AAMC
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September 20, 2018

The Honorable Larry Bucshon
U.S. House of Representatives
Washington, DC 20515

The Honorable Diana DeGette
U.S. House of Representatives
Washington, DC 20515

The Honorable Orrin Hatch
U.S. Senate
Washington, DC 20510

The Honorable Michael Bennet
U.S. Senate
Washington, DC 20510

Dear Representatives Bucshon and DeGette and Senators Hatch and Bennet:

The Association of American Medical Colleges (AAMC) appreciates the opportunity to offer academic medicine's perspectives on ensuring the clinical validity and accuracy of in vitro clinical tests (IVCTs) used for diagnostic and treatment decisions. The AAMC is a not-for-profit association representing all 151 accredited US medical schools; nearly 400 major teaching hospitals and health systems; and more than 80 academic societies. Through these institutions and organizations, the AAMC serves the leaders of America's medical schools and teaching hospitals and their more than 173,000 fulltime faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

The AAMC appreciates lawmakers' and the Food and Drug Administration (FDA)'s desire to engage in a thoughtful process and solicit information from key stakeholders as Congress considers the regulation of IVCTs. As the AAMC wrote in a previous comment letter to the FDA regarding the regulation of laboratory developed tests (LDTs), academic medical centers and teaching hospitals that are performing these tests every day are "on the front line of patient care and are best able to define the impact on their own institutions and their ability to treat patients with important information gleaned from clinically validated, well-proven, and carefully tailored diagnostic tests."

The AAMC agrees it is essential that IVCTs used for diagnostic and treatment decisions have clinical validity and accuracy. Simultaneously, we recognize that IVCTs are often an integral component of innovative, rapidly evolving, cutting-edge medical care, and share our members' concerns that any additional regulation of IVCTs not interfere unduly with delivering care, negatively impact patients and their ability to access meaningful tests, or mire the development of critical new tests in a costly and laborious process. Furthermore, the AAMC has identified the following considerations as core to any potential effort to further regulate IVCTs:

- Any proposal to further regulate IVCTs must recognize that an overly burdensome review process could hinder the clinical innovation that enables an effective healthcare system, high quality patient care, and rapid response to emerging public health threats.
- Before a new approach is finalized, there must be a more complete understanding of the number of existing tests which would be impacted, the types of modifications that

would trigger a new approval process, and the rate at which new tests are being developed. Without this information the federal and institutional resources needed to implement the requirements without negatively impacting patient care cannot be determined.

- A regulatory framework should account for a proposed test's potential risk to patients and recognize the proven success and validity of certain existing tests. Any such regulation should include a wide range of situations under which enforcement jurisdiction or grandfathering is applied to current well-known and well-developed tests without undue burden on the system as a whole.
- Given the cost of guiding even a single test through the FDA premarket approval process, the financial impact of obtaining equivalent approval for many currently administered and newly developed IVCTs could be untenable. This cost could lead to institutional decisions that would limit patient access to innovative and targeted diagnostic tests.

The AAMC read with interest the FDA's extensive technical assistance document regarding the Diagnostic Accuracy and Innovation Act and is interested in engaging in further conversation to understand how the FDA's proposed changes and the underlying draft legislation would impact the creation and administration of IVCTs at academic medical centers and teaching hospitals. While we continue to solicit feedback from our members to better understand the implications of such proposals on the patients under their care, we note several items in the technical assistance document that could particularly affect our members' ability to use IVCTs in patient care. For example, we appreciate that the FDA's proposed changes attempt to minimize burden that would otherwise occur under the underlying legislation, by enabling IVCT developers to obtain precertification of analytic and clinical validity, rendering future eligible tests exempt from premarket review, and providing the opportunity to extend such precertification to affiliated labs under common ownership. We want to emphasize that to the extent any legislation is necessary, it should serve to support and enhance, not deter or detract, the important work our academic medical centers are doing to diagnose and treat patients.

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, with any questions.

Sincerely,

Karen D Fisher

Karen Fisher, J.D.
Chief Public Policy Officer

cc: Leonard Marquez