Association of
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June 2, 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:

The AAMC (Association of American Medical Colleges) writes today in response to the committee's recently released legislation, the Food and Drug Administration Safety and Landmark Advancements (FDASLA) Act of 2022, as introduced on May 27. In particular, we would like to respond to provisions that would provide additional oversight of laboratory developed tests (LDTs) in advance of the June 8 full committee executive session.

The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, medical research, and community collaborations. Its members comprise all 155 accredited U.S. medical schools; approximately 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools and teaching hospitals and the millions of individuals employed across academic medicine, including more than 191,000 full-time faculty members, 95,000 medical students, 149,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. In 2022, the Association of Academic Health Centers and the Association of Academic Health Centers International merged into the AAMC, broadening the AAMC's U.S. membership and expanding its reach to international academic health centers.

Specifically related to Subtitle C of Title VIII which includes the Verifying Accurate Leading-edge IVCT Development (VALID) Act of 2022, we appreciate the committee's work to address concerns of the academic medicine community between the release of the initial discussion draft and formal introduction. While the changes to §587C(a)(6) regarding modifications to tests recognizes the existing high standards of CLIA-certified laboratories, we must reiterate significant concerns that have not been addressed that were previously raised with the committee, and further detailed in stakeholder letters following the initial release of the discussion draft and the bill's formal introduction. The AAMC acknowledges lawmakers' and the Food and Drug Administration's (FDA) longstanding discussions regarding the regulation of LDTs and affirms that LDTs used for diagnostic and treatment decisions should have clinical validity and accuracy. However, academic medical centers, teaching hospitals, and faculty physicians that perform these tests every day are on the front line of patient care and are best able to define the impact of these tests on their ability to treat patients with important information gleaned from clinically validated, well-proven, and carefully tailored diagnostic tests that are used in a continuum of care in a treatment decision-making process. LDTs

are often an integral component of innovative medical care, and we believe that the updated language included in the FDASLA as introduced fails to sufficiently address the community's concerns that any additional regulation of LDTs not interfere unduly with delivering care, impact patients and their ability to access meaningful tests in a timely manner, or mire the development of critical new tests in a costly and laborious process. Despite inclusion of §587AA(g) that purportedly prevents the VALID Act from interfering with the practice of medicine, the bill as introduced unquestionably will have a negative impact on the ability of physicians to access the best-available resources to care for their patients.

Academic medical center labs' hands-on, direct patient care differentiates them and their providers from other types of labs. These labs' unique patient care, research, education, and community collaboration missions, the integration of the test development and administration into the continuum of patient care, the many other safeguards for patients that such clinical labs are already subject to, and the FDA's retention of the ability to investigate and remove any test from the market regardless of the entity that develops it, are the primary reasons why the FDA has historically been amenable to academic medical center labs' development and provision of LDTs for many years. For these reasons, we urge you to take additional time to thoroughly understand the negative impact on patient care that would result from this regulatory proposal and modify the bill to explicitly exempt these "academic clinical laboratories" from the revised oversight framework presented in the VALID Act. Short of exempting these clinical laboratories from the VALID Act, lessening the burden on academic clinical labs through modifying various provisions in the bill, as supported by nearly 100 organizations, would make the new regulation less likely to decrease the number of available tests for patient care and potentially impact patients' health.

Absent substantial fundamental revisions, we cannot support the FDASLA as currently drafted and join the aforementioned stakeholders in respectfully requesting additional time for both chambers to consider this broad swath legislation that, as currently written, will have detrimental impacts on the practice of medicine and the delivery of cutting-edge, timely care to patients in need. We believe it would be harmful to patient care and to public health to move forward through what will become an increasingly rushed legislative process without significant modifications and accommodations for academic medical center clinical laboratories.

Thank you for considering the perspective of the academic medicine community. The AAMC again appreciates the opportunity to engage with you and your staff on this important topic. Please feel free to contact my colleague Leonard Marquez, Senior Director, Government Relations & Legislative Advocacy, at lmarquez@aamc.org, or Christa Wagner, PhD, Manager, Government Relations, at chwagner@aamc.org with any questions.

Sincerely,

Karen Fisher, JD
Chief Public Policy Officer
Association of American Medical Colleges

CC:
David J. Skorton, MD, AAMC President and CEO
Rep. Frank Pallone, Chair, House Energy and Commerce Committee
Rep. Cathy McMorris Rodgers, Ranking Member, House Energy and Commerce Committee
Rep. Anna Eshoo, Chair, House Energy and Commerce Health Subcommittee
Rep. Brett Guthrie, Ranking Member, House Energy and Commerce Health Subcommittee