THE CANCER LETTER

Vol. 11 No. 31
August 2, 1985

Subscription $150 year North America
$175 year elsewhere

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

NCI WOULD GET MORE MONEY FOR AIDS UNDER HECKLER PROPOSAL, BUT MOST WOULD COME OUT OF CONSTRUCTION

NCI will lose $3.5 milllion of the $6.5 million requested by the administration for construction grants funds in fiscal 1986 under HHS' proposed reprogramming request for AIDS research (Continued to page 2)

In Brief

ILLINOIS LEGISLATURE VOTES NEARLY $1 MILLION TO ICC; CAROLYNE DAVIS RESIGNS FROM HCFA JOB

ILLINOIS CANCER Council has succeeded in getting, for the first time, an appropriation from the state legislature which approved nearly $1 million to support initial phases of ICC's cancer program plan. The money, $984,545, will be used in two major areas: for epidemiologic studies to identify areas of high cancer risk in Illinois; and to extend state of the art treatment strategies by using innovative methods to expand involvement in ICC clinical trials programs.... **CAROLYNE DAVIS,** who implemented the prospective payment reimbursement system as administrator of the Health Care Financing Administration and became the leading opponent of exceptions for clinical research, has resigned, as previous reports indicated she would (**The Cancer Letter,** July 12). An RN-PhD and former dean of the Univ. of Michigan School of Nursing, Davis is said to be a leading candidate for the presidency of a medical institution .... **VINCENT DEVITA** and two other NIH institute directors, Harald Loe of the National Institute of Dental Research and A.B. Lindberg of the National Library of Medicine, have been elected to the National Academy of Sciences Institute of Medicine. . . . **STANISLAW MIKULSKI,** former special assistant to the chief of NCI's Investigational Drug Branch and a diplomate of the American Board of Medical Oncology, has joined Alfacell Corp. as medical director. The company has been conducting clinical tests of an agent it calls "Pannon" with patients in the Dominican Republic. Mikulski said he intended to submit an investigational new drug application with FDA for the agent, which he said has shown "very substantial" tumor necrosis in some of the Dominican patients.... **BARNEY LEPOVETSKY,** chief of the Cancer Training Branch in NCI's Div. of Cancer Prevention & Control, has reminded potential applicants for cancer education grants (R25) that the deadlines are Feb. 1, June 1 and Oct. 1. Applicants may request support for oncologic curriculum development, medical and dental study summer cancer research experiences, short term cancer reserch education for prebaccalaureate minority students from nearby colleges having a student body predominantly minority, and continuing cancer education. Contact him at NCI, Blair Bldg Rm 424, Bethesda, Md., 20205, phone 301-427-8898.

INCREASED FUNDING FOR AIDS WOULD NOT BE NEW MONEY FOR NCI IN HECKLER PLAN

(Continued from page 1)

funding.The proposed budget amendment would add $4.59 million to NCI's overall budget for acquired immune deficiency syndrome activities to a total of $28.44 million for FY 1986.

According to the proposed budget amendments, NCI will need 26 additional FTEs (full-time equivalents) in fiscal 1986 in order to carry out the AIDS related activities. Institute officials are hopeful that the additional positions will be added to NCI's existing personnel ceiling, although no decisions have been made regarding personnel allocation.

In addition to the reprogramming of the construction grants funds, NCI will need to redirect another $1.5 million from its overall program activities, John Hartinger, NCI's Financial Management Branch chief, told **The Cancer Letter.**

The Administration's reprogramming proposal was delivered to Congressman Henry Waxman (D-Calif.) the week of July 19 **(The Cancer Letter,** July 26). Waxman, who chairs the House's Energy and Commerce Health Subcommittee, had threatened to subpoena HHS Secretary Margaret Heckler to obtain agency documents relating to AIDS research needs.

Under the proposed budget amendment, NCI would receive the largest portion of AIDS funding within NIH, $28.4 million in FY 1986, or slightly more than the National Institute of Allergy & Infectious Diseases' proposed AIDS funding of $27.1 million in fiscal 1986.

