November 11<sup>th</sup>, 2015

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

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

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

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 The FDA's draft guidance on LDT oversight also reflects a commitment to flexibility, given the proposal's risk-based approach to oversight.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.

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**