

September 29, 2009

The Honorable Nancy Pelosi
Speaker
United States House of Representatives
Washington, D.C. 20515

The Honorable Harry Reid
Majority Leader
United States Senate
Washington, D.C. 20510

The Honorable John Boehner
Minority Leader
United States House of Representatives
Washington, D.C. 20515

The Honorable Mitch McConnell
Minority Leader
United States Senate
Washington, D.C. 20510

Dear Speaker Pelosi, Congressman Boehner, Majority Leader Reid, and Senator McConnell:

We are writing to express our support for recent actions in Congress that reflect progress toward creating a responsible and balanced approach to allow for the approval of follow-on biologics, or biosimilars. This critically important issue has a direct economic impact on our states, our nation's public health, our economic success, and our global leadership in biomedical research. Specifically, the balance struck in the Senate Health, Education, Labor and Pensions Committee on 12 years of data exclusivity for biologics represents a critical element needed to ensure appropriate incentives for continued biomedical innovation. The Senate's actions, combined with the overwhelming vote of support for at least 12 years of data exclusivity in the House Energy and Commerce Committee, demonstrates that Congress is working to craft a fair and safe pathway for the approval of biosimilars.

One of our nation's strongest economic engines is the bioscience industry. This sector continues to grow as innovators of biologic medicines invest billions of dollars annually into researching and developing new life-saving medicines. These investments are generating vital revenues and expanding job markets in our states. The biopharmaceutical and life sciences workforce in this country is nearly 700,000 strong and supports more than 3.2 million total jobs across other sectors of our nation's economy.

Biologics will revolutionize patient care in this country and will significantly increase positive health care outcomes. These advanced and complex medicines include many of the latest breakthrough therapies for serious and life-threatening illnesses such as cancer, multiple sclerosis, diabetes, HIV/AIDS and many other serious rare diseases. In universities located in our states, research institutions and company laboratories, there are more than 600 biotechnology medicines in development for more than 100 different diseases.

Because biologics are made using living organisms, they are far more complicated than traditional medicines. Importantly, follow-on-biologics are never an exact copy of the original product. Experts agree, it is unreasonable to use research and testing performed on a pioneer biologic as the basis for approving a follow-on product. As with all medicines, patients and doctors need to be confident the safety and efficacy of biologics have been proven through

clinical trials. Therefore, a regulatory approval pathway for biosimilars must include adequate measures for assuring patient safety through clinical trials.

Innovator companies must be provided with at least 12 years of non-patent data exclusivity to allow for recovery of their original investment and to ensure licensing payments to our research institutions. In order to assure these companies continue to make investments in medical progress and take the risks necessary to bring these important products to patients, innovators should be provided with appropriate incentives, including data exclusivity and protections for their patents.

We look forward to working collectively with Members of Congress to support legislation that will foster scientific innovation and grow our role as a leader in the development and delivery of lifesaving therapeutics.

Sincerely,



Governor Deval Patrick
Massachusetts



Governor M. Jodi Rell
Connecticut



Governor Bill Ritter, Jr.
Colorado



Governor Jack Markell
Delaware



Governor Martin O'Malley
Maryland



Governor Beverly Perdue
North Carolina



Governor Theodore R. Kulongoski
Oregon



Governor Donald L. Carcieri
Rhode Island



Governor Luis G. Fortuño
Puerto Rico



Governor Christine O. Gregoire
Washington