A Look Inside the National Cancer Institute Budget Process: Implications for 2007 and Beyond

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Introduction

Despite what may be one of the most difficult times in the long and distinguished history of the NIH, the National Cancer Institute's (NCI) commitment to its mission of advancing cancer research cannot falter. Federal deficits resulting from a host of unanticipated fiscal pressures in the years since September 11, 2001—the wars in Afghanistan and Iraq, increased investments in national defense, research directed at bioterrorism, hurricane Katrina, and the threat of pandemic flu—have collectively placed significant stress on the resources available for and assigned to support the country's biomedical research enterprise. In facing these fiscal challenges, the NCI has a unique opportunity to streamline its approach, increase clarity on its long-term goals, and set the stage for biomedical research to flourish in any financial environment.

The biggest challenge, and the foremost driver of uncertainty to the biomedical research community, is the discretionary portion of the annual Federal budget appropriation supporting the NIH. The amounts and allocations of those funds have been the topic of discussion at scientific meetings, in the editorial pages of peer-reviewed journals, in the national media, and among patient and professional organizations as well as researchers and administrators at academic centers across the country. This attention to stewardship of the budget has permeated the biomedical research community.

It is for these reasons that it is important for the entire cancer community to better understand the stresses on the budget and, more specifically, the process the NCI is using to optimally invest in science and to sustain the momentum brought about by the doubling of the NIH budget. The cancer community can only benefit from an open discussion of the factors that influence the budget, and the processes and procedures the NCI has instituted to effectively manage its resources.

Some History: the Decision to Double the NIH Budget

The passionate, strong voice of the cancer community provided a major impetus for the significant increase in the nation's investment in biomedical research. On September 26, 1998, thousands of cancer patients, survivors, and advocates gathered at the National Mall in Washington D.C. to advocate for a renewed commitment to eliminating the burden of cancer and a greater investment in biomedical research. As a result of this campaign, Congress generously stepped forward, and over the next 5 years, beginning in fiscal year (FY) 1999 (using FY 1998 as the base), doubled the NIH budget. Although the NCI budget did not completely double, it did grow by 80% from $2.5 billion (B) to $4.6 B over this period.

This laudable increase produced many favorable outcomes. Individual NCI investigators were able to expand their research as the average R01 grant increased nearly 30% to an average total amount of $346,000. There was increased interest on the part of university investigators in becoming involved in cancer research. Even more significantly, university leaders recognized the opportunity to invest in new laboratory buildings, to build new research programs, and to add new faculty positions. Dr. Elias Zerhouni, Director of the NIH, has recounted the story that the common standard of recent success for a university dean among his or her peers was the number of construction cranes towering above campus. You were at the top as a four-crane dean, or just getting by as a one-crane dean.

This anecdote provides a strong dose of reality. Investment in the NIH achieved a much desired increase in biomedical research, with more faculty now focused on solving the mechanisms of disease processes and more laboratories to train the next generation of investigators. The American Association of Medical Colleges (AAMC) estimates that between 1998 and 2002, $5.4 billion dollars of new biomedical construction came on line. Between 2003 and 2007, it is estimated that this figure will approximately double to $9.5 billion dollars of new research facilities (AAMC Survey of Research Facility Investments: 99 out of 125 AAMC member schools; data based on AAMC faculty roster). That such a large amount of the growth in new research space is taking place after the end of the doubling of the budget is simply a reflection of the time lag involved in designing and building facilities. Along with this growth, however, has come an increased demand for grant support, as new faculty were hired and the institutions realized that each of these new research facilities was mortgaged, to varying degrees, against future indirect cost revenues. This mortgage, in turn, will fall to the NIH Institutes and Centers to cover as part of the cost of future grants.

What Then Is Driving the NCI’s Current Budget Anxiety?

As Table 1 shows, the number of NCI Research Project Grant (RPG) applicants who received awards peaked in 2004, with 1,393 grantees (new and competing renewals) receiving 1,487 grants. All of this hoped-for growth in cancer research did not just slow down and readjust to a new equilibrium when the growth of the annual appropriation ended. Instead of a soft landing, the subsequent flat budgets of 2004 through 2006 have brought the growth of the cancer research enterprise to an uncomfortably sudden stop. The outlook for the future includes a FY 2007 President’s Budget with a projected decrease of 0.8% from the 2006 level.1 This decreasing budget is further eroded by a Biomedical Research and Development Price Index (BRDPI) inflation rate of ~3.8% per year (July 24, 2006 revision of BRDPI: Revised FY 2005 Update. Each

1 At the time of publication, the FY 2007 budget was under a Continuing Resolution. It has been suggested that the budget may be under Continuing Resolution for the entire year. However, since it is not known, this article contains the President's Budget for FY 2007.

