DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Fiscal Year 2005 Budget Request

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

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BUDGET STATEMENT

The fiscal year FY 2005 budget includes $4,870,025,000, an increase of $134,052,000 over the FY 2004 enacted level of $4,735,973,000 comparable for transfers proposed in the President's request.

2015 CHALLENGE GOAL

The Nation’s unwavering support of cancer research has enabled the National Cancer Institute (NCI) and our many partners throughout the cancer research community to make enormous strides over the past three decades. Our understanding of cancer as a disease process, and the associated opportunities to prevent, detect early and successfully treat it has improved dramatically. However, even in the face of this progress, the magnitude of the cancer burden means that the disease still affects nearly every family in America. This year, approximately 1.4 million of our citizens will face a cancer diagnosis, and over 560,000 of our citizens -- about 1,540 each day -- will die from their disease. Furthermore, the fact that cancer occurs primarily in individuals over the age of 50 means that more of our citizens will suffer the terrible burden of this disease in the next 10-20 years due to the aging and changing demographics of our population.

Fortunately, the convergence of science and advanced technologies is changing our perceptions of what is possible. In fact, we are entering a period in biomedical research where progress in cancer research can be exponential – an inflection point. Last year I informed this committee that “our nation’s investment in basic research has fueled the engine of discovery, which is rapidly illuminating the cumulative genetic changes and associated molecular mechanisms that ultimately produce cancer.” As I said then and I reiterate now “for the first time, we have within our grasp the ability to design target-specific interventions to preempt this process.” Based on the current astounding pace of progress in cancer research and the transformational effects of advanced biomedical technologies, I am even more fervent in my belief that we can achieve this vision.

To capitalize on this inflection point, I have set forth an ambitious challenge goal for the NCI, and for the entire cancer research and care community: to eliminate suffering and death from cancer by 2015. This "stretch goal" is intended to unify and focus our thinking, strategies, and actions in new ways that will optimize the use of our resources and accelerate progress against cancer. This challenge also presents new opportunities for the NCI to provide leadership for our Nation's effort to conquer cancer, especially in the development of the new synergies and partnerships needed to achieve this bold vision.

Recent progress across nearly all of biomedical research has set the stage for unimagined progress in biomedicine early in the 21st century. Thanks to research, we now understand that cancer is a disease process – where normal cells are transformed into cancer cells through a series of defined steps that begin with a simple change in the genetic material. If left unchecked, these transformed cells can progress and spread to cause the suffering and death that we recognize as the horrific burden of cancer. Thankfully, our growing understanding of this process has revealed multiple opportunities to intervene. These new intervention strategies include preventing initiation of the process; detecting it early when it is most amenable to elimination; and arresting the process to stop the spread (metastasis), which is the primary reason that patients suffer unduly and die from their disease. In short, we are rapidly learning how to "preempt" the cancer disease process. We believe in the next few years that new intervention strategies will allow us to prevent and/or eliminate many cancers – and ultimately transform cancer into chronic, manageable diseases that patients live with – not die from.

Scientific advances and major discoveries from areas such as genomics, nanotechnology, proteomics, immunology, and bioinformatics allow us to envision a not too distant future when a patient's genetic, lifestyle, and environmental risk for cancer can be combined with effective prevention and early intervention strategies especially for those at high risk. Serum genomic and proteomic patterns, and advanced imaging technologies, will be employed to detect cancers at the earliest stages. Precise molecular diagnosis and

patient-specific prognostic profiling will allow physicians to predict response to specific interventions and provide a rational basis for tailoring therapies. The result will be more efficacious and less toxic, targeted agents delivered to patients. Achieving these outcomes will result in the preemption of a great deal of cancer. I believe that this is no longer a dream but an achievable reality.

To achieve the 2015 challenge we must take the steps necessary to accelerate the pace of progress across the entire cancer research continuum. The basic research which is aimed at *discovering* the pathways that lead to cancer represents the beginning of a continuum that proceeds through development of new agents and technologies and ultimately to the delivery of these new interventions to patients. Using our ever increasing knowledge of the molecular defects in cancer cells and the biomarkers that define the cancer process will enable the development of the new targeted interventions we need to prevent, detect, and treat cancer.

