Ovarian Cancer
NATIONAL ALLIANCE
We Work To Save Women's Lives

May 1, 2014

Bryant Godfrey
Senior Lead Regulatory Counsel
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave
Bldg. 51, Rm. 3258
Silver Spring, MD 20993

RE: Guidance for Industry - Distributing Scientific and Medical Publications on Unapproved New Uses — Recommended Practices [Docket No. FDA-2008-D-0053-0132]

Dear Mr. Godfrey:

The Ovarian Cancer National Alliance (hereafter, the Alliance) appreciates the opportunity to submit these comments in response to the open comment period for Guidance for Industry *Distributing Scientific and Medical Publications on Unapproved New Uses — Recommended Practices.* The Alliance urges FDA to reconsider some of its proposed language changes, which could potentially chill off-label use of oncology drugs and the dissemination of scientific information about non-approved uses.

The Alliance is an ovarian cancer survivor-led national umbrella organization with state and local groups, representing grassroots activists, women's health advocates and health care professionals. Ovarian cancer is a highly deadly disease; according to the American Cancer Society, an estimated 21,980 American women will be diagnosed with ovarian cancer in 2014, and 14,270 will lose their lives to this terrible disease. A quarter of women will die within a year of diagnosis and over half will die within five years of diagnosis.

These grim statistics arise from the fact that there is no early detection test for ovarian cancer and there are few FDA approved medications for the disease's treatment. Furthermore, approximately 80% of women diagnosed with ovarian cancer will recur at least once, and often multiple times, leaving them with scant few FDA-approved oncology drugs for their treatment. In ovarian cancer, as in many oncology settings, patients receive "off-label" therapies, which are legal and often part of practice guidelines. Access to these therapies is critical to providing patients with the best possible care.

The 2009 version of this Guidance contained a statement in the Background section acknowledging that unapproved or off-label uses of medications may constitute a legal and medically-recognized standard of care. That Guidance contained the following language:

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> *Once a drug or medical device has been approved or cleared by FDA, generally, healthcare professionals may lawfully use or prescribe that product for uses or treatment regimens that are not included in the product's approved labeling … These off-label uses or treatment regimens may be important and may even constitute a medically recognized standard of care*.

However, the 2014 Guidance for Industry removes this acknowledgement as part of its revisions. Indeed, the new guidance contains the following language instead:

> *While physicians may exercise their professional judgment to make individual patient care decisions, the public health is often not well served when those judgments rest on anecdotal experience or even preliminary scientific study--too often, the promise of safety and effectiveness made by such sources has not been demonstrated when adequate and well-controlled studies are completed.*

The Alliance is deeply concerned that these revisions will chill off-label use of drugs and the dissemination of scientific information about non-approved uses. We strongly urge FDA to reconsider these changes and remove any language that may curb patient access to medically-accepted and life-saving medications.

Sincerely,

Calaneet Balas
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