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CALIFORNIA HEALTHCARE INSTITUTE

Statement for the Record of
The California Healthcare Institute (CHI)

Submitted to the
House Appropriations Committee
Subcommittee on Agriculture, Rural Development,
Food and Drug Administration, and Related Agencies

Fiscal Year 2014 Appropriations

March 19, 2013

CHI - California Healthcare Institute, the statewide public policy organization representing California's leading biomedical innovators -- over 275 medical device, diagnostic, biotechnology and pharmaceutical companies, research universities and private, non-profit institutes, and venture capital firms -- appreciates the opportunity to present its views on the Fiscal Year 2014 (FY14) appropriations for the U.S. Food and Drug Administration (FDA or Agency).

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.

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History shows that a strong, science-based FDA and well-articulated, predictable and consistent regulatory process are essential to biopharmaceutical and medical technology investment, innovation and patient care. For most of its history, FDA policies and organizational structure have served as models for regulators around the globe. Indeed, the technical strength of the Agency and the clarity of its regulatory processes 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 congressional funding of the Agency.

Yet the FDA performs its work with relatively little resources -- a base appropriations budget of approximately $2.5 billion. And in recent years, Congress has enlarged the Agency's scope into new fields (e.g., tobacco) and added to its overall responsibilities and authority. Yet federal appropriations have largely failed to keep up with new mandates, forcing greater reliance on industry-funded user fees. Indeed, to ensure the Agency is able to further improve its drug and device review and approval processes, the industry agreed to more user fee increases as part of the recently enacted FDA Safety and Innovation Act of 2012 (FDASIA). And this year, with Congress looking at even more new legislative initiatives (e.g., Bio-security, track and trace/anti-counterfeiting, and drug compounding), the gap in needed and necessary congressional funding continues to grow.

If the United States is to continue to maintain its position as the global leader in medical technology and biopharmaceutical innovation, it is vital that Congress provide the FDA with

adequate, appropriate, consistent and sustained funding needed to do its job. Unfortunately, at a time when its responsibilities and corresponding resource requirements are growing, the Agency is facing funding cuts. Under sequestration, the FDA faces a loss of 5.1 percent of its FY13 (current year) budget. In fact, according to an Alliance for a Stronger FDA analysis, confirmed by OMB testimony, the actual impact will be close to 9 percent, or approximately $208 million.

That is why it is important the Committee prioritize FDA funding for FY14, including for its drug and device review divisions -- the Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER), and the Center for Devices and Radiological Health (CDRH) -- and support the Agency's work in scientific outreach, training, and collaboration, including research, development and Critical Path activities that engage other agencies, global regulatory partners, academia, innovators, and consumers.

Thank you for considering our views.