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New NCAB Task Force On Clinical Trials Is Attempt To Bring NCI, Groups Together

The National Cancer Advisory Board has established a task force to bring together investigators, NCI officials, and patient advocates to discuss implementation of stronger oversight and auditing procedures for clinical trials.

NCAB Chairman Paul Calabresi formed the task force last week in response to what he described as a "schism" between clinical investigators and NCI. That split, he said, was very much in evidence at the meeting of the American Society of Clinical Oncology last month.

"Directives have been coming out of NCI which have caused some anxiety and consternation because partly the investigators do not understand

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In Brief

Ford Named Acting Deputy Director, DCPC; Fountain Leads Oncology Administrators

NCI STAFF changes: **Leslie Ford**, chief of the Community Oncology & Rehabilitation Branch in the Div. of Cancer Prevention & Control, has been appointed acting division deputy director. . . . **Thomas Cameron**, special assistant for environmental cancer in the Div. of Cancer Etiology, has retired. . . . **AMERICAN COLLEGE** of Oncology Administrators, at its annual meeting last month, adopted a resolution supporting the Agency for Health Care Policy and Research cancer pain guidelines. The college also elected new officers. **Marsha Fountain**, Harris Methodist, Ft. Worth, is president; president-elect is **Sharon MacDonald**, North Shore Medical Center, Salem, MA; secretary-treasurer is **Roy Threet**, CTRC, San Antonio; Region 7 representative is **Kathy Burns**, Scripps Cancer Center. **Cathy Harvey**, Hollings Oncology Center, will remain on the board as immediate past president. . . . **ROBERT KRIGEL**, former director hematology for Fox Chase Cancer Center, and chief of hematology and medical director of the cancer program at Lankenau Hospital, died April 24 of complications of angiosarcoma. He was 44. Krigel joined Fox Chase in 1984. He moved to Lankenau Hospital in 1993 to expand its cancer program. Two endowed lectureships have been established in Krigel's name: Fox Chase Cancer Center, Office of Institutional Advancement, 7701 Burholme Ave., Philadelphia, PA 19111, or Lankenau Hospital Foundation, 100 Lancaster Ave., Wynnewood, PA 19096. . . . **BART SEFTON** has been elected chairman of the Academic Council of the Salk Institute, succeeding Ron Evans. Selected chairman-elect was **Wylie Vale**.

New Clinical Trials Task Force To Bring Together NCI, Groups

(Continued from page 1)

the directives or feel they are duplicative," Calabresi said to **The Cancer Letter**. "The two sides have not been communicating very well. What is needed is to get the two groups together."

In an attempt to find a common ground, Calabresi proposed to revamp the board's Subcommittee on Clinical Investigations, which in the past year worked exclusively on the issue of translational research. Calabresi established two task forces within the subcommittee: a task force on translational research and a task force on clinical trials.

The clinical trials task force will include the six NCAB members who already serve on the subcommittee, as well as six cooperative group chairmen, and one consumer advocate.

The cooperative group chairmen who have agreed to serve on the task force are Ross McIntyre, Cancer & Leukemia Group B; Charles Coltman, Southwest Oncology Group; Doug Tormey, Eastern Cooperative Oncology Group; James Cox, Radiation Therapy Oncology Group; Sharon Murphy, Pediatric Oncology Group; and Ronald Herberman, NSABP.

Other members are Fran Visco, member of the President's Cancer Panel and president of the National Breast Cancer Coalition, and Emil (Tom) Frei of the Dana-Farber Cancer Institute.

The task force will be charged to "determine what steps need to be taken to reinstate the public trust in the clinical trials program, and to be sure that we do not have unilateral directives by NCI that would impair the ability of the clinical trials leaders to exercise their own judgment," Calabresi said. "We should be looking for constructive ways to bring together the scientific community, the National Cancer Institute, and the clinical trials programs."

The first meeting of the clinical trials task force took place at the NCAB meeting this week.

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NSABP Investigator Recounts Feelings Of 'Betrayal,' Anger

The National Surgical Adjuvant Breast & Bowel Project should elect new leaders who will communicate with the cooperative group members and the public, an NSABP-affiliated surgeon said to an NCI advisory board this week.

