

July 17, 2009



The Honorable Anna Eshoo
U.S. House of Representatives
205 Cannon House Office Building
Washington, DC 20515

Dear Representative Eshoo:

On behalf of the California Healthcare Institute (CHI), whose more than 250 members include our state's leading research institutes and universities, venture capital firms and biotechnology, medical device and diagnostics companies, I am writing to offer our support for your proposed amendment to the America's Affordable Health Choices Act of 2009 that would create a pathway for U.S. Food and Drug Administration (FDA) approval of biosimilars.

Considering the complexity of large molecule product development and manufacturing, CHI believes 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.

CHI has supported your legislation (HR 1548, the Pathway for Biosimilars Act) because it appropriately and thoughtfully meets these standards. That legislation has garnered more than 135 co-sponsors, including 21 from the 55-member California delegation. Your amendment, based upon HR 1548 and the biosimilars amendment recently adopted with overwhelming, bipartisan support at the Senate Health, Education, Labor and Pensions (HELP) Committee, incorporates important elements of both and will ensure a pathway benefiting both patients and the innovative life sciences community, which in California employs over 270,000 people.

Specifically, the basis of the HELP proposal, offered by Senators Hagan, Hatch and Enzi and supported by Chairman Kennedy and a dozen other Republican and Democratic members of the committee, provides for twelve years of data exclusivity for innovator biologics. We understand your amendment similarly provides for twelve years of data exclusivity as well as the identical FDA regulatory pathway framework from the HELP measure. We also understand that your amendment includes important patent dispute resolution provisions from HR 1548 that would establish 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.

CHI believes it is imperative that healthcare reform legislation include a pathway for the approval of biosimilars and strongly supports your amendment to do so. Thank you for your tireless efforts, and we look forward to continuing to work with you on this important issue.

Sincerely,

A handwritten signature in black ink that reads 'David Gollaher'.

David L. Gollaher, PhD
President and CEO