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May 14 - May 17, 2005

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July 30, 2004

Lester M. Crawford, DVM, Ph.D.
Acting Commissioner
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Dear Dr. Crawford:

The American Society of Clinical Oncology (ASCO) congratulates the Food and Drug Administration (FDA) for commencing a dialogue about impediments to development of new products for disease prevention, diagnosis and treatment in the United States. We hope that FDA's report, "Innovation/Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products," will stimulate researchers in both academia and industry to identify specific recommendations for improvement in the product discovery and development process.

As the leading organization for cancer specialists, ASCO has a deep and abiding interest in the policies and practices of FDA because products regulated by the agency, particularly FDA-approved drugs and biologics, have enabled significant progress in cancer therapy over the past several decades. As noted in the "Critical Path" report, society is currently blessed by substantial new knowledge about basic science, but we have not successfully capitalized on that knowledge by translating it into clinical applications. Certainly this is as much a problem in cancer as in any other disease entity, and there is no question that FDA must play a pivotal role in addressing this shortfall.

In cancer, however, FDA has taken an initial step toward enhancing the development process by agreeing to create a new Office of Oncology Drug Products, which will consolidate review activities that were formerly in different parts of the agency. We believe that such consolidation will improve both the speed and quality of product evaluation and will begin to provide a critical mass of oncology expertise that will help FDA assume a leadership role in product development. ASCO looks forward to working with FDA in its implementation of the new Office and the selection of a qualified cancer specialist to direct it.

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Even prior to the announcement of the new Office, ASCO has enjoyed a rewarding collaboration with FDA under the current leadership of the Oncology Drug Division within the Center for Drug Evaluation and Research (CDER). ASCO and FDA have participated in a series of workshops to consider appropriate endpoints for drugs to treat certain solid tumors, an exercise that provides industry with clearer guidance as to the standards by which their products will be assessed. ASCO expects this collaboration to continue and expand.

Of course, the endpoints identified by FDA through this process are determined within the context of current FDA policy on determinations of safety and efficacy. We assume that the "Critical Pathways" undertaking represents an opportunity to go beyond current practices to consider new policies or guidelines within existing statutory constraints as well as the possibility of changes in statute that might permit altogether new and different approaches to product development. ASCO welcomes the openness of FDA to consideration of innovative pathways to speed access to new products to prevent, diagnose and treat serious or life-threatening diseases like cancer and would be eager to make any contribution to this important effort.

Sincerely,



David H. Johnson, MD
President

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