THE CANCER LETTER

Vol. 10 No. 3
Jan. 20, 1984

Subscription $150 year North America
$175 year elsewhere

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

NCI COMMITTED TO 50 PERCENT MORTALITY REDUCTION BY 2000; DCPC BOARD HEARS HOW THAT WILL BE DONE

NCI Director Vincent DeVita has committed the Institute to the goal of reducing cancer mortality 50 percent by the year 2000, stating that commitment recently on national television. Last week, the Div. of Cancer Prevention & Control Board of Scientific Counsel-

(Continued to page 2)

In Brief

BOUTWELL DECLINES NOMINATION TO NEW NCAB TERM; ROWLEY AGAIN URGES APPOINTMENT OF SCIENTISTS

ROSWELL BOUTWELL, professor of oncology at McArdle Laboratory (Univ. of Wisconsin) whose term on the National Cancer Advisory Board expires after the next meeting, has been recommended by NCI Director Vincent DeVita for appointment to a full six year term. Boutwell is finishing out the term of Gerald Wogan, who resigned with about two years left. However, Boutwell has accepted a two year appointment as director of research at the Radiation Energy Research Foundation in Japan and has asked not to be considered for another term. The other scientists whose terms are up this year—Maureen Henderson, Janet Rowley, and Irving Selikoff--were Carter Administration appointees and not likely candidates for reappointment in the highly political Reagan Administration, but Boutwell probably would have made it. Losing him makes it more urgent than ever that at least some of the four scientific seats go to scientists. In a related development, Rowley has written another letter to "Science" magazine urging the appointment of highly qualified scientists to the Board and criticizing the last round of Reagan appointees. Rowley stirred up a storm, and considerable resentment among her new Board colleagues, with a gutsy letter to "Science" in 1982 questioning their credentials. . .

SITE VISITS to the three institutions competing for the new Organ Systems Program Coordinating Center have begun and review will be completed in time for the award to go to the NCAB in May. William Shingleton, director of the Duke Univ. Comprehensive Cancer Center, is chairman of the ad hoc review committee. The three institutions are the Univ. of Texas (Galveston), Rush-Presbyterian-St. Luke's Medical Center, and Roswell Park Memorial Institute.

DCPC LISTS OBJECTIVES FOR 1990 TO MEET MORTALITY REDUCTION GOAL

(Continued from page 1)

ors heard some details on how that goal is to be achieved.

DeVita told the Board that he feels the goal is achievable with existing technology, that it does not take into account the impact on survival new areas such as monoclonal antibodies and micro and macro nutrients will have.

DCPC Director Peter Greenwald said that it is an "ambitious objective, but with the full support of our medical and scientific colleagues across the country, the public and Congress, it is one I believe can be achieved. This division will bear much of the responsibility for meeting this goal."

Greenwald said, "There is still much to be considered and debated: What really can be achieved using present technology? What lead times are needed to show an impact—for example, smoking cessation can show an impact by the year 2000, but smoking prevention in youth will take longer to affect lung cancer rates. What are the institutional and resource needs? How best can we tie resource allocation to achieving the reduced mortality objective? How can we assure continued momentum in basic research as we strive for this reduced mortality objective? We should not lose sight of the fact that (even after meeting the goal) there is still the other 50 percent."

Greenwald said that Edward Sondik, chief of DCPC's Biometrics & Operations Branch, would take the lead responsibility for developing more detailed cancer control objectives and paths by which they may be reached. That plan will be due in January, 1985. Sondik presented an initial report later at the Board meeting (see below).

Greenwald said that a DCPC Task Force on Cancer Control Objectives and a National Cancer Control Surveillance System will be established to provide oversight and advice. Board Chairman Lester Breslow will chair the task force. Four regional meetings will be scheduled in 1984 to obtain wide advice on comment.

"Much of the initial impetus for setting objectives came from this Board and, in particular, from Dr. Breslow," Greenwald said. "We are fully committed to it. It is our highest priority."