"What the NSABP needs are leaders committed to communication, accountability, intellectual honesty, and integrity," Janet Osuch, assistant professor of surgery at Michigan State Univ., said to the National Cancer Advisory Board. "Due to the circumstances in which we in the NSABP are mired, unless we take action, we will lose our organization."

Osuch, an NSABP investigator for seven years and a member of the group's surgery committee, said she felt "intense loyalty" to ousted group chairman Bernard Fisher. However, she said she also felt betrayed by the failure of the group's leadership to disclose—and discuss—its problems openly.

"Bernie Fisher was one of my mentors," Osuch said to the NCAB. "I called myself one of his disciples. He had the capacity to enlist a feeling of passion and involvement and loyalty. He made the meetings of the membership scientifically sound, incredibly intellectually challenging, and his passion for the advancement of knowledge in breast cancer was contagious beyond description.

"For this, he deserves, and has our respect and admiration," Osuch said.

But professional admiration is but one aspect of the story. "As a physician, I have a duty to preserve two important values: the trust of my patients, and the integrity of science," Osuch said.

"The feelings of personal betrayal that I felt over the lack of public disclosure of scientific misconduct of Dr. Robert Poisson on the part of the NSABP, the NCI, and the Office of Research Integrity continue to plague me," Osuch said. "To have learned of the issue from The Chicago Tribune rather than from Dr. Fisher only serves to deepen the sense of betrayal.

"What was the purpose of keeping the issue invisible?" Osuch said to the board. "Could the NSABP membership and the scientific world in general not have learned from the resulting public discourse? Was it so hard to make a statement that

fraud in science is unacceptable? Is it not the responsibility of the principal investigator of a grant to disclose scientific fraud to the members of the organization? Is it not that person's responsibility to the journals which have published the papers containing fraudulent data to submit a reanalysis in a timely manner? Is it not the responsibility of the National Cancer Institute to protect the public health, to preserve the integrity of science and to provide leadership in scientific progress?...

"What has happened to the NSABP is wrong," Osuch said. "The membership has been betrayed. The women who have participated in the clinical trials have been betrayed. And the ethical standards of science have been betrayed. The integrity of the NSABP has been compromised. The academic culture of the Univ. of Pittsburgh that allows the lack of disclosure and the lack of timely re-publication of data and the lack of communication with the NSABP membership needs to be questioned.

"Some of my colleagues see my position as harsh," Osuch said. "Bernie Fisher is, after all, one of the greatest and most recognized breast cancer researchers in this country. However, Bernie Fisher had responsibilities which he did not meet. He failed to respect the members of the NSABP and the scientific community enough to be accountable to us. The organization has lost its integrity in the eyes of the public and among many physicians."

The NSABP and Univ. of Pittsburgh have not apologized to women or doctors who made the research possible, Osuch said. "This is very difficult for me to understand. The NCI has apologized. This underlined for me the importance of public acknowledgment of wrongdoing, the importance of apology, and the establishment of plans to keep similar events from reoccurring."

Osuch was one of six women surgeons who wrote to Congress last April expressing the belief that NSABP has been "intellectually honest" in reporting the side effects of tamoxifen to the NSABP membership (**The Cancer Letter**, May 13)

However, Osuch said, the lead article in April 29 issue of **The Cancer Letter**, which she read subsequently to writing the letter, cast doubt on the group leadership's integrity.

The article reported that four patients in protocol B-14, the tamoxifen treatment trial, had died of uterine cancer prior to the opening of the Breast Cancer Prevention Trial. According to NSABP documents obtained by **The Cancer Letter**, the group was not informed of the uterine cancer deaths for six to 20 months, and then took many months to verify and report the deaths.

Meanwhile, the written informed consent form for the prevention trial stated that "no deaths from uterine cancer were reported" in clinical trials with tamoxifen.

"There is no justification for this kind of behavior on the part of a nationally funded clinical trials group," Osuch said.

NCAB Member Seeks Broder's Resignation, Gets No Support

A member of the National Cancer Advisory Board has called for the resignation of NCI Director Samuel Broder.

In a sharply worded letter, Walter Lawrence, a member of the board since 1988, accused Broder of employing "exaggerations of fact" and resorting to "witch hunt tactics" in his handling of the controversy over the National Surgical Adjuvant Breast & Bowel Project.

