DES 8/4/83

THE CANCER LETTER

Vol. 9 No. 31
Aug. 5, 1983

Subscription $125 year North America
$150 year elsewhere

P.O. Box 2370 Reston, Virginia 22090 Telephone 703-620-4646

GOP AMENDMENT TO WAXMAN BILL WOULD LEAVE DOLLAR LEVELS THE SAME BUT WOULD DROP CENTERS LINE ITEM

The first round of House floor debate on the Waxman bill (HR 2350), the Health Research Extension Act of 1983, brought out two factors of significant importance to the cancer program:

—The Republican amendment, despite previous statements by GOP

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In Brief

HAROLD DOUGLASS NEW GITSG CHAIRMAN; NTP DEPUTY CHIEF MOORE TO BE NOMINATED FOR TOP EPA POSITION

HAROLD DOUGLASS, Roswell Park Memorial Institute surgical oncologist, has been elected chairman of the Gastrointestinal Tumor Study Group. He succeeds Philip Schein, who resigned as chairman but will continue as Georgetown Univ.'s principal investigator with GITSG. Schein, as chairman of the new Mid-Atlantic Oncology Program, could not simultaneously hold two cooperative group chairmanships. GITSG recently extended provisional membership to Dana-Farber Cancer Institute, Robert Mayer PI; SUNY-Upstate Medical Center, Robert Comis; New York Hospital-Cornell Medical Center, Richard Silver; and Montefiore Medical Center/Albert Einstein Hospital, Peter Wiernik. Fourteen CCOPs have designated GITSG as a research base. . . . **NEW ASSIGNMENTS** in the Community Oncology & Rehabilitation Branch of NCI's Div. of Resources, Centers & Community Activities: Dorothy MacFarlane, who has moved over from the Div. of Extramural Activities where she was executive secretary of the Cancer Clinical Investigation Review Committee, is the coordinator for all community programs. Robert Frelick, who has been project officer for the Community Clinical Oncology Program, is CCOP coordinator. Ted Koven, hematologist who transferred from the Food & Drug Administration, is CCOP project officer; and Carie Hunter, medical oncologist formerly at Howard Univ., is project officer for the Community Hospital Oncology Program. Harry Handlesman remains as project officer for the Cooperative Group Outreach Program. . . . **JOHN MOORE,** deputy director of the National Toxicology Program, will be nominated to a top position at the Environmental Protection Agency, as assistant administrator for pesticides and toxic substances. That job had been held by John Todhunter, who was forced to resign earlier this year along with Administrator Anne Burford, following charges of irregularities. David Rall, director of the National Institute of Environmental Health Sciences, also is NTP director, but Moore has done most of the day to day work of running the program. Moore will be replaced by Gene McConnell, chief of NTP's Chemical Pathology Branch, who will be acting deputy director. . . . **FDA COMMISSIONER** Arthur Hayes will resign to become dean of New York Medical College, effective in September.

CENTERS LINE ITEM KEY TO WAXMAN'S DEFENSE OF HIS AUTHORIZATION BILL

(Continued from page 1)

leaders opposing higher authorization levels sought by the Democrats, would leave intact those levels in the bill drafted by Congressman Henry Waxman (D.-Calif.) and his Health Subcommittee. Those levels for NCI are $1.322 billion in FY 1984, $1.4 billion in 1985, and $1.5 billion in 1986.

—The Republican amendment would eliminate the line item for cancer centers.

During the debate, Waxman used the cancer centers line item as the keystone of his defense against the proposed amendment. If he is successful in defeating the amendment and goes to conference with the centers line item in the bill, Waxman would have somewhat of a mandate from the House not to drop it (the Senate bill, which has not yet been brought to the floor, does not have a line item for centers).

The House took no votes on the bill or amendments during the first day of debate last week. It was tentatively scheduled to be brought up again this week, possibly for a final vote, but had not at press time. Congress plans to adjourn Aug. 5 for the rest of the month, and it was becoming likely that the House would not get back to the bill before September.

Opposition to the Waxman bill was centered on the major revamping of NIH authorities it would impose, including three year authorizations for each of the institutes. NCI and the National Heart, Lung & Blood Institute are the only ones with specific authorizations at present. The bill also would mandate procedures for peer review of intramural research and contracts (much of which NCI, at least, already does). It would establish a system for reviewing charges of scientific misconduct, which opponents say is adequately covered by existing regulations. It would direct increased emphasis on prevention and ordered establishment of prevention centers. It would create a new National Institute of Arthritis & Musculoskeletal Diseases, and would transfer the National Centers for Health Services Research & Health Statistics and the National Institute of Occupational Safety & Health to NIH.