Greenwald noted that concepts presented to the Board last week (for development into RFAs and RFPs) were keyed to these objectives. They included:

A. Stimulating local initiatives through an RFA entitled, "Reduction in avoidable mortality from cancer."

B. Moving along the diet and cancer/chemoprevention programs through several concepts in these areas.

C. Giving further impetus to smoking prevention and cessation thrusts.

D. Encouragement of new scientists competent in cancer control research through the small grants cancer control research program.

E. Gaining a better perspective on present research and cancer control needs related to the asbestos problem.

Greenwald said his priorities are based on "whether the concept has a high likelihood of helping in the aim of reducing cancer mortality; how it fits into one of our strategic research plans; and its context in terms of existing current research and how this will fill a research gap."

Greenwald referred to other approaches which "complement our effort to achieve this reduced mortality objective." These include:

—Analysis of the Cancer Centers Program by Jerome Yates, director of DCPC's Centers & Community Oncology Program, and the Board's committee on that program area, which included consideration of the number and geographic spread of centers and the possibility of clinical and comprehensive centers taking greater regional responsibility.

—A look by the Cancer Control & Applications Branch into working with state and local health agencies in joint cancer control initiatives.

--Plans under development related to cancer detection and occupational cancer. "We shall extend these plans in order to relate them to reduced incidence and mortality aims," Greenwald said.

--Methods of "making cancer control surveillance meaningful already are being pilot tested. Surveillance includes identification of unusually high or low incidence of survival, in order to trigger further assessment of the observation and corrective action if indicated. We are looking at how best to work with local leaders in following through on the observations from SEER and other surveillance systems. Our

medical epidemiologists and staff fellows are taking lead responsibility for this work."

--Continued promotion of the Cancer Control Research Unit and defined population study ideas, "as a crucial step in cancer control."

Greenwald acknowledged that setting of national objectives "takes us beyond the traditional bounds of NIH programs, to the assumption of responsibility for national cancer incidence and mortality rates. Since the effort extends beyond those things which we directly control to other sectors of society, leadership is needed." He asked Board members to "participate in this leadership" and to offer their suggestions on how the objectives can be met.

Sondik, after reviewing cancer mortality and five year survival rates by sites, presented some suggested sites for potential intervention:

* Lung cancer, with 135,000 cases in 1983; bladder cancer, 38,500 cases; and cancer of the esophagus, 9,000 cases would be attacked largely through prevention.

* Cancers of the colon-rectum and cervix would be approached primarily with early diagnosis.

* ALL, AML, Hodgkins disease, osteosarcoma, and ovarian cancer would be attacked primarily through treatment.

* Head and neck cancer and melanoma would be attacked through both prevention and early diagnosis.

* Cancer of the testis would be approached through early diagnosis and treatment. through early diagnosis and

* Breast cancer, with 114,900 cases in 1983, would be attacked through all three intervention areas.

Control actions would include smoking reduction, dissemination of treatment information (through PDQ and other means), public awareness campaigns through cancer centers, Community Clinical Oncology Programs, and local organizations, and nutrition.

Sondik presented some specific goals:

1. Reduce the mortality rate from all cancers (excluding lung, bronchus, and trachea) to less than 110 deaths per 100,000 persons by 1990. The impact would be 45,000 fewer deaths by 1990.

2. Reduce the mortality rate from all cancer in persons under age 25 to less than three deaths per 100,000 by 1990. The impact would be 1,400 fewer deaths by 1990.

3. Reduce the mortality rate in persons age 25-49 to below 40 deaths per 100,000 by 1990. The impact, 12,000 fewer deaths.

4. Reduce the growth in the lung cancer mortality rate from 2.8 percent per year to 1.5 percent per year by 1990. The impact, 25,000 fewer deaths by 1990.

