THE CANCER LETTER

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Senate Votes To Kill A 10% Cut For NIH; Less Severe Budget Cuts Still Possible

The Senate this week voted overwhelmingly to spare NIH from a $1 billion cut that had been proposed earlier in a resolution by the Budget Committee.

In an 85-14 vote on May 24, the Senate passed an amendment by Sen. Mark Hatfield (R-OR) to cut 0.58 percent from the budget resolution

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In Brief

Gallo Signs Agreement With Univ. of Maryland; Donor Gives $5 Million To San Diego Center

ROBERT GALLO, chief of the NCI Laboratory of Tumor Cell Biology, has signed an agreement to establish an Institute of Human Virology at the Univ. of Maryland at Baltimore. The agreement was announced earlier this week by Maryland Gov. Parris Glendening and Baltimore Mayor Kurt Schmoke. Gallo will be joined at the new institute by **William Blattner**, chief of the NCI Viral Epidemiology Branch, and **Robert Redfield**, of the Walter Reed Army Institute of Research. Earlier this year, NCI officials said Gallo planned to leave the government. Other institutions that reportedly were recruiting Gallo included Virginia Comonwealth Univ. and the Medical Univ. of South Carolina. Maryland offered Gallo $9 million to cover three years of research costs, in addition to $3 million offered by the city of Baltimore, according to a May 24 Baltimore Sun article. . . . **SIDNEY KIMMEL,** founder of Jones Apparel Group, gave $5 million to the San Diego Regional Cancer Center, an affiliate of Sharp HealthCare. The center will be renamed the Sidney Kimmel Cancer Center, **Thomas Shiftan**, board chairman, said. The center plans to use some of the new funds to start a postdoctoral program. Another portion will fund the work of **Magnus Pfahl**, a molecular biologist studying the effects of retinoids on cancer cells. . . . **JOB OPENING:** The PHS Office of the Assistant Secretary for Health, Office on Women's Health, is seeking applicants for the position of coordinator of the National Action Plan on Breast Cancer. The person who serves in this supervisory position, at the GS-15 level, will be the project officer and lead expert on breast cancer in the OWH. June 5 is the deadline for applications to be submitted to: OASH Personnel Operations, Room 17-34, 5600 Fishers Lane, Rockville, MD 20857, tel: 301/443-6900. . . . **PITTSBURGH CANCER INSTITUTE** has been renamed Univ. of Pittsburgh Cancer Institute. "This name change is intended to clearly indicate that the institute is a major

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Specter, Pledging Support Of NIH Budget, Seeks Strategy

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level and transfer the money to NIH. Hatfield is chairman of the Appropriations Committee.

Programs excluded from the new across-the-board cut will include defense, Social Security and Medicare.

The overwhelming margin by which the Senate passed the amendment represents a sorely needed bit of good news for NIH, which was slated for a 10 percent cut by the Senate Budget Committee. Similarly, last week the full House passed a budget resolution that would cut the NIH budget by 5 percent and keep it frozen through the year 2002.

Subcommittee Hearing

The congressional plans, as well as a gradual reduction program proposed by the Administration, turned the Senate Labor, HHS & Education Appropriations Subcommittee meeting last week into something of a bipartisan session to devise a strategy for preventing the funding cuts for the Institutes.

On several occasions during last week's appropriations hearing, Sen. Arlen Specter (R-PA), chairman of the subcommittee, requested NIH Director Harold Varmus and the assembled Institute directors to provide him with concise statements that could be used by lawmakers seeking to stave off the cuts.

Specter, a supporter of Hatfield's attempts to preserve the NIH funding at the FY1995 level, appeared eager to generate ammunition that could aid what was expected to be a tough fight on the floor.

At the subcommittee hearing, Specter requested that Varmus and the Institute directors provide the subcommittee with written statements that would describe the goals NIH was setting for itself.