"I urge you to consider resignation from your post as Director of the NCI, so that someone who is more objective, and less emotionally involved, can sort all of this out," wrote Lawrence, director emeritus of the Massey Cancer Center at the Medical College of Virginia and professor of surgical oncology at Virginia Commonwealth Univ.

A copy of the letter, written on NCAB stationery and dated May 10, was obtained by **The Cancer Letter**.

In the letter, Lawrence said he planned to bring up the issue at a closed session of the May 31 board meeting. However, sources who were present at the closed session said to **The Cancer Letter** that the letter was not mentioned.

Lawrence declined to discuss the letter with a reporter. The text of the letter follows:

"I appreciate the fact that you have felt threatened by congressional inquiries that relate to the dishonest reporting of NSABP data from Montreal, and by the fact that Dr. Fisher and his staff were slow in publishing the data analysis that you recommended. However, the series of public statements and administrative actions initiated or programmed by you, and at your direction by your staff at the National Cancer Institute have reached obscene proportions. By innuendo, and by some exaggerations of fact, you have methodically moved to destroy both the NCAB and its nationally recognized leaders, Bernard Fisher and Carol Redmond.

"It is apparent that virtually all of the scientific world is aghast, and unbelieving, and you have inadvertently

led the public to believe that science itself is in question and clinical trials are particularly suspect and unreliable. If you had wanted to set back clinical trials methodology in the public eye, and I don't think you do, you couldn't have been more effective than you have by the witch hunt tactics that have been employed. You have been so obsessed by your own concerns, and your fears of personal criticism, that you have emulated some of the techniques employed by the late Senator Joe McCarthy. By doing so, you have not only destroyed the spirit and the reputation of one of our nation's great scientific leaders, but you have severely wounded one of the most innovative and productive clinical trial groups in the nation. The result has been the development of a national distrust of cancer research in general, and clinical trials in particular.

"What is the solution to this terrible situation? You have carried this vendetta so far that there seems to be no way that you can reverse the course. For this reason, I urge you to consider resignation from your post as Director of the NCI so that someone who is more objective, and less emotionally involved, can sort all of this out. The direction now being taken is clearly leading to such a loss of confidence in the NCI, and in science in general, that I believe our entire research operation is in jeopardy.

"I expect there will be discussions of this overall problem during an executive portion of the closed session of the NCAB on May 31. For this reason, this letter is being shared with the appointed members of the NCAB."

Pittsburgh Broadens Scope Of Fisher Misconduct Inquiry

The Univ. of Pittsburgh has broadened the scope of the misconduct investigation against Bernard Fisher and Carol Redmond and has appointed a three-member panel to conduct the inquiry, sources said.

Originally, the NIH Office of Research Integrity ordered the university to investigate the inclusion of fraudulent data into scientific publications by Fisher and Redmond (**The Cancer Letter**, May 6).

However, in recent weeks the university expanded the probe to questions of timely reporting of deaths in the tamoxifen treatment trial, sources said to **The Cancer Letter**.

While scientific misconduct investigations are ordered by ORI, it is up to the institutions to appoint examiners and set the parameters for the inquiry.

The Fisher-Redmond inquiry panel will be led by Charles McCarthy, a senior research fellow at the Kennedy Institute of Ethics at Georgetown Univ. Other panel members are Judith O'Fallon of the Mayo Clinic and Charles Hennekens of Harvard Medical School.

The panel was given a deadline of June 27 to determine whether a full investigation is warranted.

Capitol Notes

Senate Appropriators Plan Hearing On Fisher's Removal

The controversy over NCI's removal of Bernard Fisher from his post as chairman of the National Surgical Adjuvant Breast & Bowel Project is likely to be examined June 9 at a hearing of the Senate appropriations subcommittee on Labor, HHS & Education.

The hearing, though called by Sen. Tom Harkin (D-IA), the subcommittee chairman, is being convened on request of Sen. Arlen Specter (R-PA), who came to the defense of both Fisher and the Univ. of Pittsburgh last month.

Specter softened his criticism of NCI after learning that Fox Chase Cancer Center, another Pennsylvania institution, was the leading contender for NSABP.

Fisher and Redmond are expected to appear at the hearing, along with NSABP interim principal investigator Ronald Herberman and executive officer Donald Trump.

