclusivity.

If the final legislation approved by Congress does not protect patient safety and provide sufficient incentives for investment in innovative new biologic medicines, it would deliver a devastating blow to the hope held by millions of patients and seriously undermine the region's biotech sector. Most biotechnology companies are not large pharmaceutical manufacturers. The majority of companies employ fewer than 100 people, yet help support 7.5 million jobs in the United States. Most biotech companies in

New England are largely start-up companies without profits - heavily reliant on private venture capital to fund their research, and are disproportionately vulnerable to negative investment incentives arising from public policy choices. New England's biotech companies are in large measure small businesses doing big science - unraveling the molecular mysteries of disease like cancer, Alzheimer's, Parkinson's, multiple sclerosis, HIV/AIDS, heart failure, obesity and diabetes.

Biosimilars legislation needs to ensure that incentives for investing in innovative biotechnology remain strong. The best way to do that is by guaranteeing that manufacturers of innovative biologics have an appropriate data exclusivity period of 12-years so that our region's biotech companies can continue to develop new therapies and cures for patients across the globe. With your continued support on this critically important issue, we can ensure that New England remains a global leader in the life-sciences.

Sincerely,

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President, New Hampshire Biomedical Council

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The New England Council

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