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December or early January, the Bureau of Economic Analysis, Department of Commerce, provides an estimate of the BRDPI for the fiscal year completed on the previous September 30. This number reflects changes in the cost of doing biomedical research and commonly runs several points above the country’s general inflationary index. As shown in Fig. 1, there has been an 8.3% decrease in the purchasing power of biomedical dollars from 2004 to 2007.

Figure 2 shows the NCI’s Congressional appropriations from 1998 to 2006 and the President’s Budget for 2007. The sidebar shows the appropriation in constant dollars relative to 1998. However, the greatest stress on a flat or decreasing budget comes from the fact that >85% of each year’s appropriated budget is already committed to support the “out years” of previously awarded grants and other ongoing activities.

During the period from 1999 to 2005, the applicant pool for grants increased by 53%, and application numbers increased by 63%. Presently, the amount of recycling within the grant pool is largely based on grants awarded in 2001, when we were only a few years into the doubling process. Thus, there is a lag period until the recycle pool of grant awards catches up to the peak awards of 2004 at the completion of the doubling.

To get a better understanding of the strain on the current budget, it is necessary to review the growth that NCI has experienced—and continues to experience—in the number of grant applicants and applications. As can be seen in Tables 2 and 3, during the last 5 years of budget doubling (1999–2003), there were a total of 962 new applicants. Between 2003 and 2005, there were almost as many more new applicants (799).

The pattern of new competing applications is similar, with an increase of 1,371 between 1999 and 2003 followed by an additional increase of 1,076 between 2003 and 2005. This rapid increase in the number of new applications has led to a continuing decline in the success rate, the ratio of awards to the number of applications. This indicator, which dropped from 32% to 27% between 1999 and 2003, was 19% in 2006, as the denominator continues to increase with no indication yet of a plateau.2

During this same period, the number of awards averaged 1,276 per year (range, 1,119–1,494). The data also help to dispel several common misperceptions, such as the belief that there has been a greater increase in investment in solicited projects compared with unsolicited R01s and P01s. A comparison of the percentage of solicited to unsolicited grants between 1998 and 2005 (Fig. 3)2 shows these trends to be essentially unchanged over this time period. The suggestion that there has been an increase in the number of applications per investigator is also not supported by the data, which indicate only a slight shift from 1.2 applications per investigator to 1.3.

What Happens to the NCI Appropriation Once Congress Passes the Budget?

In recent years, and again for FY 2007, it has been unusual for Congress to complete the appropriations process for the budget

### Table 1. Competing applicants and applications for FY 1995 to 2005 (data from NIH Office of Extramural Research)

<table>
<thead>
<tr>
<th>FY</th>
<th>Data on individuals</th>
<th>Data on applications</th>
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<tbody>
<tr>
<td></td>
<td>All RPG</td>
<td>R01 Equivalent</td>
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<tr>
<td></td>
<td>Reviewed (All RPG)</td>
<td>Awarded (%)</td>
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<td></td>
<td>Funded (%)</td>
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<tr>
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<tr>
<td>2000</td>
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<td>2002</td>
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<td>4,251</td>
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<tr>
<td>2004</td>
<td>4,870</td>
<td>1,393</td>
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<td>2005</td>
<td>5,050</td>
<td>1,226</td>
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**Figure 1.** Biomedical research and development price index impact.

2 NCI Office of Budget and Financial Management data.
before the October 1 start of the new fiscal year. As a result, the NCI often begins the year operating under a "Continuing Resolution," with the available funding based on the prior year's budget. This has a major effect on grantees, as resources are held back and only a percentage of their grants are paid until the actual NCI appropriation is determined.

Once there is a final NCI appropriation, a number of adjustments, including a series of decreases and mandatory taps must be made. The 2006 appropriation provides an excellent case in point. Although the 2006 appropriation dollar figure has been published and continues to be referred to as the "annual budget," there was a legislatively mandated across-the-board 1.0% decrease in the actual discretionary budget before any other requests were considered. With this reduced appropriation, the NCI then began to subtract additional funds for mandatory needs.

