BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

James C. Greenwood
President & CEO

March 17, 2009

The Honorable Anna Eshoo
403 Cannon HOB
U.S. House of Representatives
Washington, DC 20515

The Honorable Jay Inslee
205 Cannon HOB
U.S. House of Representatives
Washington, DC 20515

The Honorable Joe Barton
2109 Rayburn HOB
U.S. House of Representatives
Washington, DC 20515

Dear Representatives Eshoo, Inslee and Barton:

On behalf of the Biotechnology Industry Organization (BIO), I am writing to offer our support for the Pathway for Biosimilars Act, legislation which would create a pathway for the approval of biosimilars while also ensuring patient safety and maintaining critical incentives for future innovation.

Biologics are complex medicines manufactured using living organisms. They are different and far more complex than most small molecule drugs 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. Any pathway must recognize that any approved biosimilar will not be a generic copy of a drug, because by definition a biosimilar is similar to, but not the same as, the innovator product.

BIO supports the Pathway for Biosimilars Act because it advances the principles BIO previously developed pertaining to a pathway. Specifically, the legislation ensures patient safety; recognizes scientific differences between drugs and biologics; maintains the physician-patient relationship; preserves incentives for innovation; ensures transparent statutory and regulatory processes; and continues to prioritize FDA review and approval of new therapies and cures.

The Pathway for Biosimilars Act protects patient safety by requiring that the approval of a biosimilar must be based on the same rigorous standards as pioneer biotechnology products and further recognizes the need for clinical trial evidence and data, including immunogenicity testing, to demonstrate the safety, purity and potency of each biosimilar. The legislation also recognizes the importance of adequate post-market evaluation of the biosimilar and ensures that a biosimilar will have a non-proprietary name readily distinguishable from that of the innovative product, so as to avoid confusion. The legislation further protects patients by only allowing a biosimilar to be approved as interchangeable with its reference product if the Secretary, through final guidance, expressly permits interchangeability for a specific class of products.

The Pathway for Biosimilars Act preserves incentives for innovation by guaranteeing that manufacturers of innovative biologics receive parity with innovative drug manufacturers, which are approved under the highly successful Hatch/Waxman Act. Under Hatch/Waxman, innovative new drugs do not face generic competition until, on average, 12-14 years after approval. The Pathway for Biosimilars Act provides parity with Hatch/Waxman in terms of incentives by providing a 12 year period of data exclusivity, with an additional 2 years available if the Secretary approves a new indication for the reference product that offers a significant clinical benefit, and an additional 6 months for pediatric studies (when such studies are requested by the Secretary).

The legislation also includes a balanced procedure for the resolution of patent-related disputes, and ensures a transparent regulatory process by requiring the Secretary to issue guidance (with stakeholder input) describing the data that will be required for approval of a biosimilar in a particular product-class before approving a biosimilar in that class. Last, the bill ensures the FDA will continue to prioritize the review and approval of new therapies and cures, even while implementing a biosimilar pathway.

Thank you very much for your leadership on this very important matter. BIO stands ready and willing to work with you, and every other Member of Congress and Senator, to enact a pathway for the approval of biosimilars which meets BIO's principles.

Sincerely,

Jim Greenwood

James C. Greenwood
President and CEO