American
Clinical Laboratory
Association

February 9, 2016

The Honorable Joe Biden
The Vice President of the United States
The White House
1600 Pennsylvania Avenue, NW
Washington, D.C. 20500

Attention: Kathryn E. Mevis

Dear Mr. Vice President:

On behalf of the members of the American Clinical Laboratory Association (ACLA), we commend the establishment of the White House Cancer Moonshot Task Force. ACLA represents the nation's leading providers of clinical laboratory services, which play integral roles in the detection, genomic analysis, and treatment of cancer. ACLA member laboratories are at the forefront of the fight against cancer since they develop and perform new and innovative testing services that have helped to transform the standard of clinical care in the United States. These vanguard tests provide vital, timely information to physicians caring for patients- especially those Americans living with cancer.

Our diverse membership spans a broad array of clinical laboratories: large national independent labs, reference labs, esoteric labs, anatomic pathology labs, hospital labs, and nursing home labs. ACLA and our member labs are deeply committed to providing accurate, reliable, and clinically meaningful diagnostic testing services for the benefit of patients. ACLA members continually seek out new methodologies for laboratory medicine and stand ready to assist in the Task Force's efforts.

As the Task Force works to accelerate cancer research and remove obstacles blocking the path of progress, we want to bring to your attention two major issues affecting further scientific advances in the diagnosis and treatment of cancer: the proposed regulation of laboratory-developed tests (LDTs) by the Food and Drug Administration (FDA), and difficulties with federal coverage and reimbursement of clinical laboratory testing.

Proposed Regulation of LDTs by the FDA Is an Unnecessary Regulatory Barrier
Physicians routinely rely on LDTs, including sophisticated molecular and genetic sequencing tests, to assist in making crucial medical decisions about the best course of treatment for their patients with cancer. LDTs are the gold standard for many cancers, including breast, colon, leukemia, and lymphoma, among others. Quantum leaps in understanding the behavior of cancerous cells have resulted from these tests.

Although LDTs long have been regulated both by Centers for Medicare and Medicaid Services (CMS) and by the states, FDA announced its own sweeping efforts to regulate those services via guidance documents (Dockets No. FDA-2011-D-0360 and No. FDA-2011-D-0357) on October 2, 2014. Although Congress has conferred upon FDA the authority to regulate medical devices, LDTs are not medical devices. As such, ACLA holds that FDA lacks the statutory authority to regulate LDTs. There are numerous indications that Congress has never intended for FDA to regulate LDTs, which we discuss in greater detail in our comments to the Agency on the proposed Guidance.

Through the existing regulatory oversight framework under the Clinical Laboratory Improvement Amendments, laboratories have the flexibility and technical expertise to adapt in real time to the latest scientific advances, which is a great benefit to clinicians and patients.

Note that LDT services are diagnostic tests that are developed, validated, and performed by highly-trained professionals within a single clinical laboratory entity based on a laboratory's unique knowledge of testing protocols, performance characteristics, and means of analysis. The result is biochemical, genetic, molecular, or other forms of clinical information. LDTs allow laboratories to innovate and improve their services rapidly and continually by focusing on biomarkers and analytes for which no commercial standardized test kits yet exist. Often LDTs are the only available options for clinicians and patients, particularly when it comes to cancer. Additional FDA oversight through the proposed Guidance would institute an arduous and unnecessary regulatory barrier.

Therefore, in order to support the goals of the Cancer Moonshot Task Force and facilitate the continued unfettered development of new diagnostics, the FDA should withdraw the Draft LDT Guidance. Likewise, FDA should revisit its position on this issue in communications with the House Committee on Energy and Commerce and the Senate Committee on Health, Education, Labor and Pensions, which are endeavoring to work with all stakeholders on a more appropriate regulatory framework for LDTs than the proposed Guidance.

Difficulties with Federal Coverage and Reimbursement of Clinical Laboratory Testing Must Be Addressed

The impact of federal policy regarding coverage for and payment of clinical laboratory tests has significant repercussions in the present and in the future for the prevention, diagnosis, treatment, and the ultimate cure for cancer. If the Task Force wants to meet its stated goals, then improvements must be made swiftly to both coverage and reimbursement rates for clinical laboratory test services.

