DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

NATIONAL CANCER INSTITUTE

Fiscal Year 2006 Budget Request

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

Andrew C. von Eschenbach, M.D.
Director, National Cancer Institute

William Beldon
Deputy Assistant Secretary, Budget

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Mr. Chairman and Members of the Committee:

I am pleased to present the President's budget request for the National Cancer Institute (NCI) for Fiscal Year (FY) 2006. The FY 2006 budget includes $4,841,774,000, an increase of $16,516,000 over the FY 2005 enacted level of $4,825,258,000 comparable for transfers proposed in the President's request.

LONG TERM GOAL

The accelerating progress that the National Cancer Institute (NCI) and its partners in the cancer community have made over the past three decades in understanding the molecular mysteries of cancer is now extending the years and enhancing the quality of patients' lives. Now we are closer to the reality of eliminating the suffering and death due to cancer—the goal that NCI set to be achieved by 2015. The FY 2006 budget continues to accelerate the discovery, development, and delivery of the interventions that will transform our traditional view of cancer as a death sentence into a disease that we can prevent, eliminate, or control. Accomplishing this goal is the legacy we strive to leave our children.

Our increased knowledge in several clinical approaches has led to new treatments approved for use. For example, our understanding of the molecular mechanisms required for tumors to develop the blood supply necessary for their growth led to the Food and Drug Administration's (FDA) approval of the monoclonal antibody Avastin® as a first-line treatment for patients with metastatic colorectal cancer. Similarly, knowledge of the growth factors necessary to stimulate cancer cell proliferation led to development and approval of another targeted monoclonal antibody Erbitux® for the treatment of metastatic colorectal carcinoma and to the accelerated approval of

Alimta® for locally advanced or metastatic non-small cell lung cancer. These are just a few of the new drugs offering fresh hope for patients with advanced cancer.

We have made progress in preventing cancer from ever developing in the first place, especially in people at high risk. An example is the creation of a vaccine that has prevented women from becoming persistently infected with human papilloma viruses (HPV), an infection that is responsible for half of all cervical cancers.

Now we must quicken the pace of progress because the trajectory is clear: discovery of cancer's genetic and molecular mechanisms leads to development of innovative interventions that—when delivered to patients—save lives. Building on this knowledge, the promise of tomorrow's advances is just over the horizon. This hopeful prospect will be realized by investing in strategic research areas, including: cancer genomics, biomarkers, molecular imaging, nanotechnology, and bioinformatics.

ADVANCED TECHNOLOGY INITIATIVES

The technology revolution is speeding up and enabling the discovery process. Recent advances in molecularly-targeted imaging will allow us to locate very small tumors and interrogate their features. Nanotechnology has emerged as a key strategy for imaging molecular features of cancer that are notoriously difficult to detect. In one case, a team of NCI-supported scientists has crafted a nano-sized device—less than 1/80,000 the width of a human hair—to identify areas of new blood vessel growth, which is characteristic of growing tumors. Further, drugs attached to agents that seek out the proteins on cancer cells will target therapy to exactly where it is needed without damage to healthy cells.

The development, integration, and coordination of advanced technologies are pivotal to enabling the biomedical and cancer research advances that are necessary to achieve NCI's 2015 goal. The Institute has played a crucial role in charting the path and collaborating in efforts to support bold new programs in this crucial arena.

For instance, the National Advanced Technologies Initiative for cancer (NATIc) is a plan to create a nationwide "virtual" laboratory for cancer. The NATIc plan envisions a network of state and regional technology "hubs" focused on several strategic areas, including advanced computing, nanotechnology, and biorepositories.

NCI has already begun development of the cancer Biomedical Informatics Grid (caBIG) to create a "world-wide web" for cancer research. The goal is to create a network of interconnected data, applications, individuals, and institutions that will redefine how cancer research is conducted and care is provided. During its initial year, the caBIG enterprise began bearing its first fruits with the release of NCI's caArray, a prototype software application that is made freely available to facilitate the sharing and analysis of microarray data by the medical research community. NCI and its partners in academia and industry are also developing an online information infrastructure to support clinical trials management and electronic drug approval submissions to the FDA. The first system module—the Federal Investigator Registry (Firebird)—starts pilot testing this spring.

In addition, NCI has for the first time adopted a modern business model approach to our research and development program for cancer-imaging technologies. This entailed creation of an Imaging Integration/Implementation (I^2) Team that recently submitted a proposed business plan for a new entity to be called I^2 Imaging, Inc. The

goal is to create distinct product lines to organize NCI's imaging program and clearly define measurable goals for each of the product lines. The plan includes four R&D programs encompassing imaging technologies for: a) understanding of cancer biology and microenvironments; b) cancer prevention and preemption; c) development and preclinical validation of therapies; and d) tools for clinical trial support.

STRATEGIC RESEARCH INITIATIVES

Exponential advances in cancer research are defining, with ever increasing specificity, the many genetic, molecular, and cellular events that influence the cancer process. We now understand cancer as an ongoing process that can be interrupted at many stages—from susceptibility to initiation to disease progression. We are translating this new knowledge into innovative strategies to prevent cancer from developing, eliminate it early when it does occur, and modulate its devastating effects. This involves NCI making strategic investments in several research areas.

