

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
NATIONAL INSTITUTES OF HEALTH**

**Fiscal Year 2004 Budget Request**

**Witness appearing before the  
Senate Subcommittee on Labor-HHS-Education Appropriations**

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The early part of the 21st century promises to be a period of unprecedented progress in conquering our most debilitating diseases - especially cancer. The nation's unwavering support of the biomedical research enterprise, in particular, the unified effort by this committee, all of Congress, and the President to double the NIH budget over the past five years, has positioned us to attack this devastating disease more effectively. Cancer affects nearly every family in America. In 2003, 1.4 million of our citizens will face a diagnosis of cancer - and over 560,000 of our citizens will die from their disease this year. Every day, 1,500 Americans lose their own battle with cancer. These are daunting statistics, and the aging of the baby boomer population and shifting demographics of America during the next 15-20 years represent enormous healthcare and economic challenges that we must begin to prepare for now.

But, there is reason for optimism! Our nation's investment in basic research has fueled the engine of discovery, thereby enabling unparalleled advances in illuminating the genetic changes and molecular mechanisms that ultimately produce cancer. The sequencing of the human genome and associated progress in new areas such as functional genomics, animal models of cancer, and proteomics, provide us with a clearer picture of the disturbances that cause cancer to develop and ravage the human body. For the first time, we have within our grasp the ability to design target-specific interventions to preempt this process. We must enrich these extraordinary advances in basic science with equally extraordinary efforts to develop new agents and technologies to actualize these interventions at key steps in cancer progression. We now understand that cancer is a process - a process with multiple opportunities to develop new, more effective interventions to prevent, detect and treat cancer.

To capitalize on this knowledge, we must significantly accelerate the pace of progress across the entire research continuum. The pathway begins with discovery of knowledge

that underpins the development of new molecules and tools and ends with the delivery of diagnostics and therapeutics to patients. Discovery, development and delivery are interlinked, and it is crucial that we take the steps needed to ensure that all phases of the research enterprise are functioning optimally.

I believe that we stand at an "inflection point" in our nation's effort to conquer cancer. The research enterprise has delivered remarkable scientific achievements in biomedical research over the past decades, and we now are positioned to experience a rapid increase in the trajectory of this research. This affords us an unprecedented opportunity to harness strategically these achievements to confront the challenges of cancer today and tomorrow.

We now envision a time when the suffering and the death that are caused by cancer will be eliminated; and we believe that it is realistic to set ourselves a challenge goal to achieve this vision by the year 2015. I have presented the cancer research community with this challenge and am confident that they will achieve the goal. I want to be clear what we mean by "reduce suffering and death from cancer," and to explain why I believe that this vision is achievable.

We are not saying that all cancer will be cured or eliminated. What we are saying is that in this 12-year time-frame, many cancers will be cured, but many more will be transformed into chronic, manageable diseases that patients can live with - not die from. There is precedent for this paradigm shift. In a single generation, we made enormous strides in reducing deaths from coronary artery disease and converting this disorder into a condition that people live with and manage. Likewise, using our knowledge of the AIDS virus, molecular biology, and skills in developing target-based therapy, we have developed treatments for AIDS patients that both save lives and preserve quality of life. I think we can do the same for cancer.

This vision presents new challenges for the NCI and for everyone working to conquer this devastating disease. We will meet those challenges by further strengthening basic research, especially in advancing our understandings about the mechanisms of cancer progression. In parallel, we will intensify our focus on developing the clinical research and delivery systems needed to provide the promise of everything that science can provide to everyone in need.

In discovery, we will establish a national effort to "map" the critical events of the complex of integrated cancer disease pathways at the cellular level. This "systems biology approach" will allow us to dissect strategically the complex and redundant reactions and interactions within cells, and will enhance our technical capabilities to identify molecular targets and create new therapies. We will also focus on the exploration of new technologies, in areas such as molecular imaging, proteomics and genomics, and nanotechnology. These new technologies offer the promise of developing new platforms to monitor cells, identifying intricate molecular changes, and delivering therapeutics to specific targets within the cell. The application of these advanced technologies is no longer a dream. Advances in positron emission tomography, coupled with new molecular

imaging agents, now make functional monitoring possible, permitting clinicians to "visualize" the biologic progress of cancer. Scientists and engineers are working to achieve this goal through NCI's unique programs that foster the development of innovative technologies for cancer diagnosis and treatment.

The NCI will also place new emphasis on the development process - the translation of basic research advances into new products that are ultimately delivered to cancer patients. This is especially true in the area of cancer therapeutics. It currently takes 15-20 years for a promising new molecule to reach patients. That is just unacceptable in the 21st century. Genomics and proteomics are providing us with hundreds, potentially thousands, of new therapeutic targets for cancer; but the enterprise is not optimized to develop and deliver these "new paradigm" drugs. This is a systems problem and it can be solved. In collaboration with the NIH, the Food and Drug Administration (FDA) and other partners, we will work to "re-engineer" the clinical trials infrastructure for the evaluation of new cancer interventions. Underpinning all of these initiatives will be the deployment of a bioinformatics infrastructure that will allow us to use artificial intelligence to convert massive amounts of data into new knowledge that will inform discovery, development, and delivery to benefit patients.

The NCI will undertake programs to optimize the process of developing new drugs through an emphasis on validating new cancer targets. We will also work more closely with the FDA to facilitate the science necessary to create a seamless system of drug discovery, development, and delivery. To achieve these goals, the NCI will create novel partnerships with all of the sectors involved in developing and delivering these new drugs. In all that we do, we will encourage the removal of barriers that separate us by creating a new environment that encourages and rewards multi-disciplinary research.

The emerging field of proteomics provides us with unimagined opportunities to apply these new targeted therapies and preventive strategies by detecting cancer early enough to stop, slow, or possibly reverse disease progression. Novel disease biomarkers are finally providing us with new screening tools to detect early-stage cancer in populations and individuals; and the NCI will utilize its enormous strength in molecular epidemiology to provide rational strategies for cancer prevention and disruption of progression within populations.

All of these tactics will be directed to reducing suffering and death from cancer. That does not mean that we will lessen our emphasis on curing cancer - quite the opposite - but that will no longer be our only defining goal. We will also embrace the vision of changing the course of cancer by reducing its morbidity and mortality through the application of technologies and knowledge that were only a dream just a few short years ago. Those dreams can become reality.

Finally, I believe we stand at a pivotal crossroads - a defining moment in the history of this nation's effort to prevent and cure cancer. We now embark on a new course that will enable patients to live with cancer as a chronic, non-debilitating disease that doesn't threaten their vitality, careers, and families. An ever increasing body of scientific

knowledge and an array of advanced technologies provide us with the opportunity to detect cancer early and preempt the progression of the disease. We will be able to remove the fear of cancer for many more people, but more importantly for those who must live with their disease, life will take on new meaning. We have within our grasp the power to eliminate the suffering and death from cancer - and we will succeed.

#### BUDGET STATEMENT

The fiscal year (FY) 2004 budget includes \$4,770 million, an increase of \$183 million over the FY 2003 enacted level of \$4,587 million comparable for transfers proposed in the President's request."