THE CANCER LETTER

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NEW FUNDING MECHANISMS – COOPERATIVE AGREEMENT, CONSORTIUM GRANT – PROPOSED FOR CLINICAL GROUPS

The clinical trials review last week by NCI's Div. of Cancer Treatment Board of Scientific Counselors, awaited with considerable apprehension by the Cooperative Groups, did not produce the intense criticism or recommendations for drastic changes feared by some group members. That could still happen—a committee will review reports prepared by the groups and others, consider Board member comments made during the two day meeting along with recommendations by DCT Director Vincent DeVita, and submit its own recommendations to the Board next October.

It does not appear that those ultimate recommendations will include any of the dire possibilities feared by the groups. Those ranged from

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In Brief

CONTROL OF MANY CANCER FORMS BY END OF THE CENTURY, FREDRICKSON TELLS HOUSE COMMITTEE

"IT'S MY BELIEF that by the end of this century, we will understand the basic mechanisms of the cause of cancer, and we'll be able to use that knowledge to control many forms of the disease," NIH Director Donald Fredrickson told the House HEW Appropriations Subcommittee. Progress in genetics research is "one of the great intellectual achievements in the history of man, and the genetic code was cracked by scientists in the NIH intramural program," Fredrickson said. . . . **SURVEY OF CASES** of primary malignant liver tumor in 477 hospitals from 1970-75 neither definitely confirms nor disproves an association between oral contraceptive use and such tumors, according to a report by Josef Vana and Gerald Murphy in the March issue of the *New York State Journal of Medicine.* Of 126 hepatocellular carcinomas in all females a history of oral contraceptive use was found in 31%; in the 26-35 age group, it was 43%. The writers suggested that a possibility of the hazard does exist and called for further systematic study. . . . **CONSENSUS DEVELOPMENT** conference on the primary management of breast cancer is scheduled for NIH June 5. It will be sponsored by NCI's Div. of Cancer Treatment and the NIH Office of Medical Application for Research. . . . **HEARINGS ON** preclinical and clinical drug testing by the pharmaceutical industry will be resumed April 25 by Sen. Kennedy's Health Subcommittee, 10 a.m., Room 154, Russell Bldg. . . . **SHORT COURSE** on nursing oncology will be conducted by the Tulane School of Medicine April 16-May 25. The new program will be offered several times a year. Contact R. Davilene Carter, Tulane Medical Center, 1430 Tulane Ave., New Orleans 70112. . . . **CLEARINGHOUSE ON** Environmental Carcinogens Data Evaluation/Risk Assessment Subgroup will meet May 1, 9 a.m., NIH Bldg 31 Room 10, with the entire meeting open to the public.

NEW FUNDING MECHANISMS FOR GROUPS WOULD IMPROVE FLEXIBILITY, DCT SAYS

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outright abolition of the groups to substantial budget cuts to mandatory reorganization into geographical/-regional groups.

Instead, the most significant change could be one given first priority by DeVita and which might well be welcomed by the groups—a switch to new funding mechanisms, the "cooperative agreement" and "consortium grant."

HEW is in the process of developing guidelines for cooperative agreements, authorized by Congress last year, which apparently will have some features of both the grant and contract mechanisms.

DCT Deputy Director Saul Schepartz compared cooperative agreements with traditional research grants:

Cooperative agreements would be initiated by NCI (and other NIH institutes); traditional grants are investigator initiated. Cooperative agreements would have detailed program definitions, which would be developed within NIH guidelines; with traditional grants the investigator defines the program without guidelines. NCI program staff involvement would be substantial with the cooperative agreements, while there is little or none with traditional grants.

Cooperative groups are funded now through cooperative group grants (R10s) which are reviewed by the Clinical Cancer Investigation Review Committee. Cooperative agreements for the groups would continue to be reviewed by the CCIRC, with final review and approval by the National Cancer Advisory Board. NCAB approval is required by law for all NCI grants exceeding $35,000.

Schepartz said cooperative agreements would permit a high degree of flexibility, for the groups as well as for other clinical investigators.

DeVita said if the cooperative agreement mechanism does become available, he would recommend also that they be used to support other DCT clinical research activities such as the GI Tumor Study Group and the Ovarian Cancer Study Group. Those groups now are funded with contracts. The only DCT clinical trials that would remain under contracts would be the phase I and II studies, DeVita said.

Another funding mechanism that could be used to support clinical treatment research would be consortium grants, DeVita suggested. Schepartz explained how these would work:

One grant would be awarded to a lead institution which would direct the overall project and perform a significant portion of the work. The lead institution would be permitted to subcontract with other institutions which would perform portions of the programmatic activities. NCI would review only the lead institution, leaving it up to the principal investigator to monitor and review the supporting institutions.

DeVita said consortium grants could be used for group chairmen and through subcontracts to selected others in the group or to all members of the group. "This would allow the review process to deal with the science and get around the issue of priority scores for people contributing resources to the group," DeVita said. Consortium grants also would be reviewed by the CCIRC.

