January 19, 2010

The Honorable Barack Obama
President of the United States
The White House
1600 Pennsylvania Avenue
Washington, DC 20500

Dear Mr. President:

We are writing to express our concern about recent proposals that have been made to provisions that relate to biosimilars in the health reform bill. Specifically, we oppose limiting the period of data exclusivity for developers of biosimilar products as well as any revision to the "evergreening" language contained in both House and Senate passed bills. The balance struck by Congress – both through the Senate Health, Education, Labor and Pensions Committee and House Energy and Commerce Committee - on 12 years of data exclusivity for biologics and reasonable "evergreening" language represents a critical element needed to ensure appropriate incentives for continued biomedical innovation. We urge you to continue working with the congressional leaders to carefully evaluate the product of the extensive work that they have already done on this matter and retain the provisions that were passed in both chambers of Congress.

We also urge you to consider the jobs and investment that are at stake. Innovation drives one of our nation's strongest economic engines - the bioscience industry. This sector continues to invest billions of dollars annually into the research and development of new life-saving medicines, making the U.S. a global leader in addressing unmet medical needs. In addition, these investments generate vital revenues and expand highly valued, technology-based 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 in associated sectors of our nation's economy. In approximately 80 percent of the locations studied, employment in the biopharmaceutical sector grew more than twice as fast as all other sectors combined between 1996 and 2006. The high risk and uncertain nature of biologics R&D, combined with the economic downturn, underscores the sector's vulnerabilities. Thus 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 innovation in biomedical research.

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.

Data exclusivity serves as an important complement to patents, which may expire during the lengthy (10-15 years) pre-clinical and clinical research period required to get FDA approval.

With biotechnology products in particular, data exclusivity provides a critical incentive for innovation, as patent protections may be limited by the highly complex nature of these products, which are produced from living cells. Economic modeling has shown that a provision of at least 12 years of non-patent data exclusivity allows innovator companies to recover their original investment in the marketed therapy. Equally important, however, revenues from successful marketed therapies offset the hundreds of millions of dollars spent on drug discovery R&D on candidates that do not make it to market. Thus, these revenues support pipeline drug candidate development and investments in costly and complex manufacturing facilities for FDA approved therapies. In order to assure these companies continue to make investments in medical innovation 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 hope the Administration will work closely with Members of Congress to gain a better understanding of the complexity of this issue before making a decision that could hinder scientific innovation and jeopardize our nation's role as a leader in the development and delivery of lifesaving therapeutics. Please use us as a resource in continuing your evaluation. Thank you for your attention and consideration.

Very truly yours,

Governor Martin O'Malley
Maryland

Governor Bill Ritter
Colorado

Governor Jack Markell
Delaware

Governor Deval Patrick
Massachusetts

Governor Beverly Perdue
North Carolina

Governor Donald Carcieri
Rhode Island