Those efforts deal with reducing mortality rates. Sondik suggested two goals relating to incidence--reduce the growth in the incidence of lung cancer from two percent per year to below 1.3 percent per year by 1990, with an impact of 25,000 fewer cases; and reduce the trend in the incidence of all cancers excluding lung, bronchus, and trachea from slightly increasing to a decrease of 0.5 percent per year by 1990, with an impact of 100,000 fewer cases.

Smoking behavior is an all important key to any effort to reduce mortality and incidence. About 33 percent of adult Americans smoke, a substantial reduction from more than 40 percent 20 years ago. In persons age 12-18, the current percentage of smokers is 11.7. The NCI goal is to reduce those percentages to less than 25 for adults and less than 6 for youths by 1990, Sondik said.

Other efforts would be primarily educational, to increase awareness that one in three Americans develop cancer; that changes in bladder or bowel habits, persistent indigestion or difficulty in swallowing may signify cancer; that approximately 50 percent of cancer patients survive and that survival rates are increasing; and that surgery, chemotherapy, and radiation are effective in treating cancer.

"That was an outstanding presentation," Board member Charles Smart commented. "I'm very excited about the potential. It is achievable."

DCPC BOARD APPROVES NINE CONCEPTS, NEW SMALL CANCER CONTROL GRANTS OK'd

The Board of Scientific Counselors of the Div. of Cancer Prevention & Control approved nine concepts for grant and contract supported programs, appeared to approve another that will have to be voted upon later by mail, disapproved one and tabled another in actions at last week's meeting.

Concepts approved:

Cancer Control Small Grants Research

Number of awards antcipated: Up to 10 in FY 1984, and up to 20 in each of the next two fiscal years.

Duration of awards: Usually one year, may be longer if funding restrictions are not exceeded.

Approximate total annual budget for all awards: 1984, $250,000 direct costs, $350,000 total costs; 1985, $500,000 direct, $750,000 total; 1986, $500,000 direct, $750,000 total.

The goal of this small grants program is to facilitate the growth of a nationwide cohort of scientists with a high level of scientific research expertise in the field of cancer control. Its major objective is to encourage new investigators from a variety of academic disciplines to apply their skills to scientific investigations in the field of cancer control intervention research.

At the present time, universities do not offer degree programs in cancer control, and as a consequence there is a lack of formal opportunities to stimulate interest in cancer control research. Moreover, since cancer control intervention research has recently taken new directions, opportunities for new and established researchers to be introduced to the field are necessary. Cancer control as a field of professional activity can be promoted effectively through a program which provides financial support for small exploratory investigations. The availability of support under this program has the potential of stimulating research interest in a number of different ways. For example, a doctoral candidate's dissertation research could be supported. Similarly, a midcareer scientist with no cancer control research experience may wish to conduct a pilot study which could lead to greater commitment to scientific research in this area. Small grant research in a subject area can have the effect of encouraging the investigator to continue these activities in his subsequent professional career, thus providing a potentially cost effective means of increasing the national pool of highly qualified cancer control professionals. The proposed program is consistent with the goals of the cancer control program for the reduction of cancer incidence, morbidity, and mortality by furthering the development of qualified professionals in cancer control research.

This program is similar to the four small grants programs now operating in NIH. Although relatively new (since Feb., 1982), those programs are meeting the original objectives of soliciting proposals from new investigators. A major element of this proposed program is also the reduction of time between receipt of proposals and funding of approved ones--five months maximum as compared with the usual nine or more months.

Persons would be eligible to apply for small grants to support research on a cancer control intervention topic if: 1) they are currently enrolled in an accredited doctoral degree program, or 2) are researchers who have never received NCI cancer control research funding and are interested in cancer control intervention research opportunities.

The proposed principal investigator will be the individual scientist, and the applicant will be the institution which will administer the grant on behalf of the proposed principal investigator.

The application should contain a budget that does not exceed $15,000 in direct costs for dissertations and $25,000 in direct costs for other studies, but in no case to exceed $35,000 total costs.

