AUG 1 2 1994

# THE CALLSR LETTER

P.O. Box 15189 WASHINGTON, D.C. 20003 TELEPHONE 202-543-7665

## Fisher, NSABP Executive Committee, File Injunction Seeking Herberman's Removal

Bernard Fisher and the Executive Committee of the National Surgical Adjuvant Breast & Bowel Project Monday petitioned a judge to restore the physician to leadership at the cooperative group and called for immediate removal of the group's interim chairman.

The motion for a preliminary injunction, filed in the US District Court for the Western District of Pennsylvania, states that only an immediate (Continued to page 2)

#### <u>In Brief</u>

## Adamson Takes Job At Soft Drink Association; Zack Hall To Direct Neurological Institute

RICHARD ADAMSON, retiring as director of the NCI Div. of Cancer Etiology, will move to the National Soft Drink Association on Sept. 6. Adamson was appointed vice president for scientific and technical affairs of the Washington-based association, which represents more than 300 firms controlling more than 500 bottling plants in the US. Adamson, DCE director for the past 14 years, announced his retirement from 33 years of government service last month (The Cancer Letter, June 3). "We are fortunate to have someone with Dr. Adamson's exceptional scientific background and his broad experience in senior government posts," said William Ball III, president of the association and former Secretary of the Navy in the Reagan Administration. Adamson said he is enthusiastic about the position. "I will be responsible for representation of the soft drink industry's scientific and technical issues before the public and government agencies," Adamson said to The Cancer Letter. "Part of my job will be to enhance public understanding of the soft drink industry, which has been part of the American way of life since the 1920s." . . . . ZACH HALL, professor and chairman of physiology at the Univ. of California, San Francisco, was appointed director of the National Institute for Neurological Disorders and Stroke. Hall was identified as a top candidate for the post by a search committee. The committee cited his role in establishing one of the nation's leading programs in neuroscience research and graduate training at UCSF. In Washington, he joins UCSF colleagues Assistant Secretary for Health Philip Lee, NIH Director Harold Varmus, and National Academy of Sciences President Bruce Alberts. .... ADOLPHUS TOLIVER was named director of the National Institute of General Medical Sciences Minority Access to Research Careers Program. He was scientific review administrator, Biochemistry Study Section.

Vol. 20 No. 32 Aug. 12, 1994

(c) Copyright 1994 The Cancer Letter Inc. Price \$225 Per Year US, Canada \$250 Per Year Elsewhere

Court Filing By Fisher, Board, Attacks Interim NSABP Leadership ... Page 4

House, Senate Reform Bills Move Closer To Floor Vote ... Page 5

Oncology Societies, Cancer Centers,

List Reform Principles

Letter Protests Closed Meeting; NIH Calls Action Appropriate ... Page 6

Letter to the Editor: Closed Meetings Create Aura Of Suspicion .... Page 7

RFA, PA Available ... Page 7

## A Pre-Hearing Deal Kept NSABP At Pitt For A Time

(Continued from page 1)

court action can protect the cooperative group from irreparable harm.

Though no hearing date has been set for the motion, action in such cases usually comes in a matter of weeks (see story on page 3).

Sources said that it is likely that the hearing would explore the manner in which Fisher was removed from his post at NSABP as well as any confidential negotiations that may have taken place between NCI, the Univ. of Pittsburgh and Congressional staff.

Through interviews with sources who spoke on condition that their names would not be used, and by obtaining previously unexamined documents, The **Cancer Letter** was able to reconstruct several key events surrounding Fisher's removal and retention of the NSABP grant by the Univ. of Pittsburgh. To protect the sources, even individuals who were contacted by a reporter, but declined to comment are not being cited by name.

#### **One Removal; Three Opinions**

The question of how Fisher came to be removed from his post as principal investigator and chairman of NSABP is anything but straightforward.

Sources contacted by The Cancer Letter were unable to provide either a letter of resignation by Fisher or documents confirming his firing by the Univ. of Pittsburgh as chairman of the cooperative group. Multiple sources said that no such letters exist.

