

February 27, 2020

The Honorable Roy Blunt  
Chair  
Appropriations Subcommittee on  
Labor, Health and Human Services,  
Education, and Related Agencies  
United States Senate  
Washington, D.C. 20510

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

The Honorable Rosa DeLauro  
Chair  
Appropriations Subcommittee on  
Labor, Health and Human Services,  
Education, and Related Agencies  
United States House of Representatives  
Washington, D.C. 20515

The Honorable Tom Cole  
Ranking Member  
Appropriations Subcommittee on  
Labor, Health and Human Services,  
Education, and Related Agencies  
United States House of Representatives  
Washington, D.C. 20515

Dear Chairman Blunt, Chairwoman DeLauro, and Ranking Members Murray and Cole:

The undersigned groups are committed to ensuring that our nation's children receive quality, appropriate healthcare. A key means of achieving this objective is through laboratory tests that provide objective data to healthcare professionals for evaluating the health status of their young patients.

When making a diagnosis, the healthcare professional evaluates a laboratory test value within the context of a reference interval – a range of numeric values that would be expected in a healthy child. If the test result falls outside of the reference interval – either higher or lower – the healthcare professional may order a medical intervention to address the condition. If the diagnosis is mistaken for any reason, including a faulty reference interval, the result could be harmful for the young patient. Therefore, it is critical that reference intervals be correct.

Whereas reference intervals for adults are generally reliable, there is considerable inconsistency and large gaps in the ranges provided for children. It is imperative that reference intervals accurately reflect the physical development of patients from birth through adolescence to adulthood. Accurate and actionable reference intervals are particularly important for our youngest patients, who are often unable to verbally communicate their symptoms. Unfortunately, most laboratories are unable to obtain enough samples from healthy children to develop their own accurate pediatric reference intervals (PRIs).

Fortunately, the Centers for Disease Control and Prevention (CDC) has the infrastructure in place to address this problem. Its Environmental Health Laboratory (EHL) could generate the needed reference intervals with clinical samples obtained from its National Health and Nutrition Examination Survey (NHANES). EHL has experience developing reference intervals for chronic disease biomarkers in adults and NHANES has the infrastructure and expertise to collect the requisite specimens from healthy children. Congress recognizes the critical role the CDC can play in addressing this issue.

In December 2019, the House and Senate passed, and the President signed into law, the Further Consolidated Appropriations Act of 2020. In the accompanying report language, the two chambers identified improving pediatric reference intervals as a key priority, requesting that the CDC develop and

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submit a plan to Congress for improving PRIs. In order to advance this important initiative, we recommend that Congress provide the CDC Environmental Health Laboratory with an additional \$10 million in FY 2021 to initiate and advance this vital work.

The undersigned groups stand ready to be an ongoing resource to members of Congress on improving pediatric reference intervals and ensuring quality care for our country's children. We appreciate your consideration on this matter.

Academy of Clinical Laboratory Physicians and Scientists  
American Academy of Pediatrics  
American Association for Clinical Chemistry  
American Clinical Laboratory Association  
American Medical Technologists  
American Society for Bone and Mineral Research  
American Society for Clinical Laboratory Science  
American Society for Clinical Pathology  
American Society of Hematology  
American Society of Pediatric Hematology/Oncology  
ARUP Laboratories  
American Urological Association  
Association of Pediatric Hematology/Oncology Nurses  
Association of Public Health Laboratories  
Children's Hospital Colorado/University of Colorado  
Children's Pathology Chiefs  
Clinical Laboratory Management Association  
COLA  
College of American Pathologists  
Endocrine Society  
Laboratory Corporation of America Holdings  
Lipoprotein(a) Foundation  
National Association of Pediatric Nurse Practitioners  
Quest Diagnostics  
PCOS Challenge: The National Polycystic Ovary Syndrome Association  
Pediatric Endocrine Society  
Seattle Children's Hospital  
Siemens Healthineers  
Thermo Fisher Scientific