"Use just as strong and tough of language as you can, and we'll use it on the Senate floor," Specter said. "We all have an enormous awareness of your achievements, and I am aware that cures are not possible to predict. But to attract the attention of senators is a tough matter. It's got to be very brief, very poignant."

Testifying before the subcommittee, NCI Director Edward Sondik said the proposed cuts would cause great harm to the Institute.

"The knowledge base in cancer has exploded tremendously over the last couple of decades," Sondik said. "Today we are poised to make enormous advances. The genetic basis of the disease is becoming clearer and clearer and models for understanding its progression and how to intervene in the disease are developing every day.

"Decreases such as the one we are considering will cut into the lifeblood of the Institute," Sondik said. "We fund about 800 new grants each year, and extrapolating those numbers [from overall reductions predicted by Varmus], we are dealing with perhaps 200 to 400 new grants in the future."

Francis Collins, director of the National Center for Human Genome Research, similarly warned that any weakening of the federal efforts in genetics research would hurt the US biotechnology industry.

"If the US loses its nerve, I can promise you that other countries will step in," Collins said. According to Collins, Japan has recently increased funding for its genome project.

While the senators mainly focused on the cuts recommended by the GOP's budget resolution, Specter also used the occasion to question the Administration's commitment to medical research.

After Varmus asserted that the President's budget reflected the Administration's enthusiasm for investing in research, Specter brought up the issue of the White House budget figures that show that by FY 2000, the President would cut NIH by $1 billion.

Varmus said HHS Secretary Donna Shalala is still looking at budgets for agencies and programs under her jurisdiction on a case-by-case basis. According to Varmus, Shalala was planning to meet with NIH officials to discuss possible alternatives for the out-year appropriations.

For his part, Specter pledged to safeguard the funding levels for NIH.

"The budgeting for NIH has consistently been

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safeguarded and increased in the 14-and-a-half years that I have been in the Senate," he said.

"Now I take the seat of the chairman in a very difficult year, and I can tell you that there is a determination to maintain adequate funding levels at the NIH and not have the proposed budget resolutions come into effect."

Letter to the Editor:

Gensia: No "Threat" Implied In Questioning Drug Study

To the Editor:

Since Gensia's reputation depends on both the quality of the products we produce and the quality of the relationships we have with the scientific community, I feel compelled to respond to the issues raised in your article, "Doctor's Allegation of Drug Safety Problem Starts Controversy With Manufacturer" [**The Cancer Letter**, May 5].

The study in question purports to compare the experience of patients who received generic etoposide to the branded version, VePesid. The fact is that the hospital pharmacy has readily admitted that it could not verify which patients received which product. The study also assumes that generic etoposide replaced VePesid at the hospital in February 1994. However, the pharmacy in question had not yet received the generic version of the product in the February to April 1994 timeframe, when the study assumes all patients were on the generic version. In addition, the pharmacy continued to receive shipments of the branded product, VePesid, during the time that the generic drug was assumed to have been used in all patients. Again, the pharmacy has indicated to us that they are unable to determine which patient received the generic versus branded version of etoposide. In light of these facts, what conclusions can reasonably be drawn from this study?

Next is the issue of academic freedom. It is inexplicable to me how calling the validity of the abstract in question to the attention of its authors was somehow construed as a "threat." The overall layout of the article, and the use of quotations from third parties who were obviously not completely informed as to the facts, gives the reader the distinct impression that Gensia has engaged in the suppression of scientific research. Given the inability of the institution to identify which patients received which products, it is entirely misleading to state that the only defect in the abstract was that the data were "preliminary." Our suggestion that the abstract be withdrawn was not based on how complete the data were, only on whether the data were accurate, given the design of the retrospective analysis.

I would like to reiterate that Gensia believes that the facts of this case, as enumerated in Dr. Pertschuk's letter dated Jan. 24, 1995, speak for themselves. To the best of our knowledge, these facts have not been refuted. We are doubtful that a decision to study a third group of patients will help clarify this situation, since this current study has no ability to help us retrospectively identify which of the patients reported in the abstract received VePesid and which received the generic product.

