June 6, 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:

As physician Chiefs of Pathology and Clinical Laboratory Services for many of the leading children's hospitals in the United States, we write to express our serious concerns about Section 587B of the Verifying Accurate Leading-edge IVCT Development (VALID) Act. While we appreciate the intent of Section 587B, the section would result in serious unintended consequences on children's hospitals and pediatric health care systems, ultimately putting the care of our vulnerable children at risk.

Section 587B of the Act would override current CLIA authority and instead grant the FDA authority to review and approve lab developed tests (LDTs). A LDT is a type of diagnostic test that is designed, manufactured and used within a single laboratory under the authority of a professional (physician or PhD scientist) with licensure and board certification in the practice of pathology and laboratory medicine. LDTs can range from simple chemistry tests to very complex genetic tests.

We acknowledge that there are notable examples where LDTs with unproven clinical validity have been actively marketed to care providers and patients. This has most commonly been seen in commercial laboratories geared towards adults and common disease. We appreciate the desire to better regulate these LDTs.

However, for pediatrics hospitals, LDTs fill a critical gap in the practice of medicine. Children's hospitals are specialized to provide diagnostics and clinical care to children who are affected with conditions that are related to but biologically distinct from their adult counterparts, demanding unique testing strategies. For example, the genetic characteristics of pediatric forms of certain cancers are altogether different than in adults and are not included on many commercial testing panels because of a lack of market incentive due to the comparative rarity. This makes LDTs especially important for pediatric academic medical centers and children's hospitals. Like the situation with new pharmaceuticals which have historically been developed for adult disease with large potential marketplaces and well understood regulatory pathways, children are often left behind in the development of commercial testing, equipment and reagents given the small market and highly specialized requirements for pediatric diseases, many of which are rare disorders.

Every day LDTs are used at our hospitals to diagnose illness and provide key information for the timely diagnosis and treatment of pediatric patients. LDTs offer flexibility and nimbleness that accredited laboratories use to perform diagnostics. Such was the case during early phases of the

COVID-19 outbreak, when LDTs were rapidly deployed to understand the spread of the disease. LDTs offer major impacts on timely, cost-effective, and high-quality patient care, in particular for children and their families seeking treatment at pediatric hospitals for rare and difficult to diagnose pediatric disorders. Pediatric academic medical centers are patient-centered, research-focused institutions and are the leading centers for discovery and innovation in pediatric health. Furthermore, our institutions depend on the ability to quickly translate this work into new diagnostic testing to support the specialized care for children which we uniquely can deliver.

LDTs developed by pediatric academic medical centers and children's hospitals are already tightly regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to ensure the accuracy and reliability of all laboratory testing. All institutions that work with Medicare and Medicaid must demonstrate compliance with CLIA regulations for laboratory practice, including LDTs. Hospital laboratories are accredited by their state, the College of American Pathologists or the Joint Commission — all of which are deemed accrediting organizations under CLIA federal regulations.

Why do we think the passage of section 587B VALID will negatively impact children?

- Pediatric academic medical centers and children's hospitals must have the ability to develop and rapidly deploy LDTs to assist in the diagnosis of rare or uncommon pediatric conditions – our pediatric patients do not have the luxury of time – they need answers.
- Pediatric academic medical centers and children's hospitals need a defined pathway to continue to develop LDTs that serve our patients and their families without the administrative burden likely to be generated by going through an FDA premarket review or requesting an exemption for every LDT we develop. These potential barriers will decrease our ability to provide innovative and timely access to the pediatric diagnostics required for our patients and their families to have access to appropriate treatments.
- Our clinical laboratories must offer a broad array of LDTs given the large number of unusual and rare pediatric conditions. Pursuing large numbers of submission processes would require significant resources. In contrast, a specialized private/commercial lab with a limited test menu could better absorb this workload and costs. However, due to the profit-driven commercial lab landscape, these laboratories cannot be depended on to develop tests for pediatric conditions.
- Section 587B will jeopardize our ability to integrate the latest scientific discoveries into clinical testing and care for patients by placing an extensive administrative barrier between the development of a clinical test and its use on behalf of patients.
- Section 587B will suppress innovation and improvements of diagnostic services, ultimately delaying advances in timely treatment and management. Such a hurdle will also impede our collective ability to reduce health care costs due to delays in diagnosis / treatment and less favorable patient outcomes.
- Section 587B will limit our ability to adapt existing tests to meet the needs of pediatric patients. LDTs also include modifications to FDA-approved assays, which are common even among routine tests. Our hospitals and patients rely upon our ability to use LDT approaches to modify these tests for use in pediatric settings.
- The exceptions in the bill, including for tests "intended by the developer for use for a diagnostic purpose for a disease or condition that affects not more than 10,000

individuals in the United States per year," while helpful, will not address all the LDTs developed for use in pediatrics.

While we appreciate the intent of the VALID Act, we, the undersigned Children's Pathology Chief physicians, urge Congress to protect the unique and individualized care our hospitals provide to children by excluding pediatric hospital laboratories from Section 587B.

Sincerely,

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