National Cancer Advisory Board (NCAB)
Planning and Budget Subcommittee Retreat
February 4, 2008
6:00 – 7:30 p.m.

Bethesda Hyatt Hotel
Bethesda, MD

Summary

Participants:
Dr. Mark Alexander, NCI
Dr. Margaret Ames, NCI
Dr. Bruce Chabner, NCAB
Dr. Kenneth Cowan, NCAB
Dr. Jean deKernion, NCAB
Mr. Jim Dickens, NCI
Dr. Lloyd Everson, NCAB
Dr. Paulette Gray, NCI
Mr. Steve Hazen, NCI
Dr. James Jacobson, NCI
Dr. Tracy Lively, NCI
Dr. Diana Lopez, NCAB
Dr. John Niederhuber, NCI
Mr. Larry Ray, NCI
Dr. Carolyn Runowicz, NCAB
Ms. Lisa Stevens, NCI
Ms. Nanci Hemberger (Rapporteur, The Scientific Consulting Group, Inc.)

Mr. Dickens presented details of the FY 2009 Bypass (or Professional Judgment) Budget and the President's Budget (PB), and explained key differences between the plans. Comments and questions regarding these and other topics are discussed below.

Mr. Dickens explained that the Bypass Budget is a separate budget document that is sent directly to the President by the Director of the National Cancer Institute (the NCI) and reflects the Director's professional judgment and the NCI's priorities. The PB is prepared using guidelines from the Office of Management and Budget (OMB), the Department of Health and Human Services (HHS), and the National Institutes of Health (NIH).

The current PB proposes a total NIH budget of $29.5 billion, which includes $4.8 billion for the NCI. This figure represents $4.7 million or a 0.1 percent increase from the FY 2008 Omnibus Appropriation. Funding for the NIH Roadmap in the FY 2009 PB includes increases of $38 million or 7.7 percent, which represents money that is being appropriated from existing Institute initiatives. Dr. Chabner asked if there is evidence that the Roadmap is having a positive impact on cancer research. He commented that outside of the NIH there often is not a clear sense of the Roadmap program. Dr. Niederhuber responded that two new Roadmap initiatives include 5-year

projects in the Microbiome, a project to characterize the microbial content of sites in the human body and their relationship to disease and in Epigenomics, which is the study of stable genetic modifications and their relationship to disease.

The NCI's annual plan and budget proposal for FY 2009 consists of three primary narrative sections—empowering cancer research, reaching all communities touched by cancer, and the promise of prevention and early diagnosis—followed by the 2009 Professional Judgment Budget. The document details the state of the science regarding cancer research and the resources needed so that all patients have access to the best available standard of care.

Empowering cancer research includes information on: the promise of personalized cancer medicine; developing enabling technologies such as the cancer Biomedical Informatics Grid (caBIG); and the NCI's efforts to develop effective and efficient therapies. Cancer genetic initiatives such as the Cancer Genetic Markers of Susceptibility (CGEMS), the Cancer Genome Atlas (TCGA), and Childhood Cancer Therapeutically Applicable Research to Generate Effective Treatments (TARGET) are presented in detail. *Reaching all communities touched by cancer* describes current research on access to care and outreach, including the National Community Cancer Centers Program (NCCCP) as well as partnership efforts such as the Minority Institution/Cancer Center Partnership. International efforts and the global impact of cancer and cancer survivorship are emphasized. The *promise of prevention and early diagnosis* highlights the NCI's efforts to better understand the risk of developing cancer; the Early Prevention Clinical Trials Consortia, which is a new initiative that hopes to facilitate FDA approval criteria for drugs; and tobacco and tobacco-related cancers.

The total FY 2009 Bypass Budget request of approximately $6 billion was based on an FY 2008 estimate of $4.9 billion. This estimate ultimately was higher than the Institute was appropriated because the bill was vetoed by the President. The NCI eventually received approximately $120 million less in FY 2008 than originally estimated. The NIH's portion of lost funding was approximately $28 billion from the $500 billion HHS discretionary budget request; the NCI funding increased by approximately $7 million from FY 2007. Mr. Dickens noted that the NCI budget levels have been flat since 2005.