There are three positions on Fisher's removal from NSABP:

•Fisher's attorneys claim that the scientist could

## THE CANCER LETTER Editors: Kirsten Boyd Goldberg Paul Goldberg

Founder & Contributing Editor: Jerry D. Boyd

## P.O. Box 15189, Washington, D.C. 20003 Tel. (202) 543-7665 Fax: (202) 543-6879

Subscription \$225 per year North America, \$250 elsewhere. ISSN 0096-3917. Published 48 times a year by The Cancer Letter Inc., also publisher of The Clinical Cancer Letter. All rights reserved. None of the content of this publication may be reproduced, stored in a retrieval system, or transmitted in any form (electronic, mechanical, photocopying, facsimile, or otherwise) without prior written permission of the publisher. Violators risk criminal penalties and \$100,000 damages.

not be removed as the principal investigator or chairman of NSABP without due process, and that any compliance from Fisher was due to improper pressure by the university's administration and counsel.

•The Univ. of Pittsburgh says it had the authority to fire Fisher as the principal investigator, and that Fisher had relinquished his post as chairman of NSABP when he went on administrative leave. Pitt also claims that it had the authority—and NCI recommendation—to appoint Ronald Herberman to the position of interim chairman.

•The NSABP Executive Committee is not calling for Fisher's reinstatement as the principal investigator. However, the committee claims that the university lacked the authority to remove Fisher as chairman, appoint an interim chairman, or conduct a search for a new permanent chairman.

The Cancer Letter was able to locate two documents in which Fisher is quoted stating his intention to take administrative leave.

One is a March 29 press release from the Univ. of Pittsburgh in which Fisher is quoted saying: "I am requesting administrative leave from the chair of NSABP so that I can continue my investigations... which are so important to the women of this country" (The Cancer Letter, April 1).

The other document, the minutes of the March 30 meeting of the NSABP Executive Committee, contains the following account of Fisher's resignation:

"Dr. Fisher called the meeting to order at 6:07 p.m. and thanked everyone for coming on such short notice...

"Dr. Fisher explained that the following developments had... occurred: The NSABP had been under close scrutiny by the NCI and, as of Monday, March 28, 1994, at 6:00 p.m., he had received a phone call from the NCI stating that the NSABP was to be placed `on hold.'

"The NCI had examined the audit program and several deficiencies were noted. Although in the last grant renewal the audit program had received a glowing report, the NCI had questions regarding the lack of investigator responses to the audits.

"In order to restore confidence, it was thought advisable to have a change in leadership. Dr. Fisher announced that he was no longer the chairman and that he had taken administrative leave, but could be involved in the scientific leadership of the group. A written notification of these changes was received

The Cancer Letter Page 2 ■ Aug. 12, 1994 today... He then introduced Dr. Ronald Herberman, who would be the interim director of the NSABP..."

Two days before the Executive Committee meeting, a letter from NCI informed Pitt officials that the Institute intended to amend the NSABP award to withdraw its approval of Fisher as principal investigator. That letter reached the Executive Committee on the day of the meeting, sources said.

Sources who were present at the Executive Committee meeting said that after introducing Herberman, Fisher left the room. The minutes reflect no objections to Herberman's candidacy or the new management schema at the cooperative group.

Immediately after Fisher's departure from the meeting, the Executive Committee moved to express a vote of confidence in Fisher. "It was moved by Dr. [David] Prager [a principal investigator from Allentown, PA] and seconded by Dr. [Andrew] Glass [a PI in Portland, OR] that the Executive Committee express continued confidence in Dr. Fisher and ask that the NCI reconsider and rescind its action concerning Dr. Fisher's removal."

According to the minutes, the motion passed unanimously. The document was prepared by D. Lawrence Wickerham, a Fisher supporter and the cooperative group's administrator.

Following the meeting of the Executive Committee, Herberman wrote a letter to NSABP investigators.

The letter, dated April 1, states that Fisher had "withdrawn" from his position as chairman. "As you may have heard, our colleague Dr. Bernard Fisher has withdrawn as Chairman of [NSABP]," Herberman, identified as "interim chairman designate," wrote.

"I have been asked by the Univ. of Pittsburgh, in consultation with NCI, to assume the chairmanship on an interim basis," Herberman wrote.

