AMERICAN ASSOCIATION OF BIOANALYSTS

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March 29, 2007

Senator Edward M. Kennedy
317 Russell Senate Building
Washington D.C. 20510

Dear Chairman Kennedy:

We are writing on behalf of the American Association of Bioanalysts (AAB) regarding the Laboratory Test Improvement Act (S. 736). AAB is the leading national organization of community clinical laboratories. Our members are clinical laboratory directors, owners, supervisors, managers, medical technologists, medical laboratory technicians, physician office laboratory technicians and phlebotomists. AAB has a specialized membership section for laboratory professionals involved in reproductive biology: the College of Reproductive Biology (CRB). In addition, a significant number of AAB laboratory directors and owners live and work in Massachusetts, including Dr. Joseph Musto, director and owner of Diagnostic Laboratory Medicine, Inc., Bedford.

AAB has long been an ardent advocate for appropriate regulation of laboratory testing. For example, AAB has previously expressed its concern that the Department of Health and Human Services (HHS) has failed to apply the Clinical Laboratory Improvement Act (CLIA) to reproductive biology testing. In fact, in 1999 we filed a legal action to compel HHS to apply the basic quality control measures established by CLIA to In Vitro Fertilization (IVF) laboratories. We have also been concerned that HHS has liberally provided CLIA waivers for many tests that do not meet the statutory requirements for a CLIA waiver.

For these reasons, we respect your interest in establishing a regulatory environment appropriate for certain new tests. However, additional time is needed to assess whether the proposed regulatory structure in S. 736 will have its intended effect. In 1997, modifications were quickly made to clinical laboratory testing as part of the FDA Modernization Act of 1997 (FDAMA) that substantially expanded waived testing and resulted in a diminution in the controls on quality measures. There are also many complex issues associated with the development of customized tests within laboratories that are used in the care of certain patients that need to be carefully evaluated prior to any modification of either the FDA or the CLIA regulatory requirements.

We urge you to provide sufficient time and adequate public hearings in order to permit the clinical laboratory community and other interested parties to evaluate the potential impact of this legislation. The regulatory structure governing laboratory testing is very important. Modifications to that system should be carefully considered with sufficient time for input from knowledgeable experts in order to avoid any unintended consequences that would adversely affect patient care. We would like to meet with you or your staff to discuss our concerns and we are prepared to participate in any public hearings on this topic.

Thank you for your leadership on this and many other important issues. We look forward to working with you to ensure that any legislation in this area results in enhanced protections and an improvement in quality for laboratory testing.

Sincerely,

Mark S. Birenbaum, Ph.D.
Administrator

MSB/dlh

cc: Senator Mike Enzi
Senator Gordon Smith
AAB Board of Directors