

April 18, 2016

The Honorable Harold Rogers
Chairman
Appropriations Committee
H-305 Capitol
Washington, DC 20515

The Honorable Nita Lowey
Ranking Member
Appropriations Committee
1016 Longworth House Office Building,
Washington, DC 20515

The Honorable Robert Aderholt
Chairman
Appropriations Subcommittee on
Agriculture, Rural Development,
Food and Drug Administration,
and Related Agencies
2362A Rayburn House Office Building
Washington, DC 20515

The Honorable Sam Farr
Ranking Member
Appropriations Subcommittee on
Agriculture, Rural Development,
Food and Drug Administration,
and Related Agencies
2362A Rayburn House Office Building
Washington, DC 20515

Dear Chairman Rogers, Ranking Member Lowey, Chairman Aderholt, and Ranking Member Farr:

On behalf of the undersigned organizations, we are writing in support of the report language included as part of the H.R. 3049: Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act that would require the Food and Drug Administration (FDA) to work with Congress on the regulation of laboratory developed tests (LDTs).

On October 3, 2014, FDA issued draft guidance proposing to establish new and significant regulatory requirements on hospitals, clinical laboratories, physicians, other health care providers and industry offering laboratory developed testing services. We are concerned that the proposed draft guidance, entitled "Framework for Regulatory Oversight of Laboratory Developed Tests", conflicts with existing regulations and would impose substantial new requirements without complying with notice and comment rulemaking as required under the Administrative Procedures Act (APA).

We have previously written to the agency expressing this concern. In this letter, we indicate that FDA's statutory authority to regulate laboratory developed testing services and the scope of the proposed guidance remains a matter of significant legal controversy. Therefore, we are supportive of the report language in H.R. 3049 which asks FDA to work with Congress using a transparent process to find a pathway forward. We ask that this language be included in the report upon passage.

We look forward to working with the FDA, other federal agencies, and other stakeholders to ensure that any change in the current policy regulating laboratory developed testing services does not jeopardize the delivery of health care in the country or the practice of medicine, and that patients continue to have access to medically necessary clinical care.

Sincerely,

American Clinical Laboratory Association
American College of Medical Genetics and Genomics
Association for Molecular Pathology
Infectious Diseases Society of America
The National Independent Laboratory Association