#### **Question 2: Who Represented NSABP in Deals?**

A legal challenge to Herberman's authority, if sustained by a court, opens the question of whether the NSABP Executive Committee received proper representation at negotiations of disputes that affected the group's future.

From several interviews, The Cancer Letter was able to reconstruct decisions made at one key meeting that involved NCI Director Samuel Broder, Herberman, a congressional staff member, top NCI officials and an attorney for Pitt. At that meeting, held on the NIH campus on the evening of May 31, all parties agreed that NSABP would stay at Pitt for the near future, while NCI is engineering an orderly recompetition of the grant (The Cancer Letter, June 17).

Prior to that meeting, which was held on suggestion of the staff of Rep. John Dingell (D-MI), Herberman had protested Broder's apparent efforts to move the cooperative group's headquarters to another cancer center (The Cancer Letter, May 13).

After holding one hearing on the NSABP, Dingell, chairman of the Oversight and Investigations Subcommittee of the House Energy and Commerce Committee, was preparing another hearing.

At the time, the Fox Chase Cancer Center was described as the leading contender, and Norman Wolmark, an NSABP official who had moved to Allegheny General Hospital, was seen as the Executive Committee's likely choice for chairman (The Cancer Letter, May 27).

Participants in the meeting included Herberman, Broder, Dingell's subcommittee staff member Bruce Chafin, Pitt's Washington attorney Martin Michaelson, NCI Office of Administrative Management Director Philip Amoruso, NCI Div. of Cancer Treatment Director Bruce Chabner, NCI Acting Deputy Director Edward Sondik, NCI Grants Administration Branch Chief Leo Buscher and NIH counsel Robert Lanman.

Dingell had several reasons to engineer a peace agreement between Pitt and NCI, sources said:

•Less than two weeks remained before Dingell's scheduled hearing on NSABP. While both NCI and Pitt had accepted responsibility for the problems of the cooperative group, an open skirmish between them would have confused the message of the hearing.

•With Dingell's apparent decision that his second hearing on NSABP would be his last, the subcommittee wanted to hammer out a joint corrective action by NCI and the university.

•Sen. Arlen Specter (R-PA) was threatening to hold a hearing focusing on the disputes at Pitt. By engineering a deal, Dingell's staff was hoping to avoid the spectacle of Pitt and NCI duking it out before Specter prior to appearing before Dingell.

Though sources said that the question of a future role for Fisher at NSABP was under discussion at the meeting at NCI, no concrete plan was adopted.

The consequences of the agreement were farreaching: Specter convened a meeting of all parties in the dispute, including Fisher, but ultimately canceled the hearing.

And by the time Dingell convened his hearing, he had visibly softened his stance toward Pitt, focusing almost exclusively on Fisher's record as administrator of the cooperative group (The Cancer Letter, June 24).

# Court Filing By Fisher, Board Attacks Interim Leadership

An allegation that interim leadership of the National Surgical Adjuvant Breast & Bowel Project is driving the cooperative group into the ground is the principal claim of the motion for a preliminary injunction filed Monday by attorneys for Bernard Fisher and the group's Executive Committee.

According to the motion, filed in the US District Court for the Western District of Pennsylvania, the appointment of Ronald Herberman as interim chairman was "unfortunate, unpopular, and has had a corrosive effect from the outset," the document says.

The complaint states that Herberman is less qualified than Fisher to run the cooperative group and that he has managed the group in a "peremptory autocratic fashion," "scapegoating NSABP researchers," focusing his efforts on "appeasing the federal science establishment" and using his position to absorb the cooperative group's headquarters functions into the Pittsburgh Cancer Institute which he heads.

"Overall, the allegations against me are completely without merit," Herberman said to The Cancer Letter. "I am very disappointed that this has deteriorated to a personal attack.

"For the past four months, I have been devoting almost all my time and energy to getting NSABP on track and to preserving the important legacy of Dr. Fisher," Herberman said.

Addressing the claim that his leadership is harming the group, Herberman said, "We have been having weekly visits from NCI monitors, and we have had consistently high praise for efforts that we have been making to get the program back into full operation as quickly as possible," Herberman said.

Besides seeking Herberman's removal and Fisher's reinstatement, the plaintiffs' motion seeks a ruling to dissolve the Univ. of Pittsburgh search committee to select a new chairman for the cooperative group.

