October 21, 2013

The Honorable Duncan D. Hunter
U.S. House of Representatives
223 Cannon House Bldg
Washington, DC 20515

Dear Congressman Hunter:

We are writing as members of San Diego's innovative lifesciences sector to urge you to co-sponsor legislation – H.R. 2725, the *Food and Drug Administration (FDA) Safety Over Sequestration (SOS) Act* introduced by Representatives Leonard Lance (R-N.J.) and Anna Eshoo (D-CA) – to protect industry-paid FDA user fees from any future across the board spending cuts under sequestration.

Industry-paid user fees are intended to support FDA's drug, biologic, biosimilar, medical device and diagnostic product review activities. FDA relies heavily on user fees to supplement congressional appropriations for its product review activities. Industry user fees fund approximately two-thirds of the cost of FDA human drug and biologics review activities and approximately one-third of the cost of FDA device and diagnostics 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 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.

However, late last year, the U.S. Office of Management and Budget (OMB) determined that industry-financed user fees to FDA would be sequestered – locked away from use by the Agency – alongside congressionally appropriated monies. This year alone, sequestration has prevented FDA from accessing and using nearly $85 million in user fees to make the improvements agreed upon by FDASIA.

Thankfully, the *FDA SOS Act* would correct this terrible problem by exempting FDA user fees from future across-the-board cuts under sequestration. To date, the measure has more than 50 bipartisan co-sponsors, including 22 members of the California delegation such as San Diego-area Representatives Susan Davis, Scott Peters and Juan Vargas, and is endorsed by the California Healthcare Institute (CHI), Biocom, AdvaMed, BIO, GPhA, MDMA, PhRMA and patient groups like the ALS Association, American Cancer Society Cancer Action Network, Leukemia & Lymphoma Society and the Parkinson's Action Network.

Given the importance of this issue to the biotechnology, medical device and diagnostics sector and its more than 30,000 employees throughout San Diego County, we therefore urge you to join as a co-sponsor of the FDA SOS Act (H.R. 2725).

Thank you for your consideration, and please contact Todd Gillenwater at CHI (gillenwater@chi.org or 202-974-6313) or Laure Fabrega at Biocom (lfabrega@biocom.org or 202-449-3962) if you require any additional information.

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