

April 29, 2009

Honorable Kathleen Sebelius  
Secretary, Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

**RE: Promise of Personalized Medicine**

Dear Secretary Sebelius:

Congratulations on being selected and confirmed as Secretary of the Department of Health and Human Services (HHS)! As you assume leadership of the largest health care provider in the United States, clinical laboratory medicine professionals stand at the front line in helping to address today's most urgent health care challenge – providing better, more effective care, while reining in rising health care costs. The undersigned groups represent a broad spectrum of the providers of clinical laboratory tests including those focused on genetics and molecular methods that will advance prevention, wellness and the promise of personalized medicine.

Our message is that 21<sup>st</sup> century disease challenges require 21<sup>st</sup> century solutions and expertise. The Department of Health and Human Services should lead the effort to accelerate personalized medicine with a commitment to regulatory balance that will allow this remarkable science to progress and not place additional burdens on a now thoughtfully regulated industry.

To achieve this goal, we are always available to help HHS shape a regulatory model that:

- Improves the interagency coordination between the Centers for Medicare and Medicaid Services and the Food and Drug Administration;
- Utilizes the Clinical Laboratory Improvement Amendments to regulate clinical laboratory testing services;
- Avoids overlapping and potentially conflicting regulatory requirements that impede innovation;
- Provides a publicly transparent genomic test registry for tests that are classified as high-risk with stakeholder involvement on definitions and the relevant information to be included in the registry and;
- Allows for a participatory approach that draws on the expertise of all industry stakeholders.

Honorable Kathleen Sebelius  
April 29, 2009  
Page 2

Genetic testing currently accounts for a relatively small but rapidly growing proportion of aggregate health care expenditures. However, genetic testing forms the cornerstone of personalized medicine, delivering the 'right drug to the right patient at the right time.' Consequently, it is vital for us to maintain a regulatory environment that will continue to foster and encourage development of this nascent field, delivering important benefits to patients, while protecting the public from unnecessary risks of harm.

We will appreciate the opportunity to meet with you to discuss an appropriate regulatory balance with continued emphasis on safety and effectiveness. A representative from one of the groups below will work with your office to find a mutually acceptable time for such a meeting.

Sincerely yours,

The American Association of BioAnalysts  
American Association for Clinical Chemistry  
American Clinical Laboratory Association  
American Medical Technologists  
American Society for Clinical Pathology  
American Society for Clinical Laboratory Science  
American Society for Microbiology  
Clinical Laboratory Management Association  
College of American Pathologists  
National Independent Laboratory Association