NCI's share of AIDS-related expenditures would amount to approximately one-fourth of the total Public Health Service funding of $126.3 million requested for the disease in FY 1986.

The Centers for Disease Control would receive an additional $26.9 million under the proposed budget amendment, for a total AIDS funding level of $45.6 million in FY 1986. HHS proposes to redirect $3.5 million of the $5.5 million requested to purchase equipment for CDC's new virology laboratory under construction in Atlanta.

CDC will spend approximately $22.8 million on AIDS activities in the current fiscal year, according to the HHS reprogramming request, or some $4 million less than NCI's FY 1985 AIDS funding level of $26.95 million.

While NCI would lose slightly more than half of the $6.5 million requested for cancer construction grants in fiscal 1986, the reprogramming request notes that the resulting funding level of $3 million "is consistent with the appropriated levels in 1984 and previous years."

The HHS proposal would reprogram $10.1 million of the $13.1 million requested for facilities assistance grants in cancer, heart and eye research in fiscal 1986. The reprogramming request totally eliminates $6.6 million requested for National Heart, Lung & Blood Institute and National Eye Institute construction grants in FY 1986.

An additional $9.9 million requested for modernization of NIH's Clinical Center will be redirected to fund AIDS research under the proposed budget amendment. NIH laboratory renovations of $3.8 million for FY 1986 would also be reprogrammed to fund AIDS activities.

PHS-wide items proposed for reprogramming in order to fund AIDS activities total $37.8 million in fiscal 1986.

Heckler's request identifies "specific activities needed to address the AIDS problem."

Specific AIDS activities to be carried out by NCI include epidemiologic studies "to clarify the natural history of the disease" as well as "additional work toward the development of vaccines and antiviral agents," the proposed HHS budget amendment says.

Epidemiologic studies include an estimated $400,000 study of HTLV-3 transmission in seropositive, pregnant, drug using females and their offspring, with followup of the children to monitor seroconversion, immune function, and risk of AIDS.

Other studies and estimated funding are:

*Expansion of projects designed to pursue observations related to the high rates of viral isolation in seronegative sexual contacts of high risk group members ($400,000).

*Followup of a drug-user cohort which indicates striking geographic difference in seropositivity to assess changes in seroprevalence over time and the risk of AIDS and AIDS-related illnesses ($350,000).

*Interviews with persons occupationally exposed to HTLV-3 regarding known AIDS risk factors and details of exposures (particularly needle-stick injuries) and serial collection of blood samples ($150,000).

*Followup studies of documented regional differences in the prevalence of HTLV-3 antibody in Kenya to clarify the basis for low AIDS case rates in areas endemic for HTLV-3 ($100,000).

Activities relating to diagnostic and therapeutic agents for the disease include:

*Screening of candidate antiviral compounds for activity against HTLV-3 with the goal of selecting the most efficacious drugs for clinical trials ($2 million for NCI, $750,000 for NIAID).

*Viral titration studies in suport of clinical trials with suramin, an antiparastic drug, which

has been shown to have inhibitory effects on viral reverse transcriptase at clinically achievable levels ($1.1 million).

*Identification and purification of antigens to be used in HTLV-3 vaccine development ($150,000).

NIAID would be responsible for testing the safety and antigenicity of AIDS vaccines in humans ($1 million), as well as outreach activities such as the development of "packaged workshops on AIDS" for professional and lay organizations ($320,000).

Under the proposed budget amendment, NIAID would also receive $2.66 million for "further clinical studies with suramin and other antiviral agents such as ribavirin and HPA23; possibly combining such agents with immunologic reconstitution such as bone marrow transplantation and interleukin-2 infusion." HHS also cites "extrapolation of recent advances in the treatment of cytomegalovirus with DHPG to other immunodeficiency states."

The National Institute of Neurological & Communicative Disorders & Stroke would receive $400,000 for "expanded work using an AIDS-virus-induced animal model to study the pathogenesis of the disease, particularly further development of a new serological test which appears to accurately identify both susceptible and immune animals."

