# CHACER LETTER

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# Senate Bill Matches \$2.01 Billion Bush Request For NCI, Sets Bypass Funding For Breast Cancer

The Senate Appropriations Committee last week approved a bill that matched the President's budget request for NCI and exceeded the level the House appropriated for the Institute.

The language of the Senate bill was more sympathetic to NCI than the language of the report of the House Appropriations Committee, which expressed the committee's "impatience with the lack of overall progress" (Continued to page 2)

#### In Brief

## Alice Fordyce, Supporter Of Medical Research, Dead At 86; Broder Awarded Block Lectureship

ALICE FORDYCE, executive vice president of the Albert and Mary Lasker Foundation and former director of the Albert Lasker Medical Research Awards Program, died last week in New York City of lung cancer. She was 86. Fordyce helped her older sister Mary Lasker establish the medical research awards program in 1944, and the Albert Lasker Medical Journalism Awards, presented from 1949-1970. She was influential in philanthropic activities and was a supporter of mental health programs. She served as a director of many organizations, including the International Council for Coordinating Cancer Research. She resigned from the Lasker awards program in December 1990, but remained a member of the foundation's board. Fordyce was the widow of architect A. Grant Fordyce. She is survived by her sister, Mary Lasker, son, James Fordyce, and three grandsons. A memorial service was held Sept. 15 at the United Nations Chapel. Contributions may be made to the chamber music organization Fordyce supported, Bargemusic Ltd., Fulton Ferry Landing, Brooklyn, NY 11201. . . . SAMUEL BRODER, NCI director, is the recipient of the first Herbert J. Block Memorial Lectureship Award given by the Arthur G. James Cancer Hospital and Research Institute, Ohio State Univ. The award recognizes distinguished achievement in cancer research. . . . THOMAS SHEA has been appointed director of the bone marrow transplant program of Univ. of North Carolina hospitals, associate professor of medicine at UNC School of Medicine, and a member of the UNC Lineberger Comprehensive Cancer Center. Shea was director of the BMT program at Univ. of California, San Diego. . . . NIH CONSENSUS panel statement on diagnosis and treatment of early melanoma, from the conference held last January, is available from the NIH Office of Medical Applications of Research, Federal Bldg Rm 618, Bethesda, MD 20892, phone 301/496-1143.

Senate Raises Funding For Cervical, Ovarian, Prostate Cancer

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# Senate Bill Provides \$220 Million Bypass Request For Breast Cancer

(Continued from page 1)

in the war on cancer and made a reference to the "major role" of occupational exposures to chemicals as a cause of cancer (The Cancer Letter, July 31).

The Senate committee recommended an appropriation of \$2.01 billion for NCI in fiscal 1993, \$11.8 million above the House allowance and \$58.9 million above the current budget.

In response to an aggressive lobbying campaign by the Breast Cancer Coalition, an organization that includes patient groups, the Senate committee appropriated \$220 million to breast cancer, making it the only cancer to be funded at the level of the NCI bypass budget.

With the increase, funding for breast cancer would be \$83.3 million above the President's request and \$87.3 above the current budget.

Unless additional funds are allocated later in the budget approval process, the increase for breast cancer is likely to bring about a reallocation of funds from other NCI programs.

At this writing, Sen. Tom Harkin (D-IA), chairman of Labor, HHS, Education Appropriations Subcommittee, was expected to introduce an amendment that would take \$4.1 billion out of defense and transfer the funds into health and education programs. A number of observers said they were not hopeful for Harkin's attempt to break through the proverbial "firewall" shielding defense from raids by proponents of health and education.

Skeptics cited an earlier unsuccessful attempt by Sen. Dale Bumpers (D-AK) to eliminate the space station as well as a number of defense projects.

The budget bill approved by the Senate Appropriations Committee gave cancer researchers and

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professional societies both a reason to cheer and a cause for concern:

"I think that the bottom line is that by virtue of what Harkin and the subcommittee did for cancer during this tight budget year indicates that cancer remains a top national priority," Terry Lierman, president of Capitol Associates Inc., the lobbying group for the National Coalition for Cancer Research, said to **The Cancer Letter**.