All the reorganization provisions except for the new arthritis institute would be dropped if the Republican substitute amendment is adopted. That amendment was offered by Congressmen James Broyhill (R.-N.C.) the ranking minority member of the parent Energy & Commerce Committee, and Edward Madigan, the ranking Republican of the Health Subcommittee.

Broyhill said the Waxman bill "goes too far by making extensive and unjustified changes in the organizational structure of NIH and the research activities conducted there. These changes in my judgment will severely disrupt NIH research endeavors. . . . The record does not support the drastic changes called for in HR 2350 in the manner in which NIH manages its programs and allocates its research dollars. . . . The Waxman bill includes a wide variety of line item authorizations, earmarking funds for several new disease centers, grants for specific research and also there are two new national commissions that are authorized in this legislation."

Broyhill emphasized that the substitute would include the same dollar authorization levels for NIH that are included in the Waxman bill, and that it would provide for the new arthritis institute. But when Waxman asked him if it would also include the line item for cancer centers, Broyhill first sidestepped the question, then admitted that it did not, noting that the dollar levels were flexible, and that grants are awarded at NIH on the basis of scientific peer review.

"I wonder if the gentleman is aware that, notwithstanding scientific peer review, the Reagan Administration is proposing to terminate support for many of the nation's best comprehensive research centers?" Waxman asked. "If these centers are not authorized by a specific line item, their support will be in jeopardy."

Madigan responded that what the Reagan Administration proposes is one thing and the Broyhill-Madigan substitute something else. The substitute "is certainly not the same as the Administration position, even with regard to the total amounts of moneys that would be considered."

Waxman continued to press on the centers issue, again asking if the substitute has a specific line item authorization for cancer centers.

"I will repeat what I said just prior to this, and that is that the dollar levels are included but not a specific authorization for and a mandate that they be spent in a specific way," Broyhill answered. "We leave this to the discretion of the health professionals at NIH."

"The decision is not just that of the health professionals at NIH," Waxman said. "The Reagan Administration is proposing to terminate support for a majority of the nation's finest comprehensive cancer research centers. As a matter of fact, many of the nation's major cancer research centers—Sloan-Kettering in New York City, M.D. Anderson at Houston, and Fred Hutchinson in Seattle—believe that a line authorization is necessary to protect them from attacks such as the one this year by a shortsighted OMB."

(Waxman was referring to OMB's refusal to provide enough money for NIH to fund 5,000 competing grants without drastic cuts in other programs. NIH determined that those cuts would have to come from, among other places, NCI's centers budget. There

would be enough to fund only four of the 20 cancer center core grants which will be up for renewal in 1984.)

"Is the gentleman saying that the director of NIH has made this decision?" Broyhill asked.

"I am not suggesting that at all, but I would submit that the Reagan Administration position is to disregard the support that Congress has given in the past to these cancer centers. Without spelling out in the gentleman's substitute a line item authorization for cancer centers, they are vulnerable to an OMB intent upon reducing funding to this program."

Broyhill insisted that the Budget Control & Impoundment Act would prohibit the Administration from impounding funds approved by the Appropriations Committees, without coming back to Congress.

"We are the authorizing committee for NIH," Waxman said. "If we are going to stand on the sidelines and merely hope the Appropriations Committee will protect those biomedical research priorities we think are important, I submit we are abdicating our responsibility."

Madigan argued that a number of organizations, including the Assn. of American Medical Colleges and the Federation of American Societies for Experimental Biology, oppose the Waxman bill. Waxman came back with a list of his own, including, he said, the American Cancer Society, and the Assn. of American Cancer Institutes, which support his bill.

Madigan argued that Waxman's list included for the most part "special interest organizations interested in dollars." Waxman responded, "It is surprising to think that people who are organized to fight diseases are viewed as special interest groups while the medical schools are not, when the medical schools are the ones who receive grants from the federal government."

For the record, neither ACS nor AACI support the Waxman bill in its entirety, nor do they oppose it. ACS has gone on record supporting the dollar authorization levels for NCI in the bill, and AACI has been fighting for years to get a line item for centers.

NCI, and most of the rest of the Administration, always opposes line items in authorization bills as a matter of policy. Executive Branch agencies like to retain as much flexibility in handling their money as they can. Congress frequently has its own idea on how public money should be spent. The decision by NIH and OMB, to eliminate a major portion of the budget for cancer centers, cut the ground from under NCI's adamant opposition to the center line item. This was pointed out in a dialogue between Waxman and Congressman Lawrence Coughlin (R.-Pa.).