CDC would receive $14.7 million in fiscal 1986 for community risk reduction and health education programs to "provide information on AIDS to all segments of the public, particularly individuals at increased risk of AIDS, health care providers, researchers and other groups with responsibility for persons with AIDS."

Specific activities include the initiation of cooperative agreements with each of the 50 states to appraise community resources and needs and help build risk reduction and health education programs.

Approximately $3.35 million would be allocated to "enhanced epidemiology" projects to clarify the extent and means of heterosexual transmission and explore other potential transmission modes. CDC would also receive $7 million for demonstration and evaluation projects, with anadditional $1.87 million slated for epidemiologic studies and the natural history of HTLV-3 infection and AIDS.

The Food & Drug Administration would receive additional funds of $2.9 million in FY 1986 for activities to "increase our knowledge regarding the screening tests and enhance our ability to assure the safety of the nation's blood supply; clarify the possible transmission of AIDS through food; and expand the capacity for review and approval of new diagnostic and treatment products."

ACS TO IMPLEMENT CANCER RESPONSE SYSTEM NATIONWIDE, 8-12 FIRST YEAR

The American Cancer Society, following approval of the plan by its Board of Directors, has started implementing nationwide its Cancer Response System, the toll free phone service to answer questions from the public which it has been testing for two years.

The ACS service is based in the Society's local divisions and makes extensive use of volunteers. It is operational now at six divisions and the plan is to establish it at eight to 12 more during the first year.

Diane Fink, ACS vice president for professional education, told **The Cancer Letter** that the Society has no intention of replacing NCI's Cancer Information Service with Cancer Response System. NCI recently recompeted its CIS contracts for another five years, at a cost of about $4.7 million a year. CIS provides toll free question answering service by each of the contractors, but it also has an additional element of health education.

NCI executives have said they intend to watch the ACS service as it develops and determine after it is implemented what long range effect it will have on CIS and NCI's support of CIS.

Fink said she intends to meet regularly with NCI staff. "We will make sure that the planning and implementation are coordinated with NCI," she said. "I don't see in any way that this will supplant what NCI is doing."

Others may see it differently. Richard Bloch, member of the National Cancer Advisory Board and chairman of its Information Committee, commented at the last Board meeting, "If they (ACS) go national with it, I hope NCI will get out of the consumer information service. ACS can do a better job and do it cheaper."

CIS is operated out of the Div. of Cancer Prevention & Control. A few years ago, the DCPC Board of Scientific Counselors came very close to recommending that the CIS contracts not be recompeted. After a number of improvements were made, the Board was satisfied and voted unanimously for recompetition.

Some NCI executives and CIS contractors do not think that volunteers can be counted on over the long haul to work as effectively as CIS paid staff. However, ACS has built on its long history of working with volunteers, and the tests at eight divisions in the Midwest have convinced Fink, and now the ACS Board, that the system can be operated efficiently and effectively.

Fourteen recompeted CIS contracts have been awarded, with two still in negotiation. Five others will participate in the system, supported with funds other than from NCI.

BURTON CLINIC SHUT DOWN SEVEN YEARS AFTER PAHO SAID IT SHOULD BE CLOSED

The closing of Lawrence Burton's Immunology Researching Center in the Bahamas came more than seven years after an initial site visit by the Pan American Health Organization (PAHO) first recommended the clinic be closed.

In a report submitted to the Bahamian Ministry of Health in January, 1978, the reviewers' first recommendation was to "close the Immunology Researching Center, (IRC)." The recommendation was made "because it is understood that the purpose of the present arrangement between IRC and the Government of the Bahamas is to permit an evaluation of the treatment being performed at the Center." The site visit found that the clinic's procedures did not permit "any meaningful evaluation" and advised that "it is highly unlikely that any change in procedures will make the treatment evaluable."

The report stressed that, "Further, it is emphatically stated that no consistent treatment effect has been achieved when assessed by objective criteria."

