November 16, 2016

American Clinical Laboratory Association

The Honorable Michael Pence
Vice President-Elect
Presidential Transition Team
Office of President-Elect Donald Trump
1717 Pennsylvania Avenue, NW
Washington, DC 20006

SUBMITTED ELECTRONICALLY VIA E-MAIL

Dear Governor Pence:

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 during the Presidential transition period. The consequences of such an agency action risk widespread harm to the clinical laboratory industry and the patients and clinicians they serve, and would have a chilling effect on diagnostic innovation.

Recognizing the ongoing transition between Administrations, we respectfully request to meet with you on this critical issue at your earliest convenience and, further, ACLA respectfully requests that the Transition Team urge the FDA to not finalize the guidance.

The FDA issued the draft guidance proposing to regulate LDTs as medical devices in 2014.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 case 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.

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. In contrast, ACLA, our members and other stakeholders 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.

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 Transition Team urge the FDA to not finalize the LDT guidance.

ACLA would welcome the opportunity to discuss this matter with you and your staff in greater detail and we look forward to working with your Administration on issues affecting clinical laboratories and patients, going forward. Thank you for your time and consideration on this matter.

Sincerely,

Alan Mertz
President