However, Lierman said, "there is going to be a dramatic negative impact on the existing cancer program as a result of breast cancer initiatives being funded at the expense of other programs. Whom would you take money from? Childhood leukemia?"

While the professional societies have opposed the efforts by the Breast Cancer Coalition to fund breast cancer at a level above the NCI bypass budget, at this stage in the appropriations process both sides are squarely behind the Harkin amendment.

According to a draft obtained by The Cancer Letter, Harkin's "transfer amendment" calls for raiding the defense budget and appropriating an additional \$170 million to biomedical research in cancer. Cancer research would also receive a part of the proposed \$200 million appropriation for women's health programs, as well as part of the \$150 million increase for prevention programs run by the Centers for Disease Control.

"It is absolutely essential that the entire cancer community call, telegraph and visit their senators," Lierman said.

The day before the Appropriations Committee markup, the Breast Cancer Coalition brought several busloads of patients to convince their senators to increase appropriations for breast cancer. The coalition asked for a total of \$433.7 million, a \$300 million increase from the current year and nearly double the bypass budget.

In their packets of information, the patient lobbyists carried copies of a letter of support for their cause written by Sen. Alfonse D'Amato (R-NY) and signed by 21 other Senate members. The letter was addressed to Harkin and Sen. Arlen Specter (R-PA), ranking minority member of the Labor, HHS subcommittee.

Specter, who has been credited by Harkin with shepherding the bypass level funding for breast cancer through the appropriations committee, was a special target of the Breast Cancer Coalition's campaign to obtain funding at an even higher level.

Thus, the day before the bill's final markup, Specter was visited by about 20 constituents who had had breast cancer. Among them was Fran Visco, a

Philadelphia trial lawyer and president of the Breast Cancer Coalition.

At markup, Specter joined D'Amato in a pledge to seek additional funds for breast cancer.

The Senate members who signed D'Amato's letter were: Alan Cranston (D-CA), Dennis DeConcini (D-AZ), Dave Durenberger (R-MN), Wyche Fowler (D-GA), John Glenn (D-OH), Charles Grassley (R-IO), James Jeffords (R-VT), J. Bennet Johnston (D-LA), Nancy Kassebaum (R-KS), Edward Kennedy (D-MA), Frank Lautenberg (D-NJ), Trent Lott (R-MS), Connie Mack (R-FL), John McCain (R-AZ), Howard Metzenbaum (D-OH), Harry Reid (D-NV), Charles Robb (D-VA), John Seymour (R-CA), Richard Shelby (D-AL), Paul Simon (D-IL) and John Warner (R-VA).

Both D'Amato and Specter are facing strong Democratic challengers.

#### Highlights of Appropriations Bill

Along with an increase for breast cancer, the Senate Appropriations Committee provided increases for cervical, ovarian and prostate cancers.

Cervical cancer programs were to be funded at \$42.3 million, \$9.526 million above the President's request and \$10.5 million more than last year. Ovarian cancer programs were to be funded at \$26.4 million, \$6 million above the President's request and \$6.6 million more than last year. Prostate cancer programs were to be funded at \$37 million, \$8.5 million above the President's request and \$9.4 million more than last year.

In other highlights, the Senate Appropriations Committee:

- ▶Called for a hiring freeze in the departments of Health & Human Services, Labor and Education that requires that for every two vacancies only one would be filled;
- ▶Reversed the President's \$15.1 million cut in the cancer prevention and control program, funding the program at \$106.2 million;
- ▶Called on NCI to spend \$1 million in fiscal 1993 to initiate a four-year study of the particularly high breast cancer mortality rates in the northeastern and mid-Atlantic regions of the U.S., including Connecticut, Delaware, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, Vermont, and the District of Columbia. NCI was directed to present its plan for the study by July 1, 1993;
- ▶Called attention to "the lack of adequate geographical distribution" of cancer centers, urging the establishment of one in the upper Midwest. "The Committee is impressed with the capability of the Univ. of Iowa to help meet the need for geographical distribution," the report said;

▶Called for creation of an independent panel to evaluate the achievements of the cancer program "relative to the investment to date." Subjects to be reviewed would include the opportunities for research; development of a plan for research across the broad spectrum from basic biology to applications; cancer control efforts including the distribution and quality of preventive services, screening, diagnosis and treatment, aftercare, and rehabilitation; the barriers to state-of-the-art cancer treatment in some populations, particularly minority and older Americans.