NCI, too, is expected to be represented.

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A provision to levy a tax on health insurance premiums to finance medical research survived last week's markup by the Senate Labor and Human Resources Committee.

The provision establishes a .25 percent tax on insurance premiums in fiscal 1996, to be raised to 1 percent by fiscal 1999. Supporters of the measure estimate that it would raise $10.8 billion by 2001 and $28.4 billion by 2004.

The tax, which was originally proposed by Sens. Tom Harkin (D-IA) and Mark Hatfield (R-OR), has broad support among cancer advocacy groups. The tax is part of the committee's health care reform proposal.

Under the proposed legislation, 95 percent of the new funds would be distributed proportionally among NIH institutes. The remaining 5 percent would be distributed in the following way:

- Programs dedicated to women's health, minority health, alternative medicine, rare diseases and NIH construction projects would share 2 percent of the new funds.
- The National Center for Research Resources would receive another 2 percent.
- A yet-to-be-created program for health

information communications would be given the remaining 1 percent.

Also, the tax is likely to provide funding for research on health care reform, which the Public Health Service has been mandated to initiate.

In fiscal 1995, PHS is being given $150 million for the project. By 1998, the program will grow to $600 million.

Adamson To Retire Aug. 31, DCE Director Since 1980

Richard Adamson, director of the NCI Div. of Cancer Etiology since 1980, plans to retire Aug. 31.

Adamson is one of about 15 to 20 top-ranking NCI staff who have elected to take the Clinton Administration's offer of a $25,000 payment as an inducement to retire, **The Cancer Letter** has learned.

As part of the Administration's effort to reduce the number of high-ranking federal employees, the buy-out offer was issued to NIH employees of GS-13 level and above, and required the approval of NIH officials. About 100 NIH employees have accepted the buy-out and have been approved, sources said.

NCI could not release the names of employees who took the buy-outs, Philip Amoruso, chief of the NCI Management Analysis Branch, said to **The Cancer Letter**.

When contacted by **The Cancer Letter**, Adamson confirmed that he had taken the buy-out and will retire after 33 years in the federal government. He said he is "considering numerous options" which he could not discuss yet.

He is the second NCI division director to retire this year. Barbara Bynum, director of the Div. of Extramural Activities since 1981, retired last January.

Appointed By DeVita

Adamson was named acting director of the NCI Div. of Cancer Cause and Prevention in September 1980, soon after Vincent DeVita was appointed NCI director. Adamson had been chief of the Laboratory of Chemical Pharmacology in the Div. of Cancer Treatment when DeVita was DCT director.

Later, DCCP was renamed the Div. of Cancer Etiology. Adamson's appointment as division director became official in November 1981.

Adamson directs the division's current operating budget of $375 million, 500 full-time employees and 300 other positions. The division plans and directs laboratory, field, and demographic research on the cause and natural history of cancer and basic studies on prevention.

In the past seven years, Adamson has taken on other top positions at NCI when those posts were vacant. He served as acting associate director of the Frederick Cancer Research & Development Center from 1987 to 1988 and from 1993 to 1994, and as acting deputy director of NCI from 1990 to 1991.

Adamson received a bachelor's degree in chemistry from Drake Univ. in 1957, and a PhD in pharmacology from the Univ. of Iowa in 1961.

Adamson came to NIH in 1961 to serve two years as a commissioned officer in the Public Health Service. In 1963, he became a senior investigator and head of the Pharmacology and Experimental Therapeutics Section in the Laboratory of Chemical Pharmacology in the NCI Div. of Cancer Treatment. He became chief of the laboratory in 1973. From 1979-80, he was a senior policy analyst at the White House Office of Science and Technology Policy.

In 1976, Adamson received the highest award for civil service employees in the PHS, the Superior Service Award, for his investigations of the use of nonhuman primates for pharmacological and toxicological studies of antitumor drugs and other xenobiotics. He received the award again in 1982.

In 1989, he received the Arnold J. Lehman Award from the Society of Toxicology.

DCPC Advisors Ok $15M Trial Of Cervical Lesion Triage

Advisors to the NCI Div. of Cancer Prevention & Control have given concept approval to a $15 million randomized trial of alternatives to the clinical management of cervical lesions.

