



Better health through
laboratory medicine.

May 19, 2016

The Honorable Mitch McConnell
Majority Leader
U.S. Senate
Washington, DC 20510

The Honorable Harry Reid
Minority Leader
U.S. Senate
Washington, DC 20510

The Honorable Lamar Alexander
Chair, Health, Education, Labor &
Pensions Committee
U.S. Senate
Washington, DC 20510

The Honorable Patty Murray
Ranking Member, Health, Education, Labor
& Pensions Committee
U.S. Senate
Washington, DC 20510

Dear Senator Majority Leader McConnell, Minority Leader Reid, Chairman Alexander, and Ranking Member Murray,

On April 6th, members of the Senate Health, Education, Labor and Pensions Committee approved S.2700, *the FDA and NIH Workforce Authorities Modernization Act*, which authorizes the two agencies to spend additional funds to attract and retain top scientists. During the mark-up, the Committee approved an amendment offered by Senator Pat Roberts that would require the Food and Drug Administration to provide a public explanation when it chooses to set policy through guidance instead of utilizing the rulemaking process. AACC strongly supports this amendment.

Over past decade the FDA has issued more than 600 guidance documents, making this policy option the norm rather than the exception. AACC does not believe the agency should use guidance when making significant policy changes. Instead, the FDA should follow the Administrative Procedures Act (APA), as established by Congress, which requires federal agencies to respond to all public comments and conduct an economic analysis of the impact of the regulatory changes. The Roberts amendment doesn't prevent the FDA from issuing guidance, but does require it to provide a rationale for its decision—we believe this is a reasonable request.

AACC urges you to include the Roberts amendment in any final 'Innovation' package brought before the Senate for a vote. We look forward to working with you on this issue. If you have any questions, please email Vince Stine, PhD, AACC Director of Government Affairs, at vtine@aacc.org.

Sincerely,

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