



July 14, 2010

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, Maryland 20852

Dear Sir/Madam:

The American Association for Clinical Chemistry (AACC) appreciates the opportunity to provide input to the Food and Drug Administration (FDA) regarding the agency's oversight of laboratory developed tests (LDTs). We support the FDA's dual goals of ensuring that patient testing is accessible and accurate. AACC recognizes the challenges the agency faces as it attempts to find the appropriate regulatory balance between patient protections and scientific innovation. We stand ready to work with you to develop policy in this uncharted territory.

Although the purpose of this meeting is to discuss the appropriate level of FDA regulation of LDTs, we believe it's important to acknowledge that these tests are already subject to vigorous public and private sector oversight. All laboratories performing LDTs are high complexity under the Clinical Laboratory Improvement Amendments of 1988 (CLIA'88) and are therefore subject to stringent personnel, quality control, and proficiency testing standards, among others. In addition, CLIA laboratories must document the analytic validity of LDTs and make that information available to inspectors.

Many of the laboratories conducting LDTs are also accredited by the College of American Pathologists, one of the leading private accrediting bodies in the nation. CAP requires testing facilities in their Laboratory Accreditation Program to demonstrate the analytic validity of LDTs as well as to document how they are clinically validated. There are also state requirements in place. The New York State Clinical Laboratory Evaluation Program requires laboratories to document analytic and clinical validity prior to introducing a test. These standards apply to all laboratories conducting testing on patient specimens derived from the state. Thus, AACC believes the regulatory gap that needs to be addressed is very narrow.

AACC supports the FDA's idea of employing a risk-based classification approach for determining the level of oversight for LDTs. We believe the categories within this scheme should be high, moderate and low with the degree of regulation associated with each category determined by the level of risk to the patient. An example of a high risk test would be an assay where clinical validity cannot be independently verified (e.g., IVDMIAs). We urge you to consult clinical laboratorians as you construct any risk stratification scheme.

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AACC recommends that high risk LDTs be subject to FDA oversight, whereas low and moderate risk LDTs be regulated by CMS utilizing the CLIA'88 regulations. We believe it's important to note that a test defined as high complexity under CLIA'88 is not necessarily high risk. In fact, we would expect the vast majority of LDTs, which are well characterized, to be associated with low to moderate risk. AACC also supports a special exception for orphan tests. Unless a limited exception or other accommodation is made, no one — neither a manufacturer or a clinical laboratory—will develop these critical tests for diagnosing and treating rare diseases.

By way of background, AACC is the principal association of professional laboratory scientists--including MDs, PhDs and medical technologists. AACC's members develop and use chemical concepts, procedures, techniques and instrumentation in health-related investigations and work in hospitals, independent laboratories and the diagnostics industry worldwide. The AACC provides international leadership in advancing the practice and profession of clinical laboratory science and its application to health care. If you have any questions, please call me at (919) 966-3724, or Vince Stine, PhD, Director, Government Affairs, at (202) 835-8721.

Sincerely,

A handwritten signature in black ink that reads "Catherine Hammett-Stabler". The signature is written in a cursive, flowing style.

Catherine A. Hammett-Stabler, Ph.D., DABCC, FACB
President, AACC