At that time, the report noted, "it is important to point out that had PAHO Advisors been consulted by the Ministry of Health prior to the establishment of the clinic, they would have been advised against establishing it on the grounds that the scientific background as well as the clinical credentials of the people associated with the clinic were so poor that it would have seemed highly unlikely that any useful information would be obtained and that in fact the ability to evaluate the activities of the Center would have been doomed from the start."

Although the 1978 report maintained that closing the clinic "is in the best interest of the Government of the Bahamas and also of the patients presently being treated at the Center," it made a number of recommendations for changes needed at the clinic if the government chose to allow it to remain in operation.

PAHO emphasized, however, that "it is highly unlikely that these changes will remedy the situation; and it is predicted that the studies will never be evaluable."

PAHO's most recent site visit and report, in July, also recommended closure of the clinic.

The site visit was conducted at the request of the Bahamian Ministry of Health following reports of HTLV-3 contamination of serum obtained from the clinic.

Ministry of Health Chief Medical Officer V.T. Allen confirmed this week in a phone conversation with **The Cancer Letter** that the center had been permanently closed, but she declined to provide further details. She insisted she would answer other questions only when submitted in writing.

Reviewers visiting the clinic reportedly were unable to obtain samples of the serum for additional testing, or lists of patients treated at the center.

Burton could not be reached for comment. Phone callers to the clinic are greeted with a recorded message saying that the Immunology Researching Center is closed.

PAHO is acting as a central information bureau for matters related to the clinic.

In the 1978 report, PAHO reviewers made a series of recommendations for changes needed at the clinic if the Bahamas government chose to allow it to remain in operation.

Recommendations included the credentialing of physicians providing patient care at the clinic; the prior approval of advertising for the clinic by the Ministry of Health, and the development of informed consent forms notifying patients that the treatment at the center is experimental and carried a risk of acquiring hepatitis.

PAHO also recommended that the center submit weekly lists of patients accepted for treatment at the center, including addresses and telephone numbers in their home countries, "the date of definitive diagnosis of cancer, type of cancer, date and type of last conventional anti-cancer treatment, date of initiation of treatment at IRC, and status with regard to payment (i.e., full payment, partial payment, no payment)."

Weekly lists of patients not accepted for treatment and the reason why were also recommended, as was a weekly list of all patients who died indicating the date and whether or not an autopsy was performed.

The group also advised that the Bahamian Ministry of Health modify its agreement with the clinic in order to require a waiver of confidentiality on behalf of patients treated at the clinic, so that IRC could release names and addresses to the Ministry of Health and patients could be contacted for followup.

The 1978 site visit team was headed by William Terry, who headed NCI's Immunology Program.

The importance of patient followup in light of reports of HTLV-3 antibodies in serum from the clinic was stressed again by NCI's Gregory Curt in a July 17 letter to Allen.

Deputy director of the Div. of Cancer Treatment, Curt specifically asked for the names of patients treated at the Freeport clinic over the last 18-24 months "so that appropriate followup can be undertaken."

Curt told **The Cancer Letter** that followup studies of patients treated at the clinic could not only assess the risk of hepatitis and AIDS, but provide information about the patient's underlying tumor.

STUDY FINDS 4-20% OF THOSE WITH HTLV-3 DEVELOP AIDS IN 32 MONTHS

Tacoma medical oncologist Gale Katterhagen's identification of HTLV-3 positivity in samples of serum from the Burton clinic led to the Bahama's government request for a site visit from PAHO and the ultimate closure of the facility.

The sera's positivity for antibodies to the virus associated with acquired immune deficiency syndrome has led Katterhagen and other oncologists to express concern that patients treated at the clinic may have been exposing themselves to AIDS through contaminated sera.

Although NCI officials would like to see followup studies of patients treated at the clinic performed in order to assess their risk of developing AIDS and hepatitis, for many scientists, the relationship between a positive ELISA test for HTLV-3 antibody and the chances of that person developing AIDS remains unclear.

Speaking at the American Society for Clinical Oncology's annual meeting in May, NCI's Stanley Weiss reported that between 4 to 20 per cent of persons infected with HTLV-3 will develop AIDS within 32 months.

