Remarks of Laura Koontz, PhD, Director of Policy, Ovarian Cancer National Alliance

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Good Morning!

I greatly appreciate the opportunity to join you today to share the ovarian cancer patient's perspective on the need for regulation of laboratory developed tests.

I am Laura Koontz, Director of Policy for the Ovarian Cancer National Alliance. We are the foremost advocacy organization for everyone who has been touched by ovarian cancer. I am here today to speak on behalf of thousands of women living with or at risk of developing ovarian cancer.

Ovarian cancer is a deadly disease, but why? The simple answer is that there is NO early detection test. Many women are diagnosed when their disease is advanced.

We would love to see new tests reach the market that could help doctors detect ovarian cancer and ultimately save thousands of women's lives each year. But, these tests must be accurate, reliable, safe and effective.

A few ago, our community experienced firsthand the dangers of an unregulated and unvalidated early detection test. In 2008, a laboratory developed test claiming to be an ovarian cancer early detection test came to market.

I'd like each of you to think of a woman you know and love—Yourself. Your mother. Your sister. Imagine that, in the fall of 2008, she went to the hospital complaining of pelvic pain and bloating. An ultrasound revealed a lump on one of her ovaries. Her doctors used a new blood test – called OvaSure - to determine if the lump was ovarian cancer.

The test results came back positive, and she was rushed into surgery to undergo a complete hysterectomy and remove her ovaries. However, when the surgery was finished, the pathologists found that she actually did NOT have ovarian cancer. But by then, the damage was already done.

This is not a hypothetical example. This happened to women in the fall of 2008, when OvaSure – an LDT - was put onto the market without independent verification that it actually worked. Despite strong objections from the FDA and oncologists specializing in ovarian cancer. While

we heard stories from a few brave women who were harmed by the test and went public, we do not know exactly how many women were affected by OvaSure because adverse event reporting wasn't required by CLIA.

What we do know is that many women were given dangerous and inaccurate results – with real consequences. Ultimately, OvaSure was removed from the market—but not before countless women were put at risk.

While our community desperately wants an early detection test for ovarian cancer, we need to know that it is accurate, reliable, safe and effective. The FDA's proposed regulatory framework would go a long way toward ensuring just that.

FDA regulation would classify tests by risk and require that high risk tests, like OvaSure, undergo pre-market review to assess their analytic and clinical validity. Furthermore, FDA regulation would require adverse event reporting, allowing bad tests like OvaSure to be caught quickly and giving the community understanding of the full scope of a bad test.

FDA's common sense proposal is reasonable for test developers. Just last month, the FDA approved Myriad's LDT for BRCA as a companion diagnostic for a new ovarian cancer drug, olaparib. The drug and the test were both approved through accelerated review. Furthermore, most tests currently used in the diagnosis and monitoring of ovarian cancer are FDA-cleared or approved test kits.

FDA's proposal also includes thoughtful exceptions that would allow innovation to proceed while providing strong patient protections and would ensure that all tests are valid, reliable, safe and effective. And we believe that patients deserve no less.