November 11, 2016

American Clinical Laboratory Association

The Honorable Howard Shelanski
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
Executive Office of the President
725 17th Street, NW
Washington, DC 20503

SUBMITTED ELECTRONICALLY VIA E-MAIL

Dear Administrator Shelanski:

On behalf of the American Clinical Laboratory Association (ACLA), I am writing out of grave concern that the Food and Drug Administration (FDA) continues to seek issuance of final sub-regulatory guidance to regulate laboratory developed test services (LDTs) as medical devices in the near-term. The consequences of such an agency action risk wide-spread harm to the clinical laboratory industry, including both private labs and academic medical center labs, and chilling effect on diagnostic innovation which is critically essential, not only to patients, but also for both the President's Precision Medicine Initiative and the Cancer Moon Shot Initiative.

Recognizing the ongoing transition in the Administration, we respectfully request to meet with you on this critical issue at your earliest convenience and, further, ACLA respectfully requests that the Administration not finalize the LDT guidance.

ACLA is a not-for-profit association representing the nation's leading providers of clinical laboratory services, including local, regional, and national laboratories. Our diverse membership represents a broad array of clinical laboratories, including national independent labs, reference labs, esoteric labs, hospital labs, and nursing home laboratories.

The FDA issued the draft guidance proposing to regulate LDTs as medical devices in 2014. The draft has placed a cloud of uncertainty on the ability of clinical laboratories to innovate and deliver ever-more accurate and precise clinical laboratory diagnostics, particularly in the area of genetic and molecular diagnostic tests. Ever since the Human Genome Project, genetic and molecular diagnostic tests have led to an explosion of understanding in human health and disease, including for rare diseases, infectious disease and cancer.

President Obama has rightly launched both the Precision Medicine Initiative and the Cancer Moon Shot to further accelerate medical innovation to not only expand understanding of health,

but also to assist in accurately diagnosing and treating disease. Advanced genetic and molecular laboratory tests will be an essential component if these initiatives are to be successful.

Unfortunately, the FDA's LDT proposal risks duplicating the federal and state regulatory burden already on clinical laboratories and significantly increasing the cost of translating medical discoveries into accessible laboratory diagnostics for patients. Recognizing, however, that current statutes over laboratory tests pre-date both the Human Genome Project and our current knowledge of genetic and molecular tests, ACLA and our members have been working diligently with Congress for nearly two years on alternative statutory approaches that would ensure both innovation, and safe and accurate diagnostics for patients.

To assist in developing comprehensive reform, ACLA supports the following key principles as necessary for any new, workable statutory framework:

1. LDTs are not Devices: LDTs are not medical devices and cannot be regulated, listed, or designated as such. Accordingly, any new framework to regulate LDTs or laboratories shall be implemented by a diagnostic-specific authority (such as a diagnostic-specific center within a designated agency) and not an authority otherwise charged with medical device regulation or other medical product regulation;
2. Grandfathering and Transition: LDTs introduced prior to enactment must be grandfathered from any premarket review or design control requirements, and laboratories must be granted a reasonable transition period after enactment to come into compliance with any new applicable requirements;
3. Preemption: Any new federal framework for LDT and laboratory oversight shall preempt state requirements addressing the same subject matter;
4. Evidence Standards: The standard for approval, clearance, or marketing of a test must be based on a rational assessment of the test's analytical validity and clinical validity and not be based on the medical device standard of "safe and effective". Also, clinical trials are presumed not to be required;
5. Modifications: Agency review of modifications to an already marketed test (including grandfathered tests) should be limited to only those modifications which have a meaningful clinical impact or significantly modify the test's intended use after validation and verification;
6. Labeling: Labeling requirements applicable to laboratories will be limited to reasonable requirements appropriate for laboratory protocols, for instance not requiring a label to be affixed to the physical elements of a test where those elements are not distributed to another facility or third party. Legitimate scientific or medical exchanges or discussions will not constitute labeling or constitute a change in intended use;
7. Rulemaking: Implementation of any new framework must be carried out in a transparent process that includes formal notice and public comment;
8. Fees: Any fees associated with the new framework must reasonably take into account the resources necessary to implement the framework in addition to the impact on the entities

from which the fees will be assessed. Fees paid for oversight of laboratory operations shall be credited towards any additional fees assessed for oversight of test development;

9. Duplication: Statutory and regulatory provisions developed under the new framework shall be designed to avoid duplication of oversight of test development and laboratory operations so as to ensure continued robust patient access to high quality clinical laboratory services;
10. Innovation: Any new federal framework should drive patient access to cutting-edge, high quality, and accurate diagnostics through incentivizing the development of novel tests, taking into account the time and resources required for the research, development, and commercialization of diagnostics.

Through ACLA's continued conversations with Congress and other diagnostics stakeholders, we believe the opportunity is closer than ever before to find consensus on a comprehensive reform package. For this reason, we humbly request that the Administration not finalize the LDT guidance.

ACLA would welcome the opportunity to discuss this matter with you and your staff in greater detail and I thank you for your time and consideration on this matter.

Sincerely,

Alan Mertz
President