Coughlin referred to a letter he had received from Timothy Talbot, former president of Fox Chase Cancer Center and currently chairman of the board of AACI. Talbot's letter pointed out that a line item would provide greater stability for cancer research, and that the proposed budget cuts and elimination of 16 center grants has created considerable instability at the centers, Coughlin said.

"Is it correct that under the Administration's proposed fiscal year 1984 budget 16 of 20 cancer centers would be defunded, regardless of the excellence of their work or the peer reviews they have received?" Coughlin asked Waxman.

"The gentleman is correct in his statement," Waxman said. "That is why we have specifically authorized these cancer centers so that the officials who make these political decisions will not have the opportunity to terminate these important scientific research centers."

"Would the proposed authorization, if written into law and enacted, help to prevent such reduction proposals in the future?" Coughlin asked.

"Yes, it would," Waxman replied.

The House appropriations bill for HHS, including NCI, also appears stalled until September.

The Labor-Appropriations Subcommittee, chaired by William Natcher (D.-Ky.) completed the markup of its bill three weeks ago, but had not taken it to the full committee by press time this week. The markup was held in closed session, and subcommittee members and staff were exceptionally tightlipped about the figures, not even passing them on to other congressmen when asked.

Speculation among those who frequently have access to the subcommittee's actions is that Natcher and colleagues at the very least put enough additional money in the bill to fund the 20 centers, and to restore the amount the Administration proposed be cut from indirect costs. Restoring the centers money would require $20 million, and indirect costs, $15 million.

Subcommittee members also expressed concern about the reductions in R01 and P01 grants from recommended levels. In 1984, those grants are scheduled to take 10 percent cuts from the peer review approved levels, and it would require $15 million to restore those.

Thus, an additional $50 million above the President's request of $986 million for NCI seems possible from the House.

GOP FRESHMAN LAUNCHES DRIVE TO GET "ADEQUATE" FUNDS FOR CANCER RESEARCH

A freshman Republican congressman from New York, who developed an interest in cancer when first a neighbor and then a colleague died of the disease, has criticized the Administration for cuts in cancer research and says he intends to "spearhead a drive to see that cancer research is funded adequately."

Sherwood Boehlert launched his drive at a breakfast meeting last week, with NCI Director Vincent DeVita and Univ. of Chicago Cancer Center Director

John Ultmann briefing congressmen and staff members on the state of cancer research. DeVita, of course, refrained from commenting on budget inadequacies, limiting himself to describing areas of progress and current programs.

Ultmann was under no such constraints, contending that budget cuts are hindering progress. He pointed out that NCI's budget has not increased in real dollars since 1975, and that the Administration's request for 1984 is only an increase of three tenths of one percent.

The cutbacks have reduced the amount of research being conducted, have brought building programs to a halt, have limited training programs, have prevented centers from buying new equipment, and, worst of all, have disenchanted young scientists, Ultmann said. "We are turning away brilliant minds."

"Every penny spent on cancer research is well spent," Ultmann said. "It is spent on the best science conducted in the most economical way. There are no cost overruns."

Ultmann's comments were supported by Timothy Talbot, chairman of the Board of the Assn. of American Cancer Institutes which helped arrange the breakfast; and Robert Perry, scientist at the Institute for Cancer Research in Philadelphia.

"Great strides in curing cancer have been made in recent years," Boehlert said. "Much of the research that produced startling advances was financed by the federal government. Yet the Administration has proposed cuts in cancer research. I want to see that we are doing all we can to conquer the disease."

Boehlert's staff later told ***The Cancer Letter*** that the figure he had in mind for an adequate NCI appropriation in FY 1984 was the authorization level in the Waxman bill being debated this week in the House—$1.32 billion. The Administration's request was $986 million.

"We are on the threshold of discoveries that will help us eradicate cancer," Boehlert said. "Our scientists are up to the challenge. I want to make sure they have the resources they need."

Boehlert's friend who died of cancer last year was a young man in his 40s. Then, last December, John Swigert, who had just been elected for the first time to Congress from Colorado, died of the disease. Swigert's death impelled the group of new members of Congress to declare that they would take on the cancer program as a project of their class. When other members of the freshman class seemed to lose interest, Boehlert decided to do it himself.

Boehlert is a member of the Science & Technology and Small Business Committees.

