

April, XX 2009  
**PRESS ADVISORY**

FOR IMMEDIATE RELEASE

## **Letter to Secretary Sebelius Unites Laboratory Community in Communicating the Need for Regulatory Balance in Genetic and Molecular Testing**

*“21<sup>st</sup> century disease challenges require 21<sup>st</sup> century solutions and expertise”,  
Say Lab Groups*

A broad coalition of laboratory organizations and laboratory professional groups congratulated Health and Human Services Secretary Kathleen Sebelius and communicated the importance of an innovative regulatory model that allows genetic and molecular testing to fulfill its potential for patient care and health cost savings.

In a letter dated April xx, 2009 to Secretary Sebelius, 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 Microbiologists, Clinical Laboratory Management Association, College of American Pathologists, and the National Independent Laboratory Association communicated that 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 continue and not place additional burdens on a now thoughtfully regulated industry. These 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.

The groups offered to help HHS achieve this goal in shaping a regulatory model that;

- Improves the interagency coordination between the Center 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;
- Allows for a participatory approach that draws on the expertise of all industry stakeholders.

The groups requested a meeting with Secretary Sebelius to discuss an appropriate regulatory balance with continued emphasis on safety and effectiveness.