We have offered to participate in a prospectively defined comparative study of Gensia's etoposide and VePesid, one that would accurately track which patients received which drug. As we stated before, no study purporting to compare two products in which effects cannot reliably be ascribed to treatment should be treated with seriousness implied by publication. Academic freedom does not include the right to publish data on patients treated with drugs not in one's possession at the time of supposed treatment. The only threat in this situation is to the institution's and investigator's credibility should such a defective study be published.

Patrick Walsh
Executive Vice President
Chief Operating Officer
Gensia Laboratories Ltd.

In Brief:

Advisors Appointed To Study NIH Role In Gene Therapy

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component of the Univ. of Pittsburgh Medical Center and is based on the remarkably strong foundation of clinical and research excellence at the university," said **Ronald Herberman**, UPCI director. . . . **A NEW PANEL** is assessing the NIH investment in gene therapy research. Members of the group, which reports to the Advisory Committee to the NIH Director, are: **Stuart Orkin**, Children's Hospital, Boston; **Arno Motulsky**, Univ. of Washington; **Richard Axel**, Columbia Univ.; **David Botstein**, Stanford Univ.; **John Coffin**, Tufts Univ.; **Pamela Davis**, Case Western Reserve Univ.; **Eric Fearon**, Yale Univ.; **Uta Francke**, Stanford Univ.; **Haig**

Kazazian, Univ. of Pennsylvania; **Thomas Kelley**, Johns Hopkins Univ.; **Robert Lefkowitz**, Duke Univ.; **Bernard Moss**, National Institute of Allergy and Infectious Diseases; **Thomas Waldmann**, NCI; and **Huda Zoghbi**, Baylor College of Medicine. . . .

JAMES K.V. WILSON, professor of medicine and oncology at Case Western Reserve Univ., was appointed director of the NCI-designated CWRU Cancer Research Center and the University Ireland Cancer Center at Univ. Hospitals of Cleveland. He served previously as the center's associate director for clinical research. **Stanton Gerson**, professor of medicine, oncology and environmental health sciences at CWRU was named associate director for clinical research. **Hsing-Jien Kung**, professor of molecular biology and microbiology, and oncology, was appointed associate director for basic research. . . .

THOMAS BEHR, a research fellow at the Garden State Cancer Center, on leave from the Univ. of Erlangen-Nuremberg, Germany, has received the 1995 Mallinckrodt Prize from the German Society of Nuclear Medicine at its annual meeting in Dresden earlier this month. Behr's work involved the use of radiolabeled anticancer antibodies in the detection and imaging of colorectal cancer patients.

Grant Programs To Increase Women, Minority Clinical Trial Participation Approved By BSC

Advisors to the NCI Div. of Cancer Prevention and Control gave concept approval to two new grant programs to encourage research in interventions to encourage the participation of women and minorities in cancer prevention and screening trials.

The DCPC Board of Scientific Counselors also at its meeting earlier this month approved in concept three Requests for Proposals.

Following are excerpts of the concept statements:

Interventions for the Participation of Women and Members of Minority Groups and Their Subpopulations in Cancer Prevention and Screening Clinical Trials. Concept for a new RFA for R01 grants, four to six awards, total $5 million over four years. Program directors: Nancy Simpson and Rose Mary Padberg, Early Detection and Community Oncology Program.

This is a [concept for a] request for applications for research to develop, implement, and test well-defined, hypothesis-based interventions to improve the participation of women and minority groups as subjects in cancer prevention and screening clinical trials. The focus will be on phase III research. Populations of research interest are defined in the NIH Guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research and include women and the major racial/ethnic groups (American Indian or Alaskan Native, Asian or Pacific Islander, Black, and Hispanic) and their subpopulations. Proposed research should build on current knowledge and research findings concerning clinical trial participation and patient recruitment, compliance, and retention and physician referral factors.

