American
Clinical Laboratory
Association

May 7, 2012

The Honorable Joe Pitts
Chairman
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
2125, Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Jr.
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
2322-A, Rayburn House Office Building
Washington, DC 20515

Dear Chairman Pitts and Ranking Member Pallone:

I am writing you today on behalf of the American Clinical Laboratory Association (ACLA), which represents the leading national, regional, esoteric, and pathology clinical laboratories. ACLA members applaud the Subcommittee on Health for releasing a Chairman's Mark including provisions of interest to clinical laboratories that perform laboratory-developed tests (LDTs). Many of those tests are central to personalized medicine – the use of new methods of molecular analysis to better manage a patient's disease or predisposition to disease.

Section 203(d) of the Chairman's Mark would give the Secretary of Health and Human Services a discretionary waiver authority that the Secretary could use to waive medical device user fees in the interest of public health. FDA officials have stated for the record that if the agency is granted the proposed statutory authority to waive fees in selective instances, FDA intends to exercise that authority to ensure that no additional LDTs or laboratories would be subject to user fees due to [regulatory] changes in policy on LDTs. This waiver would sunset on October 1, 2017.

ACLA members participated in many months of negotiations with FDA and the medical device industry to develop the Administration's draft legislative language. The addition of the Section 203(d) language was a significant contributing factor in our support for the final MDUFA agreement. We urge the Subcommittee to approve this

important provision that will enable innovation in the field of personalized medicine and creation of well-paying jobs for highly skilled American workers.

Section 604 of the Chairman's Mark would prohibit the FDA from issuing draft or final guidance on the regulation of LDTs unless it notifies the Committee of its intent to take such action 60 days prior to the issuance of the guidance. FDA would also be required to include the anticipated details of the guidance. ACLA members strongly urge the Subcommittee to approve this section during tomorrow's markup session.

We appreciate the support of Representative Michael Burgess on this important issue. Because of his medical background, Dr. Burgess has been a strong advocate for the advancement of personalized medicine.

Should you like additional information or to discuss this issue in greater detail, please do not hesitate to contact me at 202-637-9466 or amertz@acla.com.

Sincerely,

Alan Mertz
President

cc: The Honorable Fred Upton
The Honorable Henry Waxman
The Honorable Michael Burgess