

James C. Greenwood
President & CEO

May 9, 2008

The Honorable Anna Eshoo
205 Cannon House Office Building
United States House of Representatives
Washington, D.C. 20515

The Honorable Joe Barton
2109 Rayburn House Office Building
United States House of Representatives
Washington, D.C. 20515

Dear Congresswoman Eshoo and Congressman Barton:

On behalf of the Biotechnology Industry Organization (BIO), I am writing to offer our support for a bill you introduced, H.R. 5629, the Pathway for Biosimilars Act, legislation which would create a pathway for the approval of follow-on biologics while ensuring patient safety and maintaining critical incentives for innovation. BIO supports the creation of a pathway, and believes that Congress should act this year. BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and 31 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental products.

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 follow-on biologic would not be a generic copy of a drug, because a follow-on biologic may be similar to, but not the same as, the innovator product.

Given the importance of this issue, BIO has developed principles (see attached) that we believe the Congress should follow in creating any regulatory pathway for the approval of follow-on biological products. These principles are:

- Ensure Patient Safety
- Recognize Scientific Differences Between Drugs and Biologics
- Maintain the Physician-Patient Relationship
- Preserve Incentives for Innovation
- Ensure Transparent Statutory and Regulatory Processes
- Continue to Prioritize FDA Review and Approval of New Therapies and Cures



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H.R. 5629 respects these principles, and for that reason BIO supports it.

H.R. 5629 protects patients by requiring that the approval of a follow-on product 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 follow-on biologic, on an application-by-application basis. BIO believes that clinical testing is necessary to ensure the safety, purity and potency of a follow-on product. This legislation would, however, allow the Secretary of the Department of Health and Human Services (HHS) to waive clinical trials. While BIO has concerns with allowing clinical trials to be waived, the required guidance process for certain clinical trials in the bill would provide important patient protections and allow stakeholder input before such a waiver could be made. H.R. 5629 also recognizes the importance of adequate post-market evaluation of the follow-on product and ensures that a follow-on biologic will have a non-proprietary name readily distinguishable from that of the innovative product, to avoid confusion and inadvertent substitution without patient and physician knowledge.

The Pathway for Biosimilars Act further protects patients by only allowing a similar biological product to be approved as interchangeable with its reference product if the Secretary, through final guidance, expressly permits interchangeability for a specific class of products. It would also protect patients by requiring that any FOB to be licensed as interchangeable be supported by data showing that the follow-on is expected to produce the same clinical result as the reference product in any given patient, and for a FOB intended to be administered more than once, that the risk of switching would be no greater than the risk of continuing use of the reference product. This is an extremely important provision, as a biosimilar that is deemed interchangeable could be, depending on state law or payor policies, automatically substituted for a reference product, i.e., provided to a patient without physician prior knowledge or oversight. BIO believes, along with many medical societies and every European country which has considered this question, that patients should not be dispensed follow-on biologics unless expressly prescribed by a physician. While the Act does not prohibit interchangeability or substitution (which generally is a matter of state law), the Act's requirement that the Secretary engage in a formal guidance process and receive stakeholder and patient input, before allowing interchangeability, provides a degree of patient protection.

Data exclusivity is absolutely necessary to preserve incentives for innovation. A follow-on biologic – by definition – will not be the same as the innovative product, and thus without data exclusivity, a follow-on manufacturer may produce a follow-on biologic that is “similar enough” for regulatory approval purposes but different enough so as to avoid the innovator's patents. To ensure continued incentives for innovation, BIO believes that a 14-year period of exclusivity is necessary. The Pathway for Biosimilars Act provides 12 years of data exclusivity for innovative biologics, 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 reports of pediatric studies, (when such studies are requested by the Secretary).

H.R. 5629 also includes a balanced procedure for the resolution of patent-related disputes that may occur with respect to follow-on biologics, making it likely that such disputes can fairly be resolved prior to the market-entry of a follow-on biologic. Such mechanisms will serve to protect the intellectual property rights of innovators and other third parties such as academic institutions that often are the inventors of new technologies, while providing certainty to follow-on manufacturers and avoiding patient confusion.

H.R. 5629 also ensures a transparent regulatory process by requiring the Secretary of Health and Human Services to issue guidance (with stakeholder input) describing the data that will be required for approval of a follow-on biologic in a particular product-class before approving a follow-on biologic in that class. Additionally, the legislation ensures that FDA will continue to prioritize the review and approval of new therapies and cures, even while implementing a follow-on biologic approval regime.

Thank you very much for your leadership on this very important matter. BIO stands ready and willing to work with you, and any other Member, who introduces legislation that meets the BIO principles, to enact a pathway for the approval of follow-on biologics.

Sincerely,

A handwritten signature in black ink that reads "Jim Greenwood". The signature is written in a cursive style with a large, looping initial "J".

James C. Greenwood
President and CEO