THE CANCER LETTER

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Senate Approves $1 Billion Budget Increase For NIH; 3.7% Raise Is Smallest Since 1995

The Senate last week passed an appropriations bill that broke a succession of double-digit increases for biomedical research, giving NIH a 3.7 percent raise, the smallest since 1995.

The bill passed by the Senate on Sept. 10 provides $27.990 billion for NIH, an increase of $1 billion over the current year, and $326.8 million above the House bill and the President's budget proposal.

The Senate bill gives NCI $4.771 billion, an amount equal to the Bush Administration's budget request. The fiscal year 2003 appropriation was $4.592 billion.

Barring an unexpected last-minute rescue, NIH and NCI will have to make a quick adjustment to lower budgets. The plunge comes at a time when NCI, working through the National Dialogue on Cancer, is planning monumental expansion of the cancer program, including development of

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In Brief:

Vanderbilt-Ingram Wins Third SPORE Grant; Ehrenfeld To Step Down As CSR Director

VANDERBILT-INGRAM Cancer Center investigators were awarded a Specialized Program of Research Excellence in breast cancer by NCI. The grant will provide $2.5 million in the first year, with total recommended funding over the five-year period of more than $13 million. Vanderbilt-Ingram teams also hold SPOREs in lung and gastrointestinal cancer. **Carlos Arteaga**, professor of medicine and cancer biology and Ingram Professor of Cancer Research, is the breast cancer SPORE director. . . . **ELLIE EHRENFELD** will step down as director of the NIH Center for Scientific Review at the end of this month. She plans to continue as chief of the Picornavirus Replication Section in the Laboratory of Infectious Diseases at the National Institute of Allergy and Infectious Diseases. In Ehrenfeld's seven years as CSR director, the number of grant applications submitted to NIH increased by 70 percent, and review committees and study sections were reorganized. . . . **PATRICK LEE**, chairman of the board of directors of the Roswell Park Cancer Institute Corp. for the past five years, will resign his position on Dec. 31. Lee is chairman and CEO of International Motion Control Inc., of Buffalo, NY. . . . **JOHN KILLEN** was named director of the Office of International Health Research, National Center for Complementary and Alternative Medicine. Killen, a 21-year NIH veteran, was head of the Office of Biodefense Research at NIAID.

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Last-Minute Attempt To Add Funds For NIH Fails In Senate

(Continued from page 1)

a multi-billion-dollar National Biospecimen Network, an initiative that its boosters compare with the space station (**The Cancer Letter**, Aug. 8).

The Dialogue is a not-for-profit group funded primarily by the American Cancer Society, pharmaceutical companies, and the American Legacy Foundation.

Last week, Sen. Arlen Specter (R-Penn.) made an unsuccessful attempt to add $1.5 billion for NIH, arguing on the Senate floor that shrinking appropriations for biomedical research constituted a national emergency, and therefore should be exempt from the requirements of the budget resolution that places caps on the appropriations bills.

"The budget resolution provides for an emergency classification if it meets the following criteria: No. 1, vital; No. 2 urgent and compelling; No. 3, unpredictable; and No. 4, temporary," Specter said during the floor debate Sept. 10.

Specter is the chairman of the Labor, HHS and Education Appropriations Subcommittee. The amendment was co-sponsored by Sens. Tom Harkin (D-Iowa), Dianne Feinstein (D-Calif.), and Susan Collins (R-Maine).

Specter's effort failed to overcome opposition from Senate Budget Committee Chairman Don Nickles (R-Okla.) and Senate Majority Leader Bill Frist (R-Tenn.), who countered that NIH appropriations were, in fact, routine, and that Specter's efforts constituted an attempt to bust the budget.

The Senate had $137.6 billion to apportion between the agencies funded by the bill, and the decision to keep down the increases for NIH couldn't be suddenly declared an accident, Nickles countered.

To exceed the spending cap imposed within the budget resolution, Specter needed to get 60 votes for his amendment. The amendment fell eight votes short of that target.