Defendants in the suit include Herberman, the

university, chancellor Dennis O'Connor, vice chancellor, health affairs, Thomas Detre. Also named is the Washington law firm of Hogan & Hartson and attorney Martin Michaelson, who represented Pitt in the early days of controversy over scientific fraud at NSABP (The Cancer Letter, Aug. 5).

### **Text Of Criticism**

The text of the plaintiffs' criticism of Herberman's leadership follows:

a. He is far less well qualified than Dr. Fisher in the critical fields of breast cancer treatment and large clinical studies;

b. He previously had no stature with or record of interest in the NSABP, and was not even a member of the organization;

c. Earlier in grant materials, he falsely sought credit for himself and the Pittsburgh Cancer Institute [which he heads] for treating patients of the NSABP;

d. Since his unlawful installation as interim chair, he has managed in a peremptory autocratic fashion, alienating both to staff and to NSABP Executive Committee members;

e. He has failed to advance the scientific mission of the NSABP, especially in terms of the design and implementation of clinical trials intended to defeat breast cancer. Indeed, he and the University defendants have excluded knowledgeable personnel such as Doctors Fisher, [chief biostatistician Carol] Redmond, and [administrator D. Lawrence] Wickerham, and others from playing meaningful roles;

f. He has attempted to diminish and/or destroy the venerable and heretofore independent NSABP by autocratically absorbing its headquarters functions into the PCI; and

g. His dilatory leadership has focused on policing and dismantling the organization, appeasing the federal science establishment and scapegoating NSABP researchers rather than on treatment, which has been stalled, thereby denying numerous cancer patients the cutting edge therapies of the NSABP.

# **Publishing Break Scheduled**

The Cancer Letter will take its annual summer publishing break shortly.

Issue No. 33 will be published next week, Aug. 19. No issues will be published for the following two weeks. Publication will resume for issue No. 34, dated Sept. 9.

# <u>Capitol Notes</u> House, Senate Reform Bills Move Closer To Floor Vote

As it abandoned the Health Security Act, the Clinton Administration has endorsed two new blueprints for health care reform: the bill introduced by House Majority Leader Richard Gephardt (D-MO) and Senate Majority Leader George Mitchell (D-ME).

The Mitchell bill, being more lenient on the definition of universal coverage and the timetable for achieving it, is expected to encounter less resistance than the Gephardt proposal, several observers said.

Hence, it has become something of conventional wisdom that the final health care reform package, if it is passed, will look more like the Mitchell bill than any other plan currently under consideration.

With the exception of universal coverage—a matter of paramount importance to cancer patient advocates—the majority of issues identified as important to the cancer lobbies are not the subject of heated debate.

At this writing, the Gephardt bill provides for universal coverage and employer mandate, while the Mitchell bill proposes to achieve coverage targets in a less rigid manner.

Under the Gephardt bill, which is closest to the Administration's proposal, universal coverage would be phased in by 1999, with businesses being obligated to pay 80 percent of insurance premiums for their full-time employees. Low income families would receive government assistance to keep up with their premiums.

The Mitchell bill seeks to provide health insurance to 95 percent of the population by the year 2000, using a system of insurance market reforms, voluntary purchasing cooperatives as well as subsidies to the needy

The Gephardt bill, according to most recent drafts, does not include reimbursement for routine care for patients involved in approved clinical trials, while the Mitchell bill does. However, cancer lobbies are trying to convince Gephardt to add that provision to the House bill. The provision was a part of the President's bill as well as the majority of other blueprints.

Both the Gephardt and the Mitchell bill include creation of a fund for biomedical research, to be financed through a tax on insurance premiums. The proposal first surfaced in a bill introduced by Sens. Tom Harkin (D-IA) and Mark Hatfield (R-OR).

Both the House and Senate bills mandate that drug companies pay 15 percent rebates to Medicare, and both bills establish a prescription drug payment review commission.

However, the Senate bill is easier on pharmaceutical and biotechnology companies since it does not create a breakthrough drug advisory committee, does not give HHS the power to negotiate rebates on drugs purchased through Medicare and does not exclude excessively priced drugs from coverage by Medicare.

