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2006 Annual Meeting

June 2–June 6, 2006

Atlanta, Georgia

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October 28, 2005

Andrew C. von Eschenbach, M.D.

Director

National Cancer Institute

31 Center Drive – Building 31

Room 11-A-48

Bethesda, Maryland 20892

Re: Critical Path Initiative; Developing Prevention Therapies;
Planning of Workshop [Docket No. 2005N—0311]

Dear Dr. von Eschenbach:

As you know, the American Society of Clinical Oncology (ASCO), with more than 23,000 members worldwide, is the leading medical society for physicians involved in cancer treatment and research. ASCO strongly supports the efforts of the Food and Drug Administration (FDA) to identify, through its Critical Path Initiative, new approaches to development of chemoprevention strategies to prevent cancer and other serious or life-threatening diseases. The planned workshop to discuss these issues among the various interested parties represents a commendable first step in achieving Critical Path successes in the important arena of chemoprevention, and ASCO is pleased to offer the following comments.

First, we note several minor additions that might bolster the case for chemoprevention of cancer. Under question no. 1.c., “prostate cancer” could be added to the relatively short list of successful chemopreventive therapies in cancer. It is also worth noting, in the “Background” discussion, that tamoxifen has been demonstrated to prevent breast cancer in women with an increased risk of developing the disease, in addition to its role in reducing the risk of recurrence of previously diagnosed and treated breast cancer.

Second, we believe that several other examples might be referenced in connection with both “specific regulatory concerns” in question no. 6 and “obstacles facing manufacturers” in question no. 7. They include the necessity for large sample sizes and the lack of clarity about acceptable endpoints. In addition, given the extended time frame required for many chemoprevention trials, we urge FDA to consider dialogue with industry as to the advisability of special intellectual property incentives to ensure that the long lead time to approval does not discourage development of chemoprevention agents.

Finally, and perhaps most fundamentally, the Federal Register Notice does not address adequately the important research and regulatory opportunities involving the role of infectious diseases in cancer etiology. Among the known associations between infectious agents and cancer are *Helicobacter pylori* in gastric cancer; Hepatitis B virus in liver cancer; human papilloma virus (HPV) in cervical cancer; and Epstein-Barr virus in Burkitt’s lymphoma, nasopharyngeal carcinoma and perhaps breast cancer.

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Antibiotic therapy has been found effective in *H. pylori* eradication, and a vaccine has been demonstrated effective against Hep B in liver cancer and, more recently, against HPV and cervical cancer. Often these infectious agents and the cancers they cause disproportionately affect people in less developed parts of the world, where prevention strategies offer even more advantages than in the United States or other developed nations.

Clearly, in certain situations, prevention strategies can be very effective against infections that cause cancer. However, from a regulatory perspective, it is important to recognize that the FDA staff reviewing such products reside in a different part of the agency from that involved with cancer drugs or cancer policy. We urge better integration of the Center for Biologics Review and Evaluation (CBER) into the Critical Path Initiative for the purpose of addressing in the most comprehensive manner possible the utilization of vaccines and perhaps other biologic interventions for cancer prevention. Vaccines and other interventions targeting the underlying infection may prove among our most effective approaches to preventing cancers that inflict morbidity and mortality on millions of people across the globe, and all the resources of FDA should be harnessed collaboratively to optimize their impact.

We appreciate the opportunity to comment on this important Critical Path Initiative and look forward to the workshop, where ASCO would be pleased to offer prevention experts from the ranks of its membership to serve as formal participants in the process.



Sandra Horning, MD
President American Society
of Clinical Oncology (ASCO)



Judy E. Garber, MD
Chair, ASCO Cancer
Prevention Committee

cc: Division of Dockets Management [HFA-305]
Food and Drug Administration
5630 Fishers Lane – Room 1061
Rockville, Maryland 20852

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