



James C. Greenwood  
President & CEO

April 24, 2012

The Honorable Tom Harkin  
731 Hart Senate Office Building  
U.S. Senate  
Washington, DC 20510

The Honorable Michael B. Enzi  
379A Russell Senate Office Building  
U.S. Senate  
Washington, DC 20510

Dear Chairman Harkin and Ranking Member Enzi:

On behalf of the Biotechnology Industry Organization (BIO), I am writing to express support for the Food and Drug Administration Safety and Innovation Act (FDASIA). I commend you for introducing this strong, bipartisan bill which will incentivize the development of lifesaving therapies for patients and strengthen America's global leadership in biomedical innovation. In addition, I'd like to thank you for legislating in a bipartisan, inclusive fashion, soliciting feedback from stakeholders of every type. We look forward to passage of FDASIA at the HELP Committee, and commit to continuing to work with you in a collaborative fashion on remaining areas of interest, including the bill's funding mechanism to ensure budget neutrality and to address any specific concerns with the current language

The bill will enhance the development and review of innovative new therapies through increased transparency and scientific dialogue, advancements in regulatory science, and strengthened post-market surveillance. It also supports a transparent, predictable, and balanced regulatory framework for the review and approval of biosimilars, by establishing reasonable performance goals and dedicated, independent funding for biosimilar review activities. BIO appreciates the inclusion of the enhanced Accelerated Approval pathway provision which will help expedite the development of modern, targeted, and personalized therapies for patients suffering from serious and life-threatening diseases, while preserving robust standards for safety and effectiveness. In addition, BIO strongly supports the permanent reauthorization of The Best Pharmaceuticals for Children Act (BPCA) and Pediatric Research Equity Act (PREA) which will result in continued investment in pediatric research and help ensure that new drugs and biologics will be used safely and appropriately in pediatric patients.

Again, BIO supports FDASIA, commends you on your efforts, and encourages swift enactment by the HELP Committee.

Sincerely,

A handwritten signature in black ink that reads "Jim Greenwood". The signature is fluid and cursive, with a large loop at the beginning.

James C. Greenwood  
President and CEO