The House and Senate leadership have vowed to delay the August recess until both chambers pass their versions of the bill.

## Oncology Societies, Centers, Lay Out Prinicples For Reform

If the war on cancer is to continue under health care reform, then members of Congress should keep in mind four critical principles as they are considering reform legislation, according to a letter from cancer organizations, cancer centers and oncology societies.

The four principles are: coverage of patient care costs for clinical trials, access to specialists, funding for academic health centers and biomedical research, and no excessive regulation of drug industry research.

The letter was sent to Sen. George Mitchell (D-ME) and Rep. Richard Gephardt (D-MO) by 13 national cancer organizations, 46 cancer centers, and 38 state and regional oncology societies.

The excerpted text of the letter follows:

"As you and your colleagues deliberate the critical issues involved in the various health care reform proposals, the cancer community urges recognition of four critical principles if the war on cancer is to go forward:

•Health insurance coverage should be required to include patient care costs for persons enrolled in approved clinical trials, including Medicare beneficiaries.

•Managed care organizations must be required to provide people with cancer, including children, timely access to any qualified oncologic specialist or specialty care centers in circumstances where the inplan providers are unable to provide state-of-the-art care for that patient's particular diagnosis.

•Current funding levels to support academic health centers should be sustained, and biomedical

research should be enhanced by a trust fund financed by a specified percentage of health insurance premiums.

•Private biomedical research, which is necessary to translate basic science into medical applications, should not be deterred by excessive regulatory burdens or other disincentives to development, including rebates, blacklisting, or oversight by breakthrough drug review committees.

#### "Message Of Hope"

"The promise of universal coverage is a message of hope to more than 8 million cancer survivors. The unfortunate fact, however, is that cures for most cancers remain to be found. Without continued support of cancer research in both the public and private sectors, those cures may never come.

"Therefore, we endorse a balanced approach to health care reform that extends coverage to the currently uninsured while preserving and even extending our capacity for research and development into prevention and treatment of cancer and other serious or life-threatening diseases."

The thirteen societies signing the letter were: American Cancer Society, American Society of Clinical Oncology, American Society of Hematology, American Society of Pediatric Hematology and Oncology, American Society for Therapeutic Radiology and Oncology, Association of Community Cancer Centers, Association of Pediatric Oncology Nurses, International Association for the Study of Lung Cancer, North American Brain Tumor Coalition, Oncology Nursing Society, Society of Gynecologic Oncologists, Society of Surgical Oncology, and the Susan G. Komen Breast Cancer Foundation.

# Letter To Shalala Protests Closed Meeting Of Advisors; NIH Says Action Was Legal

The Cancer Letter has sent a letter to HHS Secretary Donna Shalala protesting a closed and unannounced meeting of advisors to the NIH intramural research program.

In the letter, the editors seek to bring to Shalala's attention the Aug. 1 meeting held by Michael Gottesman, NIH Deputy Director for Intramural Research, with the chairmen of the 23 NIH Boards of Scientific Counselors.

The meeting, which was not announced in the Federal Register, was described to a reporter as closed. However, after reporters showed up to cover it, the meeting was opened to reporters briefly, then closed again (The Cancer Letter, Aug. 5).

The excerpted text of the letter of protest follows:

"Because we believe that all such meetings should be open to the public, we recommend that NIH be instructed to review its compliance with the Federal Advisory Committee Act and educate staff, particularly within the Office of the Director, on the provisions of this important law.

"The Act was intended by Congress to ensure public access to deliberations of expert advisory groups.

"The attempt to close the meeting to the public was, at the very least, the result of lack of knowledge of the law on the part of NIH staff. At worst, it represents a deliberate violation of the law and contempt for the principles of open government.

"While the restructuring that NIH officials are conducting is difficult and fraught with controversy, the agency should not attempt to hide these discussions from public view."

The Cancer Letter intends to cover the second meeting of the group, tentatively scheduled for mid-January.

#### **NIH Action Appropriate: Thomas**

Responding to the article in the Aug. 5 issue of The Cancer Letter, NIH Associate Director for Communications Anne Thomas maintained that NIH officials acted appropriately.

"In our view, this meeting did not fall under the Federal Advisory Committee Act," Thomas said.