Multidisciplinary research teams are encouraged to submit R01 applications that address research issues within well-defined study populations such as:

1) Determining optimum ways to recruit subjects. Examining the effects of communication strategies (e.g., channels, spokespersons, materials); community outreach strategies; referring health care provider factors; sponsoring or collaborating organizations; advocacy groups; peer group support; protocol characteristics; incentives; psychological factors (e.g., concepts of disease, trust in the medical system) and counseling of potential subjects on trial recruitment.

2) Determining factors that influence a health care professional's decision to refer patients to clinical trials. Examining logistical and attitudinal barriers and incentive strategies.

3) Determining optimum environment-related strategies for clinical trial recruitment activities (e.g., on-going Wellness clinics, health fairs, worksites) where information on clinical trials may be provided as part of a spectrum of other endeavors.

4) Determining effective ways to reduce barriers to subject participation and enhance those factors that help motivate and facilitate participation.

5) Determining optimum ways to assure subject compliance with clinical trial protocols. Examining the effect of social support systems, case management, staff composition and characteristics, and incentive and reimbursement strategies on compliance and satisfaction.

6) Determining optimum ways to retain subjects throughout the duration of a clinical trial. Examining the effect of communication patterns between researchers and subjects (e.g., physician support and encouragement, newsletters), patient education, quality of life, service and protocol characteristics of the trial, and incentive and reimbursement strategies on retention.

7) Defining issues that should be addressed in the recruitment and informed consent process for subjects and their health care providers. Measuring differential response to the informed consent process.

8) Defining the impact of participation in clinical trials on the subsequent behavior of subjects and their interactions with health professionals.

9) Identifying optimal referral sources and networks for potential clinical trial subjects.

10) Examining the role of economic barriers to subject participation in clinical trials including issues surrounding reimbursement of patient care costs.

11) Examining the role of partnerships between research institutions and communities on the participation of subjects and health care providers in clinical trials. Examining any differences in support systems used by various populations.

12) Examining ways to ensure the protection of "vulnerable" populations from research abuse (e.g., avoiding coercion or undue influence to participate or remain in a study).

Applications should propose developing and testing interventions. An experimental design is the preferred approach. Applicants are encouraged to test and compare multiple innovative strategies and to assess their relative effectiveness. Applicants should address cost issues and include measures of cost effectiveness and efficiency in their proposals. Investigators will be required to document that they have experience working with the target population(s).

Investigators may adapt and test existing participation strategies used with the general population for use with women and minority populations. They may also develop and test new strategies including those that build upon or extend current NCI programs and resources such as the Cancer Centers program, the CCOPs, the Leadership Initiatives, the Patient Education Program, the Physician Data Query system, and the Cancer Information System.

All research funded through this procurement must be undertaken within the context of an ongoing cancer prevention or screening clinical trial. Written approval in the form of a letter from the trial's PI and funding agency must be submitted with the application. The letter must state that the application and research plan was reviewed and approved.

Small Grant Program for Research on Recruitment, Compliance, and Retention of Women and Minorities in Cancer Prevention and Screening Trials. Concept for a new RFA for R03 grants, four to five awards, total $800,000 over two years.

This program will fund applications to NCI's Small Grants Program (R03) to test new ideas, gather information, or perform pilot studies that can lead to the development of new, testable hypotheses and interventions to improve the participation of women and minority groups as subjects in cancer prevention and screening phase III research.

Investigators should consider surveys of patient, provider, and/or public attitudes, knowledge, and behaviors related to clinical trials, exploratory studies, or collection of baseline information. New, as well as experienced investigators in relevant fields and disciplines, are encouraged to submit applications for exploratory studies that address research issues, such as the following, within well-defined study populations:

1) Examining knowledge, attitudes, and behaviors of physicians and other health care providers, current and potential subjects, special interest groups, or the public about health, cancer screening and prevention, and clinical research.