Mr. Dickens said that the process for developing budget estimates for the upcoming fiscal year begins in May of the previous year at the annual fiscal planning meeting of the NIH Directors. Priorities and policies for the upcoming budget are discussed at this time. He explained that the Bypass Budget is developed using two levels—the current services increase and additional resources needed. Current services include funds that are needed to maintain current NCI programs; this section of the budget accounts for approximately 6 percent of the total FY 2009 Bypass Budget, or $334 million. This figure provides for the inflationary growth of the NCI grant mechanisms, funds noncompeting grants at previously committed levels, and tries to restore budget cuts from the previous several years.

Dr. Niederhuber stated that the goal for the FY 2009 Bypass Budget was to create a more personal, targeted NCI budget that attempts to present a snapshot of cancer research progress at the NCI. At the same time, research opportunities for the Nation were highlighted. The FY 2008 Bypass Budget was analyzed to see where funding was needed to improve and expand existing programs and initiatives. Additional resources include professional judgment increases to programs that promote an increased success rate for research project grants (RPGs); basic and

translational science for personalized medicine; greater connections between science and technology; increased community outreach; and improved cancer prevention and early detection.

Dr. Cowan asked about the process involved in presenting the budget to the OMB. Dr. Niederhuber stated that the major Institutes often are invited to present the budget to the OMB; however, budget negotiations are controlled tightly by the NIH, whose primary goal is obtaining sufficient overall NIH funding, which then is apportioned to the Institutes. The Institutes have limited access to the OMB and usually are removed from budget discussions once Congressional hearings begin. Mr. Dickens noted that it is the PB that is presented to Congress annually, although there are continuing efforts to educate members of Congress regarding the Bypass Budget.

Dr. Chabner raised the issue of cancer research funding by philanthropic organizations and asked if funding amounts had changed significantly in the last several years to try to minimize budget shortfalls. Participants agreed that wealthy and large institutions are filling budget gaps through private donations or income from robust endowments. Many institutions, particularly small institutions, do not have access to such resources. Dr. Runowicz commented that donations, which mirror the stock market and general health of the economy, probably will decrease in the coming year.

The FY 2009 Bypass Budget includes funding for construction (capital improvements) and building and facilities maintenance. Dr. Niederhuber noted that infrastructure and renovation work is needed on many NIH buildings, including Building 10. He said efforts are underway to develop a 20-25 year lease plan for the NCI, which includes research and office space. Over the next 2-3 years, the NCI expects to move out of the NIH network completely and into a lower rent area, which will significantly reduce overall costs for the NIH. According to Mr. Ray, when the NCI leased the Executive Plaza footprint several years ago, which is more than 500,000 square feet of lease space, close proximity to the NIH campus was a priority. Rent costs, however, are expected to decrease across the NIH from approximately $41 to $37 per square foot, when the NCI relocates from the NIH campus and Executive Plaza to an alternative location. The new space also will offer sufficient room for the NCI to expand.

The NIH emphasis areas highlighted in the FY 2009 PB include maintaining new investigators through initiatives such as the Pathways to Independence Program, Bridge Awards, and first time R01s, and increasing support to the Roadmap/Common Fund. The NIH fiscal policies for FY 2009 include no inflationary increases for noncompeting RPGs, no average cost increase for competing RPGs, and an intramural research and Research Management and Support (RMS) increase of 1.5 percent, which is used primarily to fund salaries and salary increases for extramural programs.

The NCI estimates funding for approximately 1,369 RPGs, which is an increase of 66 grants over the FY 2008 level. Mr. Dickens commented that the increase is primarily from the current cycling of grants. Noncompeting awards in FY 2009 will drop by approximately $39 million; the total number of awards will drop from 5,160 to 5,083. Per the NIH policy, intramural research and RMS increased by 1.5 percent and all other mechanisms remained flat.

A discussion ensued regarding grant applications and grant funding. Dr. Niederhuber commented that Institute Directors this year had a more unified voice than in previous years to protest

continued decreases in funding for individual grants. Directors agreed that decisions on decreasing the number of grants funded should be made according to specific Institute needs. Directors also agreed that greater flexibility within Institutes would help better determine research needs, and more options within the Institutes regarding competing grants would facilitate research opportunities. Dr. Niederhuber stated that the average downward negotiation for competing grants has been approximately 24 percent; efforts this year will be to decrease that figure to approximately 17 percent. In response to a participant's question, Mr. Hazen noted that only a small percentage of grantees have multiple grants.

Dr. deKernion asked if there had been a decrease in the total number of first-time grant applications submitted to the NCI. Mr. Hazen replied that the overall number of R01 applications has reached a plateau, with a slight decrease in 2008. Dr. Cowan said that new researchers are reluctant to enter public service careers amidst continued flat and decreased budgets. Responding to a question, Mr. Hazen said that he was not aware of any monetary limits within the Institutes for individual researchers.

