February 16, 2012

The Honorable Fred Upton
Chairman
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton:

The American Association for Clinical Chemistry (AACC) supports your efforts to "improve the predictability, consistency, and transparency of FDA's medical device review and approval process." Last year you identified a number of legislative initiatives that could assist the committee in reaching this objective.

AACC is pleased to report that it has endorsed Representative Bilbray's *Novel Device Regulatory Relief Act of 2011*, which would streamline the FDA de novo classification process. We believe this change may provide physicians with greater access to low and moderate risk assays that could play a key role in improving patient care.

We do, however, ask that you seek more details about H.R.3207, the *Modernizing Laboratory Test Standards for Patients Act of 2011*, before including it within any committee package. Although we understand and share some of the concerns that contributed to the drafting of this bill, we recommend that a number of questions be answered before it moves forward, such as:

- What impact would this bill have on patient access to laboratory developed tests? Test innovation?
- Would H.R.3207 affect the ability of differing health providers to continue to provide LDTs (e.g., hospitals, large and small clinical laboratories, and group practices)?
- What funds would CMS need to implement this new regulatory framework?
- What would clinical laboratories be assessed by CMS to comply with these new standards?
- Would new fees adversely impact competition among testing facilities?

AACC is not opposed to additional public or private oversight of LDTs as suggested by H.R.3207. We do, however, want to make sure that any changes preserve patient access to these invaluable tests and that innovation is not inadvertently hindered. AACC looks forward to working with you and the Committee to modernize FDA practices and to ensure that patients continue to receive safe, timely, and accurate laboratory testing.

By way of background, AACC is the principal association of professional laboratory scientists--including MDs, PhDs and medical technologists. AACC's members develop and use chemical concepts, procedures, techniques and instrumentation in health-related investigations and work in hospitals, independent laboratories and the diagnostics industry worldwide. The AACC provides international leadership in advancing the practice and profession of clinical laboratory science and its application to health care. If you have any questions, please call me at (804) 828-0375, or Vince Stine, PhD, Director, Government Affairs, at (202) 835-8721.

Sincerely,

Greg Miller, PhD
President, AACC