2) Examining how population groups obtain information and how this information is translated into disease prevention and health behavior activities.

3) Determining optimum ways to recruit subjects.

4) Examining ways to reduce barriers to subject participation and to enhance those factors that help motivate and facilitate participation.

5) Determining optimum ways to assure subject compliance with clinical trial protocols.

6) Determining optimum ways to retain subjects throughout the duration of a clinical trial.

7) Determining factors that influence a health care professional's decision to refer patients to clinical trials.

8) Defining issues that should be addressed in the recruitment and informed consent process for subjects and their health care providers.

9) Defining the impact of participation in clinical trials on the subsequent behavior of subjects and their interactions with health professionals.

10) Identifying optimal referral sources and networks for potential clinical trial subjects.

11) Examining the role of economic barriers to subject participation in clinical trials including issues surrounding reimbursement of patient care costs.

12) Examining the role of partnerships between research institutions and communities on the participation of subjects and health care providers in clinical trials.

13) Examining ways to ensure the protection of "vulnerable" populations from research abuse.

Eligible grantees include new investigators, established researchers, qualified staff of public health departments and collaborating agencies, and predoctoral investigators currently enrolled in an accredited doctoral degree program. Ineligible applicants include individuals who are or were previously a principal investigator on an NCI-funded cancer control grant or contract for more than two years; previous small grant recipients; and foreign institutions. The program provides total direct costs up to $50,000 per year for a maximum of two years.

Validation of an innovative, cognitively developed food frequency questionnaire: Correlations with concurrent repeat 24-hour recalls and plasma carotenoids. Concept for a new RFP, one award, total $850,000 over three years. Project Officer: Applied Research Branch, Amy Subar, Frances Thompson, Rachel Ballard-Barbash; Biometry Branch: Charles Brown; Surveillance Program: Brenda Edwards.

Goals of this RFP concept are: 1) To test the hypothesis that correlations with nutrient intake estimated by multiple 24-hour recalls will be greater for an innovative, cognitively-developed FFQ than for two commonly used FFQs (the NCI-Block Health Habits and History Questionnaire (HHHQ) and the Harvard-Willett Questionnaire (WQ). 2) To test the hypothesis (in a 20% subsample of respondents) that the correlations between plasma carotenoid levels and the new FFQ are higher than those obtained using either the HHHQ or the WQ.

The offeror will administer all dietary intake instruments (the new NCI-developed usual diet questionnaire, the HHHQ, the WQ, and the repeat 24-hour recalls) in a free-living, adult population (20-70 years) representative of the US population in terms of gender, race/ethnicity, and education. A sample of 1600 individuals, randomized into two groups of 800, will each complete a brief questionnaire regarding topics such as demographics, body weight, smoking history, and physical activity. This will be followed by four interviewer-administered, nonconsecutive, 24-hour dietary recalls, administered by phone, and timed to occur throughout one year with one recall per season. During this same year, blood specimens will be obtained from a 20% subsample of these 1600 individuals. Following the year in which the 24-hour dietary recalls and blood specimens are collected, half of the participants in one group of 800 will complete both the new questionnaire and the HHHQ one month apart (months 12 and 13) and half will complete the two FFQs in the opposite order. In the other group of 800, half of the participants will complete the new questionnaire and the WQ one month apart and half will complete them in the opposite order.

In a 20% sample, two 10 ml fasting blood specimens will be collected from each individual at months 3 and 9. On one 10 ml sample, plasma and red blood cells will be separated and assays will be performed. Red blood cells will be stored for possible future analyses. The remaining 10 ml sample will be separated into four 1.0 ml aliquots and stored at -70° for 10 years for future analysis of promising biomarkers. The budget for this project includes storage of specimens for the period of the contract but not future analyses. It is anticipated that the first year will consist primarily of planning, interviewer training, and beginning administration of the 24-hour dietary recalls. The second year will be the most intensive, with the offeror continuing collection of 24-hour dietary recalls, collection and analyses of biological specimens, and collection of the FFQs. The third year will involve the offeror's completion of data collection and production of an edited data tape for use in statistical analysis. The data tape will contain individual level data regarding biological measures, and nutrient and food intake from the three usual diet questionnaires and the 24-hour dietary recalls.