On average, approximately $30 million (M) must be set aside to address these needs, which include taps from the Department of Health and Human Services and the NIH. Taps from the NIH meet needs on campus, such as utility and rent increases and security assessments. In 2006, for example, $6.8M was needed to support national efforts, such as the ongoing aid to victims of Katrina and staffing needs of the Centers for Medicare and Medicaid Services, which is handling overwhelming beneficiary interest in its Medicare Plan D benefit. There were also mandatory federal salary increases in 2006, as well as the usual, annual "out year" commitments of approximately $1.6B for the noncompeting RPG pool (the multi-year projects already under way and for which funds are committed). The NCI's contribution for the NIH Roadmap, a common fund that was created to help enable science across disciplines and diseases, increased to $43M.3 The NCI's investment in the Roadmap has paid dividends. Our investigators compete well for the shared funds, and the Institute has benefited from the trans-NIH collaborations this mechanism has enabled. Nevertheless, Roadmap dollars still represent an upfront tap to the appropriated budget that must be found in the fraction of uncommitted funds and cannot be used to ease the current budgetary pressures.

RPGs, which include among others P01, R01, R03, and R21 funding mechanisms for investigator-initiated research proposals, account for 46% of the NCI budget, a percentage that has remained fairly constant for at least the last 15 years. The predominant grant mechanism comprising the RPGs is the R01. The NIH established three major policy variables for RPGs for FY2006. These included (a) that noncompeting grants be awarded at a level 2.35% below the prior level of commitment and that reduction be reflected on any future year commitments for that grant, (b) that the average cost of competing RPGs be the same in FY2006 as it was in FY2005, and (c) that the number of competing RPGs in FY2006 be around the same as in 2005. It is anticipated that similar variables for RPGs for FY2007 will be established by the NIH.

Furthermore, the NCI continues to make it a priority to fund first-time investigators. There is agreement across the biomedical community that the careers of young scientists must be nurtured. The R29, a now-defunct grant mechanism, was introduced by the NIH to exclusively fund young investigators. However, the size of the award, less than half that of the standard R01 grant, as well as the lack of value placed on R29 grantee status by universities, led to its discontinuation. The NIH has also asked reviewers to de-emphasize preliminary data on R01 applications from new investigators, but this approach has also failed to increase the proportion of NIH grantees under the age of 35.

The average age of the first-time NIH grantee continues to increase. In 2002, a National Academy of Sciences panel was charged by NIH director Dr. Elias Zerhouni to address this problem. The panel's recommendations included increasing the number of first-time grant recipients, reducing the age at which NIH grants are awarded, and providing additional support for early career scientists. Since then, the NIH has taken several steps to address the issue, including increasing the proportion of early career investigator awards and providing additional support for young investigators.

### Table 2. NCI competing applicants

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<th>FY 1999</th>
<th>FY 2003</th>
<th>FY 2003</th>
<th>FY 2005</th>
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<tr>
<td>3,289 appl</td>
<td>4,251 appl</td>
<td>4,251 appl</td>
<td>5,050 appl</td>
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<tr>
<td>Increase = 962</td>
<td>Increase = 799</td>
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Abbreviation: appl., applicants.

NOTE: The increase in competing applicants in the last 2 yrs is nearly as large as the increase in applicants during the period of NIH doubling.

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NCI’s Executive Committee Budget Planning Process

During the past 2 years, the leadership of the NCI, its Executive Committee, has reduced or phased out programs, allowing the redeployment of resources to initiate new programs or to increase support for existing programs. To maintain momentum toward the Institute’s scientific goals, the Executive Committee has had to engage in a rigorous review of Division programs and make difficult decisions concerning which projects should be maintained, downsized, or eliminated in order to continue to make strategic investments. This represents a return of the planning process to the Division and Center Directors, all of whom are on the Executive Committee.

Although the “pay line” is a number of considerable interest to the research community, another major factor that drives the budget decision-making process is the number of qualified applicants and applicant institutions seeking support for unsolicited research proposals, and the success rate they are experiencing. The number of qualified applicants and applicant organizations is a difficult denominator to project, and determining a reasonable success rate to ensure the highest quality science directed at cancer is even more problematic (Fig. 5). Nevertheless, this is what the NCI must strive to quantify and attain as we plan future budgets.

