

May 29, 2012

The Honorable Brian Bilbray  
2410 Rayburn House Office Building  
Washington, DC 20515

Dear Congressman Bilbray:

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 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).

As you know, 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.

For the past two years, you have demonstrated thoughtful, principled and tireless leadership to advance bipartisan solutions that will improve FDA regulatory consistency and predictability, promoting continued biomedical investment, job creation and the development of safe and effective medicines and technologies for patients in need. Your efforts helped result in the recent 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
- Address important medical device-related policies such as “least burdensome,” 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

Notably, the legislation also includes two important measures you authored. One, the Novel Device Regulatory Relief Act, would make important improvements to the medical device “de novo” review process. The second would create a new process to expedite development and FDA review of new “breakthrough therapy” medicines targeting serious or life-threatening conditions. CHI thanks you for your leadership and looks forward to working with you to ensure the timely passage and enactment of this important package.

Sincerely,



Todd E. Gillenwater  
Senior Vice President, Public Policy