



September 19, 2012

JudyAnn Bigby, MD  
Secretary, State of Massachusetts  
Department of Health and Human Services  
One Ashburton Place, 11th Floor  
Boston, MA 02108

Dear Secretary Bigby:

The American Association for Clinical Chemistry (AACC) is contacting you regarding Senate bill No. 2400, "*An Act improving the quality of health care and reducing costs through increased transparency, efficiency and innovation.*" This legislation, which was recently signed into law, includes a series of health care reforms to improve the quality of care in Massachusetts. One of these provisions, Section 274, creates a Task Force to "study and investigate issues related to the accuracy of medical diagnosis in the commonwealth" including the "the underlying systematic causes of inaccurate diagnoses." AACC believes one of the factors contributing to this problem is the misinterpretation of laboratory test results by physicians.

In general, laboratory tests play a vital role in diagnosing, treating and monitoring patients. Experts estimate that 70 percent of medical decisions involve laboratory test results. Unfortunately not all clinicians are aware that clinical laboratories use different devices to perform the same tests. Therefore, the test results generated by one device cannot reliably be compared to the test results from another device. This lack of comparability among tests creates a number of problems, such as:

- Increasing the chances a physician may misinterpret a test result that leads to an incorrect diagnosis;
- Causing erroneous treatment decisions when interpreting lab values using clinical guideline based decision criteria;
- Reducing the value of sharing patient information across health care providers since clinicians may not know how previous tests were performed; and
- Adding to test overutilization as clinicians re-order tests previously requested by other providers.

One practical approach to improving performance and comparability is to harmonize test results. Harmonization involves establishing the traceability of laboratory devices to a common standard. This endeavor would result in medical devices generating similar numeric test results that could be more easily interpreted by clinicians.

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AACC encourages you to address this issue in your pending study. We also urge you to support public and private efforts to correct this problem. In 2010, AACC convened an international meeting on this topic to identify a process for prioritizing those tests that can and should be 'harmonized' and a mechanism for accomplishing harmonization. We are working with our colleagues in laboratory medicine to advance this effort. Your assistance could help us build a consensus towards taking action on this important issue.

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,



Greg Miller, PhD  
President, AACC

P.S. I am including a few articles that go into more detail regarding our initiative and the problems associated with this topic.