



May 23, 2007

The Honorable Edward Kennedy  
Chairman, Health, Education, Labor  
and Pensions Committee  
U.S. Senate  
428 Dirksen Senate Building  
Washington, DC 20510

Dear Chairman Kennedy:

The American Association for Clinical Chemistry (AACC) shares your concern for the quality and accuracy of laboratory tests. Over the years, we have consistently supported efforts to promote effective oversight of this area. AACC, along with other members of the laboratory community, worked closely with you to enact the Clinical Laboratory Improvement Amendments of 1988 (CLIA'88), which established uniform federal standards for patient testing. We continue to support these standards as the primary means for ensuring laboratory oversight.

AACC recognizes that there are some laboratories conducting genetic tests that provide non-diagnostic information, which are currently exempt from CLIA oversight. We would support legislative or regulatory efforts to address this issue. S.736, the Laboratory Test Improvement Act, however, goes beyond this narrow problem and, instead, increases federal regulation of laboratory-developed tests—tests already subject to stringent federal standards. AACC is concerned that this bill, in its current form, could stifle test innovation and limit patient access to care.

AACC urges you to gather more input from key policymakers before moving this legislation forward. We strongly support the provision in S.1082, the FDA Revitalization Act, which directs the Institute of Medicine to evaluate the quality and safety of genetic testing and make recommendations for improving federal oversight. IOM input, along with feedback from other stakeholders, such as HHS, the Secretary's Advisory Committee on Genetics, Health and Society, clinical laboratories and others could more clearly define the problem and identify potential remedies. AACC looks forward to working with you on this issue.

By way of background, AACC is the principal association of professional laboratory scientists--including MDs, PhDs and medical technologists. AACC's members develop and use chemical concepts, procedures, techniques and instrumentation in health-related investigations and work in hospitals, independent laboratories and the diagnostics industry worldwide. The AACC provides international leadership in advancing the practice and profession of clinical laboratory science and its application to health care. If you have any questions, please call me at (504) 568-4281, or Vince Stine, PhD, Director, Government Affairs, at (202) 835-8721.

Sincerely,

Larry Broussard, PhD  
President-Elect, AACC