#### **Text Of Senate Report**

The Committee recommends an appropriation of \$2,010,439,000 for the National Cancer Institute. This is the same as the administration's request, \$58,898,000 more than the 1992 appropriation of \$1,951,541,000 and \$11,823,000 above the House allowance.

Twenty-one years ago, Congress and the President committed this Nation on a course to aggressively address an epidemic called cancer. Since 1971, our National Cancer Program has facilitated significant progress against many of the over 100 diseases we call cancer. Overall survival rates have improved from 38 percent to over 52 percent, and nearly 70 percent of children diagnosed with cancer survive, specifically, childhood leukemia once had a mortality rate of 95 percent; today 73 percent of children diagnosed with the disease survive.

Further, the impact of our investment in cancer research can be felt across the spectrum of diseases. Progress in cancer research positioned us to respond to the AIDS epidemic with regard to identifying the virus that causes AIDS and developing drugs to fight it; it enabled us to identify human genes, such as the CF gene and develop therapies to fix the defect; and it developed the technology to build the supercomputer which has expedited drug and vaccine development for many diseases.

The time is right to assess the achievements of the National Cancer Program, to reinvigorate our National Cancer Program, and to put forth a new plan to carry us into the next century. The Committee recommends that the Director review the establishment of a knowledgeable and independent panel to undertake an evaluation of the achievements of our National Cancer Program relative to the investment to date; the opportunities which exist in our research effort; a plan for future research across the broad spectrum from basic biology to applications; cancer control efforts including the distribution and quality of preventive services, screening, diagnosis and treatment, aftercare, and rehabilitation; and the barriers to state-of-the-art cancer treatment which are detrimental to our ability to adequately address cancer in some populations, particularly minority and older Americans. The Committee expects recommendations to be made with regard to how to address those research and program gaps.

Women's Health--The Committee has provided funding to support a multifaceted plan of research and applications which focuses on all aspects of women's health.

NCI participates in the trans-NIH women's health initiative, a large-scale comprehensive effort that targets the three major causes of mortality and morbidity in women: cancer, heart disease, and osteoporosis. NCI's extensive network of outreach activities is linked through the cancer centers, clinical cooperative groups, community clinical oncology programs, and the cancer information service. They are designed to reach all women, including minority women or those who are poor or medically underserved in order to reduce the barriers that they face when seeking diagnostic, treatment, or prevention services. The development of novel therapies for women's cancers continues to be stressed as exemplified by NCI's intensive efforts to develop the drug taxol and its analogs.

Synthetic estrogen--DES--The Committee continues to be very concerned about the level of attention devoted to studying the impact of the synthetic estrogen diethylstilbestrol [DES], which was prescribed to some 5 million American women from 1941 to 1971. DES, which was prescribed to reduce the risk of miscarriage, has been linked to increased incidence of cancer, infertility, miscarriages, and other health problems in the women who took the drug, their children, and their grand-children.

The Committee has included sufficient additional funds in order to assure prompt implementation of the DES Education and Research Amendments of 1992 expected to be approved this year. An additional \$1,500,000 has been included above the amount requested in order to begin funding the national education program and longitudinal studies mandated in the legislation. As required by the legislation, the Committee expects that the institutes will work closely with organizations representing those affected by DES in developing and implementing the national education program.

The Committee was pleased that the NCI joined with the Office of Research on Women's Health and several other institutes this April in convening a research conference on DES. The Committee strongly encourages NCI and the other involved institutes to undertake efforts to implement the recommendations stemming from this conference. The Committee asks that it be provided with a report outlining the steps undertaken and planned to carry out the recommendations of this conference prior to submission

of the fiscal year 1994 budget request.

**Breast Cancer--**The Committee directs that \$220,000,000 be made available for breast cancer research, \$83,329,000 more than requested and \$87,334,000 more than last year's level.

The Committee is pleased that breast cancer is one of the highest priorities of the Institute and NCI maintains a comprehensive effort for the prevention and treatment of this disease.

