CANCER LEADERSHIP COUNCIL

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

February 24, 2003

Mark McClellan, M.D.
Commissioner, Food and Drug Administration
5600 Fishers Lane
Room 14-71
Rockville, Maryland 20857

Dear Dr. McClellan:

As you know, the oncology community has an abiding interest in steps that might be taken to improve the process of reviewing new products for the prevention, diagnosis and treatment of cancer. We have had recent discussions with officials of the Food and Drug Administration (FDA) that we believe may serve to advance that interest in a manner that not only enhances the efficiency of FDA but also measurably increases the likelihood that cancer patients can access potentially life-extending therapies at an earlier date.

We have advocated the creation of an "Oncology Center" at FDA, but, following our discussions with Dr. Janet Woodcock and her colleagues from the Center for Drug Evaluation and Research (CDER), we now appreciate that the term "Center" has a special meaning within the FDA structure. Clearly, we do not intend to press changes in that structure that would be disruptive to the agency's overall mission.

However, we do insist that review of products for cancer patients be exclusively in the hands of trained cancer specialists. To that end, we were encouraged to hear that a model for such consolidated review already exists at FDA for review of infectious disease products, which are uniformly reviewed in an "Office" dedicated to that therapeutic area. We would be pleased to see the agency move in that direction for purposes of oncology product review, and, with the announced move of many biologics to CDER from the Center for Biologics Evaluation and Research (CBER), there would appear to be a sufficient critical mass of cancer-related products within CBER to justify a dedicated Office for those products.

We urge that the agency initiate planning to achieve a smooth transition to an Office specifically assigned to the review and approval of all regulated products for people with cancer or at risk for cancer and led by trained cancer specialists. Among those products should be included drugs, biologics and devices (including diagnostic tests) currently reviewed by divisions other than the CDER Oncology Products Division if those products are indicated for cancer. This may eventually involve either coordination or shifting of resources among parts of FDA that historically have not been under the guidance of

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oncology experts. But, in the new era of molecular medicine and multidisciplinary approaches to cancer treatment, cancer-specific expertise is essential, and modern oncology principles should govern the review of a wide array of new products.

Most immediately, we would like to express our view that the transfer of products from CBER to CDER should include cancer vaccine products. We understand and agree that traditional vaccines, designed primarily to prevent bacterial or viral infections, belong in CBER. Cancer vaccines, in contrast, are therapeutic rather than preventative and are designed to treat cancer through manipulation of the immune system. It does not appear that cancer vaccines are the same as traditional vaccines in their biology, their uses or the criteria that should be employed in their review and approval. The manner in which cancer vaccines have been studied by investigators and ultimately by CBER has, from time to time, been a source of concern among both physicians and patient advocates, and we believe that review of these products would benefit from their transfer to a consolidated oncology review authority within CDER. While we appreciate that any transition must be orderly and mindful of resource needs, current planning should envision that cancer vaccines would be part of an oncology Office within CDER.

We are pleased with our discussions with both CDER officials, ranging from CDER Director Woodcock to the current head of CDER's Oncology Products Division Dr. Richard Pazdur, and are confident that this much-needed consolidation of oncology review at FDA will succeed.

Thank you again for your interest in our perspective about the role FDA plays in bringing safe and effective cancer agents and devices to market. We look forward to working with you and your staff to ensure that products for cancer patients and those at risk for cancer are in the hands of trained oncology experts.

Sincerely,

Cancer Leadership Council

Alliance for Lung Cancer
American Society of Clinical Oncology
American Society for Therapeutic Radiology & Oncology, Inc.
Cancer Care, Inc.
Cancer Research and Prevention Foundation
Coalition of National Cancer Cooperative Groups
Colorectal Cancer Network
Kidney Cancer Association
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