Quality Assurance Laboratory for Surrogate Endpoint Biomarkers Used in Clinical Trials of Chemopreventive Agents. Concept for a new RFP, one or two awards, total $5 million over five years. Project Officer: Charles Boone, Chemoprevention Branch.

The Surrogate Endpoint Biomarker Quality Assurance Laboratory will have four functional components, as follows.

A. Status Monitoring Program. On a planned schedule of continuing status checks, both the Laboratory Manager and Program Administrator will contact each Principal Investigator who is conducting clinical trials and obtain updated status reports regarding all aspects of SEB assays, including their number, type, quality control, and start-up problems. The Laboratory Manager will interact closely with members of the Chemoprevention Branch to provide expertise and program information concerning the status of clinical trials using SEB.

B. SEB Standardization Program. The staff of the SEB Laboratory will establish guidelines for specimen procurement (including smear preparation, brushings, and biopsies), specimen transport, storage, cutting in, fixation, embedding, sectioning, staining, and assay by quantitative computer-assisted image analysis.

C. Proficiency Testing Program. The Laboratory Manager and Program Administrator will set up a formal Proficiency Testing Program using established procedures and standards recommended by the College of American Pathologists.

D. SEB Development Program. In addition to SEB chosen by the Chemoprevention Branch as "core" SEB to be used in short-term phase II trials of chemopreventive agents [proliferative status, ploidy, nuclear morphometry (nuclear size, shape, texture, and variability of size, shape, texture), and nuclear morphometry, many participating laboratories are conducting SEB assays related to activated oncogenes and inactivated tumor suppressor genes, aberrant differentiation molecules (actin, keratin, adhesion molecules, blood group and mucin glycoconjugates), and regulatory molecules (growth factors and their receptors). Each of these assays will be evaluated for inclusion in the Standardization and Proficiency Testing Programs.

Continued follow-up of participants in the Breast Cancer Detection Demonstration Project. Concept for an RFP, one award, total $2.3 million over three years (DCPC and DCE combined). Project Officer: Arthur Schatzkin, Cancer Prevention Studies Branch, DCPC; Cathy Schairer, Environmental Epidemiology Branch, DCE.

The objective of this project is to extend follow-up of a large prospective cohort of older women and permit further evaluation of risk factors for breast, colorectal, and other cancers. Some of these risk factors, including diet (in earlier as well as later life), weight, physical

activity, and exogenous hormone use, are modifiable and thus amenable to prevention initiatives.

Approximately 52,700 cohort survivors would be sent questionnaires and potentially followed up through 1998. Some 45,000 women are expected to respond. The follow-up will determine the occurrence of disease endpoints including benign and malignant breast disease, other cancers, gall bladder disease, diabetes, heart disease, colon polyps, osteoporosis, fractures after age 45, and mortality. Information will be updated on several breast-cancer related factors including family history of breast malignancy, menopausal status, menopausal hormone use, mammographic screening, and method of breast cancer detection. As in several earlier phases of the study, exposure and outcome information will be obtained by a mailed questionnaire. After several attempts have been made to obtain the information by mail, attempts will be made to interview non-responders by telephone. As in earlier phases of this project, for any cancers or breast operations reported, surgeons and hospitals will be contacted to obtain copies of the hospital discharge summaries and pathology reports. Laboratory reports of estrogen and progesterone receptor status will be sought for all breast cancer cases. Copies of death certificates will be requested for any subjects found to be deceased.

This will be the final questionnaire-based follow-up of this cohort. After this, the cohort would be followed passively by means of the National Death Index and other mortality sources. This study will be conducted collaboratively with the Div. of Cancer Etiology. The DCE Board of Scientific Counselors approved a concept for this project in October 1994. The total cost will be shared equally by DCPC and DCE.

