C · H · I
CALIFORNIA HEALTHCARE INSTITUTE

July 12, 2013

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

Dear Representative Eshoo:

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 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 270,000 people, paying $15.5 billion in wages and accounting for $20 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.

Last year, passage of the *FDA Safety and Innovation Act* (FDASIA) 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.

HEADQUARTERS 888 Prospect Street, Suite 220 La Jolla, CA 92037 858.551.6677 Fax 858.551.6688
SACRAMENTO 1201 K Street, Suite 1840 Sacramento, CA 95814 916.233.3497 Fax 916.233.3498
WASHINGTON, D.C. 1608 Rhode Island Avenue, NW, 2nd Floor Washington, D.C. 20036 202.974.6313 Fax 202.974.6330
WWW.CHI.ORG

Unfortunately, sequestration is disrupting the progress of many of these agreed upon improvements, threatening to delay patient access to innovative new technologies, and further aggravating an already significant downturn in life sciences venture capital investment. In FY 2013 alone, sequestration prevents FDA from accessing and using nearly $85 million industry-paid user fees to conduct review activities and make the necessary regulatory process improvements.

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 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