A coordinating center and four clinical centers would be funded for the six-year study to determine whether human papillomavirus testing (HPV) can effectively triage women with a diagnosis of atypical squamous cells of undetermined significance (ASCUS) and low-grade squamous intra-epithelial lesions (LSIL).

The DCPC Board of Scientific Counselors, at its meeting last month, also gave concept approval to the recompetition of two contracts that support the Smoking and Tobacco Control Program, and the reissuance of a Request for Applications for the National Black Leadership Initiative.

Following are the concept statements:

A Randomized Trial on the Clinical Management of ASCUS and LSIL of the Uterine Cervix. New, RFA (cooperative agreement) for one coordinating center (with subcontract to cervicography laboratory, pathology reference center, and HPV reference center) and four clinical centers. Estimated awards over six years: coordinating center, $3.164 million; pathology, $358,000; virology, $451,000; travel, $180,000; and clinical centers, $8.16 million. Total: $15.394 million. Project officer: Donald Henson, Early Detection Branch.

This project is a study on the alternatives to the triage and clinical management of LSIL and ASCUS lesions of the uterine cervix. The program proposes to ascertain whether HPV testing can reliably triage these low grade lesions which represent the bulk of abnormalities seen on Pap smear. Currently, the standard of care is colposcopy and biopsy of all abnormalities. This type of aggressive management is expensive and probably represents overtreatment, since evidence indicates that most of these lesions eventually regress.

A three-arm randomized study of management alternatives has been proposed. One arm will consist of colposcopic referral fo all patients; another HPV testing and repeat Pap smears; and the third repeat Pap smears alone. Women assigned to the latter arm will also be tested for HPV, but the results will not be used for clinical decisions. Except for the women assigned to the standard management arm, all participants will be followed every six months, less frequently if the smears revert to normal. As a safety feature, women with worrisome cervicographic results will be removed, referred for colposcopy and analyzed separately in the analysis.

Statistical projections indicate that 3,000 women with a diagnosis of LSIL and 3,000 women with ASCUS should be enrolled in the study. Initially, 3,600 will be randomized, but about 20 percent are expected to drop out for a number of reasons. Participants will be followed for a median of three or more years.

The study is designed as a cooperative agreement. Awards will be made to a number of clinical centers that screen and treat different populations.

Of paramount importance is the safety of the participants. The standard management arm will provide the baseline values for the number of high grade and carcinomas that should be expected in the two study groups. Stopping rules have been developed. The number of CIN3 or carcinomas discovered in the two study arms should equal the number found in the standard management arm. If this number is not found, then the study will be carefully evaluated to determine whether the triage procedures are adequate.

At the end of the study, all participants in the two study arms will have colposcopy and bipsy of any lesions to insure that no participant leaves the trial with incipient or occult cancer.

Smoking and Tobacco Control Program Support Services Contract. Recompetition of a contract, total cost $2.375 million over five years, one award. Project Officer: Public Health Applications Research Branch, William Lynn.

The objective of this contract is to provide the STCP with support services essential to the development of effective research in tobacco use prevention and cessation, and to disseminate results within a national research strategy to effectively reduce cancer incidence and mortality caused by tobacco use.

Within the Cancer Control Science Program, the STCP provides the central coordination of tobacco use prevention and control research. The STCP collaborates with other NCI units, NIH, federal, state and local governments and private organizations on tobacco use prevention and control programs and intervention methodologies. The CCSP maintains an aggressive research and applications agenda to investigate intervention methodologies to successfully modify tobacco use behavior.

The support contract continues to provide essential logistical and technical support necessary to coordinate STCP's externally managed grant program and its internally managed applications program for national dissemination of research results.

The support services contract will provide STCP with scientific, technical and logistical support in the following areas: workshops, conferences and consensus development meetings; writing, editing and publications preparation; access to content-specific scientific expertise; planning, management and analysis.

Conference and Meeting Support: The support contractor will assist the STCP in the conduct of conferences, meetings, workshops and seminars by: providing strategic planning and operational support; preparing and distributing to participants necessary background and orientation materials; providing assistance with lodging and travel arrangements; and providing on-site conference services.

Writing, Editing and Publication Preparation: The support contractor will assist the STCP with: preparation of scientific and technical reports; identification and acquisition of scientific expertise specific to the topic to be addressed; and, literature searches, scientific writing and editing, copy editing, graphic preparation for figures and tables, and slides and charts for presentation.

