

May 16, 2016

The Honorable Jerry Moran
U.S. Senate
Chair, Subcommittee on Agriculture,
Rural Development, Food and Drug
Administration, and Related Agencies
Washington, DC 20510

The Honorable Jeff Merkley
U.S. Senate
Ranking Member, Subcommittee on Agriculture,
Rural Development, Food and Drug
Administration, and Related Agencies
Washington DC 20510

Dear Chairman Moran and Ranking Member Merkley,

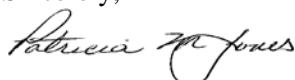
On April 19th, the House Appropriations Committee approved H.R.3049, the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill for fiscal year 2017. Included in the accompanying report is language that would direct the Food and Drug Administration (FDA) to suspend work on its final guidance regulating laboratory developed tests (LDTs) until Congress has an opportunity to take action on this issue. AACC urges you to include similar language (see attachment) in the Senate version of the legislation. We believe the inclusion of this language is important to ensuring appropriate congressional review of LDT 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 Further, our clinical laboratory professionals are concerned that the draft guidance, as written, will stifle test innovation, hinder patient care and force many hospitals and clinical laboratories to stop offering these tests.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 looks 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

Attachment

House Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill LDT report language:

Laboratory Developed Tests.—The FDA’s draft guidance issued on October 3, 2014, titled “Framework for Regulatory Oversight of Laboratory Developed Tests” (LDTs), puts forth a proposed regulatory framework that is a significant shift in the way LDTs are regulated. Such a shift deserves input from the public, and Congress has been working with stakeholders, constituencies, and the FDA to find common ground on regulating LDTs. The FDA’s guidance circumvents the normal rulemaking process and changes expectations for patients, doctors, and laboratories for the first time since the Clinical Laboratory Improvement Amendments Act was passed in 1988. The Committee directs the FDA to suspend further efforts to finalize the LDT guidance and continue working with Congress to pass legislation that addresses a new pathway for regulation of LDTs in a transparent manner.