

## Ovarian Cancer National Alliance

### Response to Food and Drug Administration Draft Guidance #1610

I was diagnosed five years ago with both ovarian and endometrial cancers. Both cancers were detected early in Stage I, where I had the best chance of survival – something only 25 percent of women with ovarian cancer can claim. I was lucky to be diagnosed early; however, it was not the result of having access to an early screening test. My good fortune was only the lucky result of my perseverance with my doctor, and my subsequent treatment by the appropriate specialist, a gynecologic oncologist.

Two years ago I joined the Ovarian Cancer National Alliance, as Executive Director, to ensure that other women can have the opportunity to be as fortunate as I have been. We cannot rely on luck for our survival. We must have the research to develop early screening tests and new and better treatments and to spread awareness to women about the risk factors and symptoms of ovarian cancer. The Alliance is an umbrella organization with 50 state and local groups, representing more than one million grassroots activists, women's health advocates and health care professionals. I am testifying on behalf of those activists, advocates and professionals to express my concern regarding Draft Guidance #1610 on In Vitro Diagnostic Multivariate Index Assays.

According to the American Cancer Society, in 2007, 22,430 American women will be diagnosed with ovarian cancer, and 15,280 will lose their lives to this terrible disease. Ovarian cancer is the deadliest gynecologic cancer and the fifth leading cause of cancer death among women in America. **Currently, more than half of the women diagnosed with ovarian cancer will die within five years.**

When detected early, the five-year survival rate increases to more than 90 percent, but when detected in the late stages, the five-year survival rate drops to 28 percent. A valid and reliable screening test, which is an important tool for improving early diagnosis and survival rates, unfortunately does not yet exist for ovarian cancer.

Since the Alliance was founded 10 years ago, close to 250,000 women have been diagnosed with ovarian cancer; more than 185,000 were diagnosed in Stage III or IV because there is no early screening or diagnostic test. Only a small portion of those women are alive today. We recognize that it may be years before there is a highly sensitive and specific early screening test for the general population. But we do know there is significant research going on, sponsored by both government and industry to develop effective diagnostic tests using multiple markers. These tests are the future for early screening, but they may be TODAY, and in the very near future, the best hope for an earlier diagnosis for women who are at a higher risk and those with an existing pelvic mass. These women's lives cannot be held hostage by a process that creates barriers to early diagnosis and treatment.

We are concerned that the Draft Guidance raises many unanswered questions. For example,

- What is an IVDMA?
- To what known deficiency in current regulations is this in response?
- What will happen to tests already used to diagnose and treat patients?

The Draft Guidance is vague and open to varying interpretations. The possibility of this ambiguity may discourage entry to the market. Further, a protracted pre-market approval will lengthen and complicate the process for getting these tests to patients, potentially discouraging firms from developing IVDMIAs. Our greatest concern is that this will delay access to IVDMIAs, without clear benefits to patient safety.

We urge the FDA to resolve this by creating a clear, predictable process with remedies. The process must allow rapid access to diagnostic or screening tests as well as increase safety. Such a process will encourage entry and research into tools that will increase survivorship. Already, ovarian cancer is a “rare disease,” not always at the forefront of medical research. Further discouragement into the ovarian cancer market will have great consequences for the lives of women and everyone around them. The process required by the FDA must be clear, predictable and speedy: many lives depend on it.