



**State of New Jersey**  
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JON S. CORZINE  
*Governor*

April, 3 2009

Honorable Frank Lautenberg  
324 Hart Senate Office Building  
Washington, DC 20510

Dear Senator Lautenberg:

I am writing to express my support for the creation of an appropriate pathway for the approval of follow-on biologics (FOBs), particularly in regards to legislative initiatives which were considered by Congress last year and are likely to reappear before the current Congress. This critically important issue has a direct impact on our nation's public health and economic future including the continuation of biomedical innovation and discovery, and the ability to make biological medicine more affordable to all Americans.

One of New Jersey's strongest economic engines is the bioscience industry. This sector has grown rapidly in recent years, as manufacturers of biologic medicines continue to invest billions of dollars annually into the research and development of new life-saving medicines. This investment has positioned New Jersey as a leading state for biotechnology, generating vital revenues for our state and expanding the job market.

Biologics are the most advanced and complex medicines and include many of the latest breakthrough medical therapies for serious and life-threatening illnesses such as cancer, multiple sclerosis, diabetes, HIV/AIDS and many serious rare diseases. Since they are manufactured using living sources, each biologic has unique features. A follow-on biologic is an attempt to copy the original biologic, to obtain a final product which is similar, but not identical to the original.

Virtually, all experts agree at this time that it is unreasonable to use the research and testing performed on a pioneer biologic as the basis for the approval of a similar but not identical follow-on product. Each new biologic should be required to go through appropriate clinical trials to demonstrate the safety, purity, and potency of the follow-on product unless the Food and Drug Administration (FDA) has a scientific basis to waive this requirement. The FDA needs to be empowered to assess post-market safety and efficacy issues.

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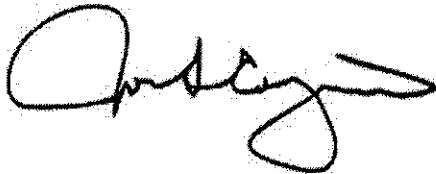
Given the commercial importance of FOB research, we believe it is important to take appropriate steps to protect intellectual property arising from this work.

There are concerns about the unintended consequences FOB legislation could have on New Jersey and the state's bioscience industry. This legislation will greatly influence the future of New Jersey's biotechnology sector for the next generation and beyond. We believe any follow-on biologics legislation requires transparent and science-based regulatory processes and contains fair incentives for the innovation of the next generation of medicines.

The bi-partisan legislation co-sponsored by Rep. Anna Eshoo (D-CA) and Rep. Joe Barton (R-TX) introduced last year (Pathway for Biosimilars Act H.R. 5629), strikes the appropriate balance between increasing access to more affordable FOBs once a fair period of pioneer-product, intellectual property protection expires while at the same time, encouraging continued development of new breakthrough medicines. I hope you will give due consideration and offer your support to similar legislation or the reintroduction of H.R. 5629 when this important issue arises this year.

I hope we are able to work collectively in this Congress to support legislation such as the Pathway to Biosimilars Act. Together we can foster scientific innovation and grow in our role as a national leader in the development and delivery of lifesaving therapeutics.

Sincerely,

A handwritten signature in black ink, appearing to read "Jon Corzine". The signature is fluid and cursive, with a large initial "J" and a long, sweeping underline.

Jon S. Corzine  
Governor