



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

November 15, 2000

Via Telecopy and Federal Express

Janet Woodcock, M.D.
Director, Center for Drug Evaluation and Research
Food and Drug Administration
1451 Rockville Pike - Suite 6027
Rockville, Maryland 20852

Dear Dr. Woodcock:

The undersigned organizations provide educational, advocacy and other services to people with cancer, their families and their caregivers. People with cancer are desperate to have access to new anticancer medicines, not only for the sake of more effective treatment but also in support of better quality of life, including less toxic and more convenient modes of therapy.

Most current anticancer drugs are accompanied by potentially serious side-effects, and, because they are administered intravenously, they require involvement of a physician, nurse, or other cancer specialist. While careful monitoring of patients receiving any type of chemotherapy is an important factor, intravenous administration of drugs can by itself create a hardship for patients living in remote rural areas not directly served by a cancer specialist.

The availability of oral anticancer medications with improved toxicity profiles and efficacy roughly equivalent to intravenous alternatives is an important step for cancer patients. If an oral compound under review by the Food and Drug Administration (FDA) exhibits efficacy that is comparable to the intravenous drug alternative, demonstration of reduced toxicity or other contributions to quality of life should be given great weight in the deliberations of reviewers. Aside from the benefits of reduced toxicity, quality of life for cancer patients can be enhanced and should be valued along with other improvements in care.

Cancer is a highly individualized disease, and the more treatment options available the better, so long as neither safety nor efficacy is sacrificed. Moreover, patient convenience and quality of life are important considerations that should argue for the availability of oral drug alternatives. We encourage the agency to take these patient-oriented concerns into account in its review of oral anticancer medications.

Many of us have previously expressed support for enhanced availability of oral anticancer drugs, but there seems to be new urgency to the matter now as several oral compounds to treat advanced colorectal cancer are awaiting approval. When one of these drugs was reviewed by FDA's Oncology

Drug Advisory Committee, it was recommended unanimously for approval, and recent reports are that it has been approved for use in metastatic colon cancer by virtually every European country. Nevertheless, it is still not available to patients here in the United States, nor is a second oral drug for colorectal cancer that seems to offer a similar clinical profile.

This situation has raised in our minds concerns about the nature of the review process for oncology products. The Advisory Committee includes some of the most respected clinical researchers in the field of oncology. If FDA's review leads it to a conclusion that is at odds with their recommendation, the quality and consistency of the review process may be subject to question.

We remain very interested in rapid availability of these pending oral drugs, but we also want to stress the need for a more generalized examination of the review of oncology products to ensure that FDA decisionmaking that affects people with cancer is in accord with the best oncologic clinical science. We look forward to working with you and your colleagues to achieve that result.

Sincerely,

Cancer Leadership Council

American Society of Clinical Oncology
Cancer Care, Inc.
Cancer Research Foundation of America
The Children's Cause, Inc.
Coalition of National Cancer Cooperative Groups
Colorectal Cancer Network
Cure For Lymphoma Foundation
International Myeloma Foundation
Kidney Cancer Association
The Leukemia & Lymphoma Society
Multiple Myeloma Research Foundation
National Coalition for Cancer Survivorship
National Patient Advocate Foundation
National Prostate Cancer Coalition
Oncology Nursing Society
Pancreatic Cancer Action Network
The Susan G. Komen Breast Cancer Foundation
The Wellness Community
US-TOO International, Inc.
Y-ME National Breast Cancer Organization

cc:

Jane E. Henney, M.D.
Commissioner, FDA