Access to Content-Specific Scientific Expertise: The contractor will assist with the start-up and implementation of STCP's research and applications programs. Implementation of these efforts will, from time to time, require specific scientific expertise in the areas of smoking intervention, cessation and prevention, biomedical, and behavioral expertise related to tobacco use and cancer.

Planning, Data Management, and Data Analysis Support: The support services contractor will assist the STCP with the development and updating of STCP operational plans including the preparation of issue and background papers and tracking progress toward program goals. The contractor will assist with the design and conduct of small studies; the identification and organization of national and international numeric and bibliographic data on smoking, tobacco and cancer and will assist the STCP with the organization and maintenance of that data.

Smoking and Tobacco Control Monographs. Recompetition of a contract, total $3 million over four years, one award. Project officer: Donald Shopland, Cancer Control Science Program.

The goal of this contract is to issue a series of state-of-the-art monographs on various topics related to smoking and tobacco use control that are specifically directed toward public health practioners at the national, state and local level involved with implementing smoking prevention and control programs.

In 1991 the Smoking and Tobacco Control Program began publishing a series of monographs on various topics related to smoking and tobacco use control. Under the original concept, monographs were intended to summarize information based on NCI's large portfolio of smoking and tobacco control research projects.

The proposed monograph project will be a four year effort with an average two monographs issued per year. While data and information based on NCI trials and similar trials from other organizations will still be an integral part of this new monograph effort, added emphasis will be placed on policy based initiatives particularly those whose effectiveness can be demonstrated. The monographs will also attempt to reach consensus on the most effective policy based interventions and recommendations for their implementation.

Possible areas of interest for the new monograph series could include: workplace smoking bans and their effect on smoking behavior; non-school based adolescent smoking prevention interventions; an empirical examination of the impact of cigarette excise taxes on smoking behavior and consumption; state regulatory actions for the reduction and control of smoking; insurance reimbursement for smoking cessation services.

NCI will require contractor support with extensive experience in the management of scientific peer reviews, manuscript production and coordination, access to outside experts and consultants knowledgeable in smoking and health issues, preparation of scientific manuscripts, experience in producing high quality graphics, scientific and copy editing capability, and ability to generate camera-ready copy compatible with existing NCI and GPO standards.

National Black Leadership Initiative on Cancer. RFA, cooperative agreement (U01), total $6.4 million over four years, one to three awards. Program director: Frank Jackson, Cancer Control Science Program.

The goals of this initiative are to stimulate the active participation of comrnunity leaders in cancer prevention and control activities; to address the barriers that limit or prevent access to quality health care by Black Americans; and to reduce cancer incidence and mortality rates and increase survival rates among Black Americans.

The Black Leadership Initiative will continue to enhance the existing national structure through which lay and professional leaders in the black community are cooperating with NCI in planning, developing, and implementing culturally competent cancer awareness activities. Such activities include cancer education serninars, professionally led cancer survivor groups, health fairs, initiating media campaigns targeting tobacco advertising, and conducting screening referrals. The involvement of community leaders ensures a greater degree of NCI access to the black community and forms the network through which communication lines are kept open. Support for evaluative activities are not included in this RFA, but will be sought from sources external to NBLIC.

The awardee institution(s) will organize and administratively support up to eight regional offices. Two new sites have been added to accommodate the dense population of Black Americans in the Southern states. Each regional office will be staffed by one paid fulltime Regional Coordinator with volunteer clerical support from the cornmunity. To the extent possible the regional office should be located at a historically black college/ university (HBCU), school of public health, or hospital in the center of targeted geographical areas. A prominent cornmunity leader, e.g., physician, researcher, minister, or educator, in the black cornmunity will serve as Regional Chairperson (non-paid) for each respective region.

The concepts of community organizing, and community wellness will be aggressively applied to continually expand and enhance the coalitions established during previous years and to build new ones. Cornmunity cancer control coalitions are comprised of volunteers who pool their talents and resources to form the base from which most program activities are facilitated. This approach is consistent with NCI belief that "A significant reduction in the cancer mortality rate is possible if current recommendations related to smoking reduction, diet changes, screening, and state-of-the-art treatment are effectively applied."

