



## Ovarian Cancer National Alliance

### Response to Food and Drug Administration Proposed Rule 21 CFR Part 312

#### Introduction

The Ovarian Cancer National Alliance is a survivor-led national umbrella organization with 50 state and local groups, representing more than one million grassroots activists, women's health advocates and health care professionals. 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. The Ovarian Cancer National Alliance submits this testimony as a patient advocacy group dedicated to conquering ovarian cancer.

We believe that by carefully defining expanded access guidelines, patients and their providers will be better able to navigate the regulatory field to advance health care for patients. We support the FDA's efforts to improve health outcomes.

#### Increased Access for Those who do not Qualify for Clinical Trials

Many cancer patients who are ineligible for clinical trials will have access to experimental therapy through this rule. For example, patients with metastatic disease are living longer and in better health than in previous years, but are often ineligible for clinical trials due to numerous previous treatments. This proposed rule will allow some of those patients potentially to benefit from newer treatments than otherwise available.

Additionally, in many trials, patients with one or more co-morbidities are often excluded from clinical trials. Most often affected by these exclusions are elderly and minority patients, who are more likely to have other health conditions such as diabetes or hypertension. Expanded access may allow some these patients to get new medications which may potentially benefit them, and their participation may also create a source of information on how co-morbidities affect the treatments in question. This is important information which can not now be gleaned from many clinical trials.

In the cancer population, there are certain cancers that do not respond to standard chemotherapy. Included in this population are women are diagnosed with low-grade ovarian tumors, which include grade 1 and 2, micropapillary serous carcinoma and progressing low malignant potential (LMP) tumors. These women may have a limited response to chemotherapy, and may choose not to endure treatment with standard chemotherapy because of the strong likelihood of a poor response. These women, then, will in some instances not qualify for clinical trials, since they have not yet gone through the process of undergoing traditional first-line therapy. Expanded access could allow these women to bypass the needless step of chemotherapy likely to fail them, and have other viable treatment options. Until such time as the clinical trial process is able to accommodate newer ways of determining who will benefit from which treatment, expanded access may be the one avenue and best hope for patients to access newer treatments without being exposed first to the rigors of traditional therapy that is likely to do no good.

Additionally, between 70% and 90% of ovarian cancer patients will recur. The fact of recurrence automatically disqualifies many patients from participating in clinical trials where first-line therapies are being tested. Under the proposed expanded access rules, women with recurrent

ovarian cancer may qualify for access to experimental drugs which they would not otherwise have been able to access.

### **Increased Access Should Be Inclusive**

The expanded access initiative poses an exciting opportunity to reach out to underserved populations, including minorities and people living in rural areas. Of course providers must still comply with informed consent procedures, allowing women to make educated decisions about their own healthcare.

Expanded access for ovarian cancer patients should specifically include access for minority women, especially African-American women, as they have the lowest rates of cancer survivorship. [While cancer mortality has declined slightly over the past decade, African-Americans have become more likely to die of cancer; 17 percent more African-American women die within five years than white women.<sup>1</sup>

According to research done at the National Institutes of Health, minorities participate in clinical trials at the same rate as non-Hispanics when they are made aware of the study, and can meet the medical requirements.<sup>2</sup> Lack of awareness is the major barrier to minority group participation, but other barriers also exist, including travel to the clinic and childcare.

Further, the Institute of Medicine has released a report that notes that new cancer therapies are not largely available for minorities and medically underserved patients.<sup>3</sup> Every effort should be made to not only increase access to clinical trials for all patients who may qualify, but also to allow access through the Expanded Access protocol. It is necessary that all patients receive the highest quality care available, in keeping with the goals of the Expanded Access protocol.

Women in rural areas or women being seen by a medical oncologist or gynecologist may face special challenges when considering enrollment in a clinical trial. They and their providers must also be aware of the options available to them under the expanded access rules. The FDA will have an opportunity to educate providers about groundbreaking research in order to make providers aware of opportunities under the expanded access rules. Women who are not being seen at major cancer centers should have the same opportunities to access potentially life-saving medications as women who are participating in clinical trials.

### **Require Record-Keeping and Reporting for Accountability**

In order to properly evaluate how well the program is working and whether economic and other issues are impacting the ability of patients to obtain expanded access, the FDA is encouraged to develop a tracking system which should include but not be limited to Investigator Information and information on patients who apply for expanded access. The FDA should also track whether or not patients requesting treatment under the expanded access rules receive treatment; if they do not receive treatment, reasons for that should be tracked as well.

Due to the fact that patients receiving treatment under the expanded access protocol may have to pay for their treatments, these actual costs should be included in the data FDA compiles. The rule may not actually expand access if cost becomes an overwhelming barrier. Access to care is an underlying problem and should be evaluated as part of the FDA rules.

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<sup>1</sup> Study done by the National Medical Association in conjunction with Pfizer, Inc. Dr. Edith Mitchell, Dr. Robin Hertz, Dr. Margaret McDonald, *Racial Differences in Cancer: A comparison of Black and White Adults in the United States* (2005).

<sup>2</sup> Wendler, D., et al., Are racial and ethnic minorities less willing to participate in health research? *Public Library of Science Medicine*, 2006. 3(2): p. e19.

<sup>3</sup> Institute of Medicine, *From Cancer Patient to Cancer Survivor: Lost in Translation* (2006).

Lastly, the outcomes of the treatments should be tracked to ascertain how meaningful expanded access is to the public in terms of treatment. Progression free survival time and 5-year mortality rates are currently used measures of cancer therapies and may be the continued appropriate measures.

**Conclusion**

We congratulate the FDA on taking positive steps forward to increase patient access to investigational drugs while maintaining the integrity of clinical trials. We support the FDA's efforts in the hopes that women with ovarian cancer will have better and faster access to appropriate medical care, including medicinal therapies.

Thank you for the opportunity to submit these comments.