



Better health through
laboratory medicine.

January 29, 2015

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Chemistry (AACC) appreciates the opportunity to comment on the Food and Drug Administration's (FDA's) October 3, 2014 draft guidance "FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)," which outlines how the agency plans to gather information regarding the number and type of LDTs performed by clinical laboratories. This information will be used to stratify LDTs by risk level. In addition, the FDA describes how laboratories would report adverse medical events.

AACC is the principal scientific association of professional laboratorians—including MDs, PhDs and medical technologists. AACC's members develop and use chemical concepts, procedures, techniques and instrumentation in health-related investigations and practice 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 medicine and its applications to health care.

Notification

FDA wants to collect data regarding 14 elements for each LDT developed and performed by a laboratory. AACC is concerned that this process is redundant and costly and presents undue administrative burden to many clinical laboratories. Much of this information is already collected by the Centers for Medicare and Medicaid Services (CMS) CLIA'88 program and/or its deemed accrediting bodies. We recommend that FDA work with CMS, the College of American Pathologists and other CLIA-approved organizations to gather these data. AACC suggests that these data be gathered during routine CLIA inspections.

The FDA states that the purpose of the notification process is to help the agency in classifying "LDTs by risk level and assist FDA in determining its priorities in enforcing premarket review requirements." However, the agency later states that laboratories will be required to inform the agency of the LDTs they perform within six months of the publication of the "final version of the LDT Framework Guidance Document." AACC strongly recommends that the FDA gather the data first before making decisions regarding the framework for LDT oversight.

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Adverse Event Reporting

The agency also states that that clinical laboratories conducting LDTs should “identify and monitor significant adverse events involving medical devices” and submit the information to the FDA within 30 days of becoming aware of the event. The agency further defines an adverse event as having “caused or contributed to a death or serious injury” or could have caused or contributed to a death or serious injury “if the malfunction were to recur.”

AACC does not believe the adverse event framework, which was developed for reporting problems involving medical devices, is appropriate for services provided by clinical laboratories. Results from LDTs do not generally result or contribute to the death or serious injury to a patient. During the FDA Public Workshop on LDTs, the Mayo Clinic reported that over the past five years it had produced more than 2.5 million LDT-based tests without a single sentinel event. One reason for the overall safety of the vast majority of LDTs is that laboratories implement internal quality controls that will detect many analytical and pre-analytical errors and prevent wrong results from being reported. AACC does recommend that when a laboratory identifies a testing error it should report that mistake to the appropriate oversight body.

We look forward to the FDA’s continued engagement of the stakeholder communities in this process. If you have any questions, please call me at (404) 616-5489, or Vince Stine, PhD, AACC Director of Government Affairs, at (202) 835-8721.

Sincerely,

A handwritten signature in black ink that reads "David D. Koch". The signature is written in a cursive, flowing style.

David D. Koch, PhD, DABCC
President, AACC