The basic criteria for review of these applications include the overall quality and scientific merit of the proposed research and involve considerations such as the research design, feasibility of the study, soundness of approach, and creativeness. The proposal must be for research related to cancer control interventions. Other evaluation factors include the availability of suitable facilities to perform the proposed study, the supportive nature of the research environment, and the appropriateness of the proposed budget. If the research will constitute a doctoral dissertation, a written statement from the applicant's dissertation chairman that the project proposal has his/her approval must accompany the application. If a dissertation project is selected for support under this program, a statement of approval of the full dissertation committee is required before funding will be made.

"How are you going to get the word out to people who might be interested in this but don't know they are?" Board member Saxon Graham asked.

Robert Burnight, chief of the Cancer Control Applications Branch, said that information on the program would be widely distributed to universities.

"We're eager about this, and encourage you get the widest possible distribution," Board Chairman Lester Breslow commented.

Core Grants for Clinical Nutrition Research Units (CNRUs)

Anticipated number of awards: Two

Duration of awards: Three years

Anticipated annual budget per award: $400,000

As a means of encouraging a multidisciplinary approach to clinical nutrition opportunities and problems, NIH seeks to foster the development and operation of CNRUs. This solicitation for core grant applications is designed to complement NIH supported project grants and training awards and relevant activities funded from other sources. The specific objectives are:

1. To create or strengthen foci in biomedical research institutions for multidisciplinary research in clinical nutrition in order to develop new knowledge about specific nutrients in health, human development, and the prevention and treatment of disease.

2. To strengthen training environments in order to improve the education of medical students, house staff, practicing physicians, and paramedical personnel in clinical nutrition.

3. To enhance patient care and promote good health by focusing attention on clinical nutrition and generating nutritional information for the public.

NCI and the National Institute of Arthri-

tis, Diabetes & Digestive & Kidney Diseases currently support seven CNRUs, which were designed to create or strengthen nutritional research, training, and education through coordinated effort, intellectual stimulation, and use of shared resources. Since the first CNRU awards were made in 1979, the institutes have invested a total of $10,545,120 in the program. The National Institute of Aging will also participate in the program.

In the institutions with CNRUs, nutrition is being effectively integrated as a component of a broad spectrum of research projects. Emphasis on shared facilities, particularly core nutrition laboratories, has proven especially valuable in increasing the number of multidisciplinary studies. An average of 31 new clinical nutrition research protocols (ranging from 21 to 35) are now active at each unit. Studies include the role of nutrition in cancer, cardiovascular disease, diabetes, renal disease, cystic fibrosis, digestive diseases, growth in infants and children, and the management of patients with serious illness or injury. Areas also being explored are nutrition throughout the life cycle, studies of nutritional requirements, assessments of nutritional status, and studies on nutrition and behavior.

In 1981 and 1982, representatives of NCI and NIADDK and several non NIH clinical nutrition scientists conducted collaborative site visits to each of the CNRUs to observe the progress of each CNRU. Reports of these site visits plus annual progress reports from each CNRU were used to prepare a report, "Clinical Nutrition Research Units: A Progress Report, 1979-83." Based on this report and other assessments of the

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CONCEPT REVIEW FIGURES ARE ESTIMATES ONLY; RFPs, RFAs NOT YET AVAILABLE

The dollar estimates with each concept review brought before the various boards of scientific counselors are not intended to represent maximum or exact amounts which will be spent on those projects. They are intended only as guides for board members to help in determining the value of the projects in relation to resources available to the entire program or division. Responses should be based on the workscope and description of goals and methods included in the RFPs (contracts) and RFAs (grants and cooperative agreements). Availability of the RFPs and RFAs will be announced when NCI is ready to release them.