ACS MODIFIES MAMMOGRAPHY GUIDELINES, NOW INCLUDE WOMEN FROM AGES 40-49

The American Cancer Society has modified the guidelines it adopted in 1980 for the early detection of cancer of the breast in women without symptoms of the disease.

To its previous recommendation it has added annual or bienniel mammography for women aged 40 to 49, thus extending the mammography recommendation to a younger age group. To date annual mammography has been recommended only for women over 50 unless otherwise ordered by a physician.

The Society's full recommendation for breast cancer detection examination now includes (a) monthly breast self examination starting at age 20; (b) physical examination of the breast at three year intervals between the ages of 20 and 40, annually thereafter; (c) a baseline mammogram between the ages of 35 and 40, followed by annual or bienniel mammograms from 40 to 49; and annual mammograms from 50 on.

The Society has notified more than 400,000 of the nation's physicians of the change in the July-August issue of its journal for the profession, *Ca.*

"There has been remarkable improvement in the quality of diagnostic accuracy of mammography in recent years, concomitant with a marked reduction in the radiation dose," a statement approved by the Society's national board of directors points out. "The risk of inducing breast cancer by the low doses now possible with modern mammography—if it exists at all—is minimal. . . . A favorable benefit/risk ratio can be expected."

OSP COORDINATING CENTER DEADLINE EXTENDED TO GET MORE APPLICATIONS

The deadline for receipt of applications for the administrative coordinating center for the Organ Systems Program was extended one month, to Aug. 15, because NCI was not satisfied with the number which had been submitted. NCI will not say whether the extension resulted in any additional institutions joining the competition.

The coordinating center will serve as the focus for the five existing national organ systems programs—Breast, Bladder, Bowel, Pancreas and Prostate—plus any additional systems which may be added. Each system will be presented by a multidisciplinary working group which will develop plans for research in their respective areas and will initiate new ideas for research. The coordinating center will manage the activities of the working groups. The working groups also will be responsible for information exchange, through workshops, conferences, newsletters, etc.

Inquiries or requests for copies of the original RFA should be directed to Andrew Chairodo, PhD, Chief, Organ Systems Program Branch, DRCCA, NCI, Blair Bldg. Rm. 3A05, Bethesda, Md. 20205, phone 301-427-8818. The RFA was published in the April 1 issue of ***The Cancer Letter.***

DRCCA COMPLETES NEW GUIDELINES FOR CANCER CONTROL RESEARCH

NCI's Div. of Resources, Centers & Community Activities has finished writing new guidelines for cancer control areas of programmatic interest, aimed at encouraging investigators to develop grant applications in cancer control research.

The guidelines place heavy emphasis on prevention, with chemoprevention, diet and nutrition, occupational cancer control, and screening and early detection suggested as priority areas for cancer control research.

Other research areas covered in the guidelines are community oncology, health promotion sciences, evaluation and cancer control operations research, and special programs on smoking and tobacco.

The guidelines, starting with the division's definition of cancer control, follow:

CANCER CONTROL is defined as the reduction of cancer incidence, morbidity, and mortality through an orderly sequence from research on interventions and their impact in defined populations to the broad, systematic application of the research results. This definition places primary emphasis on the inclusion of a cancer control intervention in any proposed studies. Cancer control research studies are classified into one of five phases which represent the orderly progression noted in the definition: (1) hypothesis development; (2) methods development and testing; (3) controlled intervention trials to establish cause and effect relationships; (4) research in defined populations; and (5) demonstration and implementation studies. The division is primarily interested in research on cancer control interventions in phases 2 through 5, with principal emphasis on studies in defined populations (phase 4). The division is not interested in studies which address only phase 1.

A. Prevention

The emphasis in this program is on research studies to identify, evaluate, and implement techniques and approaches for the prevention and early detection of cancer. Those studies capable of achieving these objectives with minimal risk and cost are preferred.

1. Chemoprevention - Involves studies in which specified doses of chemically defined agents are evaluated for their potential to reduce the incidence of human cancer.

a. Studies on the consumption and usage of chemopreventive agents in the context of human intervention trials.

1) Develop methods, including biological indicators, to monitor, assess, and validate the intake of vitamins, certain trace minerals, and other chemoprevention substances.

2) Determine the dose and exposure time at which chemopreventive agents are considered protective against cancer.

3) Determine if synthetic agents are more effective than natural agents in reducing cancer incidence.

b. Studies of toxicity and agent application in the context of large scale intervention research.

1) Examine the longterm toxicity of dosing with various chemopreventive agents in animal models as a precursor to human studies.

2) Determine dose response relationships and test for acute and chronic toxicity of chemopreventive agents in human populations.