Mr. Dickens noted that for FY 2009, the Cancer Prevention and Control item was removed from the mechanism table, which is a table that accompanies the budget. This does not mean that cancer prevention activities have been eliminated, but rather Cancer Prevention and Control initiatives are now grouped with other activities in the PB.

Mr. Dickens shared with the Subcommittee details of the FY 2009 PB (see Table 1 below).

Table 1. FY 2009 President's Budget

	FY 2008 Appropriation (in thousands)	FY 2009 PB (in thousands)	Change
Research Projects			
Non-Competing	$1,606,675	$1,572,414	-2.1%
Competing	433,442	455,339	5.1%
Subtotal	**2,040,117**	**2,027,753**	**-0.6%**
SBIR/STTR	89,121	89,121	0.0%
Total	**2,129,238**	**2,116,874**	**-0.6%**
Centers, SPOREs & Special Centers	528,374	528,374	0.0%
***Other Research Grants**	423,590	423,590	0.0%
Total Research Grants	**3,081,202**	**3,068,838**	**-0.4%**
NRSA	68,823	69,398	0.8%
R&D Contracts	569,342	569,342	0.0%
Intramural Research	719,879	730,979	1.5%
Research, Management & Support	357,922	363,422	1.5%
****Cancer Prevention & Control**	[511,019]	[511,019]	0.0%
Repair & Improvement	7,920	7,840	-1.0%
Total, NCI	**$4,805,088**	**$4,809,819**	**0.1%**

* Includes training, cooperative groups, and cancer education awards

** Cancer Prevention & Control included within other budget mechanisms

Intramural research, which includes bench and clinical research costs as well as costs associated with supporting the research, such as administrative staff salaries, accounts for approximately 15 percent of the PB. Research costs account for approximately 9 percent of intramural funding, and the other 6 percent of the funding is for overhead costs. Because of its extensive clinical program, intramural costs may be slightly higher at the NCI than at other NIH Institutes.

Dr. Niederhuber explained that the intramural research budget line consists of many miscellaneous costs that do not accurately reflect intramural costs, and may be more appropriate in other budget items; the NCI, however, has no control over what is included in this category. Dr. Runowicz suggested that renaming this budget line item to "intramural programs" would better reflect the variety of initiatives funded in this section of the budget. Mr. Dickens noted that no extramural programs are included in the intramural research line.

Dr. Cowen asked if intramural research funding has increased over the last several years. Mr. Dickens replied that funding actually has decreased over the last decade. Dr. Niederhuber added that 60 principal investigator (PI) positions have been eliminated at the NCI because of reduced intramural funding.

To help contain costs, the NCI has improved the documentation process within the intramural program regarding materials it provides to extramural scientists, such as mice and reagents. The NCI continues to be the largest supplier of such materials to research institutions and facilities. Dr. Niederhuber stressed that such services within the intramural program at the NCI are vital to the extramural community and without the NCI's support, extramural research programs would suffer.

Dr. Chabner suggested that it might be helpful for Subcommittee members to know the rate of increase in intramural costs, particularly hospital costs, and the number of current PIs at the NCI. He also suggested that fully describing what is included in the intramural research budget line would help to better explain funding requests for this area.

Within the NIH Clinical Center, the NCI is responsible for surgery, laboratory pathology, and radiation therapy. Mr. Dickens commented that because the NIH budgets have been flat for several years, the Clinical Center has been constrained in what they can request as part of the total NIH budget. A participant asked if any studies had been done on the number of patient visits and hospital stays. Mr. Hazen responded that such studies have been done in the past, but not recently.

Dr. Niederhuber said that the NCI is trying to contain costs by implementing restrictions when appropriate. Pharmaceutical expenses, for example, remain high and have been difficult to contain, although efforts are being made to reduce these costs by only allowing distribution of drugs that are part of the clinical trial protocol. Automatic distribution of blood products also has been eliminated or is being phased out in an effort to cut costs.

Dr. Niederhuber said, and participants agreed, that the NCI remains unique for clinical research. Such research comes with responsibilities and costs, however, so the NCI continues to work constructively on cost containment.

The meeting adjourned at 7:30 p.m.

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Mr. Robert Ingram Chair	Date	Mr. James Dickens Executive Secretary	Date