CNRU mechanism the NIH Nutrition Coordinating Committee has decided to reissue the CNRU RFA. tee has decided to reissue the

The characteristics of a CNRU include:

Professional personnel--The leader of the CNRU should be a scientist recognized for his or her expertise in research on clinical nutrition; there should be at least two other associated senior investigators pursuing nutrition research; and there should be other professional personnel as required, e.g. research pharmacists, dieticians, nurses trained in intravenous techniques, technicians with expertise in stable isotope and metabolic balance studies, etc.

Research activities--Research with human subjects and populations, and laboratory investigations.

Laboratory facilities--Each CNRU should have clinical research laboratories for special nutrition related studies (e.g., metabolic, immunologic, endocrine, neuroendocrine and behavioral research). The availability of an NIH supported General Clinical Research Center with a metabolic kitchen may prove useful adjunct.

Research training--Each unit should accommodate postdoctoral and young investigator training in clinical nutrition, funded under usual research training mechanisms (i.e. NRSA institutional and individual awards) or from other sources. A commitment to provide opportunities for nutrition research training is required. Although stipends will not be provided in this award, applicants must indicate the manner in which the CNRU facilities and resources will facilitate research training.

Educational programs (supported by sources other than NIH)--It is expected that a CNRU will encourage the integration of nutrition education into other educational activities in relation to health promotion and disease prevention. Furthemore, the unit should be actively involved in curriculum development, education of house staff, continuing education of physicians and other health professionals both within and outside its confines, and should provide information to the general public.

Nutritional support services (supported by sources other than NIH)--Nutritional support services should include an active clinical nutrition service for the assessment, maintenance, and improvement of the nutritional status of patients in the hospital and at home. A special unit for parenteral and enteral nutrition support is not an essential component of the nutrition support service but may be desirable.

Public information activities--It is expected that each CNRU will develop the appropriate mechanism for the application of research knowledge into public education derived from the CNRU activities.

Board member Laurence Kolonel said the existing CNRUs "are quite successful," but suggested that the emphasis on the two new awards be placed on cancer, since NCI will be providing all the NIH funding for them.

Board member Philip Archer suggested that not many institutions could meet the requirements spelled out in the concept proposals. William DeWys, director of DCPC's Prevention Program, said that a number of good applications in the 1979 round went unfunded, including one with a score of 190 which has since enhanced its nutritional research capability, including cancer related activities.

"I think there are quite a few places that could put one of these together," Board member Mark Hegsted commented.

Human Metabolism and Physiological Functions of Retinoids and Carotenoids

Anticipated number of awards: Three

Duration: Four year cooperative agreements.

Approximate annual budget: Direct cost, $530,000, total $750,000 for all three.

Goals and major objectives are (1) Improve understanding of the metabolic

processes by which dietary retinoids (vitamin A) and carotenoids are absorbed, transported and regulated in the gastrointestinal tract and quantify organ and tissue uptake and concentrations of retinoids and carotenoids; (2) study the metabolic processes over a range of dietary intakes of retinoids and carotenoids to include levels suspected of being toxic.

Dietary vitamin A and its precursors, provitamin A active carotenoids, have been shown in several epidemiological studies to be inversely related to the incidence of carcinoma at several sites. Retinoid and carotenoid metabolism are not well understood. Dietary vitamin A is obtained primarily as either provitamin active A carotenoids or as long chain fatty acyl esters of retinol. Esters of retinol are not well absorbed and first must be cleaved to free retinol either by pancreatic esterases or a brush border esterase for absorption. Carotenoids are assumed to be absorbed as is into the intestinal mucosal cell where they are cleaved to yield retinol. We do not have any clear understanding of the process whereby carotenoids are converted to retinoids in the intestines. There is no agreement as to whether the cleavage of carotenoids is enzymatic or nonenzymatic. Also, there is question about the position of the cleavage. Previously it was assumed that, for example, the cleavage of beta carotene was central yielding two molecules of retinal. Recent speculation suggests that the cleavage may also take place at other than the central double bond giving rise to other cleavage products which may exhibit particular specificities and potencies in target tissues, such as anticancer activity. It has been shown that feeding beta carotene results in more rapid wound healing than even higher levels of retinol alone. Retinol or perhaps some other cleavage products are esterfied and incorporated into chylomicrons which are transported via the lymph. Considerable areas of this important part of vitamin A metabolism are still unclear, such as the mechanism of actual uptake of retinol through the membrane and the means of movement of this very hydrophobic lipophilic compound through the cell. Liver is the storage organ for vitamin A. The release of retinol from the liver and its transport to target tissues has been well worked out in the last 15 years.

