GREATER NEW YORK HOSPITAL ASSOCIATION
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May 22, 2022

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

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

RE: The Regulation of Laboratory Developed Tests and the VALID Act

Dear Chair Murray and Ranking Member Burr:

Greater New York Hospital Association (GNYHA) appreciates the opportunity to provide input on the discussion draft of the FDA Safety and Landmark Advancements (FDASLA) Act, specifically on the provisions governing the regulation of laboratory developed tests (LDTs) in the updated Verifying Accurate Leading-edge IVCT Development (VALID) Act. GNYHA represents the interests of over 160 hospitals and health systems and 50 continuing care facilities throughout New York, New Jersey, and Connecticut. Many of our members are major academic medical centers and cancer centers that devote significant efforts to delivering innovative care and are therefore interested in any proposals that might impact the services they provide, particularly in the area of precision medicine.

GNYHA and its members appreciate the Committee's deliberate, good faith efforts to modernize the oversight of important clinical testing services. However, we believe an approach that builds upon the existing regulations of laboratories and tests rather than creating separate oversight functions by two different agencies would provide oversight in the least burdensome and most efficient and effective manner possible. At the very least, the Committee should exempt from any new oversight tests developed, authorized, and approved in states such as New York that already have an effective LDT review process. This would ensure that any additional oversight recognizes the robust regulatory oversight that New York already provides.

LDTs are a Vital Component of Personalized Medicine

LDTs are a critically important component of today's delivery of health care and have a vital role in individualized patient care. The Committee should recognize that the development and use of LDTs is a service that is integral to the practice of medicine. Board-certified laboratory professionals develop, perform, and interpret LDTs in a single laboratory, often in an academic medical center or cancer center. These laboratory professionals develop LDTs to help physicians

when no comprehensive product is available for a particular condition or purpose. Medical activities designed to address an individual's specific health needs should not be limited by unnecessary oversight of tests developed in such settings and situations. GNYHA is concerned that provisions in the VALID regulatory structure are particularly onerous for laboratories that develop such tests, may stifle innovation, limit patients' access to cutting-edge tests, and likely deter development of some tests entirely.

Additional FDA Regulation Would be Unnecessarily Burdensome

The VALID Act would regulate LDTs by amending the Food, Drug, and Cosmetic Act and creating a new regulatory framework under the authority of the Food and Drug Administration (FDA). Although the bill is framed as providing a "risk-based" approach to reviewing LDTs that gives the FDA flexibility for many requirements, it would nevertheless require premarket review for many tests. Adding LDTs to the premarket approval process would be a large undertaking, and we have serious concerns about the FDA's ability to handle this additional workload.

When Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988, it established a robust framework under which the Centers for Medicare & Medicaid Services (CMS) oversees laboratory testing and stringent Federal standards designed to ensure accurate and reliable test results. CLIA regulations require laboratories to establish numerous verification and performance specifications for all tests, and LDTs in particular, before the laboratories can report patient test results. We urge the Committee to allow the oversight of LDTs to remain in the experienced hands of CMS and state regulators under CLIA and other regulations. If, however, it is concluded that LDTs do require additional oversight, it should be undertaken by updating CLIA requirements to ensure that any stated concerns about LDTs are specifically addressed as part of the survey and/or accreditation processes, not by creating a separate set of reviews of each test by another agency.

Preemption for State Regulation of LDTs, Including New York's Wadsworth Center

In New York State, the State Department of Health's Wadsworth Center—a nationally recognized, research-intensive public health laboratory—operates a well-regarded Clinical Laboratory Evaluation Program under which the State surveys New York laboratories in lieu of CMS, given the quality of the Wadsworth Center's standards and survey process.

New York's Wadsworth Center also offers a comprehensive program that reviews and approves LDTs used in the State's laboratories. Indeed, the Wadsworth Center's procedures for reviewing LDTs are considered of such high quality and so rigorous that the FDA has approved the Wadsworth Center as a third-party reviewer on behalf of the FDA for pre-market approval purposes. Although this designation eliminates some of the burden associated with FDA pre-market approval for New York-permitted laboratories if desired for marketing or other purposes, the FDA's process still requires additional work and burden on the part of the provider to obtain such approval.

GNYHA has reviewed the updated VALID Act, and we believe that it attempts to acknowledge New York State's unique status as a leader in state-regulated clinical laboratories and reviews of LDTs. The draft bill allows state laws enacted prior to January 1, 2022, to remain in effect as long as they do not impose requirements that differ from any requirement of the VALID Act. This provision appears as an exception to the Act's preemption provision.

While we appreciate the inclusion of this exception to the preemption provision, the bill does not appear to take what would seem to be the anticipated and logical next step—recognizing that tests developed and performed pursuant to the exercise of the authority of such laws be considered exempt from pre-market approval. Alternatively, the bill could specifically recognize that tests developed and performed pursuant to such authority would be deemed to meet the pre-market approval requirements.

We believe the Committee should clarify that tests developed and performed pursuant to New York State's Wadsworth Center's comprehensive LDT program should not be subject to duplicative, unnecessary Federal requirements. We would be happy to help the Committee amend the bill's language to accomplish this.

Summary
Allowing the FDA to insert a complex, lengthy, and unnecessary regulatory regime will impede diagnostic innovation and delay the advancement of precision medicine—all at the expense of patient care, thereby undermining the Act's stated goal. We strongly urge the Committee to incorporate our recommendations into future versions of the VALID Act. These recommendations support the development of innovative diagnostics, maintain access to existing diagnostics, and do not unduly impose regulatory burdens.

Thank you for the opportunity to submit these comments. Please contact me with any additional questions.

Sincerely,

Susan Waltman
Executive Vice President for Legal, Regulatory, and Professional Affairs