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Action Plan Steering Committee Votes 13-0 To Return \$14 Million To NCI For Research

A panel of breast cancer patient advocates and government scientists last week voted to return to NCI \$14 million that Congress had earmarked for the National Action Plan on Breast Cancer.

The vote Nov. 7 was a victory for the National Breast Cancer Coalition, the group that originally forced the government to start the Action Plan, but later found itself locked in a two-and-a-half-year battle
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In Brief

National Patient Advocate Foundation Formed To Seek Health Insurance Reform

NATIONAL PATIENT ADVOCATE FOUNDATION, a nonprofit organization, has been formed to support legislative reform enabling cancer patients to obtain insurance funding for cancer care, including clinical trials. "We seek policy, regulatory, and legislative reform shaped by representatives of the insurance, health provider and patient populations," said **Nancy Davenport-Ennis**, founding executive director of the foundation, which was chartered in Virginia. A related group, the Patient Advocate Foundation, disseminates information on managed care and insurance issues, and provides legal counseling to patients in the areas of denial of insurance coverage, job discrimination and debt intervention. The NPAF may be contacted at 739 Thimble Shoals Blvd., Suite 704, Newport News, VA 23606, tel: 757/873-6668, fax: 757/873-8999. . . . **FRANK HSU** was appointed assistant professor of medicine/oncology at the Yale School of Medicine and co-director of the Immunology Research Program at Yale Cancer Center. Hsu completed a fellowship in oncology at Stanford University Medical Center prior to his appointment at Yale. . . . **ALFRED KNUDSON**, geneticist at Fox Chase Cancer Center, received the ninth annual Robert J. and Claire Pasarow Foundation Award for Cancer Research, a \$35,000 prize. Knudson also recently shared the 1996 Irving J. Selikoff Award for Cancer Research with **Joseph Fraumeni**, director of the NCI Division of Epidemiology and Genetics. This award was presented by the Ramazzini Institute. . . . **BERNARD LEVIN**, vice president for cancer prevention, M.D. Anderson Cancer Center, was named vice chair of a national campaign to raise awareness of colorectal cancer: the American Digestive Health Foundation's Digestive Health Initiative Colorectal Cancer.

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Action Plan Advisors Vote To Return \$14 Million To NCI

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with the official appointed to administer the program.

The action was a blow to Susan Blumenthal, the plan's administrator and director of the PHS Office on Women's Health. While activists wanted her to do no more than support working groups in six priority areas, Blumenthal spoke repeatedly of broadening the Action Plan's mandate as well as implementing programs.

The NBCC proposal to rescind the earmark and leave the money within NCI, where it could be used for peer-reviewed research in breast cancer, was supported by several major cancer organizations (**The Cancer Letter**, Oct. 24).

Political Theater

The Nov. 7 meeting of the Action Plan's steering committee was political theater at its finest:

First, the activists determined how much of last year's appropriation carried over into fiscal 1997. It was a sizable amount: nearly \$4.3 million in contractor services. Considering that the Action Plan spent only \$1.6 million on its operations last year, its financial security would be assured for well over two years.

Next, the activists introduced a motion to renounce the Action Plan's claim to \$14 million of

the earmark in the current year's appropriation for NCI. Blumenthal's office would be allowed to keep only \$750,000 to cover staff salaries.

The motion passed 13-0. Among those who voted for the transfer of funds were Sarah Kovner, special assistant to HHS Secretary Donna Shalala and Jo-Ivey Boufford, HHS deputy assistant secretary for health. Both are Blumenthal's superiors at HHS.

Blumenthal appeared unfazed by the vote.

"We hear what your recommendations are, and as we know, the [Action Plan] operating plan says that it's important to hear what the vote of this committee is," she said.

"Those recommendations go forward. But I think the problem in the past has been that there was a sentiment that the plan could be used actually to support at a deeper level some of these activities," Blumenthal said.

"We are hearing what you are saying."

