American Hospital Association™
Advancing Health in America

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The Honorable Patty Murray
Chair
Committee on Health, Education, Labor, and Pensions
United States Senate
Washington, DC 20510

The Honorable Richard Burr
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate
Washington, DC 20510

Dear Chairwoman Murray and Ranking Member Burr:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinical partners — including more than 270,000 affiliated physicians, 2 million nurses and other caregivers — and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to provide feedback on the Food and Drug Administration Safety and Landmark Advancements (FDASLA) Act (S.4348). Specifically, we appreciate the opportunity to share our thoughts about the Verifying Accurate Leading-Edge IVCT Development (VALID) Act of 2022, which significantly modifies the regulatory framework for laboratory developed tests (LDTs).

Many hospitals and health systems create LDTs, particularly larger hospitals and academic medical centers. LDTs are diagnostic tests that are not commercially distributed to other laboratories but, instead, are developed, validated and performed in-house by individual laboratories. These range from routine tests to more complex molecular and genetic tests in cancer, heart disease, and rare and infectious diseases. LDTs provide timely patient access to accurate and high quality testing for many conditions for which no commercial test exists or where an existing test does not meet current clinical needs. They provide physicians with important clinical information to diagnose and treat patients and are critical in the practice of all areas of medicine. These tests are typically developed at the request of, and in close collaboration with, clinical caregivers.

The AHA is concerned that, if enacted in its current form, the VALID Act could lead to a loss of patient access to many critical tests and could dramatically slow down advances in hospital and health system laboratory medicine. Given the value of these tests to caregivers and patients, any framework for regulatory oversight of LDTs must ensure that the technological and clinical innovation that is essential to their development remains unrestricted; that quality and reliability are maintained at the highest levels

possible; and that they continue to be widely accessible to patients. In contrast, we believe the provisions in the VALID Act could cause confusion and delays that could hinder the achievement of these goals and possibly prevent hospital and health system laboratories from continuing to develop cutting-edge LDTs in response to immediate clinical care needs.

Since the VALID Act would modify the existing regulatory framework for these critical medical services, it is essential that any changes protect patient access to innovative diagnostic testing. We appreciate some of the changes in the updated version of the bill, particularly those related to modifications, the request for information for grandfathered LDTs, technology certification, and the preemption provisions. However, we urge the Committee to resolve the issues surrounding the following provisions described below prior to advancing this legislation.

ISSUES FOR CONSIDERATION WITH THE VALID ACT

Scope

We believe that the scope of this legislation is too far-reaching and could hamper patient access to timely and appropriate care and will harm health care emergency readiness. The AHA recommends that the Committee tailor the VALID Act's risk-based framework to place the greatest oversight on those tests that pose the greatest risk of harm to patients and lack demonstrated validity. Specifically, the Committee should consider targeted changes, including:

- **Initially focusing its oversight on manufacturers and commercial laboratories selling and distributing test kits, rather than academic and clinical laboratories, which are integrated in hospitals and health systems providing direct medical care to patients.**

- **Prioritizing the oversight of direct-to-consumer tests and tests used outside of the physician-patient context, as these tests may impose higher risk.**

- **Expanding and clarifying the criteria for low-risk tests to include most of the non-grandfathered LDTs developed and performed by CLIA-regulated laboratories that are integrated as part of hospitals and health systems providing direct medical care to patients.**

Registration and Listing

While we appreciate that the VALID Act grandfathers LDTs that were offered prior to enactment and generally exempts these tests from premarket review and several other FDA requirements, we are concerned that hospitals and health system laboratories will

still be subject to overly burdensome requirements for registration and listing for grandfathered LDTs. The updated legislation would reduce the amount of listing information required for grandfathered tests, however these requirements remain incredibly onerous, particularly for academic medical centers with very large esoteric test menus and limited resources. Proactive requirements for registration and listing have limited value as the FDA will already have the authority, through the "request for information" provisions, to take action to address LDTs with insufficient evidence of clinical or analytic validity, those that are false or misleading claims, and those with probable serious adverse health consequences. **We recommend that the listing information proactively required should be aligned with risk and based on FDA's least burdensome principles.**

Preemption of State Requirements

Many hospital and health system laboratories participate in validity and quality review programs, such as those directed by the well-regarded New York State Department of Health's Wadsworth Center. The AHA encourages the Committee to recognize the value of such programs and prevent duplication with state efforts.

We appreciate that the Committee has revised the preemption provisions to take into consideration these special cases by allowing state laws enacted prior to January 1, 2022 to remain in effect as long as they do not differ from any requirement of the VALID Act and by stating that the Secretary may exempt such laboratories in that state from compliance. **We encourage the Committee to strengthen and provide additional certainty in the preemption provisions by including additional language that would require the Secretary to exempt authorized laboratories in an excepted state from compliance with the VALID Act.**

Transition

While we acknowledge the significant transition period included in the VALID Act, we are concerned that it will create a large backlog of "transitional" LDTs developed by hospital and health system laboratories that the FDA will need to review prior to the effective date of the Act. Further, these transitional LDTs will be developed without access to FDA guidance or regulation explaining what information will eventually be required in a submission. As a result, hospital and health system laboratories wanting to provide novel testing for their patients during the transition period will not have a comprehensive understanding of the documentation that will eventually be required. **The AHA recommends extending the grandfathering deadline for hospital and health system LDTs to the effective date of the legislation, or at least post issuance of relevant FDA guidance and regulations.**

Conclusion

Thank you again for the opportunity to provide additional feedback on the FDASLA. We look forward to continue working with you on this important issue.

Sincerely,

/s/

Stacey Hughes
Executive Vice President