To achieve this acceleration the NCI has identified six "mission-critical" research areas that we believe will offer significant potential for near term progress against cancer. These include: harnessing the power of the newly emerging science of molecular epidemiology to better identify risk populations; developing an integrative understanding of cancer (systems) biology to discover key biomarkers and targets; facilitating the development of "strategic" cancer interventions for targeted prevention, early detection, and treatment; creating a national integrated clinical trials system to more effectively test these interventions; overcoming health disparities to deliver these advances to those in greatest need; and developing a bioinformatics network to connect the cancer research community and optimize the collection, analysis, and use of the enormous amount of data and knowledge that must be managed and shared.

CANCER BIOMEDICAL INFORMATICS GRID (caBIG)

In this past year's Appropriations Committee Report, NCI was requested to explore

ways in which information could be better shared among researchers and cancer care deliverers. In early 2004, the NCI responded by launching an unprecedented program to connect cancer researchers through an advanced technology platform called the Cancer Biomedical Informatics Grid (caBIG). This pilot initiative has the potential to transform the pace of cancer research by providing the tools needed to share information and data. caBIG will be developed by connecting 50 of our NCI-designated cancer centers through an NCI-developed open source system which will in effect become the "World Wide Web" of cancer research. This platform which integrates with the NIH Roadmap informatics initiative will link individual cancer researchers and research institutions across the nation, and around the world, in an open source, federated network that will enable researchers to share tools, standards, data, computing applications, and technologies. This unprecedented bioinformatics system will facilitate the collection, storing, searching, analysis, classification, management, and archiving and retrieval of research data. caBIG will improve the quality of data, provide unimagined access to heretofore limited databases, increase the pace of cancer research and enhance the effectiveness of our investments in cancer research. caBIG has the capability to virtualize cancer research.

caBIG leverages the unique resources and capabilities of NCI's cancer centers to meet the needs of the broad cancer research and care communities. The cancer centers, along with NCI's platforms for translational research, the Specialized Programs of Research Excellence (SPORES), are our partners in this strategic effort to ensure that the fruits of fundamental scientific research can be rapidly captured for the benefit of cancer patients. This is an example of how the future can be transformed if we can successfully integrate advanced technologies across the discovery, development, and delivery research continuum. In this instance the whole will be a great deal more than the sum of the parts.

NATIONAL ADVANCED BIOMEDICAL TECHNOLOGY INITIATIVE

In developing strategies to optimize progress in NCI's high priority research areas, it became clear that we must proactively identify, develop, and deploy advanced biomedical

technologies, such as bioinformatics, across the entire cancer research continuum. This concept represents a critical new element of our overall strategy to achieve the 2015 challenge goal; however, there is clearly a gap between our current level of capabilities in advanced technologies and what is needed. I believe that we now have the opportunity to address this gap through the creation of an unprecedented national advanced biomedical technology initiative that will be transformational for cancer and other diseases.

Achieving our challenge goal will require that we fully integrate advanced "enabling" technologies with the cancer research and care enterprise. Advanced technologies represent those new tools and approaches that enable new approaches to the challenging problems of detecting, controlling, and preventing cancer. Advanced technologies allow cancer researchers to generate, collect, and analyze vast amounts of data, and to pursue innovative approaches that could not be accomplished without these sophisticated tools. As illustrated by our efforts in bioinformatics, the NCI is providing leadership in the development and integration of advanced technologies and we are also building the cross-disciplinary teams needed to implement these new strategies.

Providing advanced technology platforms to scientists working in cancer research is one of our highest priorities at the NCI; and to that end, we have undertaken a cancer-enterprise wide planning effort to develop a national advanced technology initiative for cancer. In planning for this initiative, the NCI has identified (in addition to bioinformatics) multiple areas of advanced technology development that will be crucial in building this national resource. Examples of cross-cutting capabilities, which will support the range of strategic research priorities that we have identified as pivotal areas for progress, include: advanced imaging; biomarkers and proteomics; nanotechnology; and development capabilities such as scale-up for new cancer therapies and prototyping for new diagnostics devices.

