November 15, 2012

American Clinical Laboratory Association

Mr. Daniel Levinson
Office of the Inspector General
Department of Health and Human Services
300 Independence Avenue SW
Washington, DC 20201

Dear Mr. Levinson:

We are writing with regard to an item in the Office of the Inspector General's ("OIG's") Work Plan for 2013 on oversight of Laboratory-Developed Tests ("LDTs"). The American Clinical Laboratory Association ("ACLA") is an association representing clinical laboratories throughout the country, including local, regional, and national laboratories. Almost all of ACLA's members perform LDTs, and we are concerned about possible misconceptions on the part of the OIG about what LDTs are, how their results are used, and how they are regulated.

Section V of the Work Plan, Public Health Reviews, includes a new item: "Oversight of Laboratory-Developed Tests." This section of the Work Plan states that the OIG intends to "determine the extent and nature of LDT use for health care decisions and describe the challenges in regulating LDTs." In the same section, it also includes the following statement: "LDTs, a category of in vitro diagnostics, have traditionally been used in research settings only. Because of this limited use, FDA has chosen to use regulatory discretion with respect to these tests and does not oversee them." In addition, the Work Plan also states that CLIA, which applies to all laboratories, does not apply to the clinical effectiveness of tests conducted by laboratories. We believe these statements reflect several fundamental misunderstandings concerning the nature of LDTs, which we wanted to bring to your attention.

First, it is not correct that LDTs "have traditionally been used in research settings only." In fact, the truth is just the opposite: LDTs are – and historically have been – offered by CLIA high-complexity laboratories to physicians who use them routinely to make patient care and treatment decisions in clinical settings. Today, independent clinical laboratories and hospital-based clinical laboratories, physician pathology practices, and university medical centers all routinely develop and validate tests for physician-directed patient care in their own laboratories in accordance with the Clinical Laboratory Improvement Amendments ("CLIA") and CLIA's implementing regulations. Examples of well-established LDTs range from Pap smears, manual blood cell counts, erythrocyte sedimentation rates, microbiology cultures and susceptibility tests, all the way to advanced diagnostics that derive from the mapping of the human genome and that help fulfill the promise of personalized medicine.

Further, while the FDA does have a policy of exercising enforcement discretion with regard to LDTs, that policy is not based on the view that LDTs are used only for research. In fact, the FDA has frequently acknowledged that LDTs historically have been used for treatment purposes in a wide variety of settings, not just "in research settings only." For example, in its announcement of a major public meeting with stakeholders to discuss its oversight of LDTs, it

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said that from the start that LDTs were used by physicians and pathologists to diagnose rare diseases and conditions or used as simple pathology tests and that they have been offered in "CLIA high-complexity laboratories with extensive experience in using the tests."[1] Even the FDA acknowledges that LDTs have been a valuable component of patient care in a variety of settings – not only research settings – for many years, and it has acknowledged that if it does exercise its claimed authority over LDTs, it is appropriate to proceed cautiously "so that patients will receive the desired benefits of innovative, yet safe and effective, diagnostic tests, such as tests for rare diseases and conditions."[2] While the FDA has publicly commented on the role of LDTs on numerous occasions over the years and whether or not it should attempt to regulate them, we are aware of no statement in which the agency has said that it considers such tests primarily research use tests.[3]

Second, we wish to point out that CLIA's regulatory scheme is designed to establish a comprehensive quality control framework for laboratories that ensures the validity of all tests performed, including an assessment by the laboratory director of their clinical effectiveness. And, finally, while the FDA has claimed to have authority over LDTs even while it has exercised its enforcement discretion, that legal interpretation also has been challenged and is certainly open to question.

As the OIG implements its 2013 Work Plan, we urge you to keep in mind the true nature and scope of LDTs and their value to patients being treated in a wide variety of settings. We would like an opportunity to discuss with you how LDTs are developed and used, how laboratories performing LDTs ensure their analytical and clinical validity under CLIA and its implementing regulations, and why ACLA consistently has disputed the FDA's statutory authority to regulate LDTs. The question of how LDTs should be regulated is an important one, and as the issue receives more attention, ACLA is happy to share with you our perspectives on current oversight of LDTs and the benefits and challenges presented by various oversight models. Thank you for your consideration of our concerns.

Sincerely,

Alan Mertz, President

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[1] FDA/CDRH Public Meeting: Oversight of Laboratory Developed Tests (LDTs), Date July 19-20, 2010, *available at*: http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm212830.htm.

[2] *Id.*

[3] The FDA has issued a Guidance addressing issues related to "research use only" or RUO devices; however, that Guidance specifically noted that it was not intended to apply to LDTs. FDA, *Commercially Distributed In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only: Frequently Asked Questions* at n.3 (June 1, 2011).