

September 15, 2010

Jeffery E. Shuren, M.D., J.D.
Director, Center for Devices and Radiological Health
U.S. Food and Drug Administration
Building WO66, Room 5442
10903 New Hampshire Ave.
Silver Spring MD 20993

RE: Oversight of Laboratory Developed Tests

Dear Dr. Shuren:

The undersigned groups, which represent the full spectrum of laboratory medicine operations and the providers of clinical and public health laboratory tests, are united in the desire to engage with U.S. Food and Drug Administration (FDA) in an interactive dialogue to explore and seek solutions that will not disrupt innovation and the value laboratory developed tests (LDTs) bring to patient care. As overwhelmingly communicated at the July 19th and 20th public meeting, LDTs are a value-added service to patient care. They are created to respond to patient care and public health needs and many LDTs represent the most fertile area for medical advancement.

The clinical laboratory community appreciated the public meeting as an opportunity to provide input on the regulation of LDTs. To keep the process moving forward, we ask that FDA host inter-active meetings with laboratory stakeholders to discuss specific issues about the framework for FDA regulation before FDA moves forward any proposal in this area.

LDT oversight is a complex new initiative for the agency. The potential additional resources necessary to assume this regulatory function cannot be underestimated. Currently FDA approves a single application for a test kit which can then be utilized by numerous laboratories. In question is how FDA will approach the regulation of multiple similar, if not the same, laboratory developed tests submitted by many clinical laboratories. The case for these additional resources needed to review many new (and similar) applications needs to be clearly defined and balanced, especially because oversight is already in place by federal, state and accreditation authorities.

Lacking clearly defined boundaries, the regulation of LDTs presents challenges in both the scope they represent as well as in the intrinsic complexity associated with the way they are performed in the clinical laboratory. For example, the development of multiple array, probe and marker testing presents challenges for the submission of a single intended use claim required for FDA clearance. Because of the complexity, regulatory requirements must be clear, consistent and responsive to the rapid pace of innovation.

Clinical laboratories are not *in-vitro* diagnostic test kit (IVD) manufacturers, and the differences between the two entities have never been adequately addressed, not only with regard to laboratory processes, but also physical facilities. LDTs are operationally different than medical device products. Medical device test kits are developed, packaged, labeled, sold and shipped by manufacturers to clinical laboratories throughout the U.S for use by the laboratories in the practice of clinical laboratory medicine. On the other hand, none of these are true for LDTs—with LDTs, it is a single entity that develops and performs the test and furnishes results to treating providers.

Given the significant change in policy and expansion of its regulatory oversight contemplated by FDA, with massive implications to patient care and professional standards, continued receptivity to stakeholder ideas and input is imperative before FDA moves forward any proposal in this area. FDA will benefit from insights on how tests are developed, validated and quality ensured and the laboratory community will benefit from hearing from FDA how medical device regulation can be flexibly applied to LDTs. When FDA eventually does move ahead with a proposal, it should be done through an interactive, transparent, and accountable process such as is the case with formal rulemaking.

A representative of the groups listed below will be in contact with you to work toward this important dialogue.

Sincerely yours,

American Association for Clinical Chemistry

American Clinical Laboratory Association

American College of Medical Genetics

American Medical Technologists

Association for Molecular Pathology

American Pathology Foundation

American Society for Clinical Laboratory Science

American Society for Clinical Pathology

American Society for Microbiology

Association of Public Health Laboratories

Clinical Laboratory Management Association

Coalition for 21st Century Medicine

College of American Pathologists

Cc: Margaret A. Hamburg, M.D., Commissioner U.S. Food and Drug Administration