



May 21, 2012

The Honorable John Boehner  
Office of the Speaker of the House of Representatives  
H-232 Capitol Building  
Washington, DC 20515-5117

Dear Speaker Boehner:

Recent media reports have indicated that the House of Representatives may include legislation introduced by Rep. Burgess, H.R.3207, the Modernizing Laboratory Test Standards for Patients Act of 2011, as part of the "Food and Drug Administration Reform Act of 2012," when it comes up for a vote in the Lower Chamber. AACC opposes the inclusion of this bill within the user fee legislation.

Although AACC is not opposed to additional public or private oversight of Laboratory Developed Tests (LDTs), as suggested by H.R.3207, we believe it is premature for the House to take action on this measure given that there are many unanswered questions involving this legislation, 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 requests that you to defer any action on the Burgess bill until these questions can be answered. We want to ensure that any changes to the regulation of LDTs preserve patient access to these invaluable tests and not create any new barriers to innovation. AACC looks forward to working with you to ensure that patients continue to receive safe, timely, and accurate laboratory testing.

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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,

A handwritten signature in blue ink, appearing to read "G Miller", enclosed in a thin black rectangular border.

Greg Miller, PhD  
President, AACC