Basic research in tumor genetics is being pursued to provide an increased understanding which may lead to new therapeutic and preventive strategies that interfere with breast cancer progression. Prevention research is also stressed. The role of tamoxifen as a preventive agent is currently being evaluated in clinical trials involving postmenopausal and other women deemed to be at high risk for breast cancer development. Other studies seek to determine the feasibility of achieving and sustaining a reduction in dietary fat among minority and underserved women. Specialized programs of research excellence [SPORE] have been established to address all aspects of breast cancer research including the rapid translation of laboratory findings into clinical application. Eight regional breast cancer summits are slated to be held in 1992 at NCI-designated comprehensive cancer centers to focus attention on the need for breast cancer education and screening programs.

The Committee is concerned by the high breast cancer mortality rates in the northeastern and mid-Atlantic regions of the country and directs NCI to conduct a study with update for four succeeding years for the purpose of determining the factors contributing to the high breast cancer mortality rates in Connecticut, Delaware, Maryland, Massachusetts, New Hampshire New Jersey, New York, Rhode Island, Vermont, and the District of Columbia. NCI is directed to develop a plan for conducting the study and shall provide a copy of such plan to the House and Senate Committees on Appropriations and to the Committee on Energy and Commerce of the House of Representatives and to the Committee on Labor and Human Resources of the Senate by July 1, 1993. The Committee expects that \$1,000,000 will be made available for fiscal year 1993 for this study.

The Committee has provided the full professional judgment budget level for breast cancer.

**Cervical Cancer--**The Committee directs that \$42,255,000 be made available for cervical cancer research, \$9,526,000 more than requested and \$10,500,000 more than last year.

Cervical cancer is expected to become an increasing problem for HIV-infected women, both in the US and worldwide. Because this disease is easily curable when detected early, NCI supports outreach

efforts which stress the need for cervical cancer screening.

Joint efforts between the NCI and the Centers for Disease Control [CDC] have resulted in the widely accepted Bethesda system which standardizes the classification of pap smears. NCI and CDC also cosponsor a program linking education efforts in cervical cancer detection with local and regional agencies that offer pap testing services to underserved populations such as the Appalachian poor. The development of a human papilloma virus vaccine against cervical cancer remains a high priority.

Ovarian Cancer--The Committee directs that \$26,372,000 be made available for ovarian cancer research, \$6,002,000 more than requested \$6,600,000 more than last year. Ovarian cancer is associated a marked genetic predisposition. To this end, NCI supports multi-institutional familial ovarian cancer study group which conducts clinical, epidemiological, and genetic linkage studies and is establishing a repository for tissues from women with or at risk for developing ovarian cancer.

In fiscal 1993, a new epidemiologic initiative will assess the risks associated long-term use of combination oral contraceptives, hormone replacement therapy, fertility-promoting drugs, tubal ligation, diet and physical activity, and the development of ovarian cancer. NCI is also conducting the prostate, lung, colorectal and ovarian [PLCO] trial which uses pelvic examination along with serum CA for the early detection of ovarian cancer in women ages 60 to 74.

**Prostate Cancer--**The Committee directs that \$36,976,000 be made available for prostate cancer research, \$8,511,000 more than requested and \$9,400,000 more than last year. NCI is committed to the early detection, successful treatment, and ultimately the prevention of prostate cancer.

A full range of research programs dedicated to achieving these goals includes basic studies at the genetic level to determine the molecular events that trigger prostate cancer development. Investigators are seeking improved methods for the early detection of prostate cancer and ways to identify the more benign form from its more life-threatening counterpart that warrants prompt medical treatment. Chemoprevention trials using Proscar or retinoids are under development.

NCI's PLCO trial will evaluate the effectiveness of digital rectal exams, prostate-specific antigen measurements and transrectal ultrasound examination as screening tools for prostate cancer. Specialized programs of research excellence, [SPORE] focus on the full spectrum of prostate cancer research. One such center will be named the Matsunaga Conte Cancer Research Center.