"This amendment breaks the budget deal that the chairman of the Appropriations Committee negotiated with the President," said Nickles during the debate. "Are we going to have a budget or not have a budget? This amendment says we are going to add $1.5 billion for NIH and declare it an emergency; i.e., we don't expect it to count on the budget. In other words, we don't want the budget to apply."

In the course of the debate, Nickles cited a recent press account of an NIH microbiologist claiming that he was being paid $100,000 a year and doing no work. "Basically, the headline is 'NIH Scientist Says He's Paid To Do Nothing; Agency Denies Administrator's Surreal Situation Of Collecting $100,000 Salary For No Work," Nickles said, entering the story in the Senate record. "I remember reading it, and I thought, 'Whoa, somebody is not paying attention.'"

NIH and NCI are likely to encounter additional Congressional scrutiny at the Oct. 2 hearing of the House Committee on Energy and Commerce and the Senate Committee on Health, Education, Labor and Pensions. .

That hearing will examine the implementation of the recent report of the Institute of Medicine that recommended the enhancement of authority of the NIH Director. According to IOM, NCI should lose the special status it enjoys under the National Cancer Act of 1971.

If these recommendations are followed, the NCI director and members of the National Cancer Advisory Board would no longer be Presidential appointments, and the Institute's authority to submit bypass budgets to the White House would be lost.

The removal of NCI's special status would depoliticize the Institute, removing an "unnecessary rift… between the goals, mission, and leadership of

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NIH and those of NCI," the IOM report said (**The Cancer Letter**, Aug. 1).

As federal appropriations for the cancer program are about to plunge, the National Dialogue on Cancer continues to plan a massive expansion. A document recently circulated to the Dialogue's committee on Access to Quality Cancer Care suggested the following goals:

—By 2007, "quality [cancer] care will be clearly defined, and surveillance systems will be created that allow for evaluation of quality and outcome assessments.

"These assessments will be tied to health care accreditation and practitioner licensure/certification," continued the document dated Aug. 6. "This would include complementary and alternative treatments where they have proven their effectiveness and become a part of conventional practice."

—By the year 2010, "all cancer data systems are linkable to each other, merged, and matched to other data sets to enhance prevention and care," the memorandum forecast. "Requirements include comparable, standardized data elements that are electronically linked; privacy, confidentiality, and discrimination protections in place; responsible leadership or an organizational entity with authority and funding in place."

The Dialogue is exempt from requirements of the Federal Advisory Committees Act and the Freedom of Information Act.

Senate Report Language

The excerpted text of the report that accompanies the Senate appropriations bill follows:

This committee has long recognized the worth of NIH, not only as the world's most important biomedical research establishment, but as the taproot that nourishes growth and progress in medical science.

Along with that recognition comes the understanding that the engine of progress must be maintained.

Although the private sector has an important role to play, the federal government is the only source able to provide sustained, long-term support. NIH-supported research helps supply the cadre of highly skilled investigators, stimulates investments in new technology development, and is an important precursor to innovation.

NCI Appropriations:

***Behavioral Research*—**The committee recognizes the enormous progress NCI has made in the quality and breadth of cancer-related behavioral science, ranging from basic bio-behavioral research to health communication research and tobacco control research.

Closing the gap between research and program delivery is both a challenge and a necessity if all populations are to benefit from new scientific discoveries. Behavioral science can contribute to survival, reduced morbidity and increased quality of life, and the behavioral and cognitive sciences can be highly applicable in answering critical questions regarding patient care.

***Blood Cancers*—**The committee urges the NCI to continue to implement the research priorities for leukemia, lymphoma, and multiple myeloma included in the May 2001 Progress Review Group Report.

***Bone Metastasis*—**The committee encourages NCI to continue its emphasis on studying the bone microenvironment and bone metastasis related to prostate cancer, breast cancer and multiple myeloma and to support research to delineate the mechanisms of reciprocal interactions between tumor cells and bone. To provide an infrastructure for this research, NCI is encouraged to establish a repository of human bone metastases for the scientific community and support research to generate three-dimensional in vitro and/or in vivo models that yield bone metastases.

***Brain Tumors*—**In November 2000, the NCI and NINDS convened a panel of experts to review the field of brain tumor research and make recommendations to enhance it. The committee is pleased that the Institutes followed that meeting by establishing the Neuro-Oncology Branch, an inter-institutional initiative aimed at bringing a multidisciplinary approach to brain tumor research.