Mobilization of vitamin A from liver into plasma appears to be in proportion to tissue needs. There is some support for the idea that the utilization of vitamin A by certain tissues may be compromised in the face of inadequate intake and liver stores, thus sparing vitamin A for the most critical roles. Regulation of gastrointestinal uptake and homeostatic controls are not delineated with any degree of certainty.

Do some people have a lower setpoint in the control mechanism which puts them at risk of tissue deficiency and local susceptibility to carcinogens? Also, what are the consequences of very high intakes of vitamin A and carotenoids? The molecular mechanisms involved in vitamin A action on differentiation of epithelia have not been worked out. Are there other forms of vitamin A besides retinol which play a role? Kidney, besides liver, has recently emerged as an important organ in vitamin A metabolism but we do not even know the tissue concentrations of vitamin A in the kidney. Knowledge of the potential biopotency of retinoids and carotenoids, mechanism of actions, tissue concentrations and homeostatic controls together with information on the magnitude of these components in foods will allow us to design clinical intervention studies and subsequently give dietary advice in regard to food intake for prevention and better prognosis of cancer.

Investigation of human vitamin A metabolism and utilization should be pursued using various analytical techniques such as labeled forms of the compounds commonly found in foods, multicompartmental tracer techniques to observe turnover data and gastrointestinal sac techniques.

Board member Charles Cobau asked why the studies could not be performed by the CNRUs. DeWys said that they could be, but the CNRU core grant does not provide funds for specific studies such as this.

"This reads to me like a classical RO1 project," Board member Harry Eagle said. "It is classical basic research. I don't think we should go so far as to lay out the techniques and the workscope (as would be permitted NCI staff in a cooperative agreement)."

"I agree with you," DeWys said. "But the cooperative agreement has many variations. In this instance, I see us as being very close to the boundary line between cooperative agreements and RO1s. The cooperative agreement will allow us to have annual meetings, to collaborate, to have more interaction between investigators than is inherent in RO1s. We don't intend to provide detailed direction."

After Eagle insisted that such collaboration could be had with RO1s, DCPC Director Peter Greenwald said, "We're close. Our position is that we prefer the cooperative agreement (in this case) but will give as much flexibility as possible. And we could get overruled by NIH (and told to make it an RO1)."

"Having raised the issue, I'm sure that Peter and his staff will be sensitive to it," Eagle said, and the motion to approve the RFA as a cooperative agreement was approved unanimously.

(The remaining concepts and the Board's actions will be published next week in The Cancer Letter).

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.

SOURCES SOUGHT

Project No. NCI-CN-45178-46
Title: Preclinical toxicology of chemopreventive agents.
Deadline: Feb. 13 for required statements and attachments.

NCI is seeking small business sources capable of responding to a potential request for proposals to conduct preclinical toxicology of chemopreventive agents.

A primary function of the chemoprevention program is the identification and evaluation of agents for possible utilization in clinical trials in humans. Candidate agents whether from natural sources or synthesized have been evaluated for anticancer efficacy in various screening tests. However, before a decision can be made as to their suitability for the phase 1 clinical trials in humans, they must be evaluated for toxicity in animals.

The basic objectives of this project will be to evaluate the acute, subacute/subchronic and chronic toxicity of designated agents. These studies will be performed in animals (rodents and dogs) and will include conventional short term studies, lifetime studies in rodents, and multigeneration teratogenicity studies. The agents would be given primarily by the oral route.

