



Better health through
laboratory medicine.

November 14, 2016

The Honorable Pete Sessions
U.S. House of Representatives
2233 Rayburn House Office Building
Washington, DC 20515

Dear Representative Sessions,

The American Association for Clinical Chemistry (AACC) endorses your legislation, H.R.6283, the “Truth in Regulations Act of 2016,” which would increase the administrative requirements on agencies using guidance in lieu of rulemaking. We share your concern that federal agencies are making significant policy changes through guidance as a means of avoiding provisions set forth in the Administrative Procedures Act (e.g., responding to public comments obtained through notice of proposed rulemaking). H.R.6283 would establish new limits and obligations on agencies that choose to utilize this method.

AACC is a global scientific and medical professional organization dedicated to clinical laboratory science and its application to healthcare. AACC brings together more than 50,000 clinical laboratory professionals, physicians, research scientists, and business leaders from around the world focused on clinical chemistry, molecular diagnostics, mass spectrometry, translational medicine, lab management, and other areas of laboratory science to advance healthcare collaboration, knowledge, expertise, and innovation.

If enacted, H.R.6283 would necessitate that:

- “Significant guidance” receive the approval of appropriate senior officials;
- That mandatory language be excluded (e.g., the use of the term “must”);
- The documents be posted on the internet and made available for public comment; and
- An agency publically respond to comments received regarding “economically significant” guidance documents.

AACC agrees with these recommendations. AACC suggests, however, that you amend your legislation to require agencies that issue an “economically significant” guidance also perform and publish an economic impact analysis of that policy to better inform the public about the costs and benefits associated with the suggested change.

We look forward to working with you on this important issue. If you have any questions, please email Vince Stine, PhD, AACC Director of Government Affairs, at ystine@aacc.org.

Sincerely,

A handwritten signature in black ink that reads "Patricia M. Jones".

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