Vaccine Research--The Committee is pleased with

NCI's strong support for cancer and AIDS vaccine development. Research efforts focus on viruses known to be associated with cancer development such as the hepatitis viruses, human papillomaviruses, Epstein-Barr virus and various retroviruses, including HIV that causes AIDS. A parallel effort targets cancers of nonviral etiology to develop vaccines directed against tumor-specific antigens or the protein products of mutated oncogenes or tumor suppressor genes. Phase 1 clinical trials with vaccines incorporating tumor specific antigens are slated to begin in fiscal 1992.

The Committee is pleased with the Institute's development of a vaccine program and directs that this continue with increased emphasis. The Committee continues to believe that research in the area of cancer vaccines is critical to our long-term efforts in controlling and preventing many forms of cancer, as well as providing immunotherapeutic vaccines to stimulate immunity and benefit populations at risk for the development of cancer. Development of vaccines in the management of cancer represents a novel approach to the management of this disease. Further, the Committee was pleased to learn of the recent, positive results regarding the progress in a three-yearlong study to evaluate a vaccine for melanoma, a certain type of skin cancer.

The Committee encourages the NCI to continue to bring its full breadth of efforts, from molecular and structural biology to its clinical trials network, to bear in the development of cancer vaccines. Further, the Committee urges the Director to keep the Committee informed of areas of basic research where additional efforts our progress in the development of cancer vaccines.

**Gene Therapy--**The Committee has included funding for continued research into a new form of molecular brain surgery based on gene therapy.

This has been developed to treat previously inoperable brain tumors. NCI scientists, in collaboration with researchers from the National Institute of Neurological Disorders and Stroke, have extracted a gene from a herpesvirus and inserted it directly into brain tumors in rats, rendering them susceptible to treatment with an antiviral drug.

Preliminary clinical trials to test this new treatment in humans are scheduled to begin in the fall of 1992. Other advances include the first gene therapy-engineered vaccine which has been prepared and administered to melanoma patients. Future efforts will target gene transfer studies against breast, ovarian, renal, and colon cancers.

Native Americans--The Committee is pleased that NCI is taking steps to develop strategies for increasing the number of Native Americans who participate in NCI-sponsored training programs. Other activities seek

to develop new ways of reducing cancer incidence and mortality in native American populations and increasing the number of native Americans who are principal investigators and coinvestigators on NCI-sponsored research projects.

Collaborative links are being forged between native Americans and selected cancer centers located in key regions of the nation. These institutions are ideally situated for developing and sustaining recruitment of native Americans into training programs and can identify and develop research priorities and strategies tailored to each locale.

A workshop entitled "Strategies and Opportunities for Training Native Americans in Cancer Prevention and Control" was held in August 1992. Participants included leaders from native American communities throughout the continental US, Alaska, Hawaii and American Samoa who contributed cultural perspectives and sensitivities for the development of effective strategies in cancer prevention and play a leading role in their successful implementation.

The Institute remains committed to the development of programs that address the unique concerns of these populations and, in particular, reduce the barriers faced by native American women when seeking screening for breast and cervical cancers.

To date, population-based comprehensive cancer registries on native Americans are limited only to the states of Arizona and New Mexico. These two states represent about 19 percent of the American Indian population.

Further, the Committee understands that little cancer prevention and control activities specific to American Indians, Alaska Natives, native Hawaiians, and American Samoans is made available. This may be directly related to the absence of quality research proposals. Therefore, the Committee urges the NCI to organize several research training events which emphasize development of technical skills, training in research methodology and evaluation, and proposal development in fiscal year 1993.

Behavioral Research--The Committee has included funding for the application of research findings related to health and behavior. Efforts to promote smoking prevention and cessation activities, and to reduce fat and increase fiber intake in the diet are stressed. Initiatives designed to increase the proportion of women seeking breast and cervical cancer screening are continuing, with a special emphasis on those that target minority and underserved populations. Because certain types of behavior appear to contribute heavily to cancer risk, continued emphasis will be placed on this important area of research.

Cancer Prevention and Control--The Committee strongly recommends that the cancer prevention and

control research and the Community Clinical Oncology Program [CCOP] continue to receive high priority. The CCOP has provided increased access to optimal care by making clinical research studies available at the community level.

This benefit has been extended through the minority-based CCOPs to minority populations, allowing them full participation in state-of-the-art clinical trials. NCI will continue to support these efforts which make access to the most advanced cancer therapies readily available to all Americans.

