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Oncology Drug Advisory Committee  
Food and Drug Administration  
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## **Concerns Regarding ESAs administered to patients with cancer induced anemia**

### **Introduction**

The Ovarian Cancer National Alliance is an umbrella organization with 50 state and local groups representing grassroots activists, women's health advocates and health care professionals. According to the American Cancer Society, in 2008, 21,650 American women will be diagnosed with ovarian cancer, and 15,520 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 regarding erythropoiesis-stimulating agents (ESAs) as a patient advocacy group with the aim of conquering ovarian cancer.

The Alliance works closely with Johnson & Johnson and Amgen, manufacturers of ESAs. We have received funding from both organizations in the past, and maintain working relationships in our mission to conquer cancer. We applaud the efforts of the companies to enhance the quality of life for cancer patients. Our relationships in no way influence the positions stated below.

### **Safety Signals**

In recent months, studies have raised safety signals about the use of ESAs. Specifically, the incidence of thrombotic events as well as a shortened life span were seen in patients taking ESAs. Many of these studies involved off-label use of ESAs, targeting a hemoglobin level higher than recommended. Nonetheless, the Alliance remains unconvinced that a hemoglobin level of 12g/dL, as approved by the FDA, is a magic number, below which no harm will be done.

### **Data**

Both the FDA and industry have given conflicting reports over who owns the data on ESAs, and who has the power to release these data. The Alliance has joined other organizations in calling for the release of data related to use of ESAs. Further, we continue to request that patient-friendly information be provided to all patients considering ESAs.

We are concerned about the process by which ESAs have been evaluated. This process should be science-based; instead, regulatory agencies have led the way. The FDA had a meeting in early 2007, after which CMS changed reimbursement policy. It was not until late 2007 that the NCI actually met to discuss ESAs. Evidence should guide practice and reimbursement, not the other way around.

*The Ovarian Cancer National Alliance is the nation's vision and voice for ovarian cancer issues. The Alliance, a 501(c)(3) organization, lead the national initiative to conquer ovarian cancer by uniting individuals and local, state and national organizations in a solidified movement to advance ovarian cancer research, improve health care practice and find an effective screening test and a cure for the disease.*



### **Impact on Ovarian Cancer Patients**

Anemia occurs more frequently in gynecological cancers than others. Because 70 percent to 90 percent of ovarian cancer patients have a recurrence and ovarian cancer patients may be on maintenance chemotherapy for years, ovarian cancer patients may be in a position to take more ESAs than other cancer patients. For them, and for all cancer patients, we must have sound medical and scientific advice so that patients and their health care providers can make informed decisions about treatment. Ovarian cancer has a high mortality; many patients remain on chemotherapy for years. These patients are at an increased risk of any negative effects of ESAs. A palliative care drug may be rendering the work of primary treatments useless.

The proposed studies on ESAs do not include ovarian cancer as a tumor type to be included. For this reason, it is imperative that any findings be translatable to all cancer types, and guide treatment practices for all types of cancer.

These safety signals are highly concerning. Since the aim of treatment is longer survival, any additional care should support that outcome while promoting a quality of life to the extent that palliative care is safe and feasible. Patient safety is of the utmost importance, and any FDA regulations must reflect scientifically-based evidence in furtherance of patient safety.

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