

CANCER LEADERSHIP COUNCIL

A PATIENT-CENTERED FORUM OF NATIONAL ADVOCACY ORGANIZATIONS
ADDRESSING PUBLIC POLICY ISSUES IN CANCER

June 22, 2016

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

Dear Dr. Califf:

The undersigned organizations, representing cancer patients, researchers, and providers, are writing to express their appreciation for ongoing efforts to strengthen Food and Drug Administration (FDA) review of cancer products. The Office of Hematology and Oncology Products has an outstanding record of efficient and effective reviews ensuring patients access to safe and effective cancer treatments without unnecessary delay. The Office has also given real meaning to “patient-focused” drug development by open and constructive communication with the cancer community regarding cancer drug development and review.

Despite the stellar record of the Office of Hematology and Oncology Products, the development of therapies that are increasingly targeted and even personalized will require a review approach that is collaborative and cooperative and capitalizes on expertise appropriate for the review of drugs, biologics, and in vitro diagnostics for the diagnosis and treatment of cancer. We support the establishment of an Oncology Center of Excellence capable of review of cancer drugs, biologics, and in vitro diagnostics, and we commend you for your willingness to consider such a center.

Among the strengths of the Office of Hematology and Oncology Products are reviewers with deep knowledge and experience in oncology, the development and use of new regulatory tools and endpoints, and the sense of urgency that the review teams bring to their work. These attributes must be incorporated in the Oncology Center of Excellence, and appropriate resources must be made available to ensure that the drugs, biologics, and in vitro diagnostics in the jurisdiction of the Center of Excellence are reviewed in timely fashion.

We also urge that the Oncology Center of Excellence, with appropriate staff and resources, embrace the principles of patient-focused drug development. This emphasis will ensure that patient needs are considered in all FDA matters, from clinical trial design through product review and approval.

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

Sincerely,

Cancer Leadership Council

American Cancer Society Cancer Action Network
American Society for Radiation Oncology
Association for Molecular Pathology
CancerCare
Cancer Support Community
Children's Cause for Cancer Advocacy
Fight Colorectal Cancer
Hematology/Oncology Pharmacy Association
International Myeloma Foundation
Kidney Cancer Association
The Leukemia & Lymphoma Society
LIVESTRONG Foundation
Lymphoma Research Foundation
Multiple Myeloma Research Foundation
National Coalition for Cancer Survivorship
National Comprehensive Cancer Network
National Patient Advocate Foundation
Ovarian Cancer Research Fund Alliance
Prevent Cancer Foundation
Sarcoma Foundation of America
Susan G. Komen