

July 12, 2024

The Honorable Jason T. Smith  
Chairman  
Committee on Ways and Means  
U.S. House of Representatives  
1102 Longworth House Office Building  
Washington D.C. 20515

RE: Field Hearing on Access to Health Care in America: Unleashing Medical Innovation and Economic Prosperity

Dear Chairman Smith,

ARUP Laboratories is proud to welcome the United States House of Representatives Committee on Ways and Means to our facility for today's field hearing on Access to Health Care in America: Unleashing Medical Innovation and Economic Prosperity. The committee is visiting our laboratory at a very important time in our company's history, as we are currently celebrating our 40<sup>th</sup> anniversary – a history made possible by our enduring commitment to innovation in clinical laboratory diagnostics. We believe this commitment is evident every day in the quality of work and dedication of our 4,300 employees, all of whom work to provide outstanding care for the more than 17 million patients that we serve every year.

As a nonprofit clinical laboratory enterprise of the University of Utah's Department of Pathology, ARUP was founded with goal of developing and offering the highest quality clinical laboratory diagnostic services, particularly for medical conditions where no other commercially available options exist. As such, our ARUP Institute for Clinical and Experimental Pathology® has been at the forefront of test development for clinically essential tests and diagnostic offerings for rare disorders. The recent establishment of ARUP's Innovation Business Unit – and the accompanying Institute for Research and Innovation in Diagnostic and Precision Medicine™ – exemplifies our ongoing prioritization of innovation. This is not just through strong internal development, but also through our commitment to partner with other companies developing novel diagnostic technologies that can benefit from our clinical laboratory expertise.

Innovation in clinical laboratory diagnostics also requires economic conditions that support ongoing testing and that allow for investment in new test development. Laboratory reimbursement cuts under Medicare as a result of 2014's *Protecting Access to Medicare Act (PAMA)* –paradoxically, at a time when supply and labor costs for in vitro diagnostics continue to increase – also hinders medical innovation. These cuts, scheduled to go into effect in 2025, would limit testing services upon which doctors and patients rely. We therefore ask that the committee consider and advance the *Saving Access to Laboratory Services Act (SALSA)* introduced by Rep. Richard Hudson and/or alternative legislative efforts to help remedy the unintended negative impacts of PAMA on laboratory diagnostic innovation.

Innovation also requires a broader environment that fosters research, creativity, and entrepreneurialism. At ARUP, we have supported the R&D efforts of over 100 medical directors and countless scientists to support the innovation, development, and offering of over 1,000 new diagnostic tests in support of patient care. Most importantly, we have done so in a manner that emphasizes quality, patient safety, and access to essential diagnostic services. We ask the committee to keep these guiding principles in mind as it considers how the federal government can help foster medical innovation in the future.

It is also important to emphasize that over-regulation, or regulatory structures that place an undue burden on clinical laboratories and healthcare facilities – for example, the FDA final rule on laboratory-developed tests (LDTs) and the *Verifying Accurate Leading-edge IVCT Development Act (VALID Act)* – risk significantly limiting diagnostic innovation and therefore decrease the future diagnostic options for our citizens. ARUP is committed to working with the administration and Congress to consider future in vitro diagnostic oversight structures that both protect the public health and support ongoing innovation in healthcare.

In conclusion, we are incredibly grateful to the committee for allowing us to host this important field hearing here in Salt Lake City. The constructive and dynamic discussions at this event will help guide and support medical innovation and economic prosperity. We believe that ARUP Laboratories has set a wonderful example of how this can be done to benefit the overall healthcare of the country.

Sincerely,



Jonathan R. Genzen, MD, PhD, MBA  
Chief Medical Director and Senior Director of Government Affairs  
ARUP Laboratories