The committee now urges the NCI and NINDS to establish a coordinated and multi-institutional tissue bank that would gather not only tissue but also blood and cerebrospinal fluid from patients with all varieties of brain tumors. The system should also be linked to a comprehensive database of relevant clinical, demographic, pathologic, biologic, and therapeutic information on all patients whose tissue is banked.

The committee further strongly urges the NCI to increase funding and the number of Specialized Programs of Research Excellence in Brain Tumors [SPORE] grants in the upcoming fiscal year, with particular emphasis on those proposals which include both basic research and clinical treatment applications.

***Cancer and Minorities*—**The committee remains concerned that cancer rates for Native Hawaiians and other Native American Pacific Islanders are disproportionately high. The committee encourages the NCI to expand its research in this area.

***Cancer Genomics*—**The committee commends NCI for its commitment to understanding the role of genomics and genetics in the progression of cancer. Considerable effort must now be directed toward applying those findings to tumor classification and therapeutic choice, with a focus on breast, colorectal and lung cancer, as well as leukemia and lymphoma. An important component of

this effort will be to build a public database of whole genome expression profiles from various tumor types, which includes clinical outcome information. The committee encourages NCI to ensure that this data is available to health professionals to assist physicians and patients in choosing the best treatment options.

Cancer Survivorship—With the advances that have resulted from the ongoing commitment and investment in biomedical research, and the resultant advances in cancer treatment, cancer for many has become a chronic illness.

Currently, there are over 9 million cancer survivors in the Nation, and this number is expected to grow dramatically. More must be done to improve the understanding of the growing cancer survivorship population, including determinations of physiological and psychological late effects, prevalence of secondary cancers, as well as further development of effective survivorship interventions.

The committee supports an aggressive expansion of the NCI Office of Cancer Survivorship activities and urges the NCI to continue its work to expand the Office of cancer Survivorship within NCI, as well as advance and increases opportunities in cancer survivorship. The committee was pleased to see NCI include cancer survivorship in the cancer bypass budget and urges NCI to provide increased funding for cancer survivorship research.

Chronic Lymphocytic Leukemia—The committee strongly encourages the NCI to increase the level of research aimed at determining the underlying cause and optimum therapies for CLL, the most common form of adult leukemia in the United States. The committee is encouraged by the NCI's willingness to consider a supplementary application for research funding for the CLL Research Consortium. The committee further urges the NCI to expand funding for the Consortium to speed up the progress in finding significant scientific breakthroughs.

Chronic Myeloproliferative Disorders—Polycythemia vera, idiopathic myelofibrosis and essential thrombocytosis are malignant diseases of the bone marrow that are underserved with respect to research funding, considering the number of people they strike. These disorders are chronic and can transform into acute leukemia. They offer great research promise with respect to insights into the behavior of blood cells, since the cells that they affect appear normal but behave abnormally.

The major obstacle to research into the causes and the treatment of these disorders has been the lack of Federal funds designated for this purpose. The committee strongly believes that the NCI should expand research into these disorders, and be prepared to report to the Committee during the fiscal 2005 budget hearing about existing efforts, as well as planned future efforts, to better understand these disorders.

Complementary and Alternative Cancer Therapies—The committee expects the NCI to expand its work and its collaborative efforts with NCCAM to support research on promising complementary and alternative cancer therapies as well as on their integration with traditional therapies.

DES—The committee continues to strongly support increased efforts to study and educate the public and health professionals about the impact of exposure to the synthetic hormone diethylstilbestrol. The committee expects the NCI to continue its support of research in this area, and to continue to consult with organizations representing individuals impacted by DES as they carry out DES research and education efforts.

Diet and Nutrition—The evidence is mounting that diet and nutrition play a key role in causing cancer and preventing it. For example, studies show that a diet with little fiber may be a contributing factor in colon cancer, while lycopene found in tomatoes may be useful in preventing prostate cancer. Likewise, diet can play a major role in treating a variety of cancers. The committee encourages NCI to dedicate more funding to research and education programs focused on diet and nutrition.

