

Testimony of
Richard L. Schilsky, M.D.
President, American Society of Clinical Oncology
Before the Subcommittee on Labor, Health and Human Services,
Education & Related Agencies
House of Representatives Committee on Appropriations

March 18, 2009

10:00 am



American Society of Clinical Oncology

Thank you for the opportunity to submit testimony before the Labor, Health and Human Services, Education and Related Agencies Subcommittee today. My name is Richard Schilsky, M.D. I am a medical oncologist at the University of Chicago and President of the American Society of Clinical Oncology (ASCO).

ASCO is the leading specialty society in the United States and throughout the world for physicians who treat people with cancer and conduct oncology research that leads to improved patient outcomes. ASCO is committed to ensuring that high quality, evidence-based practices for the prevention, diagnosis and treatment of cancer are available to all Americans in every community throughout the United States. To this end, on behalf of our 27,000 members, I wish to highlight the critical importance of sustaining a robust and vibrant national clinical trials system through the National Institutes of Health (NIH) and the National Cancer Institute (NCI).

ASCO has a long history of working collaboratively with federal policy makers and physicians in communities throughout the United States to promote the best interests of patients with cancer and to advance scientific discovery. ASCO also works to translate scientific developments into clinical guidelines to help inform the treatment decisions made by physicians and their patients.

My testimony will focus on the following points:

- ASCO commends Congress and President Obama for the steps you have taken to enhance funding for biomedical research. These efforts will serve the overarching goal of leading to scientific advancements that improve the outcomes for cancer patients while providing rapid assistance to local economies throughout the United States by putting talented research professionals to work. Every dollar of NIH support returns at least \$2.50 in economic growth to the local community.
- ASCO urges the Subcommittee to support the President's budget request for NIH and NCI for FY2010 and urges a sustained, multi-year commitment to increasing the levels of funding for cancer research through NIH and NCI.
- Federal funding for cancer research plays a critical role in advancing the best interests of patients and complements the research investment made by U.S. companies by addressing different scientific questions.
- Federal funding is needed to support research conducted within the United States, providing U. S. patients with access to innovative therapies and answering scientific questions in diverse patient populations within the U.S. health care system.

- To maintain the United States' leadership in innovation, federal funding is needed to support our next generation of cancer investigators.

Discussion

1. ASCO commends Congress and President Obama for the steps you have taken to enhance funding for biomedical research.

President Obama boldly called for a cure to cancer in his recent address to a joint session of Congress. We applaud him for this leadership and support his budget proposal request of over \$6 billion dollars for cancer research within NIH and his pledge to provide a sustained, multi-year plan to double funding for cancer research. NCI directs the majority of our federal cancer research activities. Most of the funding set aside for cancer research in the President's budget should support work carried out by the NCI's extramural and intramural activities, but there are also opportunities for critical collaborations with other departments and agencies, both within NIH and across the federal government, and with the broader cancer research community throughout the private sector. The President's budget is also consistent with NCI's professional judgment budget, reflecting the scientific opportunities that we could realize in the next fiscal year with adequate funding.

This country is remarkably poised to deliver on the President's challenge. Over the last 50 years, this nation has developed the world's preeminent cancer clinical trials system through its cancer centers, Cooperative Groups, Community Clinical Oncology Program, Specialized Programs or Research Excellence (SPOREs), and other mechanisms. This publicly-funded system has brought great progress in cancer prevention and treatment and has leveraged billions of dollars in philanthropic investment and commercial partnership. The number of cancer deaths has decreased for the first time in 70 years, despite a growing and aging population. Survival rates for many of the most common cancers – including breast, colon, and prostate – are rising. In fact, there are now 12 million American cancer survivors, up from 3.7 million 30 years ago. Treatments are becoming more targeted and less toxic, and we are entering an era of personalized therapies, in which treatment will be increasingly tailored to the genetic profile of an individual tumor. But the people necessary to do the work and the underlying infrastructure are at critical break points, and have been endangered by a failure to keep pace with the growing costs of conducting research and a lack of predictable funding for NIH and NCI since 2003.

The additional \$10.4 billion dollars for NIH included in the American Recovery and Reinvestment Act of 2009 presents a tremendous opportunity for biomedical and cancer research. We applaud Congress for providing this significant investment as part of the economic stimulus effort. This will allow for support of RO1s, Challenge Grants, and other research grants that have a reasonable expectation of making progress in two years, as well as administrative and competitive supplements to current grants. NCI is quickly dispersing the stimulus funds to communities throughout the U.S through its existing matrix of extramural programs. The economic benefit of this infusion will be quickly realized through the hiring of research personnel and purchasing of state-of-the-art equipment necessary to energize the entire research

enterprise. It will translate directly to increased job opportunities for young investigators, research nurses and research staff.

2. ASCO urges the Subcommittee to support the President's budget request for FY2010 appropriations and urges a sustained, multi-year commitment to increasing the levels of funding for cancer research through NIH and NCI.

The stimulus funding for biomedical research has limitations. Unfortunately, the stimulus funding will not stave off the impact of lost purchasing power in the underlying budgets for NIH and NCI – NIH has lost 15 percent of its purchasing power since 2003. This will not be recovered unless Congress puts additional funding into NIH and NCI's baseline. The results of this stagnant funding have been far reaching. Researchers are abandoning or avoiding cutting-edge projects that may be less likely to be funded. Senior investigators report that many of the brightest young minds in our country no longer see the promise of a career in science, choosing other careers instead. Investigators are spending more of their time seeking funding – time that could be spent conducting research in the laboratory or treating patients in the clinic. Clinical trials are being delayed or discontinued and patient enrollment in the United States is flagging. These losses have delayed the quest for new cures, demoralized the research workforce, and left us with few options to buttress a starving infrastructure that can no longer rely on clinical margins to counterbalance inadequacies in research dollars.

