



Better health through
laboratory medicine.

Testimony of the American Association for Clinical Chemistry to the House Committee on
Appropriations Subcommittee on
Labor, Health and Human Services, Education and Related Agencies Concerning FY18
Appropriations for Centers for Disease Control and Prevention (CDC)

Submitted for the Record, March 8, 2017

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Chairman Cole, Ranking Member DeLauro, and members of the Subcommittee, I am grateful for the opportunity to provide written testimony to the Subcommittee on behalf of the American Association for Clinical Chemistry (AACC). As you and your colleagues work on the Fiscal Year (FY) 2018 Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations bill, we respectfully request an additional \$9.2 million in funding for the CDC's Environmental Health Laboratory. This additional funding will allow CDC to continue and expand its efforts to harmonize the reporting of clinical laboratory test results. The CDC has already done incredible work harmonizing the results for a limited number of tests, but we believe with additional funding CDC could expand its efforts—benefiting clinicians and patients alike, and contributing to overall efficiencies in public health and healthcare.

Clinical laboratory testing plays an important role in medical decision-making. As the healthcare delivery system moves towards a more integrated model where health information will be shared amongst providers, patients, and payers, laboratory data will be the key piece of health information that will be used to improve the quality of care through the use of clinical guidelines, performance measures, and electronic health records. However, for a majority of laboratory tests there is not a gold standard for reporting comparable results. Unfortunately, this means that a result from one clinical test method may present a different numeric value compared to another clinical test method measuring the same patient sample, even though each result is accurate within the context of its own method. Experts call this a lack of harmonization. A test that is harmonized provides the same result regardless of the method or instrument used or the setting where it is performed.

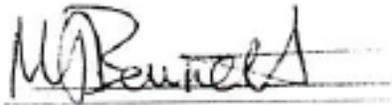
When test results are not harmonized, the entire continuum of patient care can be affected in profound — but not always obvious — ways. For example, as medicine moves toward evidence-based guidelines as a way to ensure the best care for the population, often these guidelines are anchored in laboratory test results. However, if the test results do not align with the guideline due to differences in methodology, physicians may inadvertently misinterpret the results. Benefits from harmonization include fewer medical errors and lower healthcare costs by eliminating unnecessary follow-up diagnostic procedures and treatments. CDC, medical device manufacturers and the laboratory community have already teamed up to harmonize some critical tests, like cholesterol for heart disease and hemoglobin A1c for diabetes. Now is the time to build on those advances and harmonize additional testing results.

In December 2014, the House and Senate passed, and the President signed into law, the Consolidated and Further Continuing Appropriations Act of 2015. In the accompanying report language, the two chambers identified harmonizing of clinical laboratory test results as a key priority, stating: “Laboratory professionals use a variety of test methods to obtain accurate and informative results to diagnose and treat patients, which may result in the reporting of different numeric values for the same test. CDC is urged to partner with the private sector in “harmonizing” clinical laboratory test results.” Furthermore, the House Appropriations Committee included report language to accompany the FY 2017 Labor, HHS, Ed Appropriations bill which instructed the CDC to provide the Committee with an update on the CDC’s activity on the Harmonization of Test Results in the agencies’ Fiscal Year 2018 budget request to Congress.

Harmonized test results will ensure that clinical guidelines calling for the use of laboratory tests lead to appropriate care by enhancing the reliability of screening to detect diseases early, by producing more accurate diagnoses, and by preventing treatment errors. In addition, harmonized clinical laboratory test results will prevent unnecessary — and expensive — follow-up diagnostic procedures and treatments based on misinterpretation of those results. We believe this investment in CDC will result in future cost savings and better health outcomes.

AACC is a global scientific and medical professional organization dedicated to clinical laboratory science and its application to healthcare. Our leadership in education, advocacy and collaboration helps lab professionals adapt to change and do what they do best: provide vital insight and guidance so patients get the care they need. Thank you for your attention to this important matter. Please let us know if you need additional information regarding harmonization of laboratory test results.

Sincerely,

A handwritten signature in black ink, appearing to read "M. J. Bennett", written over a horizontal line.

Michael J. Bennett PhD, FRCPath, FACB, DABCC
President, AACC