ACLA member laboratories provide millions of clinical laboratory diagnostic testing services each year to federal health care program participants, such as Medicare and TRICARE beneficiaries. Commonly, there are inconsistencies in federal coverage and reimbursement for clinical lab tests or outright payment prohibitions within federal health care programs that must be rectified. These issues not only affect beneficiary access to best practices in cancer treatment, but also influence coverage and reimbursement decisions made by other payors, including Medicaid and private insurance. Without appropriate coverage and sufficient reimbursement for pioneering clinical laboratory tests, innovation is hindered and investment deterred.

The Medicare program is in the midst of reforming reimbursement rate setting under the Clinical Laboratory Fee Schedule (CLFS). The changes brought about by Section 216 of the *Protecting Access to Medicare Act of 2014* (PAMA) constitute the first major overhaul of the CLFS since it was established in 1984. ACLA supported the legislative changes and has sought to collaborate with the Centers for Medicare and Medicaid Services (CMS) since the enactment of PAMA. We are hopeful that a predictable market-based payment model, which reflects the broad scope of the laboratory market, will encourage continued advancements in diagnostic innovation by providing a pathway to consistent coding and pricing decisions for all diagnostics.

Our optimism is tempered by the October 1, 2015 Proposed Rule (80 Fed. Reg. 59386) issued by CMS to implement these reforms. Not only was the Proposed Rule late, ignoring the June 30, 2015 deadline for release of the Final Rule contained in the PAMA statute, but it deviated from Congressional intent as

illustrated by statute in several areas. We submitted detailed comments to CMS on the Proposed Rule, which outline our concerns about the issues which will continue to have tangible impacts on Americans living with cancer, clinicians, and researchers, including the definition of applicable laboratory, the definition of Advanced Diagnostic Laboratory Test (ADLT), and Local Coverage Determinations (LCDs).

The TRICARE program also poses impediments to high quality cancer diagnosis and treatment for uniformed service members and their families, reservists and their families, as well as others deemed to be eligible. In January 2013, without notice to beneficiaries or health care providers, TRICARE ceased reimbursing clinical laboratories for more than 100 molecular pathology tests when care was obtained from the civilian provider network. Affected tests included those considered to be the standard of care in the diagnosis and treatment of leukemia, lung and other cancers. Although Congress took action to address this disparity in the *Carl Levin National Defense Authorization Act for FY 2015*, which clarified the authority of the Defense Health Agency, the problem still has not been fully remedied. While we were heartened that TRICARE established demonstration projects for LDTs, full coverage for these critical tests has yet to be reestablished to this day. We believe that TRICARE beneficiaries living with cancer should not be disadvantaged in their ability to receive the most clinically appropriate care available.

ACLA and our member laboratories remain disappointed that roadblocks continue to exist for TRICARE beneficiaries seeking laboratory testing services. The prior authorization requirements established by the managed care support contractors persist and are exceedingly burdensome. In addition, LDTs that have been approved for coverage by either of the demonstration projects continue to be on the No Government Pay Procedure Code List, without any indication they have been approved for coverage. This situation continues to cause problems for laboratories seeking reimbursement from TRICARE as well as other government payors. ACLA believes the authority granted by the *Defense Authorization Act for Fiscal Year 2015* authorizes TRICARE to cover molecular diagnostic tests through the TRICARE medical benefit, without the necessity of using demonstration authority or the coverage restrictions that have been associated with the current demonstration project.

In conclusion, ACLA applauds the formation of the White House Cancer Moonshot Cancer Task Force and strongly supports its goals. Innovations and improvements in clinical laboratory testing will help propel our nation's understanding of cancer. Our member labs are actively striving to better predict, detect, and diagnose the hundreds of cancer types. Now more than ever, American ingenuity and drive within the clinical laboratory sector will spur new testing methods and enhancements to existing ones, if the federal regulatory, reimbursement, and coverage environment will permit the fostering of such developments. We look forward to working alongside you on this remarkable initiative.

Sincerely,

Alan Mertz,
President