May 5, 2015

The Honorable Leonard Lance
2352 Rayburn House Office Building
Washington, DC 20515

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

Dear Representatives Lance and Eshoo:

As state and regional life sciences associations representing biotechnology, pharmaceutical and medical device companies, universities, research institutions, and venture capital firms across the country, all dedicated to developing and delivering life-enhancing and life-saving products, we write to express our strong support for H.R. 1078, the *FDA Safety Over Sequestration (S.O.S) Act*. We thank you for introducing this important legislation to protect industry user fees paid the U.S. Food and Drug Administration (FDA) from any future across-the-board cuts due to sequestration.

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. The United States cannot remain the global leader in medical device, pharmaceutical and biotechnology innovation without adequate funding of the Agency – including industry-paid user fees, which for more than two decades have contributed substantially to supporting FDA's drug, biologic, biosimilar, medical device and diagnostic product review activities.

Passage of the *FDA Safety and Innovation Act* (FDASIA) in 2012 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 in 2012, at the onset of sequestration, the Office of Management and Budget (OMB) ruled that these industry-paid user fees, in addition to congressionally-appropriated dollars provided to the agency, are subject to sequestration – subsequently, FDA was prohibited from accessing nearly $85 million in user fees in FY2013 alone. In January 2014, Congress passed a bipartisan spending plan that rescinded the sequester for two years (FY2014 and FY2015) and restored the $85 million in FDA user fees that were set aside during FY2013.

But restoring the user fees sequestered in FY2013 was only the first step in addressing the long-term threat that must still be resolved – sequestration threatens to disrupt the progress of many of the agreed upon improvements included in FDASIA, delay patient access to innovative new technologies, and further aggravate an already significant downturn in life sciences venture capital investment. While we understand the need to reduce our nation's deficit, we also know that sequestering user fees will have no impact on the budget deficit because they are not taxpayer dollars. In addition, because privately-paid user fees, such as prescription drug and medical device fees, can only be used for the purpose stated in their authorizing legislation, any sequestered funds would simply sit in an account at the Treasury Department, unused.

Given the possibility that sequestration may be triggered again in FY2016 – just as the next round of user fee negotiations commence – it is critically important that Congress act now to ensure FDA's ability to access user fees is unrestricted and unaffected by potential across-the-board spending cuts. These user fee 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.

We are grateful for your continued leadership on this important issue. Please let us know if we can be of any assistance to you.

Sincerely,

Arizona BioIndustry Association (AZBio)
BayBio
BEACON, Biomedical Engineering Alliance & Consortium
Biocom
BioNJ
BioOhio
Bioscience Association of North Dakota (BioND)
Bioscience Association of West Virginia (BioWV)
BioUtah
California Healthcare Institute (CHI)
Colorado BioScience Association
CURE (Connecticut United for Research Excellence)
Delaware BioScience Association
Florida Medical Manufacturers Consortium
GeorgiaBIO
Healthcare Institute of New Jersey (HINJ)
Illinois Biotechnology Industry Organization (Ibio)
Indiana Health Industry Forum
Indiana Medical Device Manufacturers Council (IMDMC)
InnovationNJ
Kentucky Life Sciences Council
Life Science Alley (MN)
LouisianaBIO
Massachusetts Medical Device Industry Council
MassBIO
MedTech (NY)
MichBIO
Missouri Biotechnology Association (MOBIO)
Montana BioScience Alliance
NewYorkBIO
North Carolina Biosciences Organization
Oregon Bioscience Association
Pennsylvania BIO
SC BIO
South Dakota Biotech
Southeastern Medical Device Association (SEMDA)
Tech Council of Maryland
Texas Healthcare & Bioscience Institute (THBI)
VirginiaBIO
Washington Biotechnology & Biomedical Association