Cooperative Clinical Research--The Committee views the work of NCl's cooperative group program as critical to the Institute's overall mission of improving the survival and quality of life of persons with cancer. Consisting of approximately 4,600 investigators, 1,300 institutions, and 23,000 patients, the cooperative group program offers NCl the opportunity for rapid and definitive clinical testing of promising new cancer therapies in large patient populations.

In the past, the program was largely responsible for major advances in treatment of patients with many forms of cancer, including childhood leukemia, Hodgkin s disease, and cancer of the esophagus. Most of the cooperative groups have evolved into multidisciplinary teams and are, therefore, capable of carrying out a range of therapies involving surgery, radiotherapy, and medical oncology.

Given its track record of success the Committee believes the cooperative group program can make a major contribution to research and treatment of women's health issues, especially breast, ovarian, and cervical cancer.

The Committee, therefore, recommends that special emphasis be placed on clinical trials in these areas.

The Committee does not concur with the recommendation of the President to cut cancer prevention and control within the budget request and has provided \$106,227,000, restoring \$15,119,000 cut by the administration request for this high-priority program. The success of our National Cancer Program is dependent upon a careful balance of research programs.

The Research Foundation for Cancer Prevention is drawn from all aspects of cancer research, particularly basic research, epidemiology, and cancer prevention and control. Cancer prevention and control programs should serve as the bridge between knowledge derived from basic and clinical research programs and its application to clinical public health settings.

Cancer Centers--Cancer centers are in the best possible position to take advantage of research opportunities, to quickly and efficiently translate basic and clinical research findings into medical application, and maximize the best possible opportunity for every patient to achieve a cure. The Committee continues to be concerned with the lack of adequate geographical distribution of cancer centers and urges the establishment of one in the upper Midwest. The Committee is impressed with the capability of the University of lowa to help meet the need for geographical distribution.

Psychosocial counseling--Last year the Committee strongly urged NCI to further explore the impact on survival and quality of life of cancer patients from psychosocial counseling services and to give greater priority to counseling services as an integral aspect of medical care. Psychosocial counseling is short-term, time-limited therapy that addresses not only the emotional and adjustment issues of coping with longterm illness, but also issues such as the need to comply with medical treatment plans.

In addition, the Committee requested NCI to conduct a study to identify payment mechanisms which should be utilized to provide these important services within cancer centers.

The Committee is pleased that NCI will initiate a new program to evaluate the efficacy of specific counseling interventions in improving quality of life and increasing medical compliance. This initiative recognizes the importance of psychosocial counseling early in the history of the disease, such as the time of identification of high risk, at the diagnosis of the cancer, and the initiation of cancer treatment. In response to the Committee's concern about the uncertainty of payment for psychosocial counseling, NCI's initiative should include an evaluation of costs of services and potential payment mechanisms. The Committee again strongly urges NCI to continue these efforts and to expand their initiative to also include the impact of psychosocial counseling on survival.

Other Priorities--The Committee urges NCI to work collaboratively with NIAMSD to address the relationship between cancer and various bone diseases, such as Paget's disease.

Retrovirus research--The Committee is pleased with the research progress related to retroviruses in domestic animals. The Committee's understanding is that the National Cancer Institute's expanded research program in domestic animal models of retrovirus infection will lead to substantial new and valuable knowledge in this area.

#### **RFA** Available

RFA CA/NR/92-27

Title: Quality of life assessment in special populations

Letter of Intent Receipt Date: Oct. 23

Application Receipt Date: Jan. 19

The National Cancer Institute and the National Center for Nursing Research invite investigator-initiated grant applications (R01s) to develop methods for assessing health-related quality of life (QOL) or specific QOL dimensions in cancer patients from diverse sociocultural backgrounds.

Applications may be submitted by domestic and foreign, for-profit and non-profit organizations, public and private. Total project period must not exceed three years. Total costs of \$1,600,000 per year for three years will be committed to fund applications. It is anticipated that five to six awards will be made.