A summary of the tasks required:
Task I. Protocol Studies

A. Develop and finalize a model chemoprevention preclinical toxicology protocol, based on the outlined procedures for preclinical toxicologic evaluation of cancer chemoprevention agents as amplified above.

B. Develop an agent specific plan for preclinical toxicology testing preparatory to human clinical chemoprevention trials. This will include a specific protocol based upon the model chemoprevention preclinical toxicology protocol.

C. Perform studies

Task II. Pharmacokinetic Studies

A, Develop a protocol for a pharmacokinetic profile for each investigational agent. The protocol and profile may build upon published data and data provided by the manufacturer of the agent or NCI staff. Additional studies necessary to complete the pharmacokinetic profiles for the rat and the dog shall be performed by the contractor. Pharmacokinetic studies will provide parameters of absorption, blood concentration time profiles, distribution and excretion. Data on tissue concentration of the test agent, determined as part of the toxicology testing, shall contribute to the pharmacokinetic profile. Information on major metabolites shall be included in order to provide as complete a picture as possible of the overall distribution and fate of the test agent. Appropriate modeling shall be applied to determine probable pattern of distribution and compartmentalization. The first studies performed shall be designed to provide absorption and half life information necessary to plan the 90 day rat and dog toxicology studies.

B. Perform studies.

Task III. Teratogenicity Studies

A. Develop and perform teratogenicity studies on chemopreventive agents that have the prospect of being administered to women of childbearing potential. These will be the standard segment 1, 2, and 3 studies as described in "Guidelines for Reproduction Studies for Safety Evaluation of Drugs for Human Use," available from the contracting officer upon request. For efficiency the male rats from the three month oral study may be used to initiate the male related reproductive toxicity studies.

Performance of carcinogenesis bioassays, while a component of the overall animal toxicology plan, will not be the responsibility of the offeror under this contract. The offeror should demonstrate knowledge of the prelimninary data necessary for the conduct of such studies and be aware of the responsibility under this proposed contract to provide data and work cooperatively with the facility performing the carcinogensis studies.

B. Technical Evaluation Criteria

Potential small business offerors who respond to this sources sought announcement must demonstrate the capability to develop and perform all aspects of the work described above. Specifically, potential offerors must:

1. Submit evidence of familiarity with a general study design, conduct, and data to undertake the tasks described including appropriate data handling capabilities. Examples of previous studies may be submitted. Describe procedures for existence of utilization and adherence to quality control procedures in areas such as animal health, hematology, clinical chemistry and histopathology. Examples of previous work may be submitted.

Describe health and safety program including awareness of hazards associated with use of experimental agents.

2. General personnel requirements including documentation of experience, training, education of principal investigator and other members of the professional staff. Requirements set forth in Good Laboratory Practice Standards for Health Effects will generally apply. The toxicologist must provide documentation of experience and background in chronic toxicity testing and must be board certified or eligible for American Board of Toxicology. A board certified or board eligible pathologist is also required. The veterinarian must be board certified by the American College of Laboratory Animal Medicine. Clinical laboratory technical assistants must be certified by the American Society of Clinical Pathology. Animal care employees must be certified or eligible for certification by American Assn. of Laboratory Animal Science.

3. Suitability of facilities and availability of equipment appropriate to accomplish tasks. Animal holding facilities for dogs must be provided with adequate environmental containment. Animal facilities must meet LTAALAS specifications; identify space dimensions and the extent of caging and equipment for cage cleaning. Facility must demonstrate design and maintenance capability to meet chemical and biological control; compliance with NCI carcinogens and handling standards; federal and state occupational health and environmental laws and regulations. On site data handling (computer), chemical and pathological facilities should be described.

4. Organization background and experience. Cite specific examples of previous experience including chronic toxicity studies conducted with dogs, examples of where data has been utilized in submissions for INDs for drugs in human use; examples of pharmacokinetic studies conducted and completed; reproductive and teratogenic studies completed; letters of recommendation from pharmaceutical industry or other users of services.