3) Assess the benefit/risk ratio of interventions with chemopreventive agents.

4) Design and evaluate delivery systems and vehicles for the regional or systemic application of chemoprevention agents.

c. Clinical trials of chemopreventive agents.

Conduct clinical trials in defined populations to test for efficacy in inhibiting the onset or progression of neoplastic changes, including:

1) Primary prevention of cancer onset in high risk populations; and/or

2) Clinical trials on populations with preneoplastic changes.

2. Diet and Nutrition - The goal of this program is the reduction of cancer incidence through dietary modificiation. Dietary modification may: involve additions, deletions, or substitutions; include specifications by food groups or nutrient content; and/or establish target levels of intake within an allowable range.

a. Studies to assess and measure dietary factors in the context of human intervention trials.

1) Determine if primary prevention is possible through food selection and/or food supplementation.

2) Identify the role of dietary substances in cancer prevention, including nutrients and food groups (e.g., fats, vegetables); minerals and trace elements; non-nutrient food substances (e.g. fiber); interactions of nutritional factors; and vitamins.

3) Evaluate dietary and nutritional approaches to prevention, including possible modifiers of host resistance to the development of neoplasms.

4) Develop and test methods, including biological indicators, to monitor, assess, and validate nutrient intake with specific relevance to clinical trials in cancer prevention.

5) Develop and test methods to quantify specific components of the food supply with preventive potential with specific relevance to clinical trials in cancer prevention.

b. Studies of toxicity in the context of large scale human intervention research.

1) Examine the longterm toxicity of dosing with various dietary and nutritional interventions in animal models as a precursor to human studies.

2) Determine dose response relationships and test for acute and chronic toxicity of dietary and nutrient interventions in human populations.

3) Assess the benefit/risk ratio of dietary and nutritional interventions.

c. Clinical trials in dietary and nutritional modification.

Conduct clinical trials in defined populations to test for efficacy in inhibiting the onset or progression of neoplastic changes, including:

1) Primary prevention of cancer onset in high risk populations; and/or

2) Clinical trials on populations with preneoplastic changes.

3. Occupational Cancer Control

a. Compare and evaluate systems of surveillance to monitor and reduce occupational exposures which are known to increase cancer risk.

b. Compare and evaluate the efficacy of education and training interventions in reducing exposure to occupational risks of cancer.

c. In the context of cancer control, develop and evaluate systems which allow the pooling of data for cancer hazard identification and control.

d. Monitor and assess trends in occupationally related cancer and/or exposure to carcinogens resulting from cancer control interventions.

e. Determine the impact of multiple, confounding risk factors associated with occupational cancer for the purposes of defining, implementing, and evaluating cancer control interventions.

4. Screening and Early Detection of Cancer.

a. Assess the intervention potential of new research findings relevant to earlier detection of cancer.

b. Evaluate new detection and diagnostic methods for specificity, sensitivity, reliability, validity and safety when applied to defined or target populations.

c. Determine the cost/benefit or risk/benefit ratios of cancer screening and detection methods when applied in defined or target populations.

d. Identify and test strategies to decrease the rates of false positive and false negative findings associated with cancer screening and detection interventions when applied in defined or target populations.

B. Community Oncology

The focus of this program is on the introduction, application, and evaluation of effective and practical cancer control intervention programs in community settings. Primary emphasis is on the integration and involvement of community physicians and allied health professionals in cancer control efforts and the promotion of linkages between community practitioners/hospitals and other regional resources for cancer control. Objectives are to: (1) reduce the time between research advances in prevention, detection, and patient management and their application in community settings; and (2) expand and extend the cancer care knowledge and applications bases.

1. Management — Studies to identify, develop, and evaluate community interventions that:

a. Broaden the use of community cancer resources and encourage wider community participation in cancer control efforts.

b. Improve survival and minimize the side effects of cancer therapy, utilizing an understanding of the current levels of knowledge, attitudes, and practices of patients, their families, physicians, and other health professionals involved in cancer care.

c. Influence positively compliance with prescribed management regimens and participation in clinical research.

d. Improve the management of pain in cancer patients.

e. Improve patient outcome based on an understanding of the interaction between old age and cancer.

f. Increase the effectiveness of the primary physician in the delivery of cancer care at the community level.

g. Improve the quality of life of cancer patients and their families based upon an analysis of different treatment outcomes and their impact on adjustment to treatment and continuing care.

h. Determine the cost/benefit and/or cost/effectiveness of cancer management activities in community settings.

i. Improve patient participation in clinical research studies.