Committee Says Role Is Not Simply Advisory

As Blumenthal spoke, activists around the table appeared to make no efforts to hide grimaces of frustration. According to the operating plan, the steering committee is not merely "important" in shaping the Action Plan's activities. In fact, the committee determines all the activities of the plan.

"I am going to be blunt," objected breast cancer survivor Kay Dickersin, opening what may have been the most dramatic monologue of the day. "We've got to get over this hump.

"If there is someone on the steering committee other than Susan Blumenthal who sees it this way, I'd like that person to speak.

"Susan, I think you keep bringing up your own agenda. I hear in every steering committee that the rest of [us] voted for a different plan than what you envision. The trouble is, it's extremely disruptive if you keep bringing up your vision.

"We can't be dysfunctional. I would like to hear agreement that we aren't going to have this discussion anymore," said Dickersin, a scientist at the University of Maryland and a member of the National Cancer Advisory Board.

No hands went up in response to Dickersin's challenge, indicating that Blumenthal indeed was in a minority of one in her attempts to broaden the mandate of the Action Plan.

To strengthen its message, the steering committee asked HHS Secretary Donna Shalala to



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reaffirm her commitment to the committee's operating plan, the Action Plan's fundamental document that gives the steering committee the power to define the activities of the Action Plan.

The vote puts Shalala in what could be an awkward position of having to choose between incurring the wrath of the activists, if she ignores the committee's actions, and the wrath of some members of Congress, if she returns to NCI the funds that the appropriations bill intended to be used for the Action Plan.

In fiscal 1997, Congress gave Blumenthal's office \$14.75 million to conduct the activities of the Action Plan. According to the report that accompanied the appropriations bill, Blumenthal could also conduct unspecified "other cross-cutting federal and private sector initiatives on breast cancer."

The language reflected Blumenthal's quest for broadening the mission of the Action Plan.

To change this mandate, Shalala will need the approval of the chairmen and, possibly, ranking minority members of the Senate and House appropriations subcommittees on the Departments of Labor, HHS and Education, sources said.

Sources said the House would be likely to go along with the change. The decision of the Senate subcommittee, however, is harder to predict. After all, the controversial language was inserted into the bill by Sen. Arlen Specter (R-PA), chairman of the subcommittee.

Activists Feeling "Hoodwinked"

Should the funds remain in Blumenthal's office, Specter and Shalala are certain to face the wrath of the patient activists.

"Are we just like every other advisory committee in the government?" asked Mary Jo Ellis Kahn, a member of the steering committee. "Do we have no more power than that? If that's true, we have been hoodwinked from the beginning.

"If we really are different, if we are a public-private partnership, when we vote, it's supposed to be meaningful--not a recommendation," Kahn said.

When the debates ended, Blumenthal said the activists were missing an "opportunity" by voting to return the money to NCI.

"The plan will do what the plan wants to do," Blumenthal said to **The Cancer Letter**. "I feel personally it's a missed opportunity."

Specifically, her office could have used the money to address the issues of possible environmental factors in breast cancer and potential use of military technology in breast cancer imaging, Blumenthal said.

"As a public health doctor, I have a broader mission," she said.

Voluntary Organizations

ACS Board Approves RFAs For Prostate Cancer Research

The American Cancer Society Board of Directors has approved a plan to target 10 percent of the Society's research budget to fund three grant programs for prostate cancer research.

The board voted to set aside about \$7.5 million to fund grant applications in response to three Requests for Applications. It is the first such targeted research program in the Society's history, sources said.

The three RFAs seek research proposals in prostate cancer in the areas of health policy and outcomes; behavioral, psychosocial and quality of life; and novel ideas in tumor cell biology.