This RFA fosters development of methods for assessing health-related QOL in cancer patients from diverse sociocultural backgrounds. Objectives include: (1) development or adaptation of existing methods for use in culturally diverse populations; (2) validation of methods in the target population; and (3) pilot testing of methods in a clinical trial in the target population.

For this RFA, special populations include Hispanic Americans, Black Americans, low socioeconomic status groups, and persons with low literacy skills. Other smaller minority or ethnic groups such as Native Americans, may be considered under defined circumstances.

Methods must focus on global health-related QOL or specific domains or aspects of QOL, such as functional status, physical symptoms, psychological function, and social function. Methods should evaluate within-person change over time. When feasible, adaptation of existing methodology for use in special populations is preferred. General acceptability of the QOL assessment method must be evaluated in patients from the target population. Psychometric validation must include demonstration of reproducibility, construct validity, and responsiveness. Applicability must be demonstrated by pilot testing in a clinical research project.

Inquiries and letter of intent may be directed to Dr. Susan Nayfield, NCI, Executive Plaza North, Suite 300, Bethesda, MD 20892, phone 301/496-8541.

### NIH AIDS Loan Repayment Program

The NIH Loan Repayment Program for AIDS Research (LRP), in order to increase the number of investigators conducting AIDS research at the NIH, invites interested health professionals to apply for LRP participation.

The LRP may pay a maximum of \$20,000 a year directly to a participant's lenders for qualifying educational debt during an initial, minimum two-year service period. The loan repayment is based, in part, on the availability of funding as well as the proportion of the participant's qualifying debt relative to their NIH basic pay or stipend. Since such payments to lenders are considered income for the participant and increases his/her Federal tax liability, the LRP also makes payments, equal to 39 percent of the total loan repayments, directly towards the participant's Internal Revenue Service account. The LRP may make additional tax reimbursements to participants who show an increase in State and/or local tax liability. Benefits are paid in addition to a participant's annual NIH basic pay or stipend.

An applicant to the LRP is accepted when his/her qualified AIDS research assignment is approved by the AIDS Research Loan Repayment Advisory Committee (LRAC) and his/her contract is executed. Specific LRP applicant and participant eligibility criteria include the following:

(1) Applicants must be citizens or permanent residents of the U.S.; (2) Applicants must have a PhD, MD, DO, DDS, DMD, DVM, or equivalent degree; (3) Applicants must have qualified educational debt in excess of 20 percent of their annual NIH basic pay or stipend on the date of program eligibility, resulting from governmental or commercial loans obtained to support their undergraduate and/or graduate education; (4) Individuals who are not NIH employees, such as Visiting Fellows, Intramural Research Training Award (IRTA) recipients, National Research Service

Award (NRSA) recipients, Guest Researchers or Special Volunteers, NIH National Research Council (NRC) Biotechnology Research Associates Program participants, and Intergovernmental Personnel Act participants, may NOT participate in the LRP; (5) Individuals employed by the NIH during the period November 4, 1987, through November 3, 1988, are ineligible; (6) Applicants may be appointed under a temporary or permanent employment mechanism, as long as their employment with the NIH has the potential to last a minimum of two years; (7) Individuals with existing service obligations to Federal, State, or other entities will NOT be considered for the LRP unless deferrals are granted for the length of the LRP service obligation; and (8) Applicants will NOT be excluded from consideration under the LRP on the basis of race, color, creed, religion, sex, handicap, age, national origin, or political affiliation.

In addition, in order to qualify for repayment, LRP applicants' debts are subject to the following limitations and restrictions: The LRP will repay lenders for the principal, interest, and related expenses (such as the required insurance premiums on the unpaid balances of some loans) of qualified Government (Federal, State, and local) and commercial educational loans obtained by participants for the following: (1) undergraduate, graduate, and health professional school tuition expenses; (2) other reasonable educational expenses required by the school(s) attended, including fees, books, supplies, educational equipment and materials, and laboratory expenses; and (3) reasonable living expenses, including the cost of room and board, transportation and commuting costs, and other reasonable living expenses as determined by the LRP.

Repayments will only be made for loans with current payment status. During lapses in loan repayments, due either to program administrative complications or a break in service, participants are wholly responsible for making payments or any other arrangements that maintain loans in a current payment status. Penalties assessed to participants as a result of LRP administrative failures to maintain current payment status may be considered for reimbursement.

