

July 9, 2013

The Honorable Mike Burgess
2336 Rayburn House Office Building
Washington, DC 20515

The Honorable Jackie Speier
211 Cannon House Office Building
Washington, DC 20515

Dear Representatives Burgess and Speier:

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 *Medical Testing Availability Act of 2013*.

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.

CHI’s membership includes manufacturers – and end users – of “research use only” (RUO) products and other products used in basic and applied research. RUO laboratory products are valuable tools in the effort to advance medical innovation and improve the quality, affordability, and accessibility of health care for patients. Through advancements in clinical diagnostics, clinicians are providing patients with the best treatment sooner thereby reducing costs, increasing quality, and saving lives.

Manufacturers take their responsibilities seriously, and our members are committed to assuring that labeling, promotional materials, and advertising for such products are compliant and avoid making clinical claims or promoting the use of RUO products for any clinical use. CHI has expressed deep concerns over the Food and Drug Administration (FDA)’s draft guidance requiring manufacturers of In Vitro Diagnostic Products to halt sales if they know or have “reason to know” that a RUO product is being used in a clinical diagnostic. “Reason to know” is a vague new standard that includes everyday business practices, such as providing technical support to customers. Manufacturers cannot be placed in the untenable position of policing end-users or in effect having to discontinue supply of products.

The FDA issued this draft guidance more than two years ago. In doing so, it has left many life sciences tools companies in a state of regulatory limbo. The *Medical Testing Availability Act of 2013* is an important temporary measure to ensure patients have continued access to personalized medicine diagnostics and individualized treatment options for conditions such as cancer, HIV, organ transplantation, and tuberculosis until Congress undertakes comprehensive diagnostics regulation reform.

Specifically, the bill clarifies that the use of an RUO product by an end user for something other than research is not in itself evidence of misbranding under the *Federal Food, Drug and Cosmetic Act* (FDCA). It also provides a statutory definition of “business communications” (e.g. customer service, technical support, installation of purchased equipment, etc.) and provides a safe harbor for such communications between a manufacturer and an end user regarding properly labeled RUO products. Finally, the bill would sunset after five years, allowing Congress, FDA, industry and other stakeholders ample opportunity to work collaboratively toward a more comprehensive solution.

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

Sincerely,

A handwritten signature in black ink that reads "Todd E. Gillenwater". The signature is written in a cursive, flowing style.

Todd E. Gillenwater
Senior Vice President, Public Policy