CHILDREN'S HOSPITAL ASSOCIATION

600 13th St., NW, Suite 500
Washington, DC 20005
p | 202-753-5500
f | 202-347-5147

16011 College Blvd., Suite 250
Lenexa, KS 66219
p | 913-262-1436
f | 913-262-1575

WWW.CHILDRENSHOSPITALS.ORG

June 10, 2022

The Honorable Patty Murray
Chair
Senate Committee on Health, Education,
Labor, and Pensions
154 Russell Senate Office Building
Washington, DC 20510

The Honorable Richard Burr
Ranking Member
Senate Committee on Health, Education,
Labor and Pensions
217 Russell Senate Office Building
Washington, DC 20510

Dear Chair Murray and Ranking Member Burr:

On behalf of more than 220 children's hospitals across the country, the Children's Hospital Association (CHA) appreciates the opportunity to provide feedback on the provisions of the Food and Drug Administration Safety and Landmark Advancements (FDASLA) Act (S.4348) that would modify the regulatory framework for laboratory developed tests (LDTs). Those provisions, which are incorporated into S. 4348 as the Verifying Accurate Leading-edge IVCT Development (VALID) Act, could have serious unintended consequences on children's health and health care. We urge you to address the unique implications of the VALID Act on children's health and pediatric providers before advancing this legislation.

Children are not little adults. They are constantly growing and developing, and their health care needs and the delivery system to meet those needs are different from those of adults. Pediatric care requires specialized medications, therapeutics and equipment that the nation's children's hospitals provide. Children's hospitals account for less than 2% of hospitals in the United States, but they care for almost one-half of children admitted to hospitals and serve the majority of children with serious illnesses and complex chronic conditions. We are patient-centered, research-focused institutions and are the leading centers for discovery and innovation in pediatric health.

Children's hospitals' diagnostics and clinical care demands unique testing strategies and LDTs are critical to our ability to provide timely, cost-effective and high-quality care for all children and particularly for children in need of treatment for rare and difficult-to-diagnose pediatric disorders. As you know, LDTs are not commercially distributed to other laboratories but are developed, validated and performed in-house by individual laboratories in hospitals and health systems. Similar to the development of new pharmaceuticals, which are usually developed for adults, children are often left behind in the development of commercial testing, given the small market and highly specialized nature of pediatric diseases. LDTs fill a critical gap in the practice of pediatric medicine as they allow for accurate, timely and high-quality testing for many pediatric conditions for which no commercial test exists or where an existing test does not meet current clinical needs.

We understand the committee's interest and intent in better regulating LDTs developed by commercial laboratories as there have been examples of those laboratories marketing LDTs—most commonly geared towards adults and for more common diseases—with unproven clinical validity to providers and patients. We encourage you to focus this legislation on the oversight of manufacturers and commercial laboratories that sell and distribute test kits, rather than on LDTs developed and used by children's hospitals that rely on those tests to meet the specialized health needs of children. LDTs developed by children's hospital laboratories are already tightly regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to ensure their accuracy and reliability, and children's hospital laboratories are accredited by their state, the College of American Pathologists or the Joint Commission in accordance with the CLIA regulations.

The VALID Act's modifications of the existing regulatory framework for LDTs would impede those CLIA-regulated children's hospital laboratories from developing tests to rapidly diagnose pediatric-specific illnesses, including the large number of unusual and rare conditions affecting our child patients. For example, children's hospital laboratories adapt existing tests, and modify FDA-approved assays, to meet the unique needs of their pediatric patients. We must be able to adapt, modify, develop and rapidly deploy a broad array of LDTs without the additional administrative burden of going through an FDA premarket review or requesting an exemption for each LDT, as would be required under the legislation. While the bill includes a helpful exception for tests intended to diagnose conditions affecting fewer than 10,000 individuals in the United States per year, there are many pediatric LDTs that will not meet that threshold. These tests offer the flexibility and nimbleness that our accredited laboratories need and use to perform pediatric diagnostics. Unfortunately, the VALID Act would impose barriers to innovation in pediatric diagnostic testing that would limit advances in treatment and lead to less favorable outcomes for children and higher health care costs.

We urge you to address the unique implications of the VALID Act on children's hospital laboratories' development and use of LDTs before advancing this legislation. We look forward to working with the committee to ensure that children and families continue to have access to the life-saving diagnostics they need.

Thank you for the opportunity to weigh in on these important issues.

Very best regards,

Leah Evangelista
Chief Public Affairs Officer
Children's Hospital Association

Cc:
Senator Michael Bennet
House Energy and Commerce Committee Chairman Frank Pallone
House Energy and Commerce Committee Ranking Member Cathy McMorris Rogers
Rep. Diana DeGette
Rep. Larry Bucshon