Planning for the 2007 budget began in the spring of 2006, with an intensive two-day retreat of the Executive Committee in which directors of the Divisions and Centers presented their program portfolios and indicated their funding preferences for 2007. Executive Committee members evaluated programs based on their respective priority assessments. The resulting priority assessments were evaluated during subsequent meetings. This process, which has involved a great deal of planning and preparation, is providing the entire NCI leadership with an in-depth understanding of the major initiatives within the Institute and, perhaps more importantly, a clearer view of what can be done across Divisions to achieve greater efficiencies in the use of resources. The sessions have also provided an opportunity to strategically explore the possibility of enhanced cross-Division scientific opportunities. This scientific retreat was followed this summer and fall by a similar in-depth review of the NCI’s infrastructure support.

Throughout the year, the Executive Committee receives updates on both scientific and administrative programs with an eye towards monitoring progress and being prepared to adapt to budgets that may be reduced or flat for the foreseeable future. In an era of flat or deficit budgets, there is a natural hesitancy to commit to long-term obligations. The key to making future commitments is determining where the most worthwhile opportunities lie. During these meetings, the Division and Center directors work as a cohesive leadership group. I have been thoroughly impressed by their ability to work together, and with extensive input from external advisors, to make difficult decisions with a unified mission to sustain scientific progress.

External Community Involvement Is Critically Important

These decisions on resource allocation and prioritization are not made in a vacuum. NCI leaders rely on guidance from our key advisory boards, which provide scientific review of research proposals and counsel on establishing priorities. This feedback—during regularly scheduled meetings, such as subcommittee meetings, the Division and Center directors work as a cohesive leadership group. I have been thoroughly impressed by their ability to work together, and with extensive input from external advisors, to make difficult decisions with a unified mission to sustain scientific progress.

Table 3. NCI competing applications

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<th>FY 2003</th>
<th>FY 2003</th>
<th>FY 2005</th>
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<tr>
<td>appln.</td>
<td>3,878</td>
<td>5,249</td>
<td>5,249</td>
<td>6,325</td>
</tr>
<tr>
<td>Increase</td>
<td>1,371</td>
<td>Increase</td>
<td>1,076</td>
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Abbreviation: appln., applications.
NOTE: The increase in competing applications in the last 2 yrs is nearly as large as the increase in applications during the period of NIH doubling.
deliberations and the annual January advisory boards retreat—figures prominently in the Executive Committee’s budget deliberations. The Director and Division and Center heads have historically had close relationships with the external scientific community, through personal contacts and through their Program Staff, who serve as the point of contact for extramural researchers to the NCI. Additionally, there are numerous workshops, think tanks, working groups, and scientific meetings sponsored each year by the NCI that are widely attended by clinicians, researchers, advocates, and others in the oncology community. These formal and informal interactions provide not only insights into emerging scientific opportunities, but also serve to expose other issues that need airing.

The NCI is fortunate in the number of scientists, advocates, and others who give of their time to serve the Institute on advisory boards and ad hoc scientific committees, and by participating in advocacy activities and disparities programs. The number of people who come to the NCI each year to participate in these various meetings and workshops is in the hundreds, if not thousands. All of these activities—whether it is a review of an intramural research program, a workshop on the state of the science, a meeting on cancer control, or participation in an advocacy summit—contribute to defining the scientific direction of the Institute.

There are also opportunities for scientific input during meetings of the Cancer Center directors and Specialized Programs of Research Excellence principal investigators, as well as during the American Association of Cancer Research and American Society of Clinical Oncology annual meetings. Throughout each year, the NCI is visited by various groups who come to Bethesda or Frederick, first and foremost, to discuss science, but also to talk about strategic direction, administrative and management issues, and other topics that affect them. The NCI has always been willing to

![Figure 3. NCI's unsolicited RPGs versus solicited RPGs.](image)

![Figure 4. NCI budget allocation by mechanism in FY 2005.](image)
meet with groups and carefully listen to their concerns and ideas about resource allocation. In all situations, when a new scientific initiative is considered, a group of experts is assembled to provide appropriate advice.

The Future: Some Personal Thoughts

There is broad agreement among NCI leaders about our path forward. First, we must continue to address the NCI's strategic priorities by funding new initiatives. Second, we are committed to striving to maintain the number of competing awards near the level achieved by the doubling of the NIH budget. In addition, we are firmly committed to funding new investigators. As a nation, we need to continue to make biomedical research an attractive career choice. It would be devastating if the best minds are kept away from a field so vital to our nation's health and economics.