2. Continuing Care and Rehabilitation

a. Identify and test measurable indicators of morbidity to be used in establishing outcome measures for subsequent cancer control intervention studies.

b. Identify and test community cancer control interventions to reduce morbidity and the consequences of cancer for patients and their families.

c. Develop and test interventions to improve the utilization of the home as a care setting.

d. Conduct applied research and promote new techniques in rehabilitation.

C. Health Promotion Sciences

The development and testing of intervention strategies to modify personal, social, and lifestyle factors known to contribute to the development and/or increased risk of cancer are of particular interest.

Studies to identify and test interventions that:

a. Educate the public at large, with special emphasis on children of school age and populations at high risk to cancer, about lifestyle and personal health habits related to the prevention of cancer.

b. Educate cancer patients and their families about available resources and mechanisms for coping with the disease; and methods to resume a productive way of life following cancer management.

c. Disseminate and evaluate state of the art cancer information to health professionals who deal directly with cancer patients or their families.

d. Improve risk identification and counseling techniques.

e. Modify behavioral patterns and lifestyle factors associated with cancer risk, especially for population groups.

f. Modify behavioral patterns associated with the successful practice of early detection strategies and participation in screening programs.

g. Modify aberrant cancer related beliefs and behavior in disadvantaged and high risk populations.

h. Modify counterproductive patient behavior associated with treatment of cancer.

i. Decrease delay behavior associated with seeking medical care when symptoms are present.

j. Improve the behavioral and social adjustment of surviving cancer patients and their families.

D. Evaluation and Cancer Control Operations Research

Studies of mathematical and computer techniques for the analysis of data obtained from cancer control intervention studies.

E. Special Program: Smoking, Tobacco, and Cancer Program

This program emphasizes intervention activities aimed at reducing cancer incidence related to smoking and tobacco use. Primary interest is in research on interventions to prevent smoking/-tobacco use onset or habitual use. Research on interventions related to cessation of smoking/-tobacco use are also of interest. Emphasis will be placed on studies with potential for broad impact, including:

1. Prevention programs targeted at school-age youth.

2. The use of mass media to influence and reinforce prevention and cessation behaviors.

3. Self help programs for smoking cessation.

4. The role of health professionals (particularly physicians) as exemplars and intervenors in prevention and cessation efforts.

5. Smoking/tobacco patterns and interventions in minority populations.

Grant applications should be prepared as for other NIH investigator initiated grants, using PHS Form 398, available from most institutional business offices or from NIH, DRG, Bethesda, Md. 20205.

The following should be included in both the "Abstract of Research Plan" and "Research Plan, A. Specific Aims" sections of the PHS Form 398:

—The specific cancer problem under study.

—The cancer control hypothesis being investigated.

—The proposed cancer control intervention.

—The cancer control research phase of the study.

For additional information, write to Chief, Cancer

Control Applications Branch, DRCCA, NCI, Blair Bldg. Rm. 1A07, Bethesda, Md. 20205.

NOTICE OF AVAILABILITY: RFA

Title: National Cooperative Drug Discovery Groups
Application Receipt Date: Oct. 17, 1983

A prior announcement, "Participants Sought for National Cooperative Drug Discovery Groups" (The Cancer Letter, Jan. 7) invited leading scientists from academia, research institutions, and industry to submit expressions of interest in participating in National Cooperative Drug Discovery Groups and indicated the Div. of Cancer Treatment plans to issue a request for applications outlining the specifics of the program.

The RFA is now available from Dr. John Venditti, Chief, Drug Evaluation Branch, Blair Bldg. Rm. 428, National Cancer Institute, Bethesda, Md. 20205.

Applicants are not restricted to those who responded to the previous announcement. Following is a summary of the RFA:

Exciting leads in molecular biology, medicinal and organic chemistry, biochemistry, and pharmacology present unprecedented opportunities for design and preclinical evaluation of powerful new entities and strategies for the treatment of cancer. Exploitation of these leads and their extrapolation to new treatments can be accomplished by mobilizing the most creative scientists in a number of scientific disciplines regardless of their organizational affiliation. The NCDDG program will assist these scientists to interact, with NCI support, as a unit.

It is envisioned that each NCDDG will be multidisciplinary and multi-institutional; and will consist of a group director and a number of program leaders. The group director will be responsible for the application and for performance of the group and will be accountable for funds awarded. Thus, each NCDDG will have capacity to generate new inventions, to translate rapidly their concepts into new treatments, to conduct adequate preclinical biological evaluations, to carry out biochemical and pharmacological studies at the preclinical level, and to identify new treatment entities worthy of development to clinical trial.