Gynecologic Cancers—The committee is encouraged by the success of the Gynecological Cancer SPORE program but believes an increased investment is needed as the survival rate for ovarian cancer remains disappointingly low. The committee believes the CanCOR program should be expanded to help identify barriers to receiving optimal care among women with newly diagnosed gynecological cancer. The NCI should also develop prophylactic and therapeutic HPV vaccines to prevent cervical cancer and strengthen research in the biology of endometrial cancer in order to improve prevention and treatment, thus sparing women the need to undergo hysterectomy and other cancer therapy.

The committee also believes that the NCI should be partnering with the NICHD Reproductive Sciences Program to investigate gynecological cancer.

Health Communications—The committee is pleased at the growth of this program of research, since health communications is such a vital contributor to the public health and health care generally. Understanding and improving communication between health providers and patients, improving communication with low literacy populations, and understanding what aids and hinders public health messages is critically important for building a healthier Nation. The committee particularly encourages NCI to provide additional information about the HINTS survey that will commence this year. This will be the first national health communications survey, involving some 8,000 adults.

Imaging Systems Technologies—The committee is encouraged by progress made by the NCI following its August 1999 conference on biomedical imaging, and it urges the NCI to continue to take a leadership role with the Centers for Medicare and Medicaid Services and FDA to avoid duplicative reviews of new imaging technologies which may prevent their benefits from reaching patients

on a timely basis. The committee is aware of the great potential for improved patient care and disease management represented by molecular imaging technologies, especially positron emission tomography through its ability to image the biology of many kinds of cancer and other diseases. The committee continues to support the NCI's increased emphasis on examining the molecular basis of disease through imaging technologies such as PET and MicroPET.

The committee continues to encourage the large-scale testing of women for breast cancer and men for prostate cancer to demonstrate and quantify the increased diagnostic and staging capabilities of PET relative to conventional diagnostic and staging technologies, including mammography.

Kidney Cancer—The committee is concerned about the growing incidence of kidney cancer. The committee strongly urges the NCI to place a greater emphasis on and dedicate expanded resources to research on kidney cancer. The committee requests the NCI to convene an expert conference by December 2003 to develop a short- and long-term research agenda and action plan for improving the diagnosis and treatment of kidney cancer. The committee recommends that the conference include patient advocates.

Liver Cancer—The committee is concerned that primary liver cancer continues to be one of the few forms of cancer for which incidence is growing. This has serious implications for public policy, cancer being a significant factor in transplantation. NCI is planning a joint meeting with NIDDK for April 2004. It is critical that this meeting result in a strong plan for future research in primary liver cancer that will reverse the current increases.

Lymphoma Research—The committee recommends that NCI increase its efforts to examine the issue of environmental and viral links to lymphoma. Although many studies have suggested an increased risk of lymphoma associated with environmental factors such as chemicals, pesticides and herbicides, other investigations have reported inconsistent results. However, many of these studies are weakened by limited sample sizes, flaws in study design, and imprecision in the measurement of environmental carcinogen exposures. The committee recommends that NCI work to develop a well-constructed prospective study, using a multidisciplinary, approach to examine environmental links to lymphoma.

In a recent report (October 2002) the Institute of Medicine concluded that there is moderate to strong biological evidence supporting a role of Simian Virus 40 in human cancer. Recent reports suggest that more than 40 percent of lymphomas tested were positive for this virus.

Additional research studies have also found an association between other viruses, such as human herpes virus 8 and hepatitis C, and lymphoma. As a result of these studies, it is possible that more than half of all lymphomas may be attributed to viruses. The committee therefore recommends that NCI also increase its efforts to examine the viral etiology of lymphoma.

The committee notes that there have been significant advances in the treatment of Hodgkin's lymphoma over the last 30 years and some improvements in the treatment of NHL. However, NHL treatments are not adequate, and treatment improvements are absolutely critical for this group of cancer patients. Although industry has recently developed several new NHL therapies, the involvement of NCI in lymphoma research is still critical. The committee urges that NCI increase its investment in clinical research on lymphoma and strengthen its collaboration with industry to improve the efficiency and timeliness of the lymphoma drug development process.