Following are the excerpted texts of the RFAs. Contact names and phone numbers are listed below:

Health Policy and Outcomes Research—Prostate Cancer

In order to make a significant and specific impact on the control of cancer, the Board of Directors of the American Cancer Society is targeting 10 percent of the research budget to high priority needs. The Society has identified critical needs in three broad areas of cancer research: 1) Behavioral, Psychosocial, and Quality of Life; 2) Health Policy and Outcomes; and 3) Novel Ideas in Tumor Cell Biology. Because cancer of the prostate is the most commonly diagnosed noncutaneous malignancy in the United States, and represents one of the most significant medical and socioeconomic challenges facing our country as well as being one of the most diverse and perplexing problems in tumor biology, the American Cancer Society has made \$7.5 million available for three broad areas of research in relationship to prostate cancer. In contrast to the Society's regular Research Project Grants, which are

restricted to beginning investigators, application for these targeted funds is open to investigators at any stage of their careers.

In 1996, the American Cancer Society estimates 317,000 new cases of prostate cancer will be diagnosed in the U.S. In addition to the problems posed by the sheer numbers of individuals affected, it is estimated that prostate cancer will cause more than 41,000 deaths this year. In an effort to serve the patients affected and assist the medical and scientific community in making a substantive and rapid impact on improving the status of prostate cancer, this RFA is soliciting focused innovative research in Health Policy And Outcomes Research In Prostate Cancer. In 1997, \$3 million has been earmarked for this area. These funds are in addition to funds currently available to beginning investigators for health policy and outcomes research in all cancers.

There is a critical need for scientific knowledge that documents optimal patient care outcomes for screening/early detection, diagnostic treatments, palliation, and care of end-stage or hormonally refractory prostate cancer. Within each of these areas, there are significant health policy issues related to the rapidly changing landscape of access and reimbursement brought on by managed care and health care reform. These issues are of particular concern for underserved population, i.e., African Americans and the elderly, in which prostate cancer is so prevalent and devastating.

Health Policy and Outcomes Research in Prostate Cancer should focus on clinical effectiveness using patient-centered outcome measures. Patient-centered outcomes emphasize health status, functional status, quality of life, and satisfaction with specific care components. Applications may include but should not rely on survival and progression. Outcomes should be assessable over and two- to three-year time frame and include cost effectiveness. These studies should consider the full range of costs for patient, family, and society. Examples of needed outcomes research in prostate cancer include but are not limited to: A) cost effectiveness of screening/early detection based on use of prostate specific antigen and digital rectal examination; B) impact on access to contact, payor mix, and managed care; C) outcome measures of intervention; and D) outcomes measures of public and professional information and education.

Preference will be given to applications that address new problems or propose innovative

approaches to previously identified problems. The methods and design must address the problem and represent the current state of knowledge. Quasi-experimental or other non-experimental designs may be proposed if adequately justified as the most appropriate approach to the problem. Methodology studies may be appropriate for some topics. These applications will be reviewed and ranked by experts in health policy and outcomes research. The prioritized list of applications from the Peer Review Committee will be considered separately from other applications by the Council for Extramural Grants. The first deadline for these applications is April 1, 1997. Subsequent deadlines will be Oct. 15, 1997, and on those same dates through 1999. The grants awarded in response to this RFA will be for three years, up to \$250,000 per year, including 25 percent indirect costs. At least four grants will be awarded each year, contingent on the quality of the applications. Grants will be renewable under the terms of this RFA for as long as Health Policy and Outcomes Research in Prostate Cancer remains a targeted priority area for the Society. Grantees will be expected to provide information necessary for evaluation of the targeted research program.

Applicants may contact the Office of Sponsored Programs at their institutions after Jan. 1, for a special ACS Response to RFA Grant Application form, or download it from the Society's Web site at <http://www.cancer.org> after Jan. 1. Beginning investigators interested in health policy and outcomes research in other cancers are encouraged to apply through the Society's regular extramural grants program for Postdoctoral Fellowships, Clinical Research Training Grants, and Research Project Grants.

Applications should be mailed to: American Cancer Society, Extramural Grants Department, 1599 Clifton Rd. NE, Atlanta, GA 30329. Questions concerning this RFA may be directed to Dr. Ralph Vogler, tel: 404/329-7562 or Dr. Frank Baker, tel: 404/329-7795.

