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October 26, 2009

Francis Collins MD, PhD  
Director  
National Institutes of Health (NIH)  
9000 Rockville Pike  
Bethesda, Maryland 20892

Dr. Collins:

We appreciate your welcoming the leadership of scientific societies and advocacy organizations to the NIH campus on September 9. In response to your request at that meeting, the American Society of Clinical Oncology (ASCO) is providing our thoughts about priorities for the Institutes.

As you continue to plan the direction of the Institutes, we hope you will consider the priorities identified by ASCO in the attached document. ASCO is the professional oncology society, with over 27,000 members in the US and worldwide, whose members are researchers and clinicians devoted to the cancer problem and to cancer patients. ASCO shares your interest in maintaining sustained funding for NIH that keeps pace with increases in the cost of biomedical research and scientific advancements.

ASCO is eager to work with you, the National Cancer Institute, and the other Institutes that support cancer research to achieve your goals for our federal biomedical research enterprise. We will be in touch as we identify opportunities for partnership. We welcome you to contact our CEO and your former colleague, Allen Lichter ([allen.lichter@asco.org](mailto:allen.lichter@asco.org)), as well. We appreciate your leadership of the Institutes during this time of transition.

Sincerely,

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

cc: John Niederhuber, MD, Director, National Cancer Institute

## **Translating Scientific Discoveries into Patient Care**

The American Society of Clinical Oncology (ASCO) appreciates the opportunity to inform the NIH regarding ASCO's priorities for the Institutes. ASCO looks forward to continued collaboration with the NIH and appreciates the important priorities you have established for our research enterprise.

### **Increasing NIH Support for Clinical Trials:**

ASCO's members have a firm commitment to increasing our translation of basic scientific discoveries into improved clinical outcomes for our patients. NIH and NCI have assembled a federally funded clinical trials mechanism (through the Cooperative Groups, Community Clinical Oncology Program, and National Community Cancer Centers Program) that reaches into every community in which cancer care is delivered. This infrastructure generates evidence that leads to practice-changing treatments. As we move into an era in which tumors are divided into distinct molecular subsets, the NCI clinical trials network is unique in its ability to assemble sufficient numbers of patients to conduct complex clinical trials. The recent infusion of stimulus funding will generate vital basic and translational scientific advancements. We must ensure that we have a vibrant clinical trials mechanism to reap the clinical benefits from these advances.

ASCO recognizes that the stimulus funds could not be used to stimulate new clinical trials because of the 2-year timeframe. As a result, NCI funding for clinical research has remained essentially flat since the end of the NIH budget doubling period. Unless there is a substantial investment in the clinical trial system, we will be unable to increase the number of clinical trials or expand patient participation in clinical trials. Furthermore, ASCO is concerned that the per-case reimbursement that the NCI provides to help sites cover the costs of conducting clinical research is inadequate to account for the actual costs. As a consequence, there is a disincentive for sites to participate in NCI-funded trials. To grasp the significance of this issue, ASCO polled sites conducting Cooperative Group trials. Of the 518 responding sites, 32% indicated decisions to limit Cooperative Group participation and 75% cited inadequate reimbursement as their reason to limit accrual.<sup>i</sup> Of sites limiting Cooperative Group participation, 42% reported plans to increase industry trial participation. These data signify an ongoing commitment to clinical research, but highlight the constraints that arise from insufficient NCI funding. Importantly, many sites expressed a clear preference for conducting NCI-funded clinical trials because of their scientific rigor, but were limited by financial constraints.

The long-term effect of these trends can be devastating, jeopardizing the Cooperative Group infrastructure that facilitates adequate accrual on trials of small populations, collection of epidemiologic and biospecimen data unattainable through industry trials alone, and access to trials in community settings where the majority of patients receive care. Furthermore, these research networks will be critical to conducting the clinical studies that are necessary to validate NCI's important investment in The Cancer Genome Atlas.

An ASCO study completed in 2003 determined that the actual cost of conducting clinical trials averages \$6,000 per patient. NCI's current \$2000 payment falls far short of meeting these needs. Increasing rates to this more realistic amount would require spending an additional 2.4% of NCI's current budget or adding \$120 million to the NCI budget.

Translating basic science into clinical practice requires a successful clinical trial infrastructure. ASCO strongly urges NIH to reevaluate per-case reimbursement and strengthen the infrastructure that supports this important research area. In addition to the NCI, significant funding for cancer research also comes through various NIH institutes and ASCO encourages a harmonized effort to support the many dimensions of cancer research.

