Good morning, Mr. Chairman and distinguished Members of the Subcommittee. My name is Dr. Charles Sawyers. I am an oncologist and a cancer researcher, and the chair of a cancer research department at Memorial Sloan Kettering Cancer Center in New York.

I am also the immediate past president of the American Association for Cancer Research (AACR), the world's oldest and largest cancer research organization. AACR has over 35,000 members -- basic, translational, and clinical researchers, health care professionals, patients and patient advocates in the US and abroad.

I am honored to appear before you today to provide you with a perspective from the AACR on the recent notification offered by the FDA regarding the regulation of Laboratory Developed Tests (LDTs).

In 1971 our country made a significant commitment to defeat cancer through the National Cancer Act. Now, more than 4 decades later, that commitment is finally paying off. Over 45 new, lifesaving cancer drugs were approved just in the last 10 years alone.

What happened during those 40 years that made this success possible?

1) We finally understand the cause of cancer. Cancer is a disease of mutant genes. By knowing the names of these genes and how they cause cancer, we can discover new drugs that kill cancer cells by attacking them at their roots.

2) The Human Genome Project -- by knowing the names of all the genes in our DNA, we have been able to catalogue all the ones that are mutated in cancer. This knowledge teaches us that cancer is not 10-20 different diseases called lung, colon, breast and prostate cancer, but 100s of diseases defined by the mutant genes that cause them. This also empowers us to develop drugs to treat each cancer more effectively.

3) Technology -- Just 5 years ago DNA sequencing was so specialized that it could only be carried out in a research setting using highly curated tumor specimens. Today this technology is routinely deployed in major cancer centers throughout the country. Tomorrow, it will be a part of the routine workup of all cancer patients.

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15 years ago, I led the first clinical trial of a drug called Gleevec that is highly effective in a form of blood cancer known as chronic myeloid leukemia or CML. All patients with CML have a very specific gene mutation and, prior to Gleevec,

had a life expectancy of just a few years. Now CML patients live for decades simply by taking a pill once a day that targets the cancer cells without the side effects of chemotherapy or radiation. In fact, many of the patients I treated on the first clinical trial in 1999 are alive and well today.

Similar stories can now be told for melanoma, lung cancer, colon cancer, sarcoma and so on. Medical historians will look back and call this the golden age of cancer therapy.

Why am I here to talk to you about LDTs?

Because diagnostics are critical to the success of targeted cancer therapy! Indeed, the mantra of personalized medicine is "the right drug for the right patient." The FDA recognizes this and approves new targeted therapies in conjunction with a *companion diagnostic*, which undergoes a rigorous validation process, just like the drug. A safe, reliable and effective diagnostic test is as important as a safe, reliable and effective drug.

Since gene sequencing will soon be a routine part of cancer care, hundreds of thousands (if not millions) of patients will be impacted by this sophisticated technology. Physicians and patients must be able to trust the claims made by developers of these tests, especially when they are used to determine the treatment

regimen for a cancer patient. Too much is at stake to compromise on the regulatory standards that govern them.

Gene sequencing technology is evolving rapidly. We are just at the tip of the iceberg of what may be possible. Soon we will be able to detect cancer mutations in a single drop of blood. Many innovative companies are entering the field, but are looking for clarity from the FDA on how to commercialize these and related technologies. As with drug approvals, a clearly defined regulatory process will lead to greater innovation and investment.

For all these reasons, AACR applauds the FDA for proposing a classification of LDTs based on the risk posed by the test to the patient. Having a single, strict, regulatory approval standard will reassure the American public that the tests used in high-risk health care decision-making are safe, accurate, and effective and will encourage the private sector to invest in this promising new area of medicine.

I close by submitting for the record the AACR's policy statement on regulation of diagnostics titled "Reliable and Effective Diagnostics Are Keys to Accelerating Personalized Cancer Medicine and Transforming Cancer Care".