The following parameters define whether a proposed research assignment meets the criteria for coverage under the NIH AIDS Research Loan Repayment Program--that is, whether the incumbent will be "primarily" engaged in AIDS research. "Primarily" engaged in AIDS research is defined as AIDS research activities that constitute at least 80 percent of a researchers time. Clinical Associates, whose intent is to primarily engage in AIDS research, must engage in qualified AIDS research for at least 3 months in the first year of the program, with a total of 15 months of qualified AIDS research during their 2-year contract. AIDS research includes studies of the human immunodeficiency virus, the pathophysiology of HIV infection, the development of models of HIV infection and its sequelae, cofactors predisposing to HIV infection and therapeutics.

AIDS researchers include scientists who are intellectually engaged in the process of providing scientific direction and guidance in programs of original AIDS research, specifically epidemiologists, statisticians, and others who are involved in the design and conduct of research studies. The duties of such scientists may include the generation and design of studies, the collation and analysis of data, and/or the preparation and publication, as author or co-author, of studies in peer-reviewed journals. AIDS researchers also include physicians who are providing care for HIV-infected individuals who are subjects of HIV-related research.

Individuals wishing to apply to the LRP must first obtain a firm employment commitment from an Institute, Center, or Division (ICD) Personnel Department. An initiating official, who may be a laboratory or branch chief, must recommend an individual for

application to the LRP, and the ICD Scientific Program Director and ICD Director must concur. LRP participation is contingent, in part, upon employment with NIH, and candidates may not be recommended for loan repayment by an ICD until a firm employment commitment has been made by the recommending ICDs Personnel Department. Applicants must submit a signed contract, along with the completed LRP application package, to be considered for participation in the program.

At the conclusion of the initial contract, participants may reapply and be considered for subsequent, one-year continuation contracts. Continuation contracts are based upon the same review criteria as the initial contract, in addition to a description of AIDS research accomplishments made during the initial contract.

Written and telephone inquiries are encouraged and may be directed to Marc Horowitz, Director, NIH Loan Repayment Program for AIDS Research, Office of AIDS Research, National Institutes of Health, Bldg 31, Room 5C12, Bethesda, MD 20892; phone 800/528-7689.

### **Program Announcement**

PA-92-97

Title: Developing and improving institutional animal resources Application Receipt Date: Oct. 1

The National Center for Research Resources assists institutions in developing, modernizing, and improving animal resources for biomedical research and research training by awarding research and resource grants. Animal resource improvement grants (G20) are awarded for this purpose and to assist institutions in complying with the provisions of the Animal Welfare Act and Public Health Service policies related to the care and use of laboratory animals. Requests are limited to alterations and renovations and to purchases of major animal resource equipment (with a unit value of at least \$1,000). Support for new construction, including completion of shell space, is not authorized. Projects may address improvement of animal facilities and related activities, including centralized experimental surgical facilities, diagnostic laboratories, and transgenic animal resources.

Any domestic public or private institution, organization, or association with one or more research projects supported by the PHS that involve the use of laboratory animals is eligible to apply. Institutions and commercial firms providing only services or products and without a clearly defined animal related research component are not eligible to apply. Also, this program will not support requests for equipment used for teaching purposes and for housing non-research animals. Applicants may not submit more than one application or apply for other NCRR support for developing and improving institutional animal resources in the same Federal fiscal year.

Requests for basic general purpose equipment items for centralized surgeries, diagnostic laboratories, transgenic animal facilities, and other similar associated activities are allowable when well justified and integral to the proposed project. The total budget request for the improvement grant application and award is limited to a total of \$700,000 (direct costs), of which not more than \$500,000 may be used for alterations and renovations. Matching funds from non-Federal sources, equal to or exceeding one-half of the total award (\$2 Federal to \$1 non-Federal), are required.

Inquiries (include two self-addressed mailing labels) may be directed to:

Director, Laboratory Animal Science Program, Comparative Medicine Program, National Center for Research Resources, Westwood Building, Room 857, 5333 Westbard Ave., Bethesda, MD 20892-4500, phone 301/496-5175; fax 301/480-0868.