The study has followed more than 600 people since 1981: 85 homosexual men from New York City; 160 homosexual men from Washington, D.C.; 250 homosexual men from Denmark; 56 drug abusers from New York City; and 69 hemophilia-A patients from Pennsylvania.

The highest infection rate was seen among homosexual men from New York City. In 1982, slighlty more than half of that group, 54 per cent, were infected with HTLV-3. By early 1985, 20 percent of those infected had developed AIDS and an additional 25 percent had developed "some lesser manifestations of immune deficiency," Weiss said.

Drug abusers in NYC had an infection rate of 46 percent, and of these, 4 per cent developed AIDS.

Among homosexual men tested in D.C., 26 per cent were infected with HTLV-3 in 1982, as compared with 54 per cent in New York. Of those D.C. men infected, 12 per cent subsequently developed AIDS and 11 per cent developed "lesser AIDS."

In the Danish group of homosexual men studied, 10 percent were infected with HTLV-3, and of these, 8 per cent developed AIDS.

The study defines lesser AIDS as patients with oral candidiasis; herpes zoster; or idiopathic thrombocytopenia, without any apparent reason to have the conditions. While the conditions appear to be related to HTLV-3 infection and AIDS, they are generally not life-threatening.

Weiss suggested that the higher rate of AIDS among homosexual men in New York "most likely reflects the longer duration of exposure in the New York group although other factors such as dose or route of HTLV-3 infection, concurrent infection with other viruses, or other life style variables may be involved."

The hemophilia-A patients had an infection rate of 38 per cent in mid 1982, and of these, 7 per cent developed AIDS and 19 percent lesser AIDS.

"The long interval between initial infection with HTLV-3 and the development of clinical and immunologic abnormalities is illustrated by the data for the hemophilia-A patients," Weiss said.

Of 10 hemophilia-A patients infected with HTLV-3 before 1981, "all of them had developed generalized lymphadenopathy or other immunologic abnormalities by early 1985," he reported.

IMPASSE BROKEN, CONFEREES AGREE ON 6,200 NIH COMPETING GRANTS IN 1985

The impasse over the number of competing NIH grants that will be funded in the current, 1985 fiscal year has finally been broken. House and Senate conferees on the 1985 supplemental appropriations bill agreed that no fewer than 6,200 new and competing renewals will be funded.

Conferees also agreed that at least 532 research centers will be supported with 1985 funds.

The Office of Management & Budget had sought to slash the number of competing NIH grants from more than 6,500 provided for in the regular 1985 appropriations bill to 5,000 by using the controversial, and probably illegal, method of multiple year funding of some grants entirely with 1985 money. NIH and the scientific community were outraged, and the Senate, led by Lowell Weicker (R.-Conn.), compromised with OMB on 6,000 grants.

William Natcher (D.-Ky.) and Silvio Conte (R.-Mass.), chairman and ranking minority member of the House Labor-HHS Appropriations Subcommittee, balked. The House had in its bill, before compromising with the Senate, 6,200 grants, and Natcher and Conte insisted on going at least that high. Their view prevailed. OMB also had wanted to cut the number of centers to 500.

The House subcommittee gave up on its attempt to mark up the 1986 appropriations bill before the August recess. That had been held up until the final 1985 number was in on NIH grants. Mark up in both houses now probably will be first on the respective subcommittees' agendas when Congress reconvenes in September.

The NCI priority score payline for grants, which had been estimated as low as 158 with the 5,000 limit, could be lifted as high as 170 with the new level, depending on how many of the additional number are allocated to NCI.

ACS SURVEY FINDS NEED FOR EDUCATION PROGRAM AMONG HISPANIC AMERICANS

An urgent need for extensive cancer education programs directed to Hispanic Americans was underscored by reports this week of a new study of this group by the New York survey firm, Clark, Martire & Bartolomeo for the American Cancer Society.

Robert McKenna, ACS national president, said that the results showed that Hispanic Americans are not adequately aware of most of the warning signs of cancer or ways of reducing cancer risk, and that they tend not to seek early detection or treatment.

