



Making a world of difference in cancer care

**Recommendations from the American Society of Clinical Oncology
Relating to the National Institutes of Health and the National Cancer Institute
for the HHS Agency Review Team**

January 5, 2009

The American Society of Clinical Oncology (ASCO) is the world's leading professional organization representing physicians who treat people with cancer. Approximately 1.5 million Americans will be diagnosed with cancer this year, and 1 American dies of the disease every minute. ASCO is dedicated to promoting the best interests of cancer patients, and we look forward to working with President-Elect Obama, HHS secretary-designate Daschle, the National Institutes of Health (NIH) and the National Cancer Institute (NCI) on these issues to ensure patients have meaningful access to high-quality cancer care and cutting edge clinical cancer research.

Representing over 27,000 oncology professionals, ASCO is uniquely positioned to serve as a resource for scientific and practical guidance for policy makers. In particular, ASCO has longstanding initiatives designed to help support cancer research, translate scientific evidence into clinical guidelines, and ensure that all patients have access to high quality cancer care within their communities.

We welcome the opportunity to offer the following recommendations about how best to position NIH and NCI to address the opportunities and challenges that face cancer patients in the United States in the coming years.

Provide an Increase of \$3 Billion to NIH as Part of the Economic Stimulus Package:

Our nation's commitment to funding cancer research is waning. Adjusted for inflation, the NIH budget has fallen 13 percent since 2003, and the NCI budget has fallen 12 percent since 2004.¹ This is occurring at a most inopportune time – when our expanding knowledge about the molecular basis of cancer presents us with unprecedented opportunities for clinical research on new treatments. Although cancer deaths are decreasing, incidence is stabilizing, and survival rates are increasing. The need to be innovative in cancer prevention, diagnosis, and treatment could not be greater. Cancer accounts for more deaths than heart disease in persons under age 85 years² and the aging of the Baby Boom population will lead to a 48% increase in demand for oncology care by 2020.³

In addition to improving the quality of cancer care, reversing the longest sustained period of flat funding for research will provide a critical and timely economic stimulus to our communities. For every dollar spent on NIH, there is an economic benefit of \$2.21 of new business activity.⁴ This benefit can be realized in a matter of weeks, with NIH disbursing grants that allow continuation of groundbreaking work in institutions across the U.S. We also request that any NIH increase included in the economic stimulus bill be included in the NIH base budget for subsequent funding years.

Provide Stable Funding to NIH and NCI in Future Years:

We support President-Elect Obama's plan to double the NIH budget over the next ten years. It is important that this overall goal be accomplished through predictable and steady increases. We should also ensure that another period of funding stagnation does not follow any budget-doubling effort. In the long run, stable funding will provide the greatest opportunity for NIH planning and fostering the most promising scientific opportunities.

¹ Biomedical Research and Development Price Index

² Jemal A, et al. Cancer Statistics 2008. CA Cancer J Clin; 58:71-96; 2008.

³ Erikson C, et al. Future Supply and Demand of Oncologists: Challenges to assuring access to oncology services. J Oncol Pract 3:79-86; 2007.

⁴ In Your Own Backyard: How NIH Funding Helps Your State's Economy. Families USA Global Health Initiative, June 2008.



Strengthen the National Clinical Trials System within the United States:

NCI funding currently helps link hundreds of academic and community-based researchers in the conduct of NCI-funded research. Collectively, NCI-funded investigators enroll approximately 60,000 patients annually on clinical trials and generate practice-changing treatments. The emphasis of the trials is on the best treatment approach for the patient, providing the ability to combine different drugs and treatment modalities, and answering questions aimed at assessing clinical effectiveness. In addition, these trials are generating specimen databanks with annotated clinical data that provides invaluable information to further treatment advances. Results of NCI-supported clinical trials not only improve outcomes for cancer patients but will help to reduce the costs of cancer care by independently and objectively comparing available therapies and determining how best to apply existing and new treatments to individuals most likely to benefit while not expending healthcare resources for treatments likely to be ineffective.

The entire system is run with extremely limited resources, allowing testing of innovative therapies for the most reasonable cost. However, the system is heavily subsidized by hospitals and practitioners and is in jeopardy of collapse as clinical margins are eroded and diverted to sustaining quality clinical care rather than research. This system is in desperate need of greater resources to more adequately compensate for the costs of doing research and modernize with the increasing complexity of molecularly targeted agents. The need for more resources is partly evidenced by the fact that an increasing number of clinical trials are done by industry and conducted outside of the United States. These studies address different and more limited scientific questions and in a different demographic than those in the United States, thereby taking critical resources from our own nation's research organizations, depriving American patients of early access to promising new therapies and potentially limiting the application of new research findings to US populations.

Relieve Unnecessary and Unintended Regulatory Burdens on Clinical Research:

The federal regulatory requirements related to the conduct of research have grown immensely over the past decades. While it is without question that research involving human participants requires careful review and oversight, the trend has been to layer on new, mainly process-based requirements with no assessment of whether existing requirements are meeting their stated goals. Institutions are becoming more risk averse and over-interpreting regulatory requirements, rather than assessing the value of advancing treatments. One example of this is the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. The HIPAA requirements have created conflicting and difficult to interpret requirements. While seeking to protect the privacy of individuals' health information, the Privacy Rule has imposed restrictions that have made clinical research cumbersome and, in some cases, simply impossible. ASCO has examined the impact through a qualitative study involving structured interviews with researchers and compliance officials. The Institute of Medicine will also be issuing recommendations based on its assessment of the impact of HIPAA on research. We call on the Administration to carefully review and consider implementing these recommendations.

Ensure Patients have Meaningful Access to Clinical Trials in their Communities:

The cancer research enterprise depends on a nationwide system of community and academic researchers. Nearly half of cancer patients placed on NCI Cooperative Group trials come from community-based practices, but without appropriate reimbursement for administrative and clinical costs associated with participating in clinical cancer research, this network cannot remain viable. The \$2000 per-case reimbursement, which has not increased since 2000, falls far short of the actual costs of research.⁵ Continuing reductions to Medicare reimbursement for cancer treatment, reduced support through NIH/NCI funding, and an ever-growing administrative burden threaten continued participation by these crucial sources of patient accrual. We look forward to working with the Administration to address these issues.

Train the Next Generation of Clinician-Scientists:

A study commissioned by ASCO has projected that, by 2020, the nation will have approximately 30% fewer oncologists than necessary to care for cancer patients and survivors. This shortage will have tremendous implications on the time available for oncologists to engage in clinical research. ASCO, through its Workforce Advisory Group, is undertaking a series of efforts to address these issues and will be sharing experiences and insights as they develop. We welcome the opportunity to work with you in overcoming these challenges.

⁵ Emanuel, E. et al. The Cost of Conducting Clinical Research. *Journal Clinical Oncology* 21:4145-47; 2003.