May 6, 2015

The Honorable Sylvia M. Burwell
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Madam Secretary:

I am writing on behalf of the Clinical Laboratory Improvement Advisory Committee (CLIAC) to express the Committee's recommendation pertaining to clinical laboratory biosafety, especially with regards to emerging infections in the United States (US).

BACKGROUND

CLIAC is the federal advisory committee charged with the responsibility of advising HHS on issues related to the Clinical Laboratory Improvement Amendments of 1998 (CLIA), as well as technological advances affecting general clinical laboratory quality and laboratory medicine. This includes issues of clinical laboratory safety that fall under the overarching umbrella of laboratory quality. During the November 5-6, 2014 CLIAC meeting, the Committee deliberated on laboratory biosafety in the United States. The topic of laboratory safety and quality, with lessons learned through the Ebola response, was again presented to the Committee for consideration during the April 15-16, 2015 CLIAC meeting. Background information was given from the clinical and public health laboratory perspectives, as well as a presentation on the importance of safety assessments from a NIOSH industrial hygienist. After deliberating on the issues, the Committee voted to provide the following recommendation to HHS.

RECOMMENDATION

With regard to emerging infections, HHS should:

1. Provide oversight that ensures assessment of the safety and decontamination of laboratory instrumentation by manufacturers.
2. Ensure that biosafety training and assessment is required of all CLIA-certified laboratories, including personnel responsible for the preanalytical, analytical, and postanalytical phases of testing.

3. Ensure oversight, input, and resources into studies evaluating the safety of all laboratory practices, instrument testing, etc., so that studies are sound, robust, evidence-based, and applicable.

4. Develop a process for investigating and reporting laboratory acquired infections.

CLIAC appreciates the significant and continuing efforts made by HHS and its operating divisions to advance laboratory safety and quality in the US. CLIAC is committed to providing HHS thoughtful advice in support of this effort. Thank you for your consideration of this recommendation.

If you have any questions regarding CLIAC's recommendation, please feel free to contact me via my personal email at burton.wilcke@med.uvm.edu or by telephone at 802-860-2925.

Sincerely,

Burton W. Wilcke, Jr., Ph.D.
Chairperson
Clinical Laboratory Improvement Advisory Committee (CLIAC)

cc:

Dr. Thomas Frieden
Director, CDC

Dr. William R. Mac Kenzie CLIAC Designated Federal Official
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