April 1st, 2016

Senator Thad Cochran
Chairman
Senate Committee on Appropriations
Room S-128, The Capitol
Washington, DC 20510

Senator Barbara Mikulski
Vice Chairwoman
Senate Committee on Appropriations
Room S-128, The Capitol
Washington, DC 20510

Senator Jerry Moran
Chairman
Senate Appropriations Committee
Subcommittee on Agriculture, Rural Development
Food and Drug Administration, and Related Agencies
Room S-128, The Capitol
Washington, DC 20510

Senator Jeff Merkley
Ranking Member
Senate Appropriations Committee
Subcommittee on Agriculture, Rural Development,
Food and Drug Administration, and Related Agencies
Room S-128, The Capitol
Washington, DC 20510

Dear Chairman Cochran, Vice Chairwoman Mikulski, Subcommittee Chairman Moran and Subcommittee Ranking Member Merkley:

The undersigned organizations, representing patients, advocates, caregivers and health care professionals, would like to emphasize the important role FDA can and needs to play in the regulation of laboratory developed tests (LDTs).

Concerns have been raised that FDA involvement in LDT regulation will impede patient access to innovative tests. However, it is important to note that the FDA has a track record of exercising regulatory flexibility to bring new technologies to patients in a timely manner. For example, in 2013 FDA allowed marketing of four next-generation sequencing (NGS) diagnostic devices, the first-ever clearance of its kind. The FDA developed the expertise and tools to conduct a thorough review and used separate approval pathways to reflect the risk associated with each device. The FDA's draft guidance on LDT oversight also reflects a commitment to flexibility, given the proposal's risk-based approach to oversight.

Beyond providing timely access to new products, the FDA can effectively fill current gaps in oversight that have led to uncertainty surrounding the quality of some tests. The discovery of faulty and clinically invalid tests being used in ovarian cancer (OvaSure) and cardiology (KIF6 testing) highlights examples of inadequate oversight. Apart from these examples, the general lack of publicly-available information about many LDTs has raised concerns among many that not enough is known about many tests currently in use.

As Congress weighs various proposals to reform LDT oversight, we urge lawmakers to recognize that FDA involvement does not mean a threat to patient access. Moreover, patients deserve to have confidence in the results of *in vitro* diagnostic tests, since such tests inform a variety of treatment decisions. The FDA can provide the assurance that when tests are performed they lead to the proper use of associated treatments, a step that's necessary to improve the public health.

Sincerely,

Action to Cure Kidney Cancer
Addario Lung Cancer Foundation
Addario Lung Cancer Medical Institute
The ALS Association
Alliance for Aging Research
American Association for Cancer Research (AACR)
American Autoimmune Related Diseases Association
American Cancer Society Cancer Action Network
American Heart Association
American Medical Student Association
American Society of Clinical Oncology (ASCO)
Annie Appleseed Project
Cancer*Care*
Cancer Prevention and Treatment Fund
Cancer Support Community
C-Change
Cutaneous Lymphoma Foundation
Fight Colorectal Cancer
Friends of Cancer Research
Kidney Cancer Association
Kids v. Cancer
The Leukemia & Lymphoma Society
Lung Cancer Alliance
LUNGevity
Lupus and Allied Diseases Association, Inc.
MRSA Survivors Network
National Brain Tumor Society
National Coalition for Cancer Survivorship
National Consumers League
National Patient Advocate Foundation
National Physicians Alliance
Ovarian Cancer Research Fund Alliance
Prevent Cancer Foundation
US Pain Foundation
WomenHeart: The National Coalition for Women with Heart Disease
Woody Matters