

LYMPHOMA

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July 30, 2004

The Honorable Lester Crawford, D.V.M, Ph.D
Acting Commissioner
Food and Drug Administration
Parklawn Building
5600 Fishers Lane
Room 1471
Rockville, MD 20857

RE: Docket No. 2004-N-0181

Dear Dr. Crawford:

The Lymphoma Research Foundation (LRF) is the nation's largest lymphoma-focused voluntary health organization devoted exclusively to funding lymphoma research and providing patients and healthcare professionals with critical information on the disease. We appreciate the opportunity to comment on the report, "Innovation/Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products," and to offer recommendations to improve the development of new cancer therapies.

We appreciate FDA's effort to identify problems in the development of new therapies and to invite proposals from the public regarding ways to improve product development. Over the last decade, the federal investment in basic research has accelerated, resulting in significant advances in our fundamental understanding of many diseases and yielding important information about possible new treatments for a wide range of diseases. However, the translation of basic science into new treatments is much too slow. We propose several FDA initiatives that will contribute to a stronger and more efficient cancer product development process.

Reliability of the Regulatory Process

In previous debates on reform of FDA and authorization of a system of user fees, Congress has urged FDA to make its regulatory process more predictable to sponsors of new products and to foster more productive communication between sponsor and regulators. In spite of progress on this matter, some believe the relationship between the agency and drug sponsors remains too adversarial. We hope that the establishment of the new Office of Oncology Drug Products, which will consolidate the review of many oncology products, will lead to a more constructive relationship between sponsors and regulators.

By placing most oncology product review responsibilities in one office, the agency can nurture a group of experienced and well-trained oncology reviewers. We urge that improved communication with drug sponsors – initiated at the earliest possible point in the regulatory process – be a core goal of the new Oncology Office.

Enhancing the Clinical Trials Process

One of the principal complaints we hear from clinical researchers is that the clinical trials process remains inefficient. Among the problems cited are inefficiencies in data collection and monitoring and duplicative review by institutional review boards (IRBs). We acknowledge that these matters extend beyond the jurisdiction of FDA, but we also note the recent formation of the Oncology Program, which will have cross cutting cancer policy responsibilities. The Oncology Program is charged with facilitating expert consultation across agencies, taking the lead in the development of new policies and procedures related to review of new cancer products, and ensuring collaboration among various cancer constituencies. We recommend that one of the top priorities of the Oncology Program be a review of

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obstacles to the efficient completion of cancer clinical trials, with a goal of producing recommendations for reform at FDA and sister agencies within the Department of Health and Human Services (HHS).

Availability of Public Information about Clinical Trials

The Food and Drug Administration Modernization Act of 1997 (FDAMA) authorized the development of a database of clinical trials for treatments of serious and life-threatening illnesses, and this database became operational in 2000. Despite the availability of this resource and the clinical trials educational and outreach efforts of LRF and similar organizations, cancer clinical trials enrollment still totals only about 3-5 percent of all cancer patients. We will continue our lymphoma-related clinical trials education activities, and we feel certain other research and patient advocacy organizations will, as well. However, there would be tremendous benefit from coordination of clinical trials education and outreach. This is another area where leadership from the new Oncology Program would be appropriate.

Standard for Approval of Cancer Drugs

When Congress enacted FDAMA in 1997, it endorsed the assumption that, as a general rule, two adequate and well-controlled studies are needed to prove a product's safety and effectiveness. At the same time, Congress acknowledged that in certain circumstances one clinical investigation may be the basis for product approval. The consolidated Oncology Office will presumably contribute to the consistent application of regulatory standards and will hopefully also lead to more approvals on the basis of a single clinical trial. We note that the average drug development time of more than seven years exceeds the anticipated years of survival for those diagnosed with many forms of lymphoma. All parts of the drug development process must be accelerated, including review by FDA.

We appreciate the opportunity to comment on the Critical Path document and look forward to continued collaboration with FDA on strategies to improve cancer product development.

Sincerely,



William D. Hawley, MD
President

Cc: Joseph R. Bertino
Chairman, LRF Scientific Advisory Board
Suzanne R. Bliss
Executive Director