



Better health through
laboratory medicine.

July 25, 2019

The Honorable Patty Murray
Ranking Member
Subcommittee on Labor, Health and Human Services,
Education, and Related Agencies
Committee on Appropriations
United States Senate
156 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Ranking Member Murray,

The American Association for Clinical Chemistry (AACCC) urges you to include \$6 million for the harmonization of clinical laboratory testing results in the fiscal year (FY) 2020 Departments of Labor, Health and Human Services, Education and Related Agencies appropriations bill. This amount is contained in the House-passed FY 2020 Labor, Health and Human Services, Education, Defense, State, Foreign Operations, and Energy and Water Development spending package (H.R. 2740). The CDC has already completed incredible work harmonizing the results for a limited number of tests, but we believe that with additional funding CDC can expand its efforts—benefiting clinicians and patients alike and fostering improved efficiencies in our nation’s public health.

As the healthcare delivery system moves towards a more integrated model, laboratory data will be critical to improving the quality of care through the development and use of clinical guidelines and performance measures. Most laboratory tests, however, do not have a “gold standard” that helps provide a mechanism for reporting comparable results between different methods. This lack of a reference point means that test methods may report different numeric values for the same patient sample, although each may be 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.

When test results are not harmonized, the entire continuum of patient care can be affected. For example, as medicine moves toward evidence-based guidelines 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, 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 and the healthcare community have already teamed up to harmonize critical tests, such as cholesterol for heart disease and hemoglobin A1c for diabetes. Now is the time to build on those advances and harmonize additional testing results.

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Recent interest in this issue is the result of work done by this subcommittee. In 2014, under the leadership of Chairman Harkin, report language was included in the Consolidated and Further Continuing Appropriations Act of 2015 that urged CDC action in this area:

***Harmonization of Laboratory Test Results**— 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.*

Since then, Congress has taken the next step and provided funding for CDC to move forward in this effort. In FY2018 and FY2019, the House and Senate allocated \$2 million to CDC for harmonization activities. This year, the House increased this amount by \$4 million. AACC urges you to include a similar amount in the subcommittee’s Labor HHS appropriations bill. We believe that expanded CDC activities in lab test harmonization will result in future cost savings and better health outcomes. AACC and its partner groups (see attachment), stand ready to assist you in advancing this policy initiative.

If you have any questions, please email Vince Stine, PhD, AACC’s Senior Director of Government and Global Affairs, at vstine@aacc.org.

Sincerely,



Carmen L. Wiley, PhD, DABCC, FAACC
President, AACC