Novel Ideas in Prostate Cancer Cell Biology

This RFA is soliciting focused research in Novel Ideas in Prostate Cancer Cell Biology. In 1997, \$1.5 million has been earmarked for this area.

Prostate cancer presents unique and intriguing challenges for cancer biologists. Why is this tumor so universally prevalent and associated with other

processes of aging, yet is progression to clinical disease varies widely with racial and environmental correlates? What are the mechanisms that govern the unpredictable, slow, nonthreatening progression in one patient versus the rapid emergence of virulent, lethal disease in another? What factors determine the evolution of androgen-independent phenotypes that are relatively refractory to current therapies, and what potentially curative or palliative strategies of intervention are the most effective early and late in the course of this disease? Among the variety of important biologic fields of inquiry, the Novel Ideas in Prostate Cancer Cell Biology program stresses the following areas: prostate cancer tissue specificity; metastasis; angiogenesis; tumor progression; androgen receptor interaction; androgen resistant growth; host-tumor interactions; gene therapy.

Proposals presenting promising and creative speculative ideas for which there are limited (or no) preliminary experimental data are strongly encouraged. The rationale supporting the ideas, the feasibility of testing them, and their potential to solve a prostate cancer problem are important criteria for successful funding. Applications will be evaluated by the appropriate Peer Review Committee. The prioritized list of applications from the Peer Review Committee will be considered separately from other applications by the Council for Extramural Grants.

The first deadline for these applications is April 1, 1997. Subsequent deadline will be Oct. 15, 1997, and on these same dates through 1999. The grants awarded in response to this RFA will be for three years, up to \$65,000 per year, including 25 percent indirect costs. Approximately eight non-renewable grants will be awarded each year for three years. These initial grants are intended to allow the investigator to generate the data necessary to obtain a standard peer reviewed grant. Grantees will be expected to provide information necessary for evaluation of the targeted research program.

Applicants may contact the Office of Sponsored Programs at their institutions after Jan. 1, for a special ACS Response to RFA Grant Application form, or download it from the Society's Web site at <http://www.cancer.org> after Jan. 1.

Applications should be mailed to: American Cancer Society, Extramural Grants Department, 1599 Clifton Rd. NE, Atlanta, GA 30329. Questions concerning this RFA may be directed to Dr. Peter

Ove, tel: 404/329-7952.

Behavioral, Psychosocial, Quality of Life—Prostate Cancer

This RFA is soliciting focused innovative research in Behavioral, Psychosocial and Quality of Life Research in Prostate Cancer. In 1997, \$3 million has been earmarked for this area. These funds are in addition to funds currently available to beginning investigators in behavioral, psychosocial, and quality of life research in all cancers.

Prostate cancer exemplifies the enormous toll that cancer places on the human condition. It has a profound impact on sexuality, and therapy can profoundly affect the quality of life. To relieve the burden on this disease, research is urgently needed in many areas, including but not limited to: A) Studies in the emotional, psychological, cultural, racial, and gender factors influencing decision-making regarding early detection, screening, treatment selection, compliance, and coping strategies, particularly focusing on high-risk groups such as African Americans, those with a positive family history, and assessing the differences between very young versus elderly men at risk; B) the impact of emotional support groups, the optimal psychological strategy or modality for males in the age range affected by prostate cancer, and the comparability of these measures with those applied to other patient populations, such as breast cancer patients; C) the psychosocial impact of prostate cancer on the family (spouses and children); and D) psychosocial and quality of life consequences of modern methods of androgen ablation, especially when applied in younger populations over long time frames.

Proposed research methodology should incorporate designs and data analysis procedures that are appropriate for the research questions. Evaluation criteria will include the originality and rigor of the research question, design, and analysis procedures, the projected ability of the applicant to conduct the research; and the projected value and impact of the research for prostate cancer prevention and control. Applications will be reviewed and ranked by experts in behavioral, psychosocial, or quality of life research. The prioritized list of applications from the Peer Review Committee will be considered separately from other applications by the Council for Extramural Grants.