GSA Management Regulations, page 52, 41 CFR Ch. 101, subpart 101-6.1004, lists examples of advisory meetings or groups not covered by the act. Thomas quoted part i: "Any meeting initiated by a Federal official with more than one individual for the purpose of obtaining the advice of individual attendees and not for the purpose of utilizing the group to obtain consensus advice or recommendations."

For future meetings of the BSC chairmen, Thomas said, "Dr. Gottesman has indicated to me that he believed he would have an open component of the meeting to satisfy needs of the press without compromising what he intended to accomplish."

Thomas said she did not know whether the next

meeting of the group would be announced in the Federal Register. "We will have to discuss it with our lawyers, and many people are on vacation right now," she said.

The Cancer Letter contend s that another part of the GSA regulations quoted by Thomas applies. Part i continues: "However, agencies should be aware that such a group would be covered by the Act when an agency accepts the group's deliberations as a source of consensus advice or recommendations."

By claiming this exemption, NIH officials are saying that they don't want this panel to develop consensus or provide advice, Kirsten Goldberg, editor of **The Cancer Letter**, said.

"We find it hard to believe that this group will make no recommendations," Goldberg said. "More likely, this is an attempt by NIH officials to avoid public discussion of restructuring of the intramural program."

# <u>Letter to the Editor</u> Closed Meetings Create "Aura Of Suspicion, Secrecy"

To the Editor:

We at NCCS were very disturbed to read about the closed meeting of advisors to the NIH intramural program in the Aug. 5 issue of **The Cancer Letter**.

By keeping the public and the press out of these meetings, NIH creates an aura of suspicion that only serves to increase needless friction between the public and government officials.

The unfortunate belief held by many is that consumer groups sometimes overreact to actions undertaken by NIH and others—a belief fueled by our response to situations like this. To the contrary, it is important that we <u>do react</u> to activities like this where, by all outward appearances, decisions seem to be cloaked in secrecy.

We want what the NIH wants: the best science and the most appropriate use of precious grant monies going toward research to prevent, treat and cure diseases.

We are all depending on NIH officials to make very important decisons to defend medical research. Decisions made in the public interest should be open to public participation.

> Ellen L. Stovall Executive Director National Coalition for Cancer Survivorship

## **RFA Available**

RFA CA-94-028

Title: Molecular Epidemiology Of Prostate Carcinogenesis

Letter of Intent Receipt Date: Oct. 17 Application Receipt Date: Nov. 23

The NCI Div. of Cancer Etiology; the Div. of Kidney, Urologic, and Hematologic Diseases, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK); and Chemical Exposures and Molecular Biology Branch, National Institute of Environmental Health Sciences (NIEHS) invite investigator-initiated research grant applications for molecular epidemiologic studies to further the understanding of prostate cancer etiology. A major emphasis of this RFA is to stimulate the use of biochemical and molecular markers for identifying and assessing risk factors of prostate cancer, which could lead to effective prevention strategies. Domestic and foreign, non-profit and for-profit, and units of local, State, and Federal governments are eligible to apply. Foreign institutions and organizations are not eligible for the FIRST awards. Minority and women investigators are encouraged to apply.

Support of this program will be through the NIH individual research project grants (R01), FIRST awards (R29), and competing supplements (S01) to current R01 awards. The total project period for applications submitted in response to the present RFA may not exceed five years. The earliest award date is July 1, 1995.

Because the nature and scope of the research proposed may vary, it is anticipated that the size of an average award will vary also ranging from \$150,000 to \$500,000 in total costs per year. If direct costs exceed \$500,000 in any year, the funded study may be considered for an award as a cooperative agreement (U01). Total direct cost award for the five-year R29 grant period may not exceed \$350,000 and the direct cost award in any R29 budget period should not exceed \$100,000.

Approximately \$3.75 million (\$2,000,000 from NCI, up to \$1,000,000 from NIDDK, and \$750,000 from NIEHS) in total costs per year for five years will be committed to fund applications. It is anticipated that 8 to 12 awards will be made.