"What's so helpful about this survey of Hispanic attitudes and practices is that it has identified the key barriers which impede the fight against cancer in this important and sizeable segment of the population," McKenna said. "Some barriers are psychological, some cultural, and a great number are created by economics."

The study, conducted between December 1984 and Februrary 1985 of over 800 randomly selected Hispanic Americans, was based on extensive interviews by specially trained and supervised bilingual interviewers. ACS said it believes it to be the first major study on cancer conducted among Hispanic Americans.

McKenna pointed out that the study examined the three major groups within the Hispanic American population in this country—Mexican Americans, Cuban Americans and Puerto Ricans. These groups were compared to each other and to a base line set of figures derived from a 1979 ACS study of the general American population.

Among the important trends brought to light were:

--Forty eight per cent of the adult Hispanic American population are 35 years or younger, thus making cancer more of a general concern rather than an immediate threat to the majority.

—A third of Hispanic Americans tend to have incomes below $10,000, one half completed their education before graduating from high school, and among those employed, three of four hold limited blue collar jobs. One third have no medical insurance. Cost is the major reason given for not seeking checkups or treatment.

—While important differences exist between the three Hispanic American groups, there is significant similarity of attitudes towards cancer, cancer prevention, early detection and education.

—Spanish is the language spoken at home by 63 per cent of the sample indicating a strong preference for information programs given in that language.

—The majority (62%) are most comfortable with Spanish speaking physicians. Most indicate preference for male physicians in private practice.

—Discrimination when seeking health care is claimed by 22 per cent.

—Two out of three Hispanic Americans have seen a physician in the last five years, but 50 per cent indicate that the visit was in connection with a specific problem and not for a checkup.

—Fifty seven per cent of Hispanic American women did breast self examination in the last year compared to 67 per cent of all women surveyed in 1979.

—Hispanic Americans today are somewhat more fearful of getting cancer than the general population was in 1979 (59% to 54%), believe to a lesser degree that early detection increases chance of cure (74% vs. 91%), and lag behind in the level of awareness of the early warning signs and tests for cancer.

—One out of two Hispanic Americans tend to be fatalistic, 28 per cent feel there is a stigma attached to cancer, and most have many concerns about treatment and costs.

—One set of positive findings shows that there are somewhat fewer smokers among this group. Those who smoke, smoke less, smoke filter cigarettes, and recognize the danger of smoking. Sixty per cent say they want to quit.

"New concepts must be developed to reach across the gap in communications described in this study," McKenna said. "The impact on health from lack of knowledge is something that the American Cancer Society can change. There is no substitute for action. This research is our starting point. If ACS extends its help into every community in this country, we can save thousands and thousands of lives every year."

REAGAN FAMILY HISTORY SHOWS STRONG RISK FACTOR FOR COLORECTAL CANCER

President Reagan's family history exhibits a strong risk factor for colorectal cancer, Henry Lynch, president of the Hereditary Cancer Institute at Creighton Univ., pointed out following the President's surgery for colon cancer.

"There are definite risk factors in colorectal cancer," Lynch said. "One of the strongest is the presence of a positive family history of this disease." Reagan's older brother, Neil, 76, underwent the same type of surgery that was performed on the President. Neil Reagan was diagnosed for colon cancer.

Offspring or siblings of colon cancer patients are three times as likely to suffer the same disease as are other members of the population, according to studies cited by Lynch. Another risk factor is the presence of polyps.

Lynch added that it might have been prudent to perform a colonoscopy on the 74 year old President earlier. "I realize this is second guessing, but in a patient of the President's age, we now know it would have been prudent to have performed an earlier colonoscopy, and it may have altered the prognosis significantly."

Request for Applications Available

RFA 85-CA-06
Title: Development, validation and application of biochemical markers of human exposure for use in epidemiologic studies
Deadlines: Letters of intent, Oct. 1; applications, Nov. 4

The Div. of Cancer Etiology of NCI invites applications for cooperative agreements to further the effective use of biochemical markers as exposure indices in future epidemiologic studies. Although the awards will be made and managed by NCI, staff involvement and participation in funding on the part of the National Institute for Occupational Safety & Health, the National Institute of Environmental Health, and the Environmental Protection Agency is anticipated.

