American Cancer Society
Cancer Action Network
555 11th Street, NW
Suite 300
Washington, DC 20004
202.661.5700
www.acscan.org

November 16, 2015

The Honorable Fred Upton
Chairman
Energy and Commerce Committee
U.S. House of Representatives
Washington, DC 20515

The Honorable Frank Pallone, Jr.
Ranking Member
Energy and Commerce Committee
U.S. House of Representatives
Washington, DC 20515

Re: Examining the Regulation of Diagnostic Tests and Laboratory Operations

Dear Chairman Upton and Representative Pallone:

The American Cancer Society Cancer Action Network (ACS CAN) is pleased to offer comments on the Energy and Commerce Committee's discussion draft legislation updating oversight for all diagnostic tests regardless of origin, including laboratory developed tests (LDTs). ACS CAN is the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society, supporting evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem. Our organizations have a critical interest in ensuring that patients and their physicians have access to accurate information to make decisions about their cancer treatment. We appreciate the Committee's continued work and due diligence to address issues important to cancer patients.

The recommendations included in this letter build upon the comments ACS CAN provided to the committee in January on general oversight parameters for LDTs as well as the more detailed comments we provided in June on a draft version of legislation.

As you know, cancer is literally hundreds of different related diseases that share common hallmarks, but are treated in very different ways. Therefore, the ability to accurately diagnose the type of cancer and to identify a tumor's particular molecular characteristics is absolutely critical in optimizing each patient's treatment. The current regulatory paradigm for diagnostic tests includes two different oversight systems. Tests that are sold as complete kits are required to undergo pre-market clearance and approval from the FDA to verify analytical and clinical validity of the test. Similar tests that laboratories create for their own internal use (LDTs) are not subject to the same level of review even if they purport to perform the same function as FDA-approved kits. It is paramount that patients and their physicians know that regardless of how or where a test is manufactured or performed, they can trust the information produced by that test.

While we support the Committee's desire to harmonize the oversight of diagnostic tests regardless of where they are created and conducted, and calibrating the level of oversight to a

test's risk, we have concerns about many of the details of the current draft legislation. First, we remain concerned that the risk classification proposed in this legislation still does not fully take into account risk to a patient's health, but rather incorporates aspects of technology in defining whether a test is high, moderate, or low risk. Secondly, this legislation still contemplates grandfathering tests developed prior to enactment of the bill, which would leave potentially dangerous tests without adequate oversight. Lastly, the legislation contains provisions that would "deem" a test approved if its application was not acted upon quickly enough by FDA.

We are gratified to see that the discussion draft recognizes that FDA is the most appropriate agency to evaluate the analytical and clinical validity of diagnostic tests along with their safety. We do not, however, believe that the creation of a new Center at FDA is necessary, and it could be potentially burdensome on the agency. We believe that the FDA currently has all the authority, expertise, and regulatory infrastructure necessary to oversee diagnostic tests. As we have stated previously, we support the FDA's October 2014 proposal to begin actively overseeing LDTs under a risk-based framework.

We look forward to continuing the discussion, and being of assistance in creating a final legislative product that meets the needs of cancer patients, survivors, and those who are helping them in the fight against the disease.

Thank you again for the opportunity to comment on this proposal. Please do not hesitate to contact me (Dick.Woodruff@cancer.org) or Mark Fleury (Mark.Fleury@cancer.org) if you have any questions.

Sincerely,

Dick Woodruff
Vice President, Federal Relations
American Cancer Society Cancer Action Network