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BIOTECHNOLOGY
INDUSTRY ORGANIZATION

James C. Greenwood
President & CEO

August 27, 2007

The Honorable Jay Inslee
403 Cannon House Office Building
United States House of Representatives
Washington, D.C. 20515

Dear Congressman Inslee:

On behalf of the Biotechnology Industry Organization (BIO), I am writing to offer our support for a bill you introduced, H.R. 1956, the Patient Protection and Innovative Biologic Medicines Act of 2007. We continue to urge, however, that the matter of establishing a regulatory pathway for the review of follow-on biological products should be considered by regular order, and with thorough deliberation and consideration of the complexities of this issue, after the Congress completes its reauthorization of the very important Prescription Drug User Fee Act reauthorization. BIO represents more than 1,100 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.

BIO supports the development of a pathway for the approval of follow-on biologics but, as your bill recognizes, such a pathway must ensure that patient safety is protected and that incentives for innovation are preserved. 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 follow-on biologics are not generic drugs, because – whereas generic drugs are exact copies of innovator drugs – follow-on biologics may be similar to, but not the same as, the innovator products.

Given the importance of this issue, BIO has developed principles (see attached) that we believe the Congress should adopt in creating any regulatory pathway for 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

H.R. 1956 respects these principles, and for that reason BIO supports it.

To ensure patient safety, H.R. 1956 requires that the follow-on product must be based on the same rigorous standards as pioneer biotechnology products and further requires clinical trial evidence and data, including immunogenicity testing, to demonstrate the safety and effectiveness of each follow-on biologic, on a product-by-product basis. The legislation 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 legislation addresses the scientific differences between drugs and biologics by recognizing that the methods used to show that one small molecule chemical drug is the same as another are not sufficient for follow-on biologics and that even minor product or manufacturing differences in biologics can result in significant safety and/or effectiveness differences.

H.R. 1956 maintains the physician-patient relationship by prohibiting a similar biological product from being characterized as interchangeable with its reference product. BIO strongly believes, as do many medical societies representing physician specialists who treat patients with biologics, patients should not be given follow-on biologics unless expressly prescribed by a physician; prohibiting interchangeability determinations accomplishes this objective.

Importantly, the Patient Protection and Innovative Biologic Medicines Act preserves incentives for innovation by providing 14 years of data exclusivity for innovative biologics, with an additional year available if the Secretary approves a new indication for the reference product that offers a significant clinical benefit. This period of 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 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, making data exclusivity essential. To ensure continued incentives for innovation, a substantial period of exclusivity is necessary, and H.R. 1956 provides this.

We encourage you, recognizing that data exclusivity is but one necessary way to protect innovative biologics, to add to your legislation appropriate mechanisms for the

resolution of any patent-related disputes that may occur prior to market entry of a follow-on biologic. Such mechanisms will serve to further protect the intellectual property rights of innovators and other third parties such as academic institutions that often are the inventors of new technologies.

H.R. 1956 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,

James C. Greenwood
President and CEO