NCCS
NATIONAL COALITION FOR CANCER SURVIVORSHIP
The power of survivorship. The promise of quality care.

December 5, 2014

Margaret Hamburg, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Request for Comments on Disease Areas for Patient-Focused Drug Development Meetings (FDA-2012-N-0967-0595)

Dear Dr. Hamburg:

The National Coalition for Cancer Survivorship is a national organization that represents survivors of all forms of cancer in public policy advocacy. Our public policy program focuses on activities to improve cancer care delivery and payment, and our fundamental goal is to guarantee all cancer patients access to high quality cancer care.

We appreciate the opportunity to respond to the request for comments regarding the series of patient-focused drug development meetings that have been convened to date and the list of disease topics for meetings in 2016-2017.

Addition to the List of Diseases

We commend the Food and Drug Administration (FDA) for convening a patient-focused drug development meeting related to lung cancer in 2013, proceeding with plans for a breast cancer meeting in 2015, and identifying ovarian cancer and melanoma (specifically unresectable loco-regional disease) as 2016-2017 meeting topics. This list includes cancers that have a very significant effect in terms of incidence and mortality as well as cancers for which treatment options are quite limited. These are important topics for the patient-focused drug development meetings.

We strongly recommend that cancer survivorship be identified as a topic for an FDA meeting. Cancer survivorship as a health state or status meets the criteria that the agency has identified for qualifying as a meeting topic.

Improvements in cancer care are yielding better outcomes and more long-term survivors of a cancer diagnosis. However, those survivors often bear serious medical, psychological, and functional consequences of cancer and its treatment. The late and long-term effects that cancer survivors experience will vary according to diagnosis and the treatments that they received. Regrettably, few cancer patients will escape their diagnosis with no late and long-term effects.

Although clinical trials yield important information about the side effects of a treatment, it is unlikely that at the time of approval all late and long-term effects of a drug will be known and included in product labeling. Over time, long-term side effects of therapies will be identified and that information communicated to patients. However, patients must often make initial treatment choices with imperfect or incomplete information about the long-term consequences of their therapy.

Although there are interventions for many of the long-term adverse events associated with cancer treatment, appropriate and timely delivery of those treatments is a significant challenge. And for some long-term side effects of cancer and its treatment, there are no interventions. Cancer survivors must be monitored over their entire lifetime

according to a schedule appropriate for their diagnosis and treatment, and interventions to address the effects of treatment must be delivered in timely fashion.

The Institute of Medicine reported in its 2013 report, Delivering High-Quality Cancer Care, that there were about 13.7 million cancer survivors in the United States in 2012. Almost 60%, or 8 million, of those cancer survivors are over the age of 65. The impact of cancer survivorship is felt across the entire population, but the burden is especially severe for senior citizens.

In summary, cancer survivors face chronic health issues that may affect their functioning and activities of daily life. Interventions may be available for certain of their health issues but must be delivered at the appropriate time and according to a long-term monitoring schedule. Senior citizens are over-represented among cancer survivors, but the problems of cancer survivorship are not limited to seniors.

We recommend that cancer survivorship be a topic for a patient-focused drug development meeting because the issues identified by cancer survivors and their caregivers would inform therapy development and the regulatory review of new cancer therapies. For example, cancer survivors bring a long-term perspective on the balance of risks and benefits in drug therapies. They may also offer an important perspective regarding assessment of the impact of therapies on quality of life. Finally, they can offer advice about the quality and quantity of information they desire for treatment decision-making. Cancer survivors may also have opinions about the palliative use of chemotherapy. The experience and insights of cancer survivors hold promise for informing the approach of FDA to its regulatory responsibilities, including the manner in which product labeling is structured and the strategies for timely updating of labeling to reflect information about late and long-term effects of the drug.

Agency Responsibility for Patient-Focused Drug Development Meetings

In an earlier response to the request for comments about patient participation in medical product discussions, NCCS recommended that responsibility for design and implementation of the patient-focused drug development meetings rest with the relevant review office. For cancer meetings, we propose that the Office of Hematology and Oncology Products assume a key role in organizing the meetings. We believe that this structure would lead to meetings of high quality with strong agendas, ensure that the findings of the meetings inform regulatory activities, and encourage appropriate meeting follow-up.

We understand that our recommendation places on busy review staff a new responsibility. We are mindful of the potential impact on review activities and urge FDA leadership to consider resource allocation that would permit review staff to be engaged in these patient-focused activities that are defined and mandated by the Food and Drug Administration Safety and Innovation Act (FDASIA).

We appreciate the opportunity to comment on the patient-focused drug development meetings.

Sincerely,

Shelley Fuld Nasso
Chief Executive Officer