Breast Cancer Action Plan Funding Mechanisms Issued

The National Action Plan on Breast Cancer is a major public/private partnership created to eradicate the epidemic of breast cancer. The implementation of the Plan is coordinated by the Public Health Service's Office on Women's Health. Several mechanisms have been established for funding of projects that directly address the six high priority areas identified by the Plan. The six priority areas include: information dissemination, national biological resource banks, consumer involvement, breast cancer etiology, clinical trials accessibility, and issues related to breast cancer susceptibility genes.

Innovative Small Grants: The NAPBC announced (**The Cancer Letter**, April 14) an innovative small grants (R03) solicitation. This initiative will fund grants up to $50,000 a year direct costs for up to two years. The goal of this initiative is to provide support for novel, creative pilot research and outreach projects that, if successful, will yield exceptionally important new information on breast cancer. The applications will be evaluated for scientific and technical merit by NIH peer review groups. The applications will be evaluated for relevance to the priority areas identified by Working Groups of the Plan. Applications must be submitted to the NIH Div. of Research Grants by June 14.

Administrative Supplements To Existing Federal Grants:

1. PHS Administrative Supplements—The NAPBC announced (**The Cancer Letter**, April 21) an Omnibus PHS Administrative Supplements solicitation for administrative supplements to existing PHS grants for up to $100,000 for one year. Any currently funded PHS grant relevant to breast cancer that addresses one or more of the six priority areas is eligible for an administrative supplement under this announcement. All requests for supplements must be within the scope of the parent grant. The parent grant can deal with breast cancer, other cancers, other diseases, or any of the above six priority areas. The program director for each grant must be contacted for questions about the consistency of the proposed supplemental project's aims with the parent project. The parent grant must have a minimum of one year remaining (end date no sooner than Sept. 30, 1996) in the project from the time the supplement is awarded. A copy of the official initial peer review comments for the grant (e.g., summary statement or the equivalent) must be submitted. For grants sponsored by agencies outside of NIH, the funds will be transferred to those agencies via interagency agreements. The receiving agency must obligate funds before the end of the fiscal year in accordance with that agency's operating policies and procedures. Contracts are not eligible for this supplement program. Applications must be submitted to the PHS Office on Women's Health by June 14.

2. Grants from Other Federal Agencies— The NAPBC also solicits with this notice requests for administrative supplements for up to $100,000 for one year to existing grants from Federal agencies outside the PHS. Any currently funded Federal grant relevant to breast cancer that addresses one or more of the six priority areas is eligible for an administrative supplement under this announcement. All requests for supplements must be within the scope of the parent grant. The parent grant can deal with breast cancer, other cancers, other diseases, or any of the above six priority areas. The program director for each grant must be contacted for questions on the consistency of the proposed supplemental project's aims with the parent project. The parent grant must have a minimum of one year remaining (end date no sooner than Sept. 30, 1996) in the project from the time the supplement is awarded. A copy of the official initial peer review comments for the grant (e.g., summary statement or the equivalent) must be submitted. The funds will be transferred to those agencies via interagency agreements.

The receiving agency must obligate funds before the end of the fiscal year in accordance with the agency's operating policies and procedures. Contracts are not eligible for this supplement program. Instructions for applicants can be obtained from PHS OWH. Applications must be submitted to the PHS OWH by June 14.

Intramural Federal Projects

1. Public Health Service Projects—The NAPBC solicits with this notice requests for administrative supplements to existing intramural Federal projects and contracts supported by PHS-based agencies. This mechanism will fund supplements for up to $100,000 a year total costs for one year to PHS projects. Any existing PHS intramural project or contract that has relevance to breast cancer that addresses one or more of the six priority areas is eligible for an administrative supplement under this announcement. The parent project can deal with breast cancer, other cancers, other diseases, or any of the above six priority areas. For projects in agencies outside of NIH, the funds will be transferred to those agencies via interagency agreements. The receiving agency must obligate funds before the end of the fiscal year. Instructions for applicants can be obtained from PHS OWH. Applications must be submitted to PHS OWH by June 14.