We have made significant progress in cancer diagnosis and treatment based on static

imaging of the body's organs provided by x-ray, CT, PET, and MRI. The new generation of advanced imaging technologies will target specific molecules and cells. We will be able monitor cellular processes to assess the effectiveness of experimental treatments and to define cancer cells at their earliest stages. Nanotechnology will provide opportunities to develop biosensors that have the capability of detecting changes in cells at the earliest stages of cancer and "report" back on them. This breakthrough technology will also facilitate the design of new technologies to probe cell functions, measure cellular events with unimagined precision, and specifically deliver molecular entities to attack cancer. The combination of advanced imaging and nanotechnology offers the promise of realizing these advances to achieve the exponential progress that is possible at the current inflection point.

The post-genomics era in cancer research has produced vast amounts of information about the genetic basis of cancer, but perhaps of more importance, we are learning that the functioning of normal and tumor cells is controlled by the proteins that are transcribed from these abnormal genomes. These proteins, along with genes and other indicators of the processes and pathways that distinguish cancer, are called biomarkers. Through the use of advanced technologies NCI is developing innovative strategies to discover and validate biomarkers for use in clinical applications. Biomarkers, along with advanced imaging, nanotechnology, and other advanced technology platforms, will comprise an unprecedented National Advanced Biomedical Technology Initiative for Cancer (NABTIc).

This initiative is a major element of our strategy to achieve NCI's challenge goal to eliminate suffering and death due to cancer by 2015. The NABTIc would leverage and align the capabilities and resources in advanced technology development across the nation - and gain strength from all sectors. Through a network of technology "nodes" it would capitalize on capabilities in our cancer centers and SPORES and optimize the deployment of NCI's existing strengths in advanced technologies that currently exist at our Frederick campus. This initiative is currently being refined and further developed with the aid of our

advisors and partners in the extramural community, and a plan to purse this concept is under development.

STRATEGIC PARTNERSHIPS

Finally, to implement many elements of our strategic plan, we will partner broadly with all of the sectors that comprise the cancer community, including other federal agencies and private industry. The NCI is an active partner with many federal agencies, including the Department of Defense, the Veterans Administration, the Centers for Disease Control and Prevention, the Agency on Healthcare Research and Quality, and the Centers for Medicare and Medicaid Services. One partnership that is critically important to optimizing the pace at which laboratory discoveries progress to become new interventions for cancer is our alliance the Food and Drug Administration (FDA). Early last year we created the NCI/FDA Interagency Oncology Task Force to leverage the expertise of both agencies for the expressed purpose of streamlining and accelerating the development of preventive, diagnostic, and therapeutic interventions for cancer. Considerable progress has already been made in the areas of joint training and fellowships, developing markers of clinical benefit, improvement in the overall process of oncology drug development, and creation of a common bioinformatics platform (caBIG) to improve the organization and reporting of data from oncology clinical trials. These partnerships are critical. Each agency, along with the other sectors involved in the development, commercialization, and delivery of the new inventions we desperately need to preempt cancer, is a valued partner who can unite with us to facilitate and speed the overall process.

Last year, I closed by telling members of this committee that we stand at a pivotal crossroads – a defining moment in this nation's effort to prevent and cure cancer. Over the past 12 months we charted the future course forward - through the creation and implementation of innovative strategies - and have undertaken initiatives that will allow us to move rapidly toward a day when cancer will become a chronic disease. What was once a vision is becoming reality through the combined efforts of researchers and leaders

from all sectors, patients and their families - and so many others. I believe that together we will realize the economic and human benefits of eliminating the suffering and death due to cancer, and in this quest, inform our efforts to transform our overall health care system.

