



July 30, 2004

Lester M. Crawford, D.V.M., Ph.D.  
Acting Commissioner  
Food and Drug Administration  
5600 Fishers Lane  
Room 1471 – Parklawn Bldg.  
Mail Stop HF-1  
Rockville, Maryland 20857

RE: Docket Number 2004N-0181

Dear Dr. Crawford:

The National Coalition for Cancer Survivorship (NCCS), a national organization advocating for survivors of all types of cancer, is pleased to comment on the Food and Drug Administration (FDA) report, "Innovation/Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products."

For a number of years, NCCS has recommended reform of cancer product review at FDA to ensure that new therapies are made available to cancer patients as rapidly as possible. NCCS notes that the establishment of the Office of Oncology Drug Products, including the Oncology Program, may contribute to an enhanced review process for cancer products. This letter identifies ways in which the Oncology Office and Oncology Program may function to improve and accelerate cancer drug development and address drug development issues identified in the Critical Path report.

#### **Strengthened Cancer Drug Review Staff**

Of central concern to cancer patients is the speed and efficiency of the FDA review process. We are concerned that a delay in the review of a product not only postpones the availability of that particular product, but may also slow the overall cancer drug development process and adversely affect the investment in cancer product research and development. The consolidation of review of many cancer products in a single office and hiring of oncologists with clinical trials expertise should address some of the inefficiencies of the review process.

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NCCS commends FDA for its commitment to conduct a national search for an oncologist to head the Oncology Office. It is important that this search be initiated soon and the leader of the office be named expeditiously. The appointment of a strong leader with clear authority over cancer product review will significantly influence the ability of the office to attract and retain other oncologist reviewers. A high-quality oncology review staff is the single most important element of an improved cancer drug review process.

### **Evaluation of Cancer Review Reorganization**

The Critical Path document explains that agency reviewers "... see the complete spectrum of successes and best practices during clinical trials, as well as failures, slowdowns, barriers, and missed opportunities that occur during product development." According to the Critical Path, reviewers are in a position to share with drug sponsors, including through guidance documents, information about drug development best practices. With the consolidation of significant oncology product review in a single office, the opportunity to observe and share oncology drug development best practices will be enhanced. NCCS urges that new Oncology Office to undertake this sort of education of sponsors on an ongoing basis.

### **Improved Clinical Trials Information**

The speed of cancer drug development is tied to the rate of completion of clinical trials, and a serious obstacle to more rapid completion of cancer clinical trials is the low rate of participation in those trials by adults. The cancer community – patient advocacy organizations and cancer care providers – has for a number of years been engaged in efforts to boost the rate of clinical trials participation. We believe that the necessary tools in this campaign are accurate information about available clinical trial opportunities, education about the benefits and burdens of clinical trials participation, removal of financial barriers to participation, and oncologists willing to refer patients to trials.

For a number of years, FDA has played a role in dissemination of information about cancer clinical trials. FDA has the authority, under the Food and Drug Administration Modernization Act of 1997 (FDAMA), to establish a database of information on clinical trials for treatments for serious and life-threatening illnesses. This database, implemented in 2000, has recently been criticized because of its incomplete listing of trials. Although NCCS supports improvements in the database, we do not believe that tool alone will significantly affect cancer clinical trials enrollment rates. Instead, the comprehensive education and information effort of the cancer community must be expanded.

The Oncology Program, a component of the Oncology Office with cross-cutting responsibility for facilitating collaboration among HHS agencies and ensuring collaboration among cancer constituencies, can provide important leadership on issues related to clinical trials enrollment.

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We urge that strategies for boosting cancer clinical trials participation, including strategies that can be implemented through the existing network of Cancer Cooperative Groups, become an area of focus for the Oncology Program.

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NCCS appreciates the opportunity to comment on the Critical Path document. We look forward to working with FDA to enhance the drug review process and speed access to life-saving cancer therapies.

Sincerely,



Ellen L. Stovall  
President & Chief Executive Officer

cc: Division of Dockets Management (HFA-305) ✓