Awards will be made as cooperative agreements. These are assistance relationships involving substantial involvement of NCI staff during performance of the project. The nature of NCI staff participation is included in the RFA. However, the applying group must define its objectives in accord with its own interests and perceptions of novel approaches to the discovery of more effective cancer treatment. The role of NCI staff will be to provide assistance, advice, and guidance via information input at group meetings. Final decision making authority during performance will rest with the group director.

NCI hopes to make multiple awards for project periods of five years and has set aside $2 million for the initial year's awards.

RFA—NIH-NCI-DRCCA-DCB-83-5

Title: Phase III trial of a low fat diet in women with stage II breast cancer
Letter of Intent Receipt Date: Sept. 15
Application Receipt Date: Oct. 17

The Div. of Resources, Centers, and Community Activities and the Div. of Cancer Treatment, NCI, invite applications for cooperative agreements to support participation in a multi-institution randomized clinical trial of a low fat diet (20% of calories) aimed at prolonging the disease free survival and overall survival in surgically staged breast cancer patients who have involvement of the axillary lymph nodes. The investigators will identify, enroll and follow participants in this trial using a protocol developed jointly by the investigators and NCI staff.

Applications are solicited to fund participants in three categories: 1) clinical units, 2) nutritional coordinating unit(s), and 3) a statistical coordinating unit. Applicants may apply for more than one category (clinical, nutrition, statistical), but the applications should be cast as separate documents for review. The requirements for each of these units are outlined in the complete request for applications.

The trial, a single protocol, will be initiated in three stages. The first stage will involve a meeting between the investigators and NCI staff for the purpose of writing the protocol for this study. The second stage will be a feasibility study, during which the protocol will be implemented at three institutions (selected on the basis of priority score and accrual potential) with particular emphasis on documenting protocol adherence in the study and control groups. In stage 3 the protocol will be implemented in all remaining clinical units.

Copies of the complete RFA and additional information may be obtained from Ritva Butrum, PhD, Diet, Nutrition & Cancer Branch, NCI, Blair Bldg. Rm. 619, Bethesda, Md. 20205, phone 301-427-8753.

PROGRAM ANNOUNCEMENTS

SURGICAL ONCOLOGY RESEARCH

NCI's Div. of Cancer Treatment desires to expand support of surgical oncology research. This announcement invites applications for individual research project (R01) and program project (P01) grants.

The treatment of cancer has evolved as a multidisciplinary effort involving (but not limited to) the disciplines of surgical oncology, medical oncology, pediatric oncology, and radiation oncology. The disciplines of medical, pediatric and radiation oncology have developed strong cadres of academic investigators but academic development in surgical oncology has not kept pace, probably because of an insufficient number of surgical oncology research programs and an insufficient number of surgeons undertaking research related to cancer. Continued development of multidisciplinary treatment of cancer is the long range objective of DCT and the attainment of the goal requires sufficient academic strength in surgical oncology.

DCT is seeking applications for research grants concerned with research in surgical oncology. Examples of relevant studies include mechanisms of metastases, effect of surgery on tumor cell kinetics, and host responses to surgery. Preclinical and clinical research are encompassed in this program. Categories of research include (but are not confined to) the following:

1. Pathophysiologic studies in laboratory models or in humans related to surgery and cancer.
2. Laboratory and clinical studies which examine the biochemical, cytokinetic, immunological, or nutritional effects of cancer surgery.
3. Therapeutic studies in which surgery or a surgical question is the primary treatment modality.
4. Studies relevant to staging of patients and identifying prognostic factors relevant to the treatment of cancer patients.
5. Surgical supportive care.
6. Regional chemotherapy or hyperthermia in which a surgical approach to the treatment site is a major aspect of the procedure.

In making this announcement it is not the intent of NCI to make or imply any delimitation of investigator initiated research in the cancer field.

Applications should be submitted on form PHS 398, which is available in the business or grants and contracts office at most academic and research institutions or from the Div. of Research Grants, NIH. The title "Surgical Oncology Research" should be typed in section 2 of the first page of the application. Additionally a brief covering letter should accompany the application indicating it is being submitted in response to this program announcement.

The original and six copies of the application should be sent or delivered to Application Receipt Office, Div. of Research Grants, NIH, Westwood Bldg. Rm. 240, Bethesda, Md. 20205.