Small businesses (number of employees does not exceed 500 persons) which believe they posses the capability to perform the above tasks are invited to submit a statement of corporate qualifications. This statement must address the preceding technical evaluation criteria and may not exceed 20 pages (8 1/2 x 11 inches) of double spaced, typewritten, original text. Preprinted statements of corporate capability may be attached as additional information. Resumes of key personnel are required and may also be attached to the original text. Letters of recommendation from clients for whom similar work has been accomplished must also be attached.

Submit six copies of the required statement and attachments.

Contract Specialist: Deborah Smith-Castle
RCB Blair Bldg Rm 2A07
301-427-8745

RFP NCI-CO-44017-30
Title: Cancer Information Dissemination and Analysis Center (CIDAC)—Therapy
Deadline: Feb. 27

NCI is seeking an organization with scientific and technical capabilities to assume the operation of a Cancer Information Dissemination and Analysis Center for the International Cancer Research Data Bank Program. One contract will be awarded in the subject area of cancer diagnosis and therapy. Major activities include:

1. Assuming regular production of 21 different CANCERGRAMS, monthly current awareness bulletins containing 30-100 abstracts of recently published cancer research. For each CANCERGRAM topic, a CIDAC staff member (subject specialist) monthly screens abstracts retrieved from computerized searching of an ICRDB data base and prepares a package of some 50-100 abstracts for review by a consultant (identified by the CIDAC) who is currently involved in research pertinent to the CANCERGRAM topic area and who need not be an employee of the organization.

2. Producing annually five different ONCOLOGY OVERVIEWS, retrospective compilations of 100-500 selected abstracts on high interest cancer research topics. These publications are developed by the subject specialists in consultation with researchers (identified by the CIDAC) who are recognized as experts in the subject area of each ONCOLOGY OVERVIEW.

3. Responding rapidly to requests for information in specific cancer research subject areas. Subject specialists must be able to interact knowledgeably and professionally with scientists requesting information, and formulate and use computer search strategies for retrieving the needed information from ICRDB data bases.

The organization must have previous experience in analysis and processing of cancer research information of similar biomedical information as well as involvement with cancer research (preferably either in house or via a teaming arrangement). The project director must have a PhD or MD in a biomedical subject relevant to cancer research areas covered by the CIDAC, current or very recent involvement in cancer related research, and administrative experience. Subject specialists must all have at least an MS or equivalent (approximately half should have a PhD or equivalent) plus research experience in a biomedical subject area relevant to the CIDAC subject area and, collectively, they must be able to cover all subject areas relevant to the CIDAC. The consultants must all have a PhD or MD and current research involvement in biomedical subaject areas directly relevant to the CANCERGRAM each will be reviewing. Collectively, they must cover all CANCERGRAM topics within the CIDAC'S purview, and they should be located in sufficiently close proximity to the CIDAC office to permit rapid turn around in their review of CANCERGRAM materials.

It is anticipated that the project will require each year the following staffing levels (person years): Project director, 0.25-0.5; subject specialists, 4.0 (including full and part time employees); and clerical/support staff 2.0. Consultant services may be required at the rate of approximately 0.5 days per month per CANCERGRAM and 1-3 days (total) per ONCOLOGY OVERVIEW. This project is for a four year period.

Contract Specialist: Elsa Carlton
RCB Blair Bldg Rm 314
301-427-8745

SOURCES SOUGHT

Title: Antitumor prescreen studies, in vitro and in vivo development, and a study of potential antitumor agents from marine and other unique sources.
Deadline: Feb. 5

The Natural Products Branch of NCI will conduct negotiations for the conduct of fermentation and related research to discover, identify, or develop microbial products that are of significance to cancer chemotherapy. Interested persons are invited to identify their interest and capability to respond to such requirement or to submit proposals.

Contracting Officer: Helen Kelly
RCB Blair Bldg Rm 228
301-427-8745

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.