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CALIFORNIA HEALTHCARE INSTITUTE

January 14, 2014

The Honorable Sam Farr
Ranking Member
Subcommittee on Agriculture, Rural Development and FDA
House Committee on Appropriations
1126 Longworth House Office Building
Washington, DC 20515

Dear Congressman Farr:

On behalf of California Healthcare Institute (CHI) – the statewide public policy organization representing California's leading biomedical innovators, including over 275 medical device, diagnostic, biotechnology and pharmaceutical companies, research universities and private, non-profit institutes, and venture capital firms – I am writing to thank you and Rochelle Dornatt of your staff for your dedicated leadership to address the sequestration of industry-paid U.S. Food and Drug Administration (FDA) user fees, including the provision freeing the FY2013 fees in the recently released Consolidated Appropriations Act (Omnibus).

California's nearly 2,500 biomedical companies and institutions, clustered throughout the state, lead the world in life sciences research and development, which has led to groundbreaking therapies and technologies to diagnose, treat and prevent conditions such as cancer, cardiovascular disease, diabetes, HIV/AIDS and others. Just as important, the sector is an increasingly significant component of our state's economic engine, employing nearly 270,000 people, paying $27 billion in wages and accounting for $21 billion in exports annually. None of this would be possible without a science-based FDA, consistent, predictable and transparent product review processes, and adequate Agency funding – including industry-paid user fees.

Unfortunately, as you know, these user fees were included in sequestration, threatening to slow down implementation of the 2012 FDA Safety and Innovation Act (FDASIA) user fee reauthorization measure, risking continued delays in patient access to innovative new technologies and further aggravating an already significant downturn in life sciences venture capital investment. Indeed, in FY2013 nearly $85 million in industry-paid user fees to conduct review activities and make the necessary regulatory process improvements required under FDASIA were sequestered.

As you have stated, sequestration of user fees simply makes no sense. We agree. That is why we have been so appreciative of your diligent attention and leadership in addressing this issue, including the successful inclusion of language in the omnibus to unlock the FY2013 user fees and urge the Administration to "reconsider the inclusion of FDA user fees when calculating sequester" in future years.

Thank you again for your support and leadership.

Sincerely,

Todd E. Gillenwater

Todd E. Gillenwater
Senior Vice President, Public Policy

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