The first deadline for these applications is April 1, 1997. Subsequent deadline will be Oct. 15, 1997, and on these same dates through 1999. The grants awarded in response to this RFA will be for three years, up to \$250,000 per year, including 25 percent indirect costs. At least four grants will be awarded each year, contingent on the quality of the applications. Grants will be renewable under the terms of this RFA for as long as Behavioral, psychosocial, and Quality of Life Research in Prostate Cancer remains a targeted priority area for the Society. Grantees will be expected to provide information necessary for evaluation of the targeted research program.

Applicants may contact the Office of Sponsored Programs at their institutions after Jan. 1, for a special ACS Response to RFA Grant Application form, or download it from the Society's Web site at <http://www.cancer.org> after Jan. 1. Beginning investigators interested in behavioral, psychosocial, and quality of life research in other cancers are encouraged to apply through the Society's regular extramural grants program for Postdoctoral Fellowships, Clinical Research Training Grants, and Research Project Grants.

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RFA Available

RFA RR-97-001

Title: **Extramural Research Facilities Construction Projects**

Letter of Intent Receipt Date: Dec. 20

Application Receipt Date: Jan. 24

The National Center for Research Resources is authorized to "make grants to public and nonprofit private entities to expand, remodel, renovate or alter existing research facilities or construct new research facilities" for biomedical and behavioral research and research training. The fiscal 1997 appropriation for the NIH includes \$20 million in the NCRR budget for extramural facilities construction grants to be awarded competitively, with special provisions made for institutions of emerging excellence, designated under section 739 of the PHS Act as revised in PL 102-408, and the Regional Primate Research Centers. The NCRR is issuing this RFA for

support of construction and renovation of facilities for biomedical and behavioral research and research training. It is anticipated that 15 new awards (C06) at different levels will be made.

Inquiries: A technical workshop to assist applicants unfamiliar with the requirements for extramural construction applications and to clarify any issues or questions from potential applicants will be held Dec. 8-9, in Bethesda, MD. For additional information regarding the workshop, call 301/435-1302. A summary will be provided upon request for those unable to attend.

The RFA may be obtained from Dr. Charles Coulter, Research Facilities Improvement Program, National Center for Research Resources, 6705 Rockledge Dr., Room 6142-MS-C 7965, Bethesda, MD 20892-7965, tel: 301/435-0766, fax: 301/480-3770, email: charlesc@ep.ncrr.nih.gov.

NCI Epidemiology/Genetics Postdoc Fellowship Available

The NCI Division of Cancer Epidemiology and Genetics has established a three-year postdoctoral fellowship program emphasizing training in the epidemiology and clinical, molecular, quantitative genetics and genetic epidemiology of cancer.

The program provides opportunities to conduct interdisciplinary research to identify factors that predispose to cancer and elucidate the role of gene-environment interactions in conferring cancer risk within individuals and populations at large.

The training includes didactic courses and clinical and laboratory rotations, and is up to three years. Access to the NIH Warren G. Magnuson Clinical Center, a hospital and ambulatory care facility, enhances the opportunity to combine clinical, laboratory and epidemiologic research.

Candidates must have either an M.D., Ph.D., or equivalent degree in a related discipline with less than three years postdoctoral experience, and be U.S. citizens or resident aliens eligible for citizenship within four years.

Deadline for applications is Nov. 30, for the July 1, 1997, start date. Applications are to include curriculum vitae, bibliography, three letters of recommendation, and a letter describing the basis for interest. Contact: Dr. Dilys Parry, NCI, DCEG, 6130 Executive Blvd., EPN Rm 400 MSC 730, Bethesda, MD 20892-7360, tel: 301/496-4947, fax: 301/496-1854, email: parryd@epndce.nci.nih.gov. DCEG's Web site is <http://www-dceg.ims.nci.nih.gov>.