Discussing priority setting and budget planning in this and other venues ensures greater transparency and openness. Hopefully, it will have another outcome: to unify the voice of advocacy for cancer research and care. Often fragmented, support for cancer research is tied to individual cancer types or specific scientific programs. To make the kind of impact that is needed today, the cancer community must speak with a unified voice. We must propose solutions as a community if we are to be effectively heard.

I have personally experienced major swings in biomedical research funding over the past 30 years. Such swings can take their toll on scientific momentum and discourage new researchers from committing to a career in research (Fig. 6; ref. 1). I am urging us, as a cancer research community, to speak for a national plan in support of the biomedical research enterprise. I believe that such a plan is needed to maintain the United States' position as a worldwide scientific leader. The future of science and the economic vigor of our country will depend on investment in the life sciences, genetics, and biotechnology. We need to recognize the importance of healthcare, of reducing mortality from disease, as a critical driver of the country's economic welfare.

As Director of the NCI, I am working hard to find new ways to leverage resources. We are continuing our collaborations with other NIH Institutes and Centers and Federal agencies. NCI has long-standing partnerships and collaborations, such as the Surveillance, Epidemiology, and End Results program with the Centers for Disease Control and Prevention and the National Program of Cancer Registries; the Interagency Oncology Task Force with the Food and Drug Administration; and Cancer Control PLANET with the Agency for Healthcare Research and Quality, the Substance Abuse and Mental Health Services Administration, and the Health Resources and Services Administration within the Department of Health and Human Services. The Surveillance, Epidemiology, and End Results program and Cancer Control PLANET are also supported by the American Cancer Society. Each of the Divisions and Centers at NCI has been extraordinarily successful in developing collaborations with academia, other Federal agencies, and other NIH Institutes and Centers. For
example, NCI cofunds programs across the oncology research spectrum in behavioral science, clinical research, epidemiology, genetics, molecular biology, proteomics, nanotechnology, and basic scientific discovery, just to name a few. I also plan to increase public–private partnerships during my tenure at NCI.

Aside from the logical hand-offs in drug development for new oncology drugs and biologies coming out of the intramural translational research program, the NCI has unique capabilities on the Frederick Campus. The technology expertise, core facilities, and advanced biomedical technology development opportunities at NCI-Frederick are a unique national resource. The NCI Research Technology Program is home to advanced technologies in imaging, analytic and protein chemistry, genomics, structural biology, and supercomputing capabilities. When the NCI undertakes a new initiative such as large-scale technology-based programs, intramural and extramural experts are asked to help advise and plan the program with NCI staff. Advice is sought through think tanks, working groups, state-of-the-science meetings and advisory board ad hoc subcommittees. Additionally, advisory board approval is obtained prior to implementation. I am committed to NCI’s continuing leadership in developing enabling technologies, such as bioinformatics, nanotechnologies, and The Cancer Genome Atlas (a comprehensive description of the genetic basis of human cancer), and the necessity of making these and other resources accessible to the entire cancer research community. There is no other organization or institution that can fill this need.

Although it is important to be realistic about the possibility of any influx of Federal discretionary dollars flowing into the NCI soon, I continue to be optimistic because I have seen what the cancer research community is capable of accomplishing, regardless of the obstacles presented. By the mid-1990s, the inexorable climb of cancer mortality rates, a trend since the first mortality statistics were compiled in 1930, was finally halted and reversed. This downward trend has now been sustained for over a decade, and through the efforts of our community, can not only continue, but accelerate (2).

Our responsibilities at the NCI and as a cancer community are to continue conducting quality research, to make biomedical research an attractive career choice, to offer solutions to our challenges, to speak with a more unified voice, and to make the difficult decisions among competing priorities that will be necessary to maintain our momentum. The NCI remains steadfastly committed to the RPG pool as its highest priority. As evidenced by the advances and progress recently made in cancer mortality, our past investment has paid dividends. These are exciting times in which science must flourish, but we must continue to foster and nourish our opportunities. We cannot stand on our laurels; we cannot maintain the status quo. The NCI will do its part to foster and enable new discoveries, new technologies, and the development of the scientific leaders of tomorrow. It is up to others, with the reminder that one in two men and one in three women will receive a diagnosis of cancer in their lifetime, to ensure that NCI has the resources and the authority to capitalize on the recent, historical decline in the number of people dying from cancer each year.

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