October 6, 2010

Alberto Gutierrez, Ph.D.
Director, Office of In Vitro Diagnostic Device Evaluation and Safety
U.S. Food and Drug Administration
Building WO66
10903 New Hampshire Avenue
Silver Spring, MD. 20993

Re: Impact of Registration and Listing on Clinical Laboratory Industry

Dear Dr. Gutierrez:

The undersigned groups, which represent a full spectrum of laboratory medicine operations and the providers of clinical laboratory tests, understand that the Food and Drug Administration (FDA) is currently considering how to compile a complete list of laboratory developed tests (LDTs) offered by laboratories. We further understand how this information will assist FDA as it considers a regulatory framework for LDTs. An option that FDA could consider is to require that clinical laboratories register as medical device manufacturers, who must then list their LDT services as products.

Our concern with this option is that requiring laboratories to register as medical device manufacturers and list their LDTs as medical devices would have serious unintended consequences on the clinical and public health laboratory community. Moreover, this change would apply not just to independent clinical laboratories, but to the numerous hospitals and physician pathology practices that also operate laboratories that create and use LDTs. Thus, we think the approach in this area must be carefully and thoughtfully considered before it is implemented – including the important need to reach consensus on the definition of an LDT.

We believe the following consequences could result from this FDA's action:

- Laboratories could face increased liability and insurance costs as a result of their change in status from service providers to "medical device manufacturers."

- Laboratories, which today carry professional liability insurance, may be forced to obtain new insurance to cover potential product liability claims—insurance that could be extremely costly, if it is even available.

- Laboratories could be subject to a variety of other federal and state requirements, which were clearly never intended to cover their services, resulting in increased burdens, costs and, ultimately, higher fees for patients.

- The recently enacted health care reform law included several provisions applicable to device manufacturers, which were never intended to apply to laboratories or LDTs. However, FDA action could result in significant new regulatory requirements—and attendant increased burdens and costs—for laboratories.

Although we appreciate that FDA seeks a comprehensive list of laboratory tests in order to better understand the range of services laboratories offer, we believe that either CMS or NIH could successfully compile a list of LDTs in a manner that provides FDA with the information it needs while avoiding the unintended consequence of subjecting laboratories to the legal standards and requirements discussed above. The CLIA program currently maintains a list of all laboratories performing non-waived (moderate and high complexity) tests. It would be far easier for CMS, which already maintains a list of clinical laboratories, to request a list of the LDTs these laboratories offer, than for FDA to request complete registration and listing information from the laboratories. Efforts are underway at NIH to create a registry of genetic tests, the majority of which are LDTs. The NIH Genetic Test Registry could be used as a platform for NIH to create a comprehensive list of LDTs. Given the resources that have already been dedicated to creating a list of genetic tests at NIH, it would make sense to use this approach rather than creating a parallel list at FDA, thus saving scarce FDA resources.

We hope that FDA will consider the potentially drastic and adverse unintended consequences of a registration and listing approach for clinical laboratories. We believe the alternative approaches described in this letter will accomplish FDA's goals while avoiding the undue burdens on laboratories that a registration and listing approach would create. Before FDA moves forward with any proposed guidance in this area, we hope to have the opportunity to discuss these matters in greater detail.

Sincerely yours,

American Association for Clinical Chemistry

American Clinical Laboratory Association

American College of Medical Genetics

Association for Molecular Pathology

American Medical Technologists

American Pathology Foundation

American Society for Microbiology

Clinical Laboratory Management Association

Coalition for 21st Century Medicine