



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

November 5, 2004

Via Telecopy

Lester M. Crawford, D.V.M., Ph.D.
Acting Commissioner
Food and Drug Administration
5600 Fishers Lane
Room 1471- Parklawn Bldg.
Rockville, Maryland 20857

Dear Dr. Crawford:

The undersigned organizations have been engaged in discussions with officials of the Food and Drug Administration (FDA) over the course of the past several years in support of a reorganization of the agency to provide better review and regulation of products to prevent, diagnose, and treat cancer. We were pleased when FDA announced in July 2004 that a new Office of Oncology Drug Products would be established within the Center for Drug Evaluation and Research (CDER), and we are now writing about the appointment of the Director of the new Office.

The success of the new Office and enhancement of cancer product review will depend significantly on the qualifications and qualities of the new Director. We realize that FDA has the ability to tailor its search and appointment process to ensure that the new Director has the skills that are necessary for this important position. We are pleased that FDA has made commitments to include outside experts as part of the selection panel for this position and to recruit a seasoned cancer clinical researcher. As the process for recruiting and evaluating candidates moves forward, we urge FDA to retain as a basic qualification that the Director be a board certified medical oncologist or hematologist with substantial experience in designing and conducting cancer clinical trials. Beyond these fundamental qualifications, the new Director should have the administrative and leadership skills necessary to ensure the smooth functioning of the Office and to attract a critical mass of oncologists to complete the important work of the Office.

Lester M. Crawford, D.V.M., Ph.D.
November 5, 2004
Page 2

Because we have been engaged in discussions about the Office for a number of years and can see the potential for positive results from it, we have a great sense of urgency about the appointment of the new Director. We urge FDA to move with all deliberate speed to evaluate candidates from inside and outside the agency who possess the necessary qualifications to make the Office a success.

Thank you for your consideration of our views on this important matter.

Sincerely,

Cancer Leadership Council

American Society of Clinical Oncology
American Society for Therapeutic
Radiology & Oncology, Inc.
Cancer Care, Inc.
Cancer Research and Prevention Foundation
The Children's Cause for Cancer Advocacy
Coalition of National Cancer Cooperative
Groups
International Myeloma Foundation
Kidney Cancer Association
The Leukemia & Lymphoma Society

Lymphoma Research Foundation
Multiple Myeloma Research Foundation
National Coalition for Cancer Survivorship
North American Brain Tumor Coalition
Sarcoma Foundation of America
The Susan G. Komen Breast Cancer
Foundation
Us Too International Prostate Cancer
Education and Support Network
The Wellness Community
Y-ME National Breast Cancer Organization

cc: Janet Woodcock, M.D.
Acting Deputy Commissioner for Operations