

May 14, 2012

The Honorable Fred Upton  
2125 Rayburn House Office Building  
Washington, DC 20515

The Honorable Henry Waxman  
2322A Rayburn House Office Building  
Washington, DC 20515

Dear Chairman Upton and Ranking Member Waxman:

On behalf of the California Healthcare Institute (CHI), the statewide public policy association representing California's innovative life sciences sector – biopharmaceutical and medical device companies, venture capital firms, and research universities and institutes – I am writing to voice our support for important, bipartisan legislation addressing the U.S. Food and Drug Administration (FDA), including reauthorization of the Prescription Drug User Fee Act (PDUFA) and Medical Device User Fee Act (MDUFA).

California is the global leader in biomedical research, investment and innovation. Our state is home to more than 2,300 life sciences companies, employing nearly 270,000 workers who are hard at work developing the next generation of medicines and technologies to improve patient and public health here and around the world. Critical to their efforts are a strong, science-based FDA, vigorous and science-based safety and efficacy standards, and consistent, predictable and transparent product review processes.

That is why PDUFA and MDUFA reauthorizations are so important. Both agreements represent the next step in an ongoing partnership between the FDA and industry. And importantly, the agreements are highly focused, providing the FDA significant resources and improving processes and performance goals to re-center the Agency toward its dual missions of protecting and promoting public health.

CHI applauds and appreciates your thoughtful, principled and tireless efforts that resulted in an overwhelming 46-0 vote by the full House Energy and Commerce Committee during its consideration of this package of FDA user fee and related measures, including provisions to:

- Promote the development of much-needed new antibiotics
- Establish an enhanced accelerated approval pathway for therapies targeting patients suffering from serious unmet medical conditions
- Permanently reauthorize the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA)
- Address important medical device-related policies such as “least burdensome,” the de novo process, humanitarian device exemptions (HDEs) and the Agency’s recent “device modification” document
- Correct problems resulting from overly-stringent FDA Advisory Committee conflict of interest rules

We look forward to working with you as this measure proceeds to ensure its timely passage and enactment into law.

Sincerely,



Todd E. Gillenwater  
Senior Vice President, Public Policy

cc: California congressional delegation