In order to alert the DCT to the submission of the proposals with primary thrust directed to surgical oncology research, a copy of the covering letter and an additional copy of the application should be sent under separate cover to Ernest deMoss, MD, MPH, Head, Surgery Section, Clinical Investigations Branch, Div. of Cancer Treatment, NCI, Landow Bldg. Rm. 4B04, Bethesda, Md. 20205, phone 301-496-4844.

In addition, for P01 grant applications, two complete copies should be sent under separate cover to Referral Officer, Grants Review Branch, Div. of Extramural Activities, NCI, Westwood Bldg. Rm. 826, Bethesda, Md. 20205.

Applications in response to this announcement will be reviewed on a nationwide basis in competition with each other, and in accord with the usual NIH peer review procedures. They will first be reviewed for scientific and technical merit by a review group composed mostly of nonfederal scientific consultants. Following this initial review, the application will be evaluated for program relevance by the National Cancer Advisory Board.

Where applicable to a particular project, review criteria will consist of the following:

1. Relevance of the project to surgical oncology research and to the national cancer effort.
2. Feasibility of reaching the proposal's objectives.
3. Significance and adequacy of pilot data to the proposal's objectives.
4. Qualifications of the principal investigator and supporting personnel to achieve the project goals.
5. Adequacy of core facilities and basic equipment to support the project.
6. Availability of suitable patient and control populations if required.

For further information regarding this announcement and the review criteria for the P01 grant application and the R01 grant application, investigators are encouraged to contact Dr.DeMoss at the address and phone number above. Before submitting a P01 application discuss a letter of intent with him.

SPECIAL PROGRAM AREAS OF INTEREST

The National Institute of Environmental Health Sciences is the principal federal agency for biomedical research on the effects of chemical, physical and biological environmental agents on man's health and well being. The institute supports efforts to identify potentially hazardous environmental agents, including the development, testing, and validation of biological test systems which can be used to measure and predict human toxicity from exposure to environmental factors. The purpose of this general announcement is to summarize those areas of research considered important to the Institute, as follows:

ALTERNATIVE DESIGNS OF STANDARD CANCER BIOASSAY

The objective is to stimulate interest in the development of alternative designs of the standard cancer bioassay in order to make the end results more amenable to low-dose extrapolation and risk estimation. Alternative designs should maintain the cancer screening potential of the current bioassay.

STUDIES RELATING HUMAN HEALTH EFFECTS TO PBB

The objective is to provide information which will aid in the assessment of the real and potential dangers to man from exposure to commercial preparations of PBBs. Areas of research currently of interest should emphasize information relative to toxicity of PBB congeners for humans, including storage, metabolism and excretion, additive, synergistic or otherwise interactive reactions with other pollutants, studies of immune functions in populations exposed to PBBs, development of means for clearing the body of PBBs and similar compounds and central nervous system manifestations in children exposed to PBB.

IMMUNOTOXICOLOGY OF ENVIRONMENTAL AGENTS

Objective is to stimulate high quality research in areas of immunotoxicology including applications of immune function tests, changes in immune response following exposure to environmental chemicals, development of immunoogic models to study hypersensitization and allergy, and the effects of inhalation exposure on immune elements in the lung.

BIOLOGICAL EFFECTS OF CHEMICAL INTERACTIONS

Objective is to study all facets of biological effects of interactions of chemicals of environmental concerns. Of particular interest are projects aimed at developing new methods for study of interactions.

ENVIRONMENTAL MEDICINE

Objective is to generate interest in the use of laboratory or clinical tets that aid in the detection and measurement of toxicity demand from chemical exposure at levels which do not produce acute symptoms but which may produce detectable damage years later. Of particular interest are the effects of exposure that may occur in occupational settings, therapeutic levels of unexpected episodes of chemical exposure such as might occur with populations exposed to hazardous chemical wastes.

The details of the individual programs can be obtained from Dr. Edward Gardner, Program Director, Regular Research Program Section, Scientific Programs Branch, Extramural Program, P.O. Box 12233, Research Triangle Park, N.C. 27709.

Applications should be submitted on form PHS 398, the application for the traditional research grant. Application kits containing this form and the necessary instructions are available in most institution business offices or from the Div. of Research Grants, NIH. Applications must be sent to Div. of Research Grants, NIH, Westwood Bldg. Rm. 240, 5333 Westbard Ave., Bethesda, Md. 20205.

The Cancer Letter _Editor Jerry D. Boyd

Published forty-eight times a year by The Cancer Letter, Inc., P.O. Box 2370, Reston, Virginia 22090. Also publisher of The Clinical Cancer Letter.