NCI program staff will work cooperatively with the principal investigator(s) and NBLIC project staff to provide overall technical support and guidance for the Initiative.

RFAs Available

RFA CA/DK-94-024
Title: **The Role Of Helicobacter In Cancer**
Letter of Intent Receipt Date: June 17
Application Receipt Date: Aug. 11

NCI and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) invite investigator-initiated research grant applications to support basic studies on defining the role of the bacteria Helicobacter in human cancer.

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, public and private. The NIH R01 grant will be used. Total project period for each application may not exceed four years. Anticipated award date is April 1, 1995. Approximately $2 million ($1.5 million from NCI and $500,000 from NIDDK) in total costs per year for up to four years will be committed to fund applications. It is anticipated that eight to nine awards will be made.

Inquiries: Thomas Nightingale, Div. of Cancer Etiology, NCI, Executive Plaza North Rm 540, Bethesda, MD 20892, Tel: 301/496-1951; or Frank Hamilton, Div. of Digestive Diseases and Nutrition, NIDDK, Westwood Bldg Rm 3A15B, Bethesda, MD 20892, Tel: 301/594-7571.

RFA CA-94-019
Title: **Cancer Prevention And Rural Health**
Letter of Intent Receipt Date: June 20
Application Receipt Date: Aug. 19

The Public Health Applications Research Branch of the NCI Div. of Cancer Prevention and Control invites research grant applications for research projects to develop, implement, and evaluate cancer prevention and early detection intervention strategies for rural populations.

Applications may be submitted by domestic, public and private, for-profit and non-profit organizations serving a substantial rural population. Collaborating applicant organizations and/or institutions with multidisciplinary expertise and access to rural populations are encouraged. Awards will not be made to foreign institutions and applicants from domestic organizations may not include international components.

Support will be through the NIH R01 grant. Total project period may not exceed four years. Anticipated award date is March 1, 1995. Approximately $1 million in total costs per year for up to four years will be committed to fund applications. It is anticipated that three to five awards will be made and that the average annual direct costs will be $175,000 per award.

NCI is interested in stimulating research to develop effective methods for increasing cancer prevention and early detection services in rural populations and settings. The primary goal of this project is to develop, implement, and evaluate cancer prevention and early detection intervention strategies for rural populations and settings.

Inquiries: Marianne Haenlein Alciati, Public Health Agency Section, NCI, Executive Plaza North Rm 233, Bethesda, MD 20892, Tel: 301/496-8584.

RFA CA-94-015
Title: **Research In Innovative Strategies To Reduce Tobacco Use**
Letter of Intent Receipt Date: June 29
Application Receipt Date: Sept. 22

The NCI Div. of Cancer Prevention and Control invites research grant applications to study strategies to develop, implement, and disseminate effective tobacco control interventions. Tobacco control interventions are those interventions that can influence large populations to reduce tobacco use. These interventions include, but are not necessarily limited to, restrictions on the sale of tobacco to minors, restrictions on indoor smoking, increases in tobacco excise taxes, and restrictions on tobacco advertising. The goal of this research is to assist policy makers and public health professionals in the enactment and enforcement of effective tobacco control policy interventions.

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, public and private institutions. The NIH R01 grant will be used. Total project period may not exceed four years. Anticipated award date is July 1, 1995. Approximately $4 million in total costs for four years ($1 million per year for each of four years) will be committed to fund applications. It is anticipated that three or more new awards will be made.

Legislation and other policy interventions can decrease tobacco use. Effective policy interventions include increases in tobacco excise taxes, restrictions on indoor smoking, restrictions on tobacco

advertising and promotion, and restrictions on minors' access to tobacco products. There remain many questions about the most effective strategies to develop, implement, enforce, and disseminate

tobacco control policies. This program is intended to stimulate innovative behavioral, public health, and economic research on tobacco control policy interventions, including the analysis of their feasibility, effectiveness and consequences of implementation. The goal of this research is to assist policy makers and public health professionals in the enactment and enforcement of effective tobacco control policies.

Inquiries: Marc Manley, Div. of Cancer Prevention and Control, NCI, Executive Plaza North Rm 233, Bethesda, MD 20892, Tel: 301/496-8584, FAX: 301/496-8675.