

NEWS

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CALIFORNIA HEALTHCARE INSTITUTE SUPPORTS INTRODUCTION OF BIOSIMILARS LEGISLATION

LA JOLLA, CALIF. March 18, 2008 – The California Healthcare Institute (CHI) submitted a letter on Friday, March 14, to Congresswoman Anna Eshoo (D-Menlo Park) commending her for the introduction of H.R. 5629, the “Pathway for Biosimilars Act,” legislation that would create a science-based approach for U.S. Food and Drug Administration (FDA) approval of follow-on biologics, while preserving important provisions necessary to encourage future biomedical innovation. CHI is a non-profit public policy research organization for California’s biomedical industry.

California’s biotechnology industry leads the world in the development of innovative medicines, giving hope to patients with devastating diseases like cancer, diabetes, Alzheimer’s, HIV/AIDS and other infectious diseases. Biotech innovators understand that the increasing cost of healthcare is a growing burden for private-sector and government budgets. In the long term, biosimilar products may offer savings within the U.S. healthcare system. Still, the complexity of developing and manufacturing biotechnology drugs , demands a careful approach.

CHI believes that the “Pathway for Biosimilars Act” meets this standard. This bill would grant FDA the appropriate authority to formulate scientific standards for approval and determination of interchangeability through a clear, public guidance process. Clinical testing standards, informed by state of the art science, will assure that a product defined as a “biosimilar” will approximate the approved reference biologic. The measure also will protect

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biotechnology innovation by providing at least 12 years of data exclusivity before a follow-on manufacturer can use the expensive and time consuming safety and efficacy testing conducted by the innovator. Finally, the legislation includes important patent protections for California's universities and private research institutions, whose scientific breakthroughs are licensed to the private sector for commercial development.

“We are encouraged by the introduction of this legislation by Congresswoman Eshoo and Congressman Barton. The measure creates a safe and effective follow-on pathway with appropriate standards to encourage investment into the next generation of biotech innovations,” said David Gollaher, Ph.D, president and chief executive officer of CHI. “Were legislation to move forward without these important protections, the effect would be devastating to California's biotechnology industry and would ultimately adversely affect public health and innovation in the state.”

The full letter is available on CHI's website at www.chi.org. CHI represents more than 250 leading biotechnology, diagnostics, medical device and pharmaceutical companies and public and private academic biomedical research organizations. CHI's mission is to advance responsible public policies that foster medical innovation and promote scientific discovery.

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