2. Projects in Other Federal Agencies—The NAPBC solicits with this notice requests for administrative supplements to existing intramural Federal projects and contracts supported by Federal agencies outside of the PHS. This mechanism will fund supplements for up to $100,000 a year total costs for one year. Any existing PHS intramural project or contract that has relevance to breast cancer that addresses one or more of the six priority areas is eligible for an administrative supplement under this announcement. The parent project can deal with breast cancer, other cancers, other diseases, or any of the above six priority areas. For projects in agencies outside of NIH, funds will be transferred via interagency agreements. The agency must obligate funds before the end of the fiscal year. Instructions can be obtained from PHS OWH. Applications must be submitted to PHS OWH by June 14.

Support Of Peer-Reviewed, Unfunded Grant Applications

1. Public Health Service Grants—The NAPBC solicits with this notice requests for the funding of grant applications addressing the six priority areas that have been peer-reviewed and recommended for funding between Sept. 30, 1994, and Sept. 30, 1995, but not awarded due to lack of sufficient funds. The initial awarding of funds cannot exceed one year. Additional funding for up to two years may be considered. Applications eligible for this mechanism should be brought to the attention of the Plan. Principal investigators who believe that their unfunded grant applications are eligible for this program should contact the PHS OWH and their PHS program administrator. A copy of the original grant application and a copy of the official initial peer review comments for the application (e.g., summary statement or the equivalent) must be submitted to the Plan. Program administrators who identify eligible grant applications must obtain written permission from the principal investigator to submit official initial peer review comments for the application (e.g., summary statement or the equivalent) and a copy of the original grant application for funding consideration to the Plan. For selected grant applications submitted to PHS agencies outside of NIH, funds will be transferred via interagency agreements. Funds must be obligated before the end of the fiscal year. The application with a copy of the original grant application and the summary statement of review must be submitted to the PHS Office on Women's Health by June 14.

2. Grant Applications Submitted to Other Federal Agencies—The NAPBC solicits with this notice requests for the funding of grant applications addressing the six priority areas that have been peer reviewed and recommended for funding between Sept. 30, 1994, and Sept. 30, 1995, but not awarded due to lack of sufficient funds. The initial awarding of funds cannot exceed one year. Additional funding for up to two years may be considered. Grant applications eligible for this mechanism should be brought to the attention of the Plan. Principal investigators who believe that their unfunded grant applications are eligible for this program should contact the PHS OWH and their program administrator. A copy of the original grant application and a copy of the official initial peer review comments for the grant (e.g., summary statement or the equivalent) must be submitted to the Plan. Program administrators who identify eligible grant applications must obtain written permission from the principal investigator to submit official initial peer review comments for the grant (e.g., summary statement or the equivalent) and a copy of the original grant application for funding consideration to the Plan. If selected for support, the funds will be transferred to those agencies via interagency agreements. Funds must be obligated before the end of the fiscal year. The application with a copy of the original grant application and the summary statement of review must be submitted to PHS OWH by June 14.

Inquiries: For more information on the National Action Plan on Breast Cancer FY95 funding programs, contact: Susan Blumenthal, Deputy Assistant Secretary for Health (Women's Health), Co-Chair, The National Action Plan on Breast Cancer, ATTN: Suzanne Haynes (etiology; consumer involvement), Cheryl Marks (clinical trials; information dissemination), Debbie Saslow (breast cancer susceptibility genes; tissue banks), Diane Wagener (general information), PHS Office on Women's Health, Hubert Humphrey Bldg Rm 730-B, 200 Independence Ave. SW, Washington, DC 20201, tel: 202/401-9587 or 202/690-7650, fax: 202/401-9590.