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April 15, 2010

John E. Niederhuber, MD  
Director, National Cancer Institute  
National Institutes of Health  
31 Center Drive, Building 31  
Bethesda, MD 20892-0160

Dear John:

I am writing on behalf of the American Society of Clinical Oncology (ASCO) to express our strong support for the recommendations contained in the Institute of Medicine (IoM) report, "A National Cancer Clinical Trials System for the 21<sup>st</sup> Century: Reinvigorating the NCI Cooperative Group Program." As you know, ASCO represents more than 28,000 oncology professionals in the US and throughout the world who are engaged in research and treatment of cancer patients in both the academic and community setting.

The IoM report comprehensively articulates the vital role that Cooperative Group research plays in advancing cancer prevention and treatment. The report notes that our Cooperative Group infrastructure is the "primary mechanism by which the value of therapeutic agents can be assessed within the medical milieu of the U.S. health care system." Since their inception in the mid 1950s, Cooperative Group trials have provided or enabled virtually all the important scientific advances in cancer prevention, treatment, and quality of life of the last half century. The importance of these collaborative networks will increase exponentially as NCI leads the way in our growing understanding of the cancer genome.

Without doubt, the Cooperative Group system faces many challenges. The NCI is already playing an important role in helping to prioritize trials and address inefficiencies in the system. ASCO supports work the NCI is already undertaking to implement the recommendations of both the Clinical Trials Working Group (CTWG) and Operational Efficiency Working Group (OEWG). The IoM report builds on these recommendations by calling for consolidation of Cooperative Group operations, improved collaboration, and a revised role for NCI in facilitating cooperative group trials. ASCO believes that the combination of CTWG, OEWG, and IoM recommendations will help pave the way for a clinical trial system that is the "robust, standing cancer clinical trials network" that the IoM envisions.

Administrative changes alone cannot sustain this vital clinical research system. Without adequate funding, continued success of Cooperative Group trials is in jeopardy. In a recent survey of cooperative group participants, ASCO learned that one-third of participating sites plan to limit participation in cooperative group

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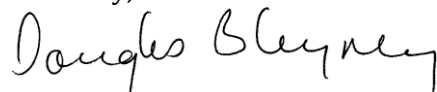
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trials in the coming year. Inadequate reimbursement was a key factor in this decision. To reverse this trend—and to correct persistent, longstanding erosion of funding—ASCO calls on the NCI to double funding for Cooperative Clinical Research. This would increase the current funding levels from approximately \$250 million today to \$500 million by 2015. This increase would provide support to the Cooperative Groups, Cooperative Group member institutions, and the Community Clinical Oncology Program (CCOP).

In real dollars, total funding for Cooperative Clinical Research is less today than a decade ago. While overall NCI funding has increased, funding for Cooperative Group trials has been virtually flat since 2002. We certainly understand the difficult decisions that NCI makes as it considers priorities across the entire spectrum of research. The increase we are requesting will likely require both internal reallocations, as well as increased funding from Congress. ASCO is already actively involved in advocating for increased funds for FY2011 and will continue to make the case in light of the IOM report. However, we believe the system is at a critical juncture and increased funding is essential to ensure that it continues.

As the IoM notes, “the ability to translate biomedical discoveries into advances in care for patients with cancer remains dependent on the clinical trials system.” We cannot stress enough the importance of having a federally funded trials system as an active participant in the clinical trials system. We are eager to work with NCI to increase funding for Cooperative Clinical Research and implement the changes called for by the IoM report.

Sincerely,

A handwritten signature in black ink that reads "Douglas Blayney". The signature is written in a cursive, flowing style.

Douglas W. Blayney, MD  
ASCO President  
Professor of Internal Medicine,  
University of Michigan School of Medicine