ACLA
American
Clinical Laboratory
Association

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Comment to the
Clinical Laboratory Improvement Advisory Committee

February 14, 2007

The American Clinical Laboratory Association (ACLA) represents local, regional and national hospital and independent clinical laboratories. Many, if not all, of our members perform genetic testing and thus have a keen interest in the issue of proposed rulemaking for a genetic testing specialty. ACLA shares the goal of the committee to bring the full promise of genetic/molecular medicine to the health care system incorporating the highest quality of diagnostic tests.

ACLA is very much aware that regulatory agencies, legislators, policy groups, the media and others have recently communicated the need to bolster oversight of laboratory developed genetic testing. Much of that concern appears to be directed at ensuring the laboratory services performed are clinically relevant and effective for patient care. ACLA concurs and believes that any concerns in this area can and should be addressed through better enforcement and possible enhancement of the regulations promulgated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

CLIA is the Congressionally designed regulation for clinical laboratories and includes many requirements for clinical relevance. CLIA regulations explicitly require the laboratory director to ensure that selected test methodologies are capable of providing;

- Quality laboratory services for **all aspects of test performance** [subsection 493.1445(e)1] and

- The quality of results required for **patient care** (Subsection 493.1445(e)(3)(i)).

This provision implicitly requires the selection of medically relevant tests that have an effective clinical purpose. Likewise, CLIA regulations require the laboratory to have a clinical consultant (Subsection 493.1417), who is responsible for communicating information about the appropriateness of a test in the clinical context.

CLIA regulations also require the laboratory to validate the performance characteristics of laboratory-developed tests and further require the laboratory director to ensure that the ordering clinician can properly interpret results by including pertinent interpretive information in the reports and making consultation available.

ACLA has heard from the regulatory agencies that there are some "very colorful players" that are performing direct to consumer tests with questionable clinical validity. This was detailed in a recent GAO report and subsequent Congressional hearing. All laboratories that do human clinical testing should be CLIA certified, provide tests that advance patient care, and be held responsible for false marketing and advertising claims.

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In summary, the foundations for the clinical relevance of laboratory testing and interpretive guidance for clinicians exist within the CLIA regulations. Enhancements to the CLIA Interpretive Guidelines or to the CLIA regulations themselves, if deemed necessary, coupled with systematic and rigorous enforcement is recommended.

ACLA appreciates this committee's thoughtful deliberation on this and all the issues that will fulfill the promise of genetic testing but not at the expense of innovation and timely patient access.

ACLA thanks you for the opportunity to comment and looks forward to working with the committee and the agencies on this important issue.

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