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January 19, 2006

Ernest Hawk, MD, MPH  
Director, Office of Centers, Training, & Resources  
National Cancer Institute/Office of the Director  
6116 Executive Boulevard, Room 7000  
Rockville, MD 20852

Dear Dr. Hawk:

As the world's leading medical society for physicians involved in clinical cancer research and treatment, the American Society of Clinical Oncology (ASCO) has had a longstanding interest in and commitment to translational research as the pathway to improved outcomes for people with or at risk for cancer. Thus, ASCO welcomes the charge given by the National Cancer Institute (NCI) to the Translational Research Working Group (TRWG): "to help chart the Institute's future course by evaluating the status of NCI's investment in translational research and suggesting a vision for its future."

ASCO itself has convened a Translational Research Task Force, which is in the process of finalizing recommendations for consideration by the ASCO Board. These recommendations will guide ASCO in refining its scientific and educational programs and research policy to realize the promise of translational research for the benefit of our members' patients. Like the TRWG, the ASCO Task Force recognized at the outset that, in order to make recommendations to the Society to promote translational research, it was essential to deliberate and agree upon its definition. The proposed ASCO definition is considerably more succinct than that developed by the TRWG, and we commend the ASCO definition to the TRWG for its consideration:

"Translational research is the spectrum of scientific investigation that links basic discovery to causation, prevention, detection and treatment of human disease."

If the TRWG retains its more lengthy definition, ASCO would point out that it seems to contain no reference to cancer prevention. ASCO believes that prevention is a vital area of translation from basic science discovery to clinical application, and we urge the TRWG to make prevention an important focus of its deliberations and include prevention in its definition of "translational research."

ASCO recommends that the TRWG, in developing its definition, consider the potential for significant translational research through the entire spectrum of clinical investigations. A comprehensive view of translational research should extend beyond early phase testing in order to continue to exploit discovery opportunities as they arise in phase 2 and phase 3 clinical trials.

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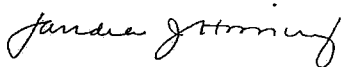
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ASCO would also encourage the TRWG to convey a sense of urgency about the risk of missed opportunities in this arena. Over a recent five-year period, the budget of the National Institutes of Health, including NCI, has been doubled by the Congress. A great deal of new information is becoming available about disease mechanisms and the Congress and the public expect these scientific advances to translate to clinical advances in cancer prevention, detection and treatment. The work of the TRWG should be central to identification by NCI of a coherent and persuasive strategy for the timely and effective linking of basic discovery to clinical application, which is essential to continued public support of the cancer research enterprise.

Aside from the importance of justifying the investment of vast public resources in biomedical research, a clear pathway for translational research advances is necessary to keep the next generation of researchers engaged in the effort. ASCO believes that a major focus of the TRWG should be the development of new funding mechanisms that are specifically designed to bridge the gap between basic and clinical science. Such new approaches are required to attract and retain the best scientific talent in the quest for new methods of preventing, diagnosing and treating cancer. Although the consideration of new mechanisms will cover the current questions about the future of the Specialized Programs of Research Excellence (SPOREs) in their present form, we urge the TRWG to broadly consider potential funding mechanisms, which might include modifications of the SPORES or other disease-based or mechanistic-based programs.

ASCO appreciates the chance to comment on the TRWG process, which is arguably the most significant current initiative of NCI. As the mission and goals of the group are further developed, ASCO will look forward to continued dialogue with the leadership of the TRWG to help ensure the best possible recommendations and strategies in support of translational research.

Sincerely,



Sandra J. Horning, MD  
ASCO, President

cc: Andrew von Eschenbach, Acting Commissioner of the U.S. Food and Drug Administration  
John E. Niederhuber, Chief Operating Officer of the National Cancer Institute  
William G. Nelson, M.D., Ph.D., Co-Chair, NCI Translational Research Working Group  
Lynn Matrisian, Ph.D., Co-Chair, NCI Translational Research Working Group