



May 29, 2012

The Honorable Fred Upton
Chairman
House Energy & Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20510

The Honorable Henry Waxman
Ranking Member
House Energy and Commerce Committee
2322A Rayburn House Office Building
Washington, DC 20510

Dear Chairman Upton and Ranking Member Waxman:

BIOCOM strongly supports passage of H.R. 5651, the Food and Drug Administration Safety and Innovation Act of 2012, which is designed to reauthorize a regulatory fee program for drugs and medical devices, and establishes new regulatory review programs for biosimilars and generics.

BIOCOM leads the advocacy efforts of the Southern California life science community with more than 560 life science member companies including biotechnology, medical device, diagnostic, renewable energy, wireless technology, universities and research institutions. We share a common desire to improve communication between the industry and the FDA, and improve patient care and safety by bringing innovative, high quality products to market in a timely fashion. BIOCOM supports the swift passage of Chairman Fred Upton's FDA user fee reform bill, H.R. 5651.

Throughout the user fee negotiations, BIOCOM has weighed in with the FDA and numerous members of congress communicating the importance of the specific sections outlined below:

- **Section 602 Advisory Committees and Conflicts of Interest:** The FDA Amendments Act of 2007 imposed stricter conflicts of interest standards which resulted in the FDA experiencing problems securing qualified unconflicted experts to serve on advisory panels, especially advisory committees for rare and neglected diseases. The FDA has cited the strict conflicts of interest standards as a major obstacle which has contributed to slowing the approval process and patient access to more effective innovations. Section 602 will change the FDA conflicts of interest policy to allow better access to a wider range of appropriate experts. This issue has been a priority for the FDA, BIOCOM, and many industry and patient groups across the nation.

- **Section 721 Modification of De Novo Application Process:** The current de novo process, used for novel, innovative devices, currently takes too long because it requires 510(k) applications to have a Not Substantially Equivalent (“NSE”) finding from FDA before a company can initiate a request for a de novo classification. Section 721 would streamline the de novo classification process by striking the requirement that a sponsor receive a NSE determination before entering the de novo process. Section 721 is expected to help streamline the system and reduce costs by putting an end to duplicative reviews now required because the application must go through two tracks, that of the 510(k) as well as the de novo track.
- **Section 773 Addressing the Regulatory Framework for Health IT Products:** Under this section the Secretary of HHS, in consultation with the FDA Commissioner, the National Coordinator of Health Information Technology, and the Chairman of the Federal Communication Commission, would be charged with developing a report containing (1) recommendations on an appropriate regulatory framework for health information technology that is risk based and (2) a strategy to avoid regulatory duplication. This report would save money overall as it would compel regulators to speak to one another and work together to avoid duplication of resources.
- **Sections 831-835 Addressing Antibiotic-Resistant Infections:** These sections would provide new incentives for the development of new products that combat antibiotic-resistant infections. These sections streamline the FDA regulatory process for new antibiotics in order to get them to patients faster, and require the FDA to issue guidance to improve the clinical development of antibiotic drugs.
- **Sections 841-843 Enhancement of Accelerated Patient Access to New Treatments:** These sections rework the accelerated pathway to help shorten the approval times for a wide range of treatments, while preserving high standards for safety. These changes will enhance product safety, encourage more innovative product development and will help improve access to the accelerated approval pathway, including treatments that address rare and neglected diseases.
- **Section 851 Reauthorization of the Critical Path Public-Private Partnership:** The Critical Path Initiative (CPI) is FDA's national strategy for transforming the way FDA-regulated medical products are developed, evaluated, and manufactured. BIOCUM supports CPI and this section will reauthorize the Critical Path public-private partnership program at the current level.
- **Section 869 Breakthrough Therapies:** Creates a drug designation designed to expedite the development of more targeted drugs that show promise for serious or life-threatening conditions. The therapies are required to show substantial improvement over existing drugs on one or more clinically significant endpoints, insuring that drugs within this designation are therapeutically important.

BIOCOM supports H.R. 5651, the Food and Drug Administration Safety and Innovation Act of 2012 as currently presented. The legislation seeks to expand the FDA's use of accelerated approval, while preserving strict standards for safety. It provides transparent, predictable performance goals, and requirements that foster early, more regular and interactive communication between industry and reviewers during the regulatory process. The legislation includes provisions that deal with antibiotic development, and requirements which will help expedite the development of therapies for patients suffering from serious and life-threatening diseases. H.R.5651, is expected to enhance product safety and development, as well as bring more innovative therapies to patients faster.

If you have any questions or require additional information, please contact Maddie Baudoin at mbaudoin@biocom.org or (858) 455-0300 x 108.

Sincerely,

A handwritten signature in black ink, appearing to read "Joe Panetta". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Joe Panetta
President and CEO
BIOCOM