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CALIFORNIA HEALTHCARE INSTITUTE

January 30, 2015

The Honorable Anna G. Eshoo
241 Cannon House Office Building
Washington, DC 20515

The Honorable Leonard Lance
2352 Rayburn House Office Building
Washington, DC 20515

Dear Representatives Eshoo and Lance:

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 express our strong support for the *FDA Safety Over Sequestration (S.O.S.) Act*, your legislation to protect industry user fees paid to the U.S. Food and Drug Administration (FDA) from any future across-the-board cuts due to sequestration.

California's more than 2,300 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 arthritis, cancer, cardiovascular disease, chronic pain, diabetes, HIV/AIDS, Alzheimer's, Parkinson's Disease, and others. Just as important, the sector is an increasingly important component of our state's economic engine, employing nearly 270,300 people, paying $27.4 billion in wages and salaries, and accounting for $22.2 billion in exports.

History shows that a well-funded, science-based FDA and consistent, predictable and transparent product review processes are critical to and necessary for biomedical investment, innovation and improvements in patient care. It is the technical strength of the Agency and the clarity of its regulatory processes that helped the United States – with California front and center – become the global leader in medical device, pharmaceutical and biotechnology innovation. None of this would be possible without adequate funding of the Agency – including industry-paid user fees, which contribute substantially to supporting FDA's drug, biologic, biosimilar, medical device and diagnostic product review activities.

Passage of the *FDA Safety and Innovation Act* (FDASIA) in 2012 renewed FDA's authority to collect user fees and provided much-needed improvements to drug and device regulatory review processes. In fact, industry agreed to pay *increased* user fees in order to facilitate the needed system and process improvements under the renewed FDA user fee law. This important legislation was developed with input from industry, the Agency, patient groups and other stakeholders, and passed into law with overwhelming and bipartisan support.

Unfortunately, the Office of Management and Budget (OMB) ruled in late 2012 that these industry-paid user fees, in addition to congressionally-appropriated dollars provided to the agency, are subject to sequestration – subsequently, FDA was prohibited from accessing nearly $85 million in user fees in FY2013 alone.

In January 2014, Congress passed a bipartisan spending plan that rescinded the sequester for two years (FY2014 and FY2015) and restored the $85 million in FDA user fees that were set aside during FY2013. But restoring the user fees sequestered in FY2013 was only the first step in addressing the long-term threat that must still be resolved – sequestration threatens to disrupt the progress of many of the agreed upon improvements included in FDASIA, delay patient access to innovative new technologies, and further aggravate an already significant downturn in life sciences venture capital investment..

Given the possibility that sequestration may be triggered again in FY2016 – just as the next round of user fee negotiations commence – it is critically important that Congress act now to ensure FDA's ability to access user fees is unrestricted and unaffected by potential across-the-board spending cuts. These funds are critical not only for FDA to meet its Congressionally-mandated product review responsibilities, but for sustaining biomedical investment, innovation and improvements in patient care.

Thank you for your continued leadership on this important issue. Please let me know if CHI can be of any assistance to you – I can be reached at gillenwater@chi.org or (202) 974-6313.

Sincerely,

Todd E. Gillenwater

Todd E. Gillenwater
Senior Vice President – Public Policy