



May 1, 2012

The Honorable Joseph R. Pitts
Chairman, Subcommittee on Health
Energy and Commerce Committee
U.S. House of Representatives
2125 Rayburn House Office
Washington, DC 20515

Dear Chairman Pitts:

The American Association for Clinical Chemistry (AACC) agrees with your concerns regarding the Food and Drug Administration's (FDA's) June 1, 2011 "Draft Guidance for Industry and FDA Staff: Commercially Distributed In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only: Frequently Asked Questions." AACC is concerned that the agency's draft guidance, if strictly implemented, could adversely affect patient care by hindering the development of new tests and limiting access to specialized testing for rare disorders.

Although we understand the FDA's concerns regarding the use of RUO/IUO products, we believe the agency needs to balance this concern with the potential impact its new policy may have on the development of new assays. Limiting laboratory access to these products may hinder the development of new assays, since RUO/IUO reagents are often the key building blocks in the creation of these tests. This is particularly true in the field of molecular diagnostics where new tests to detect infections and define the molecular basis of cancer are greatly improving a clinician's ability to diagnosis and treat disease.

AACC is also concerned that the FDA's draft policy may adversely affect patient care. For example, all 50 states now screen infants for at least 30 inborn metabolic errors. Follow-up testing to confirm and define these disorders relies almost exclusively on RUO/IUO reagents for mass spectrometry. Tests monitoring immunosuppression in transplant patients and detecting exposure to toxic substances also commonly depend on these same instruments and reagents. There are many other orphan tests that are only available in RUO and IUO formats. Limiting access to these reagents will have serious consequences for patient care.

It's important to note that the vast majority of laboratories using RUO/IUO reagents comply with the stringent federal and private sector requirements for using such products. These laboratories conduct rigorous validation studies, establish appropriate performance controls, and participate in regular proficiency testing to ensure test performance. If a laboratory fails to comply with any of these requirements, the accrediting body can impose a series of penalties, including revocation of their certificate.

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AACC recommends that the Centers for Medicare and Medicaid Services (CMS), as the agency responsible for testing-related issues, be encouraged to devote more time and resources during inspections to identify and sanction those facilities not meeting the federal laboratory standards. Further, we believe the FDA should narrow its draft guidance to focus on those few 'bad' laboratories inappropriately marketing assays utilizing RUO/IUO reagents, rather than promulgating an expansive document that prevents quality laboratories from providing vital patient services. AACC appreciates your active involvement on this critical issue. We stand ready to work with you if you need our assistance.

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 (804) 828-0375, or Vince Stine, PhD, Director, Government Affairs, at (202) 835-8721.

Sincerely,

A handwritten signature in blue ink, appearing to read "G Miller", enclosed in a thin black rectangular border.

Greg Miller, PhD
President, AACC