COMMITTEE ON ENERGY & COMMERCE
DEMOCRATS
RANKING MEMBER FRANK PALLONE, JR.

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Statement of Ranking Member Frank Pallone, Jr., as prepared for delivery
House Energy and Commerce Committee
Subcommittee on Health
Hearing on "Examining the Regulation of Diagnostic Tests and Laboratory Operations"

Mr. Chairman, thank you for holding today's hearing. I also want to thank both Dr. Shuren and Dr. Conway for being here today to discuss the regulation of lab developed tests.

There has been much discussion over how to appropriately oversee lab developed tests and it is important that as the Committee considers this issue, we have a better understanding of the strengths and limitations of both FDA and CMS's authority in this area.

Congress gave FDA authority over lab-developed tests under the Medical Device Amendments in 1976. At that time, most LDTs were relatively simple tests used most often for rare conditions. Since then advances in technology and medicine have resulted in LDTs that are increasingly more complex, more readily available to physicians and patients, and used to diagnose and treat a wider range of diseases, including breast cancer and heart disease. LDTs are also increasingly used to provide personalized treatments, such as through genetic tests that help physicians to detect the risk of certain diseases earlier or to choose more targeted therapies.

Unfortunately, many of these tests have not been reviewed or cleared by FDA prior to coming to the market to confirm that these tests are accurate, reliable, or provide clinically accurate results. This can result in patients going undiagnosed with certain medical conditions, or undergoing treatment that is not medically necessary.

For example, tests have been developed to identify certain gene sequences that can help determine appropriate treatment for ovarian cancer. I am sure many members here are familiar with the example of OvaSure, which claimed to detect early stage ovarian cancer in high-risk women. This test though was not properly validated and was found to provide high numbers of false-positive and false-negative results. This means many women who received a false positive

result may have undergone unnecessary surgery to remove healthy ovaries, or some women may have gone undiagnosed after receiving a false negative result.

Patients deserve to know that the test results they are relying on to diagnose or treat a condition is accurate, a comfort that they do not always have today. As we have heard from many organizations, patients and their physicians should be able to trust the results of their tests regardless of how or where a test is developed or performed. It does not make sense to regulate tests differently based on who develops them.

I also believe that we can provide patients and providers with this certainty without endangering or inhibiting the medical innovation that is occurring today. Scientific progress has been made to help facilitate the development and use of personalized medicine, which we all agree is the future of medicine. But this development can only be successful if we know that these complex, sophisticated tests are clinically valid.

I am glad that today we will have the opportunity to better understand FDA and CMS's authority in this area and hear their perspective on what regulatory changes, if any, are needed to address the future development of lab-developed tests. I hope moving forward that both agencies will work with the Committee on the discussion draft circulated today to ensure that any legislation that moves forward will ensure that LDTs are accurate, reliable, and safe for patient use.

I yield back.

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