CURRICULUM VITAE

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Birth Date and Place: October 30, 1941; Philadelphia, Pennsylvania

Education:

1963-1967	M.D.	Georgetown University, Washington, D.C.
1959-1963	B.S.	St. Joseph's College, Philadelphia, PA

Postgraduate Training:

1967 – 1968	Internship: Surgery/Medicine, University of Pennsylvania Division Philadelphia General Hospital, Philadelphia, PA
1971 – 1972	Residency: General Surgery, Pennsylvania Hospital, Philadelphia, PA
1972 – 1975	Residency: Urology, Pennsylvania Hospital, Philadelphia, PA
1976 – 1977	Fellowship: Urologic Oncology, The University of Texas M.D. Anderson Cancer Center, Houston, TX 77030

Post Graduate Continuing Education:
Stanford Executive Program in Organization Change, 1991
Stanford University Graduate School of Business, June 23 - July 5, 1991
Executive Development Program in conjunction with Rice University, 1991
University Jesse H. Jones Graduate School of Administration, 1991

Academic and Professional Appointments:

1975 – 1976	Instructor in Urology, The University of Pennsylvania School of Medicine Department of Surgery, Philadelphia, PA
1975 – 1976	Staff Physician, Pennsylvania Hospital, Philadelphia, PA
1975 – 1976	Staff Physician, St. Agnes Hospital, Philadelphia, PA
1977 – 1980	Assistant Professor of Urology, Department of Urology, The University of Texas M.D. Anderson Cancer Center, Houston, TX
1978 – 1980	Assistant Professor, Department of Surgery, The University of Texas Medical School at Houston, Houston, TX
1980 – 1985	Associate Professor of Urology, Department of Urology, The University of Texas M.D. Anderson Cancer Center, Houston, TX
1980 – 1994	Professor, Graduate School of Biomedical Sciences, The University of Texas Health Science Center at Houston, Houston, TX
1981 – 1986	Associate Professor, Department of Surgery, The University of Texas Medical School at Houston, Houston, TX

1985 – Jan. 2002	Professor of Urology, The University of Texas M.D. Anderson Cancer Center, Houston, TX
1985 – Jan. 2002	Consulting Professor of Cell Biology, The University of Texas M.D. Anderson Cancer Center, Houston, TX
1986 – Jan. 2002	Professor, The University of Texas Medical School, Houston, TX
1988 – Jan. 2002	Adjunct Clinical Fellow, The Institute of Religion, Houston, TX
1990 – Oct. 1994	Irving and Nadine Mansfield and Robert David Levitt Cancer Research Chair
1994 – Jan. 2002	Roy M. & Phyllis Gough Huffington Distinguished Chair in Urologic Oncology

Administrative Responsibilities:

Sept.1979 – Sept. 1983	Deputy Head, Department of Urology, The University of Texas M.D. Anderson Cancer Center, Houston, TX
Sept. 1981 – 1986	Chief, Section of Sexual Rehabilitation, The University of Texas, M.D. Anderson Cancer Center, Houston, TX
Sept. 1983 – Nov. 1996	Chairman, Department of Urology, The University of Texas M.D. Anderson Cancer Center, Houston, TX
Sept. 1990 – Aug. 1993	Administrative Director of Laser Program, The University of Texas, M.D. Anderson Cancer Center, Houston, TX
1996 – 2002	Director, Prostate Cancer Research Program, The University of Texas M.D. Anderson Cancer Center, Houston, TX
Feb. 1997 – Sept. 1997	Vice President for Academic Affairs (*ad interim)* The University of Texas M.D. Anderson Cancer Center Houston, TX
Oct. 1997 – Dec. 1997	Executive Vice President/Chief Academic Officer (*ad interim)* The University of Texas M.D. Anderson Cancer Center Houston, TX
Jan.1, 1998 – Jan. 22, 1999	Executive Vice President/Chief Academic Officer The University of Texas M.D. Anderson Cancer Center Houston, TX
Jan. 25, 1999 – Jan. 2002	Director, Genitourinary Cancer Center Special Assistant for External Affairs The University of Texas M.D. Anderson Cancer Center Houston, TX

Department of Health and Human Services

Office of Budget

William R. Beldon

Mr. Beldon is currently serving as Acting Deputy Assistant Secretary for Budget, HHS. He has been a Division Director in the Budget Office for 16 years, most recently as Director of the Division of Discretionary Programs. Mr. Beldon started in federal service as an auditor in the Health, Education and Welfare Financial Management Intern program. Over the course of 30 years in the Budget Office, Mr. Beldon has held Program Analyst, Branch Chief and Division Director positions. Mr. Beldon received a Bachelor's Degree in History and Political Science from Marshall University and attended the University of Pittsburgh where he studied Public Administration. He resides in Fort Washington, Maryland.