

March 17, 2009

The Hon. Anna Eshoo  
205 Cannon HOB  
Washington, D.C. 20515

The Hon. Jay Inslee  
403 Cannon HOB  
Washington, D.C. 20515

The Hon. Joe Barton  
2109 Rayburn HOB  
Washington, D.C. 20515

Dear Representatives Eshoo, Inslee and Barton:

On behalf of the California Healthcare Institute (CHI), whose more than 250 members include our state's leading biotechnology, medical device and diagnostics companies, venture capital firms and research institutes and universities, I am writing to offer our support for your legislation to provide for U.S. Food and Drug Administration (FDA) approval of follow-on biologics (FOBs), the "Pathway for Biosimilars Act."

While focused on the development of the next generation of innovative medicines, we understand that the increasing cost of health care is a growing burden for private-sector and government budgets. In the long term, competition among biosimilar products is likely to yield savings within the U.S. healthcare system. Considering the complexity of large molecule product development and manufacturing, CHI believes that it is possible to develop a successful, science-based FOBs approval pathway. This pathway must employ the best science to make sure that products are safe for patients, encourage price competition among manufacturers, and provide ample incentives to encourage continued private-sector investment in the next generation of breakthroughs.

The Pathway for Biosimilars Act meets these standards:

1. **Clear Guidance:** As suggested by the FDA's Chief Scientist in his recent letter to Congress, requires the FDA to formulate scientific standards for FOBs approval and determination of interchangeability through a flexible, clear, and public guidance process;
2. **Clinical Trials and Safety:** Ensures that no follow-on product is approved without appropriate and careful scientific demonstration, including the assessment of immunogenicity, that the product is "biosimilar" to the approved reference biological product;
3. **Patent Dispute Resolution:** Establishes an equitable framework for exchanging information among innovator manufacturers, biosimilar manufacturers and third-party patent holders, such as universities and private research institutes whose scientific breakthroughs are often licensed to the private sector for commercial development.
4. **Innovation:** Encourages future investment in biotechnology research and development by providing at least 12 years of data exclusivity before the FDA can reference the expensive safety and efficacy testing conducted by an innovator in order to approve a follow-on product. This critical element recognizes that follow-on manufacturers, developing products that are "similar" to innovators' products, may work around innovators' patents. The protection of clinical trials data is thus far more important for biologics than for traditional chemical pharmaceuticals; we believe that 12 years of protection will produce outcomes for biotechnology companies similar to those currently in place for traditional pharmaceuticals under Hatch-Waxman.

For all these reasons, CHI is very pleased to support the Pathway for Biosimilars Act.

Sincerely,



David L. Gollaher, Ph.D.  
President and CEO