The committee also recommends that, in addition to initiatives to improve the lymphoma drug development process, NCI increase its investment in several other areas of research, including research on nonablative transplants, immunomodulatory regimens, central nervous system lymphoma, the late and long-term effects of current lymphoma treatments, and lymphoma etiology and prevention.

The committee also urges NCI to cooperate with private organizations in the development of a comprehensive lymphoma tissue bank.

Multiple Myeloma—The committee acknowledges that NCI has developed the Academic Public Private Partnership Program to facilitate public-private partnerships in research on orphan cancers, including but not limited to blood-related cancers.

The committee is pleased by this action, but in light of the serious burden associated with the blood cancers and the limited treatment possibilities for many blood cancers, it strongly urges additional efforts to accelerate the development of blood cancer therapies. The committee encourages NCI to develop funding mechanisms for translational blood-related cancer research that will facilitate multi-disciplinary and multi-institutional research collaborations instead of research focused at only one institution.

Multi-institutional cooperation is critical if new therapies are to be efficiently developed. The committee also urges NCI to increase its overall investment in blood cancer research, including but not limited to its investment in these multi-institutional research grants. The committee requests that NCI submit a report on the status of its blood cancer research program by April 2004.

Myelodysplasia and Myeloproliferative Disorders—The committee is pleased with NCI's efforts to address the lack of basic knowledge about myelodysplasia and myeloproliferative disorders. The committee urges NCI to carry out recommendations of its recent conference on these diseases and advance new research initiatives into developing effective treatments.

Nanosystems Biology—The committee encourages NCI to support a collaborative effort to bring nanotechnology, systems biology and molecular imaging

together to examine the molecular basis of cancer. Bringing these three disciplines together may allow researchers to identify specific sub-types of cancer and to better target new interventions. Successful results of such an effort could lead to a molecular classification of many types of cancer and to targeted molecular treatments for molecular-specific diseases.

***Neurofibromatosis*—**Neurofibromatosis [NF] research has significant potential for cancer patients since NF genes have been implicated in the signaling processes that determine cell growth and cell differentiation. It will contribute to the development of new technologies and enhance understanding of the fundamental processes of both cancer and NF. The committee encourages NCI to intensify and expand its NF research portfolio in such areas as molecular biology, development of animal models, natural history studies, malignant transformation in tumors, therapeutic intervention, and clinical trials. It recommends that NCI use all available mechanisms, including requests for applications, program announcements, and the national cooperative drug discovery group program to achieve this end.

The committee expects NCI to coordinate its efforts with other Institutes where appropriate and to be prepared to report on its progress at the fiscal year 2005 appropriations hearings. The committee thanks NCI for conducting phase II clinical trials of NF1 patients with plexiform neurofibromas. Finally the committee encourages NCI to increase its NF research portfolio in such areas as further development of animal models, natural history studies, therapeutic experimentation, and clinical trials.

***Organ Cancers*—**The committee acknowledges NCI has developed the Academic Public Private Partnership Program to facilitate public-private partnerships in research on orphan cancers, including but not limited to blood-related cancers.

The committee is pleased by this action, but in light of the serious burden associated with the blood cancers and the limited treatment possibilities for many blood cancers, it strongly urges additional efforts to accelerate the development of blood cancer therapies.

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Multi-institutional cooperation is critical if new therapies are to be efficiently developed. The committee also urges the NCI to increase its overall investment in blood cancer research, including but not limited to its investment in these multi-institutional research grants.

To ensure that progress on blood cancer research initiatives continue, the committee requests that NCI submit a report on the status of its blood cancer research program by April of 2004.

***Pancreatic Cancer*—**The committee is concerned that research funding for pancreatic cancer has not increased commensurate with the severity of this disease or the overall increase afforded the NCI within the past 5 years.

The committee strongly urges the NCI to complete the immediate and short-term strategies identified in the 'Strategic Plan for Addressing the Recommendations of the Pancreatic Cancer Progress Review Group,' which was issued by the NCI in September 2002. In addition, the committee asks the NCI to complete a professional judgment budget to carry out those strategies, and to provide it to the committee by April 1, 2004.

