November 11th, 2015

Congressman Fred Upton
Chairman
House Energy and Commerce Committee
2183 Rayburn House Office Building
Washington, DC 20510

Congressman Frank Pallone
Ranking Member
House Energy and Commerce Committee
237 Cannon House Office Building
Washington, DC 20510

Senator Lamar Alexander
Chairman
Senate HELP Committee
SD-428 Dirksen Senate Office Building
Washington, DC 20510-6300

Senator Patty Murray
Ranking Member
Senate HELP Committee
SD-428 Dirksen Senate Office Building
Washington, DC 20510-6300

Dear Chairman Upton, Chairman Alexander, Ranking Member Pallone and Ranking Member Murray:

In anticipation of next week's House Energy and Commerce Committee hearing entitled "Examining the Regulation of Diagnostic Tests and Laboratory Operations," 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 The FDA's draft guidance on LDT oversight also reflects a commitment to flexibility, given the proposal's risk-based approach to oversight.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 Brain Tumor Association
American Cancer Society Cancer Action Network
American Heart Association
American Medical Student Association
American Society of Clinical Oncology (ASCO)
Annie Appleseed Project
Breast Cancer Action
Cancer*Care*
Cancer Prevention and Treatment Fund
Cancer Support Community
C-Change
Connecticut Center for Patient Safety
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.
Melanoma Research Alliance
MRSA Survivors Network
National Brain Tumor Society
National Coalition for Cancer Survivorship
National Consumers League
National Multiple Sclerosis Society
National Organization for Women (NOW)
National Patient Advocate Foundation
National Physicians Alliance
Ovarian Cancer National Alliance
Prevent Cancer Foundation
US Pain Foundation
WomenHeart: The National Coalition for Women with Heart Disease
Woody Matters