

May 24, 2013

The Honorable Harold Rogers
Chairman
Committee on Appropriations
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Nita Lowey
Ranking Member
Committee on Appropriations
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Robert Aderholt
Chairman
Subcommittee on Agriculture, Rural
Development and FDA
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Sam Farr
Ranking Member
Subcommittee on Agriculture, Rural
Development and FDA
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairmen Rogers and Aderholt, and Ranking Members Lowey and Farr,

As members 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 – we are writing to urge you to include in your *FY14 Agriculture, Rural Development and FDA Appropriations Bill* a restoration of all of the industry user fees being paid to FDA in 2013, and ensure that future across-the-board cuts will not impact user fees paid to FDA.

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 cancer, cardiovascular disease, diabetes, HIV/AIDS, chronic pain, 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 annually.

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.

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.

Unfortunately, sequestration is likely to result in many of these agreed upon improvements being implemented much more slowly, risking continued delays in patient access to innovative new technologies and further aggravating an already significant downturn in life sciences venture capital investment. Specifically, sequestration prevents FDA from accessing and using nearly \$83 million in industry-paid user fees to conduct review activities and make the necessary regulatory process improvements.

As you prepare your priorities for funding in FY14, we urge you to rectify this unacceptable sequester of fees by restoring to FDA all of the user fees being paid in 2013, and ensure that future across-the-board cuts will not impact user fees paid to FDA. We were pleased that this problematic issue was raised at the April 26 subcommittee hearing. These funds are critical for FDA to meet its Congressionally-mandated responsibilities, and are also important for sustaining biomedical investment, innovation and improvements in patient care.

Thank you for your attention to our concerns. Should you have any questions, please contact Todd Gillenwater, CHI senior vice president of public policy, at gillenwater@chi.org or (202) 974.6313.

Sincerely,

Allergan, Inc.
Irvine, CA

Amgen, Inc.
South San Francisco, and Thousand Oaks, CA

Arena Pharmaceuticals, Inc.
San Diego, CA

Baxano, Inc.
San Jose, CA

BD (Becton, Dickinson and Company)
San Diego, San Jose, and Redlands, CA

Biogen Idec
Weston, MA

BioMarin Pharmaceutical, Inc.
Novato, CA

Boehringer Ingelheim
Fremont, CA

Boston Scientific Corporation
Fremont, Laguna Hills, Los Gatos, San Clemente,
San Jose, Sunnyvale, and Valencia, CA

Dexcom, Inc.
San Diego, CA

Edwards Lifesciences Corporation
Irvine, CA

Exploramed Development, LLC
Mountain View, CA

Genentech, Inc.
Dixon, Oceanside, South San Francisco and
Vacaville, CA

Genzyme Corporation – a Sanofi company
Cambridge, MA

Gilead Sciences
Foster City, CA

Ground Zero Pharmaceuticals, Inc.
Irvine, CA

Histogen, Inc.
San Diego, CA

Interventional Spine, Inc.
Irvine, CA

Johnson & Johnson
Baldwin Park, Diamond Bar, Fremont, Irvine,
Irwindale, Los Angeles, Menlo Park, Milpitas,
San Diego, San Francisco, San Jose, Santa
Barbara, and Vacaville CA

Kleiner Perkins Caufield & Byers
Menlo Park, CA

KYTHERA Biopharmaceuticals, Inc.
Calabasas, CA

Medivation, Inc.
San Francisco, CA

Medtronic, Inc.
Goleta, Mira Loma, Northridge, Palo Alto, Santa
Ana, and Santa Rosa, CA

Metabolex, Inc.
Hayward, CA

Neuropace
Mountain View, CA

NuVasive, Inc.
San Diego, CA

Okapi Venture Capital, LLC
Laguna Beach, CA

Oligasis
Palo Alto, CA

OncoMed Pharmaceuticals
Redwood City, CA

Orexigen Therapeutics
La Jolla, CA

Pfenex, Inc.
San Diego, CA

Regulus Therapeutics, Inc.
San Diego, CA

ResMed, Inc.
Chatsworth, Moreno Valley, and San Diego, CA

Rigel Pharmaceuticals, Inc.
South San Francisco, CA

Sangamo BioSciences, Inc.
Richmond, CA

Sangart, Inc.
San Diego, CA

Santarus, Inc.
San Diego, CA

Siemens Healthcare Diagnostics
Berkeley, Concord, Cypress, Los Angeles,
Mountain View, Pleasanton, Santa Barbara, and
West Sacramento, CA

Sonitus Medical, Inc.
San Mateo, CA

St. Jude Medical, Inc.
Irvine, Sunnyvale, and Sylmar, CA

Strathspey Crown, LLC
Newport Beach, CA

Theravance, Inc.
South San Francisco, CA

Trius Therapeutics
San Diego, CA

XOMA Corporation
Berkeley, CA