***Prostate Cancer*—**The committee is aware of the considerable investment that has been made in prostate cancer, the leading cause of cancer death among men, and encourages NCI to continue to support research to improve the accuracy of screening and early detection of prostate cancer. Emphasis should also be placed on the development of new, more effective therapies for cancer that was not detected early enough and is no longer confined to the prostate capsule.

The Institute has worked with the urologic scientific community to identify research needs in other urologic oncology, including bladder, kidney and testis cancers. The committee expects the Institute to increase the research resources directed to these other urologic cancers, which affect thousands of men and women annually.

The success in treating prostate, and other cancers, means that there are many individuals in society who are cancer survivors. There are a series of distinct physical and emotional issues facing these individuals, and the committee encourages NCI to develop programs that address these problems.

The report titled 'Prostate Cancer Research Plan Fiscal Year 2003—Fiscal Year 2008' that NCI provided to Congress in August 2002 did not include a professional budget judgment. The committee requests the NCI to provide such a budget for fiscal year 2004 through fiscal year 2008 by April 2004.

The House Report

The text of the report that accompanies the House bill follows:

The Administration's FY04 budget for NIH includes $1,625,000,000 for bioterrorism activities. The committee recognizes the importance of this research activity, but is concerned about the limited increases this budget makes available for important non-biodefense research. The committee has not identified a specific funding level for biodefense research, choosing to give the Director of NIH flexibility in determining what share of NIH resources should be considered biodefense activities. If, during 2004, the Director determines that a different allocation of resources is possible to increase support for high priority non-biodefense activities, the committee would look

favorably upon that reallocation.

Balance in the research portfolio—The committee reiterates its longstanding view that NIH should distribute funding on the basis of scientific opportunity. The committee urges the Director and the Administration to continue to resist pressures to earmark, set aside and otherwise politicize these resources.

To enhance NIH's flexibility to allocate funding based on scientific opportunity, the committee has attempted to minimize the amount of direction provided in the report accompanying the bill. For example, there are no directives to fund particular research mechanisms, such as centers or requests for applications, or specific amounts of funding for particular diseases.

In stating that scientific opportunity should be the basis for allocating research funding, the committee understands that other factors also are relevant to NIH's decisions, including such considerations as the infectious nature of a disease, the number of cases and deaths associated with a particular disease, the Federal and other costs of treating a disease, the years of productive life lost due to a particular disease, and the estimated proximity to research breakthroughs.

The committee does not presume to judge, which criteria should take precedence or carry the greatest weight in individual funding decisions, but urges NIH to consider the full array of relevant criteria as it constructs its research portfolio.

Prostate cancer—The committee encourages NCI to place an increased priority on research through all available mechanisms, as appropriate, including clinical trials that result in earlier, more reliable detection methods and more effective and less disfiguring treatment regimes.

The committee encourages NCI to identify a budget strategy with specific prostate cancer funding opportunities and priority investments.

Cancer centers—The committee is pleased with the substantial progress in cancer research and the many opportunities that have been created by the sustained investment in biomedical research and technology. One of the most successful investments by NCI is the Cancer Centers program, which has the potential to accelerate progress further by linking its state-of-the-art resources with the broader cancer community.

In order to speed progress and promote greater collaboration among scientists, the committee requests that NCI explore innovative and creative ways to share information throughout the cancer community, utilizing the infrastructure of the national cancer centers program.

Given that minority populations suffer disproportionately from virtually every form of cancer, the committee encourages NCI to give consideration to the establishment of a comprehensive center at a minority institution focused on research, treatment, and prevention of cancer in African American and other minority communities.

Neurofibromatosis—The committee is pleased that NCI is conducting phase II clinical trials of NF1 patients with plexiform neurofibromas. The committee is concerned about recent declines in funding for NF research, recognizing NF's connection to many of the most common forms of human cancer. The committee encourages NCI to substantially increase its efforts in NF research in further development of animal models, natural history studies, therapeutic experimentation, and clinical trials.

