

June 17, 2016

The Honorable Robert M. Califf
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Califf:

The Children's Cause for Cancer Advocacy (the Children's Cause) is pleased to respond to the proposal for a new Oncology Center of Excellence. The Children's Cause, established in 1999, was founded to ensure the needs and perspectives of children with cancer and survivors are integrated into federal health care, research and cancer policy.

The Office of Hematology and Oncology Products within the Food and Drug Administration has an outstanding record of efficient and effective reviews that ensure patients access to safe and effective cancer treatments without unnecessary delay. However, challenges remain regarding access to viable treatments for the small population of children with cancer. Scant market incentive exists for the biopharmaceutical industry to develop new pediatric oncology drugs. Thus, children with cancer are currently treated with drugs that were developed several decades ago for adults. These drugs can be very damaging to their physical and intellectual development. At the same time, childhood cancer remains the leading cause of disease-related death for children, and new and better therapies are sorely needed for children battling cancer.

For this reason, we support the establishment of an Oncology Center of Excellence that is capable of review of cancer diagnostics, drugs, and biologics for children with cancer. In short, we encourage any plans for an Oncology Center of Excellence to include a focus on the particular needs of children with cancer. The development of effective therapies for children will require a disciplined, tailored and even personalized approach to the review of drugs, biologics, and diagnostics for the diagnosis and treatment of cancer.

Thank you again for your engagement with the cancer community to enhance cancer drug, biologic, and diagnostic review. We look forward to continued collaboration with you and the new Oncology Center of Excellence.

Sincerely,

Children's Cause for Cancer Advocacy