

March 16, 2007

Senator Edward M. Kennedy
Chairman, Committee on Health, Labor, Education and Pensions
United States Senate
428 Dirksen Senate Building
Washington D.C. 20510

Dear Mr. Chairman:

The undersigned organizations, which represent a very broad spectrum of interest in the promise of personalized medicine, respectfully request time for more careful analysis and discussion of the Laboratory Test Improvement Act. We share your interest in ensuring that all laboratory tests are safe and effective, but we believe these complex issues deserve their own legislative hearing and stakeholder input, and should not be part of the Food and Drug Administration user fee reauthorization bills under consideration this spring.

The organizations that have signed this letter have varying views on the need for additional oversight of laboratory developed tests. However, we are fully united in our request for more time to provide feedback and discuss pathways that will not have unintended consequences on laboratory services. We are further united in the opinion that any new legislative initiative in this area should be carefully crafted to focus on the areas of concern and not be so broad as to encompass laboratory tests that are clinically established or that are serving a valuable purpose for rare disease groups and public health needs.

We thank you in advance for your consideration of our request and look forward to working with you and your staff on this important public health area.

Sincerely,

American Association for Clinical Chemistry
American Clinical Laboratory Association
American College of Medical Genetics
American Medical Technologists
American Society for Clinical Laboratory
Science
American Society for Clinical Pathology
American Society for Microbiology
AmeriPath, Inc.
ARUP Laboratories
Association for Molecular Pathology
Association of Pathology Chairs
Aureon Laboratories, Inc.

BioReference Laboratories
Clariant, Inc.
Clinical Laboratory Management Association
College of American Pathologists
Genetic Alliance
Genomic Health
Laboratory Corporation of America Holdings
Mayo Clinic
Monogram Biosciences, Inc.
Oncotech, Inc.
Quest Diagnostics Incorporated
RedPath Integrated Pathology, Inc.
The Coalition for 21st Century Medicine

cc: Senator Mike Enzi
Senator Gordon Smith