The purpose of this announcement is to solicit applications directed toward the further development of biochemical markers of exposure to increase the power of epidemiologic studies in which they can be utilized. It is expected that positive results would be widely applied by the epidemiologic research community in the design of future studies.

The specific objective of the initiative is to encourage investigations designed to develop, characterize, validate and apply measurement methods for biologic markers of human exposure (which has occurred in the recent or distant past) which would be useful in the conduct of epidemiologic studies.

Applications funded under this RFA will be supported through the cooperative agreement mechanism. An assistance relationship will exist between federal staff and the awardees to accomplish the purpose of this activity. As more completely described in the RFA, the recipients will be totally responsible for the development and conduct of the research. Involvement of staff members of the federal organizations specified above will be nondirective and will not, under any circumstance, control the research activities to be carried out. It will be limited to consulting on proposed methodologies to maximize their epidemiologic utility; providing a resource of information on the extent of distribution of exposures; providing information on and access to cohorts of exposed individuals which could provide material for methods development and validation; and faciliting the exchange of information and materials among the awardees. Nonprofit and for profit organizations and institutions may apply. All applications submitted in response to this announcement will be classified as new grants.

The starting date for these grants will be July 1, 1986.

The concept from which this RFA was derived was approved by the DCE Board of Scientific Counselors last winter and reported in The Cancer Letter March 15, pages 3-4.

Copies of the complete RFA and additional information may be obtained from John Cooper, PhD, Extramural Programs Branch, Landow Bldg Rm 8C16, NCI, Bethesda, Md. 20205, phone 301-496-1882.

RFA 85-CA-15
Title: Cooperative agreements for national collaborative chemoprevention projects
Deadline: Oct. 25 for applications

The Div. of Cancer Etiology invites applications for cooperative agreements for national collaborative chemoprevention projects (NCCP). The projects are conceived as new approaches to cancer prevention in order to acquire basic knowledge in significant biological systems for carcinogenesis/anticarcinogenesis; derive new insights into practical means for chemoprevention of the carcinogenic process; and rapidly translate these understandings into new chemopreventive entities with known ranges of efficacy and defined pharmacologic/toxicologic properties.

DCE has responsibility for support of basic research and development efforts in chemoprevention of cancer. As a program mechanism in addition to individual grants and contracts, the new projects are envisioned as means to enhance and expand multidisciplinary/interdisciplinary basic studies in development of new chemopreventive entities and strategies for cancer prevention. Each NCCP would consist of a number of laboratory research programs representing diverse scientific disciplines and expertise. Scientists in a given project could derive from any combination of the academic, nonprofit and for profit communities. Scientists in an NCCP could also be drawn from a single organization possessing necessary diversity and in depth expertise to accomplish project objectives. Each project is envisioned to consist of a project director, program leaders in several broad scientific disciplines and an NCI coordinator. The project director has the responsibility for organizing the project, assembling the multidisciplinary group of program leaders, preparing the cooperative agreement application and serving as principal investigator. This individual provides scientific and administrative leadership and, in addition, is expected to provide a laboratory program. A high degree of interaction and focus are expected in project efforts.

Many classes of chemopreventive agents have been investigated in numerous biological systems, and of these, a significant number appear promising for substantial development efforts. These classes include, among others, protease inhibitors, antioxidants, dithiolthiones, dehydroepiandrosterone and related analogs, cyanates and isothiocyanates, inhibitors of arachidonic acid metabolism, nucleophiles and potential new classes of inhibitors existing in natural products such as foods consumed by man, as exemplified by green and yellow vegetables. Since there is already extensive activity in

retinoids research and development, applications in this area will be considered nonresponsive.

Awards will be made as cooperative agreements. These are assistance relationships involving substantial involvement of NCI staff during performance of the project. However, the applying project must define its objectives in accord with its own interests and perceptions of novel approaches to cancer prevention. The role of NCI staff will be to provide assistance, advice and guidance after an award is made. Final decision making authority during performance will rest with the project director.

