May 4, 2016

The Honorable Paul Ryan
Speaker
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Nancy Pelosi
Democratic Leader
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Kevin McCarthy
Majority Leader
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Steny Hoyer
Democratic Whip
U.S. House of Representatives
Washington, D.C. 20515

Dear Speaker Ryan, Leader Pelosi, Leader McCarthy, and Whip Hoyer:

On April 19th, the House Appropriations Committee approved H.R.3049, the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill for fiscal year 2017. Included in the accompanying report is language that would direct the Food and Drug Administration (FDA) to suspend work on its final guidance regulating laboratory developed tests (LDTs) until Congress has an opportunity to take action on this issue. AACC strongly supports the inclusion of this language to ensure appropriate congressional review of this policy and prevent unwarranted regulatory action.

AACC supports federal oversight of LDTs, which are currently regulated by the Centers for Medicare and Medicaid Services (CMS) and its deemed private accrediting organizations under the Clinical Laboratory Improvement Amendments (CLIA). We are concerned that substantive, costly changes are being proposed by the FDA despite the lack of evidence that current processes are insufficient. Further, our clinical laboratory professionals are concerned that the draft guidance, as written, will stifle test innovation, hinder patient care and force many hospitals and clinical laboratories to stop offering these tests.

AACC is also troubled by the FDA's use of the guidance process in lieu of the normal rulemaking process. The changes proposed by the agency significantly alter federal policy. By following the congressionally enacted Administrative Procedures Act (APA) the agency would have been required to enter into a dialogue with the public and provide justification for its actions. The APA requires federal agencies to respond to all public comments, thereby providing a rationale for its policy decisions, as well as conduct an economic analysis of the regulatory changes and its impact on affected parties. Unfortunately, under the guidance process the FDA does not have to take any of these actions.

AACC urges you to retain the report language in the Agriculture appropriations bill, which suspends further FDA work on the LDT final guidance pending congressional action. We look forward to working with you on this most important issue. If you have any questions, please email Vince Stine, PhD, AACC Director of Government Affairs, at vstine@aacc.org.

Sincerely,

Patricia M. Jones, PhD, DABCC, FACB
President, AACC