### **Managing Workforce Concerns Through Innovative Training:**

As the population ages and pediatric and adult 5-year cancer survival rates increase (79% and 64% respectively<sup>ii</sup>), the need for oncology-trained specialists becomes ever more apparent. Results from ASCO workforce studies conclude that demand for oncology care will increase by 48% by the year 2020, but the predicted number of oncologists will only increase by 14%.<sup>iii</sup> Fellowship directors report that despite continued excellence in the available pool of applicants, limited funding prevents efforts to expand the size and number of oncology-training programs. The unintended consequence is that qualified applicants are turned away from the field. Of the directors who plan to expand oncology-training programs, 22% say they will do so with support from industry funding, a practice that is the focus of increased scrutiny and becoming less available.<sup>iv</sup>

ASCO encourages NIH to enhance innovative training methods that promote the development of clinical researchers and increase accessibility to evidence-based education. A strategic review of current and predicted trends should guide the development of K, T32, and R25 grants with the goal of ensuring that medical professionals and clinical researchers are trained in underrepresented areas. ASCO has also engaged fellowship programs in our Quality Oncology Practice Initiative (QOPI®). This program introduces fellows to the principles of data-driven practice improvement, and self-assessment regarding the use of evidence-based medicine.

### **Harmonizing Biospecimen Collection and Regulatory Compliance:**

The future of our understanding and treatment of cancer is being shaped by current clinical and translational research. The latter is highly dependent on the collection of biospecimens. NCI has led the way in developing standards for biospecimen collection and storage. Although this leadership is critical, a successful effort to collect specimens also depends on adequate compensation for appropriate informed consent as well as specimen collection and storage. In addition, we believe that NCI should address challenges that may be unique to collecting biospecimens in community-based settings where 76% of oncology patients currently receive care.<sup>v</sup> NCI's Office of Biorepositories and Biospecimens (OBRR) is beginning to address these issues with National Community Cancer Center Program sites, and ASCO urges continued expansion of this effort. Expanding community involvement assures that biospecimens are acquired from diverse patient populations and are linked to longitudinal clinical information collected by the primary oncologist.

Regulatory compliance is still a major obstacle when conducting clinical research. The HIPAA Privacy Rule has added undue expense, complexities, and delays in initiating certain types of cancer studies.<sup>vi</sup> An ASCO study indicates that the ambiguity and confusion regarding HIPAA accounts for a myriad of difficulties. ASCO is working with experts in the oncology field to develop case-based guidance regarding survivorship research, germline DNA studies, and biorepositories.<sup>vi</sup> We plan to share these draft documents with NIH for its consideration.

ASCO encourages NIH to continue developing resources such as caBIG that promote standardized and real-time reporting. ASCO and NCI are currently working together on efforts to harmonize EHR capabilities specific to oncology-care and continue to see this as a priority. Standardization of Institutional Review Board functions are also needed, especially in cases of multi-center trials when inconsistency among IRBs can affect the way a study is conducted and potentially influence the validity of the outcomes. Regulatory burden is a real issue limiting clinical research and exhausting study resources. ASCO encourages NIH to work with the Food and Drug Administration, Office for Human Research Protections, and Office for Civil Rights to focus on harmonization of federal regulatory requirements for research. We are eager to assist with these efforts.

**Transforming the Pipeline:**

Researchers voice interest in increasing partnerships between private and public sectors regarding pharmaceutical, device and biotech development. Millions of compounds with potential anti-cancer activity exist but few are sufficiently studied and developed by Industry. Inadequate development is a frequent problem in diseases that affect small patient populations because of modest potential for producing significant return on investment. Developing partnerships in the public sector to fund and study these treatments will ensure that development is possible and costs are controlled when they reach the market. We applaud NCI's focus on this issue with its Chemical Biology Consortium. We also encourage the NCI to continue to promote collaborations between industry, the investigator community, and government to advance our understanding of marketed and pipeline agents and devices. To the greatest extent possible, these partnerships should recognize the value contributed by the publicly funded clinical trials system, preserve scientific inquiry, and protect the intellectual property of all parties involved.

Once again, ASCO appreciates this opportunity to inform the NIH and hopes to strengthen collaborative efforts as we work together to make "a world of difference in cancer care."

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<sup>i</sup> American Society of Clinical Oncology. (Expected Publication January 2010). Cooperative Group Poll. Arlington, VA.

<sup>ii</sup> American Society of Clinical Oncology. (2005). ASCO Undertakes Oncology Workforce Study. *Journal of Oncology Practice*, 127.

<sup>iii</sup> Erikson, C., Salsberg, E., Forte, G., Bruinooge, S., & Goldstein, M. (2007, March). Future Supply and Demand for Oncologists. *Journal of Oncology Practice*, 79-86.

<sup>iv</sup> Erikson, C., Schulman, S., Kosty, M., & Hanley, A. (2009). Oncology Workforce: Results of the ASCO 2007 Program Directors Survey. *Journal of Oncology Practice*, 62-65.

<sup>v</sup> American Society of Clinical Oncology. (2008, November). Current Procedural Terminology 2009 Coding Changes for Drug Administration. *Journal of Oncology Practice*, 298-299.

<sup>vi</sup> Goss, E., Link, M., Bruinooge, S., Lawrence, T., Tepper, J., Runowicz, C., et al. (2009). The Impact of the Privacy Rule on Cancer Research: Variations in Attitudes and Application of Regulatory Standards. *Journal of Clinical Oncology*, 4014-4020.