The purpose of this RFA is to stimulate innovative molecular epidemiologic research into the origins of prostate cancer, including the biological basis for the striking increase in prostate cancer incidence with age. The types of studies could include, but are not limited to: characterization and validation of biomarkers relevant to prostate carcinogenesis including consideration of variables such as ethnicity, genetic predisposition, diet, and lifestyle; assessment of sex hormonal profiles in body fluids; identification of premalignant lesions; elucidation of the natural history of invasive cancer or progressive stages of the carcinogenic process; exploration of timing of environmental exposures relevant to prostate cancer development; evaluation of micronutrients, macronutrients, xenobiotics and their interactions with hormones and hereditary factors; and clarification of the possible relationships of benign prostatic hyperplasia or chronic prostatitis to prostate cancer.

Successful grant awardees under this RFA are strongly encouraged to participate in two, one-day program meetings to be held in Bethesda, Maryland during the second and fifth years of the grant. NIH program staff will coordinate the meetings, which will provide the opportunity for investigators to discuss their work in progress and to consider methodological and scientific issues. The respondents may request sufficient funds within the budget to accommodate expenses for one to two participants at each meeting.

Inquiries: Kumiko Iwamoto, Epidemiology and Biostatistics Program, NCI, 6130 Executive Blvd, Room 535, Bethesda, MD 20892, Tel: 301/496-9600, Fax: 301/ 402-4279.

## **Program Announcement**

#### PAR-94-084

#### Title: Animal Facility Improvement For Small Research Programs

Application Receipt Dates: October 1, February 1, June 1

The National Center for Research Resources encourages the submission of individual animal resource improvement grant applications from small biomedical research institutions.

The major objectives of this program are to upgrade animal facilities, develop administratively centralized programs of animal care, and enable institutions to comply with the USDA Animal Welfare Act and DHHS policies related to the care and use of laboratory animals. These awards do not require matching funds from the awardee institution.

Support is limited to alterations and renovations (A&R) to improve laboratory animal facilities, and the purchase of major equipment items for animal resource, diagnostic laboratory, transgenic animal resources, or similar associated activities.

Any domestic public or private institution, organization, or association is eligible to apply for this grant if it meets the following two requirements:

(1) The institution must have one or more research projects supported by the PHS that involve the use of laboratory animals, and

(2) The institution must have received less than \$1,500,000 (direct costs) of PHS support for research projects during the most recently completed Federal fiscal year.

Separate applications may be submitted from different colleges or schools on the same campus of a university within the same Federal fiscal year if they have different organizational component codes. If this is done, documentation from an appropriate institutional official, stating that the applications are part of a coordinated, campus-wide plan to improve the animal facilities, must be provided.

The applicant institution is strongly encouraged to develop a single application for a campus-wide program with a single, centralized animal care program whenever possible or feasible.

The mechanism available for the support of improvement projects is the Grant for Repair, Renovation, and Modernization of Existing Research Facilities (G20).

The total budget request for the improvement grant application and award is limited to \$300,000 (direct costs), of which not more than \$200,000 may be used for alterations and renovations. Matching funds are not required.

Because the nature and scope of the projects proposed in response to this PA may vary, it is anticipated that the size of an award will vary also. Items that may be requested under this grant mechanism include:

•A&R to improve existing laboratory animal facilities, and allowable fees associated with the A&R project

•Major resource equipment related to the improvement project, such as animal cage systems and cage washers

•Equipment items, or an aggregate of identical equipment items, that have a total cost of at least \$1,000. Items that are part of a system and require the purchase of small component parts (e.g., a rack and cages or microisolator units) may be requested and priced as a single item. A description of the individual components of such systems must be provided.

•General purpose equipment items for centralized surgeries, diagnostic laboratories, transgenic animal facilities, and other similar associated activities when an integral part of the animal facility and available to all investigators

•Basic diagnostic equipment (e.g., microscopes, centrifuges, refrigerators, etc.) to be used in support of the animal facility, but not for research

•Environmental monitoring systems. However, if such a system has multiple uses (e.g., the monitoring of research data or security), only those costs related to monitoring or providing for animal care (e.g., environmental monitoring) are allowable

Inquiries: Director, Laboratory Animal Sciences Program, Comparative Medicine Program, National Center for Research Resources, Westwood Bldg. Room 857, Bethesda, MD 20892-4500, Tel: 301/594-7933.