Liver cancer—The committee is concerned that primary liver cancer continues to be one of the few forms of cancer for which incidence is growing. While progress is being made, much more needs to be done. NCI is planning a joint meeting with NIDDK for April 2004. The committee hopes that this meeting will result in a strong plan for future research in liver cancer that will reverse the current increases.

Lymphoma—The committee recommends that NCI increase its efforts to examine the issue of environmental and viral links to lymphoma. The committee recommends that NCI work to develop a well-constructed prospective study, using a multidisciplinary approach to examine environmental links to lymphoma. The committee encourages NCI to increase its efforts to examine the viral etiology of lymphoma.

Pancreatic cancer—The committee encourages NCI to begin to implement the short- and medium-term strategies identified in the strategic plan to address the recommendations of the pancreatic cancer progress review group. NCI is encouraged to place particular emphasis on developing a critical mass of researchers in pancreatic cancer. The committee requests a report in March 2004 of the specific budgetary and programmatic actions planned to respond to the strategic plan.

Hodgkin's and Non-Hodgkin's lymphoma—The committee encourages NCI to increase its investment in clinical research on lymphoma and strengthen its collaboration with industry to improve the efficiency and timeliness of the lymphoma drug development process.

The committee recommends that, in addition to initiatives to improve the lymphoma drug development process, NCI increase its investment in several other areas of research, including research on nonablative transplants, immunomodulatory regimens, central nervous system lymphoma, the late and long-term effects of current lymphoma treatments, and lymphoma etiology and prevention. The committee also encourages NCI to cooperate with private organizations in the development of a comprehensive lymphoma tissue bank.

Myelodysplasia and myeloproliferative disorders—The committee is pleased with NCI's efforts to address the lack of basic knowledge about myelodysplasia and myeloproliferative disorders, two very different types of chronic diseases of bone marrow cells that can develop into acute leukemia. The committee encourages NCI to carry out the recommendations of its recent conference of

experts on these diseases and to advance new research initiatives into developing effective treatments.

***Brain tumors*—**The committee encourages NCI, in cooperation with the National Institute of Neurological Disorders and Stroke, to more fully support brain tumor research, including the brain tumor specialized programs of research excellence grants. The committee is aware of the ongoing need to develop brain tumor tissue banks and encourages NCI and NINDS to consider developing a plan to establish coordinated tumor banks that would bank not only tissue but also blood and cerebrospinal fluid from patients with all varieties of brain tumors. The committee requests a copy of the plan within six months of enactment of this bill.

***Cancer genomics*—**The committee commends NCI for its commitment to understanding the role of genomics and genetics in the progression of cancer. Considerable effort must now be directed toward applying those findings to tumor classification and therapeutic choice, with a focus on breast, colorectal and lung cancer, as well as leukemia and lymphoma. An important component of this effort will be to build a public database of whole genome expression profiles from various tumor types, which includes clinical outcome information. The committee encourages NCI to ensure that this data is available to health professionals to assist physicians and patients in choosing the best treatment options.

***American Russian Cancer Alliance*—**The American Russian Cancer Alliance is established to implement long-term collaborative programs for clinical and research activities that ultimately benefit cancer patients worldwide. The committee recommends that NCI promote, facilitate, and support the development of the Alliance in order to bolster cancer research and treatment opportunities in the United States Cancer Centers.

***Bone metastases*—**The committee urges NCI to continue its emphasis on studying the bone microenvironment and bone metastasis related to prostate cancer, breast cancer and multiple myeloma and to support research to delineate the mechanisms of reciprocal interactions between tumor cells and bone. NCI is also encouraged to establish a repository of human bone metastases for the scientific community and support research to generate three-dimensional in vitro and/or in vivo models that yield bone metastasis.

***Tobacco harm reduction*—**The committee is aware that NCI has established the Tobacco Control Research Branch, designed to reduce cancer incidence and mortality caused by tobacco use through a comprehensive research program, and applauds the establishment of a collaborative research effort between the NCI and the CDC related to the analysis of tobacco products and harm reduction. NCI should be prepared to report to the committee during the fiscal year 2005 budget hearings regarding the findings of this collaboration with regard to the effectiveness of harm reduction for those tobacco users who are unable to quit.

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