



**American Hospital
Association**

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Margaret A. Hamburg, M.D.
Commissioner
Division of Dockets Management (HFA-305)
Food and Drug Administration
Docket No. FDA-2011-D-0305
5630 Fishers Lane, Room 1061
Rockville, MD 20852

***RE: Docket No. FDA-2011-D-0305, Draft Guidance for Industry and FDA Staff: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; (Vol. 76, No.105), June 1, 2011.***

Dear Dr. Hamburg:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 42,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Food and Drug Administration's (FDA's) *Draft Guidance for Industry and FDA Staff: Commercially Distributed In Vitro Diagnostic Products Labeled for Research Use Only (RUO) or Investigational Use Only (IUO): Frequently Asked Questions*. The draft guidance clarifies the FDA's regulatory requirements applicable to manufacturers of in vitro diagnostic products intended for RUO or IUO and warns that products so labeled should not be used in clinical diagnosis or patient management.

Hospitals laboratories perform a variety of clinical diagnostic testing, including some laboratory developed tests that incorporate RUO- or IUO-labeled instruments and reagents. The AHA is concerned that the draft guidance would prohibit manufacturers from selling RUO or IUO in vitro diagnostic products to clinical laboratories that the manufacturer "knows, or has reason to know" use the product for clinical diagnostic purposes.

The AHA appreciates the FDA's efforts to ensure the appropriate use and quality of all components of clinical laboratory testing. However, we are concerned that the agency's draft guidance, if strictly implemented and enforced, would adversely affect patient care by limiting access to specialized testing for rare disorders. For instance, its provisions could compromise care of patients in need of life-saving organ transplants because manufacturers would no longer be permitted to provide hospitals with the RUO and IUO reagents that are currently used to identify compatible donors for transplant patients. Similarly, laboratory testing in other areas,



Margaret A. Hamburg, MD

August 30, 2011

Page 2 of 2

such as in molecular pathology, immunopathology and genetics, routinely employs RUO and IUO components, and patients requiring such testing could be harmed by the policies contained in the draft guidance.

The AHA recommends that FDA use its enforcement discretion to allow hospital laboratories that comply with requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to be permitted to continue to use properly validated RUO or IUO products for clinical care. The draft guidance overlooks the significant oversight of laboratory testing provided by enforcement of CLIA. Hospital laboratories that use these RUO and IOU products comply with the stringent CLIA regulations that require that they undertake rigorous validation studies, establish appropriate performance controls and participate in regular proficiency testing to ensure test performance. Failure to comply with any of these requirements can result in a series of penalties, including revocation of the hospital laboratory's CLIA certificate. Of particular relevance, current CLIA regulations (42 CFR 493.1253(b)(2)) permit laboratories to use test systems that have not been approved or cleared by FDA, such as those that include RUO or IUO products, so long as the lab establishes the performance characteristics for the test and the test is properly validated. These regulations ensure the safety and effectiveness of laboratory developed tests that use RUO and IOU products.

If FDA nevertheless decides to move forward to finalize the provisions in the draft guidance, the AHA recommends that it provide a reasonable grace period for implementation to avoid disruptions in patient care. While the guidance is intended for manufacturers and distributors of RUO and IUO in vitro diagnostic products, its implementation will have a serious impact on hospital laboratories. If the RUO and IUO products were simultaneously removed from the market, hospital laboratory testing in many disciplines would no longer be available, and patient care would be greatly harmed. The AHA believes that the length of the grace period should be adequate to allow manufacturers that wish to do so to seek clearance of their instruments and reagents for clinical diagnostic use through FDA's established regulatory framework, including adherence to the quality systems regulations. We believe that a reasonable grace period would benefit patients' continued access to care and also provide adequate time for the manufacturers of RUO and IUO products to seek and achieve FDA approval for clinical use.

Thank you again for the opportunity to comment. If you have any questions, please contact me or Roslyne Schulman, director for policy development, at (202) 626-2273 or rschulman@aha.org.

Sincerely,

Rick Pollack
Executive Vice President