Cancer prevention, early detection, and prediction New evidence-based interventions encourage lifestyle improvements in diet and physical activity, discourage tobacco use, and promote safe and fully-tested chemoprevention approaches for people at risk. Pioneering proteomic and biomarker advances, and the promise of nanotechnology, give us new hope for the early detection of cancer and prediction of patient responses to treatment.

Development of strategic cancer interventions One of NCI's key strategies is to optimize the development and speed delivery of targeted cancer diagnostics, therapies, and preventives to patients. This is evidenced by NCI's investments into the Cancer

Genome Anatomy Project, Academic Public-Private Partnership programs, and Rapid Access to Intervention Development (RAID).

An integrated clinical trials system NCI provides leadership, resources, and expertise for clinical trials programs that span the discovery of novel molecules to the evaluation of new agents and interventions. To make clinical trials more efficient and to accelerate and improve the regulatory approval process, NCI is enhancing its working relationship with the FDA and the Department of Health and Human Services' (DHHS) Office of Human Research Protections to develop more streamlined policies and procedures for the conduct of clinical trials.

Integrative cancer biology Integrative cancer biology is the study of cancer as a complex biological system. NCI's initiatives in this cutting-edge area include creating computational models of the complex networks within and among cancer cells, building our understanding of the tumor microenvironment, and studying the role of the tumor macroenvironment in cancer development.

Molecular epidemiology NCI is developing novel ways to unravel the complexities of inherited and environmental contributions to cancer causation. Future investments will help scientists uncover risk factors, identify genetically susceptible individuals, and generate individual and public health strategies to avoid or mitigate adverse genetic exposures.

INTERAGENCY COLLABORATIONS

Cancer is a large and complex problem with scientific, medical, social, cultural, and economic dimensions. Addressing this problem requires that NCI work across institutional and sector boundaries, share knowledge, and bring together the diverse

members of the DHHS family of agencies, as well as other Federal offices, that can help develop systems-based solutions to the cancer problem. Just within the National Institutes of Health (NIH), NCI collaborates with virtually all of the 27 Institutes and Centers. Likewise, NCI also has many ongoing collaborations with several DHHS agencies. The ultimate beneficiaries of this continued cooperative effort will be cancer patients and their families.

NCI and FDA created an Interagency Oncology Task Force (IOTF) to remove bottlenecks in the process of developing and approving safe, more effective cancer interventions. IOTF, which is comprised of senior representatives from both agencies, has been meeting regularly to define key areas of mutual interest and concern. As a result, the NCI-FDA Cancer Training Fellowship Program was launched in 2005. The program will train a cadre of scientists in research and research-related regulatory review so that they can develop skill sets that bridge the two distinct processes.

NCI is also an active participant in the Medical Innovation Task Force established last year by DHHS. The group—which also includes the FDA, the Centers for Disease Control and Prevention, the Centers for Medicare & Medicaid Services, and the NIH—is weighing new ideas and solutions to encourage innovation in health care. The interagency panel seeks to speed the delivery to market of effective new medical technologies, such as drugs, biological products, and medical devices.

NIH ROADMAP

NCI's contributions to NIH Roadmap initiatives will increase NCI's ability to support the collaborative research critical to cancer studies. Cooperation across the cancer continuum is vital for continued progress. The NIH Roadmap mechanisms

support research in cancer biology that will also enhance continued interdisciplinary research to address vital questions related to cancer and the immune system, the interface of aging and cancer, and the role of microbial agents in the etiology of human cancers. By encouraging interdisciplinary teams to evolve in both directed and serendipitous ways, these new funding mechanisms complement and enlarge NCI's efforts toward the integration and cross-fertilization of research efforts that span the cancer spectrum.

CHALLENGES AND OPPORTUNITIES

In the coming years, we will face a number of critical challenges and opportunities. We stand on the brink of a new age of "personalized oncology"—delivering the right treatment to the right patient at the right time to halt cancer-causing processes in the body before they cascade into advanced disease states. NCI is driven to meet the 2015 challenge goal. Cancer is a public health and financial challenge for the United States. NIH estimates that in 2003, the total cost of cancer was over $189 billion: $64 billion in direct medical costs (much of it paid by Medicare) and $125 billion from lost productivity due to illness and premature death. More telling, 570,000 Americans lost their lives to the disease last year, according to the American Cancer Society. 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 future due to the aging and changing demographics of our population. NCI and its partners are committed to making progress toward the goal of eliminating suffering and death due to cancer in the next 10 years.

Thank you, Mr. Chairman. I would be pleased to answer any question that the Committee may have.

CURRICULUM VITAE

NAME: **Andrew C. von Eschenbach, M.D.**

Present Title and Affiliation:
Director, National Cancer Institute
31 Center Drive, MSC 2590
Building 3l, Room 11A48
Bethesda, MD 20892-2590
Phone: 301-496-5615
FAX: 301-402-0338

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

Specialty Boards:
American Board of Urology - February 8, 1978

Military or Government Service:

1968 – 1971	Lieutenant Commander, U. S. Navy Medical Corps

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
2003 – Present	Distinguished Professor of Surgery, Department of Surgery, F. Edward Hebert School of Medicine, Uniformed Services University of the Health Sciences, Bethesda, MD

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. 1998 – Jan. 1999	Executive Vice President/Chief Academic Officer, The University of Texas M. D. Anderson Cancer Center, Houston, TX
Jan. 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 Deputy Assistant Secretary, Budget in the Department of Health and Human Services. He has been a Division Director in the Budget Office for sixteen 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 more than 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.