The stimulus funding will not help ensure the long-term viability of our research system. Clinical research does not take place without physician investigators, research nurses, pharmacists, clinical research coordinators, data managers, and research administrators to interact with patients and gather clinical trials data. Lapses in funding jeopardize our ability to keep these people in place, ensure their training and attract a future workforce.

Yearly increases that keep pace with inflation are also necessary to ensure we can invest in the clinical trials that are necessary to transform laboratory findings into diagnostics and therapeutics that will improve patient care. While we would like the process to be quicker, the reality is that clinical trials are multi-year projects from conception to implementation to completion and analysis. This is especially true in cancer where we do not yet have many alternatives to demonstrate effectiveness other than the impact on survival rates or other surrogate endpoints such as time to progression. Because of the nature of the therapies we are testing, we also have to follow patients for extended periods after the clinical trial has closed to ensure we understand the long-term effects that may jeopardize the quality of life for cancer survivors. Ultimately, sustained annual research funding will increase physician and patient participation in clinical trials, which will help accelerate the development of new cancer diagnostics and treatments.

3. A federally-funded system for cancer research plays a critical role in advancing the best interests of patients.

It is critical that the United States preserve a vibrant federally-funded clinical trials system as a complement to the trials performed by private entities. While manufacturers are often effective at bringing a new treatment to market, it is federally-funded research – particularly in the case of cancer – that ultimately helps us understand how to best use cancer treatments to treat patients.

Federally-funded trials answer comparative effectiveness questions by comparing one treatment directly to another. By independently and objectively comparing available therapies, we can determine who will benefit, who will not, and in doing so, avoid the cost of treatments that are unlikely to be effective for specific patients. Federally-funded trials develop biospecimen repositories that enable the development of molecular tests to predict prognosis and response to treatment. Federally-funded researchers also are often the only ones able to focus on diseases in small populations and in children. The trials conducted to gain initial approval are often done in patients with advanced disease. NCI-funded research has helped us understand how to use drugs in multiple disease settings and for patients with earlier stages of disease where the potential benefits are much greater.

4. Federal funding for cancer research is needed to support research conducted in all settings within the United States.

We are moving into the frontier of personalized medicine, beginning to treat patients not just by the site of their tumor but by the genetic composition of their disease and of their normal DNA. This enables us to determine which patients will benefit from a treatment, and just as importantly, which patients will *not* benefit from a treatment. These are questions that industry might not be willing to fund. Research presented at last year's ASCO meeting demonstrated that, for colon cancer patients whose tumors possess a particular mutation of the gene, KRAS, certain drug treatments will not be effective. Based on this data, ASCO now recommends that all patients with metastatic colorectal cancer be tested for the KRAS gene mutation and that those who possess it not be treated with these drugs. These research results not only allow better outcomes for patients and avoidance of unnecessary treatment, but result in enormous savings for our health care system.

While the private sector plays an important role in the development of new therapeutic options, there is also concern that many industry-funded trials are increasingly conducted overseas. There are several reasons for this development, but the long-term result may be that trial results may be inadequate to guide U.S. clinicians seeking to prescribe the treatments to U.S. patients. In addition, U.S. researchers will participate less in the discovery process, and our country will lose this vital portion of the economy. More troubling is the fact that U.S. patients will have less access to state-of-the-art treatment options. A robust federal research infrastructure will help protect against this brain drain and loss of options for patients.

We have made important strides in ensuring that clinical studies are performed at the community level, providing patients with access to innovative therapies and answering scientific questions in diverse patient populations – but more needs to be done.

Improvements in anti-cancer and supportive care treatments enable us to offer treatments to 85 percent of cancer patients in their communities and near their homes. NCI has followed this with development of a robust extramural mechanism that funds access to its trials throughout the U.S. in virtually every community in which cancer care is offered. Non-academic, community sites accrue at least 50 percent of the patients participating in the Cooperative Group system – which conducts the majority of NCI-funded clinical trials (25,000-30,000 patients per year). The Community Clinical Oncology Program also brings cancer prevention trials into the community

setting, and the Minority-based Community Clinical Oncology Program enrolls 60 percent minority patients. Investigators participate in this research because it addresses important scientific questions and to provide a full range of treatment options to their patients. However, the funding the federal government provides to enable this participation only covers one-third of the actual research costs. It is vital that a portion of the FY2010 budget be dedicated to addressing this disparity.

5. To maintain the United States' leadership in innovation, federal funding is needed to support the next generation cancer investigators.

NIH provides critical funds to our training institutions to ensure that we are continually developing our next generation of investigators. The economic environment is making it increasingly difficult for these institutions to continue this vital mission. Coupled with the growing concern about whether we will have an adequate workforce in the coming years, this is making trainees reconsider pursuing a career as a clinician investigator. Increasing funds in this area would help ensure that we continue to bring the best minds to the field of translational and clinical research.

If Congress chooses to provide over \$6 billion for cancer research at the NIH, the benefits will not accrue to cancer patients alone. Cancer research is a paradigm for other diseases. Therapeutic breakthroughs in cancer research have led to treatments for many other diseases, including rheumatoid arthritis and macular degeneration.

Thank you for the opportunity to present ASCO's views on appropriations to the Subcommittee today. We look forward to working with you to ensure a vibrant federally-funded clinical trials system for people with cancer. Only by rapidly translating basic science discovery into clinical application and ensuring widespread access to life-saving treatment will we continue to improve the outcomes for all Americans with cancer.