NCI anticipates the funding of multiple awards for project periods of five years and has set aside $1.5 million for the initial year's funding. The expected starting date for these awards is Aug. 1, 1986. Although this program is provided for in the financial plans of NCI, awards are contingent upon availability of funds for this purpose and the receipt of applications of high scientific merit.

The concept from which this RFA was derived was approved by the DCE Board of Scientific Counselors at its winter meeting and reported in The Cancer Letter March 15, pages 3-6.

Copies of the RFA and further information are available from Carl Smith, PhD, Program Director, Biological & Chemical Prevention, Chemical & Physical Carcinogenesis Program, DCE, NCI, Landow Bldg Rm 9B06, Bethesda, Md. 20205, phone 301-496-4141.

RFPs AVAILABLE

Requests for proposal described here pertain to contracts planned for award by the National Cancer Institute unless otherwise noted. NCI listings will show the phone number of the Contracting Officer or Contract Specialist who will respond to questions. Address requests for NCI RFPs, citing the RFP number, to the individual named, the Blair building room number shown, National Cancer Institute, NIH, Bethesda, MD. 20205. Proposals may be hand delivered to the Blair building, 8300 Colesville Rd., Silver Spring, Md., but the U.S. Postal Service will not deliver there. RFP announcements from other agencies will include the complete mailing address at the end of each.

RFP NCI-CN-55434-50

Title: Support for formulation, dosage form preparation and packaging of chemopreventive agents.

Deadline: Approximately Oct. 11

Organizations with the capability of performing one, two or all three of the following tasks may submit proposals for task order, term type contracts with five year duration: Task 1, preparation of solid oral dosage forms (6,080 hours); Task 2, preparation of soft gelatin capsule dosage forms (14,200 hours); Task 3, calendar pack-daily dose packaging of chemopreventive agents.

The cancer chemoprevention program is aimed at testing the concept that certain natural or synthetic agents may lower cancer incidence. Potential chemopreventive agents include but are not limited to naturally occurring substances such as retinoids, ascorbic acid, alpha tocopherol, selenium and others from the laboratory such as antioxidants, phenolic, protease and prostaglandin synthesis inhibitors, tumor growth factor inhibitors, secondary plant constituents, miscellaneous chemicals, etc. The chemoprevention program has a need to establish qualified contractors who possess the feasibility, personnel and equipment to handle quick response production of finished dosage forms and/or capable of providing these forms appropriately packaged and labeled according to randomized allocation schemes in accordance with the good manufacturing practice regulations of FDA.

The concept from which this RFP was derived was approved by the Div. of Cancer Prevention & Control Board of Scientific Counselors last year and reported in The Cancer Letter May 25, 1984, page 3.

Contract Specialist: David Monk
RCB Blair Bldg Rm 2A07
301-427-8745

RFP-NCI-CP-EB-51016-67

Title: Support services to develop a computerized comparison population for occupational studies.

Deadline: Approximately Oct. 2

This contract will support computer related research in support of the scientific activities of the Environmental Epidemiology Branch. The contractor will be responsible for completion of tasks specified and monitored by NCI in a support context with no independent research on the part of the contractor.

NCI has begun a collaborative effort with the National Institutes for Occupational Safety & Health to develop a large comparison population which will be used to generate expected frequencies of deaths from specific causes for epidemiologic studies of employed populations. The large comparison group system to be developed by this project will produce standard population data in formats suitable for the Monson, OCMAP, and NIOSH packaged analytic programs. The development of the system includes computer programming, writing documentation, editing and recoding and writing command procedures. All work will be done using the NIH computer facility (IBM 370/3081K, MVS/VS) located in Bethesda, and the contractor will be expected to use this facility by remote access.

Contract Specialist: Camille Battle
RCB Blair Bldg Rm 114
301-427-8888

The Cancer Letter _Editor Jerry D. Boyd Associate Editor Patricia Williams

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.