One problem the Cooperative Groups have encountered is that the CCIRC is required to review individual members of each group, as well as the overall activities of the group itself. Priority scores are assigned to each member, and lower ones can lose their funding. This sometimes is unfair and inappropriate, when the work or contribution of those members is important to the group but does not fit the review criteria.

DeVita said consortium grants could be used to support intergroup protocols or very large group protocols such as the National Surgical Adjuvant Breast Project. They also could help facilitate geographic orientation of groups.

Under cooperative agreements, projects "would be defined as they are now," DeVita said. "We would spell out the government's involvement. We could spell out in the agreement the extent of cooperative funding that would be needed in the future. NCI might be persuaded to put additional resources into the groups, with Board concept review."

Barth Hoogstraten, chairman of the Southwest Oncology Group, asked that, considering the regulations that will accompany cooperative agreements, "Where will that leave academic freedom?"

"There will be zero difference from the way it is now," DeVita said. "Groups will have the freedom not to be changed at all. It ought to make it easier for you to reach out if you want to, with consortium grants."

"How will this new instrument, with our flat (NCI) budget, promote more research for the dollar?" asked Board member Henry Kaplan.

"Nothing makes a flat budget palatable," DeVita said. "The groups will have more flexibility. The way we can write the agreement could make it easier for a group chairman to withdraw support from someone who is not contributing."

Kaplan suggested that geographic orientation of groups could result in some savings, particularly travel. "If we knew that restructuring would buy us more research, it would be more palatable," Kaplan said. "My own bias is that it would. There are groups and sections of groups that would like to do this."

DeVita emphasized that no group would be forced to reorient itself along geographical or regional lines. Some groups may want to undertake arrangements with community oncologists in certain regions, perhaps with some of the regional, unfunded groups that have been or are being organized. They would be en-

couraged to do so, DeVita said, and the flexibility of the new funding mechanisms would facilitate it. "Improved access to patients may be enhanced by more attention to geography by the groups," DeVita said.

DeVita opened the review with a statement which described the rationale for the review, problems, and possible alternatives (excerpts follow):

Clinical treatment research; definition, budget and problems

A. Clinical treatment research refers to research on human subjects encompassing any or all aspects of treatment involving individuals or groups of cancer patients, including validation of preclinical research findings in a clinical setting. Clinical treatment research is particularly concerned with efforts to determine the best possible treatment of each type of human cancer based on knowledge of the natural history of the disease. Clinical treatment research includes all clinical trials, but not all clinical research involving human subjects and materials.

B. Clinical treatment research by this definition consumes 10.5% of the NCI budget and includes all clinical trials research conducted in the institute under any existing mechanisms. This amount of dollars includes funds for support services for clinical trials and a share of the NCI management fund.

C. There are characteristics of clinical treatment research that are unique. Research with human subjects is generally more expensive than preclinical research and there are ethical considerations which complicate study logistics. Duplication of clinical treatment research studies is a problem, involving both ethics and fiscal considerations. Duplication presents an ethical problem since it implies the research is utilizing more subjects than are necessary to answer a specific question. Fiscally, duplication means that resources are consumed beyond what is necessary to answer a question.

Reasons for the Board review of the clinical trials program

A. Program reviews are a routine responsibility of divisional boards.

B. Between 1974-78 there was a real increase in the purchasing power of the Cooperative Group program beyond the increase of some other NCI programs. The range of increase was from zero to 300%. The average increase in the budget of the Cooperative Groups is approximately 70%.

C. Previous reviews of the Cooperative Group program recommended continued review at reasonable intervals. The main difference between this review and the reviews conducted at the Williamsburg and Potomac conferences is that the DCT board will serve as the reviewing body because of its overview responsibility for DCT programs.

D. The board will review the progress in the clinical trials program scientifically and operationally since 1974.

E. Finally, the board will be asked to make recommendations on specific questions raised from various quarters over the past few years in reference to the clinical trials programs.

Questions for board consideration

A. The climate for success.

1. Past clinical trials have resulted in the successful treatment and cure os some malignancies. What was the climate for success? What can we learn from that climate to improve the program in the future?

2. Was there a particular type of research instrument, associated with successful clinical trials, that provided the flexibility for past advances in clinical treatment research? Were they Cooperative Group grants (R10), program project grants (P01), regular research grants (R01s), or core type grants?

B. The organizational structure

1. Do researchers in the current clinical trials program have access to the proper patient population for future multimodality studies?

2. Do investigators of all disciplines in the clinical trials program have equal access to the resources?

3. Does the current organization structure foster duplication of effort in clinical treatment research?

4. Are there differences between disease-oriented Cooperative Groups and multi-disease groups in the capacity to innovate and to complete clinical treatment research projects? Should more or less emphasis be given to specialty oriented groups?

5. Should support services for the clinical trials program be centralized more than they now are? For example, should NCI support statistical centers, pathology reference centers, etc., for clinical trials regardless of the mechanism used, or should these remain decentralized within each existing program?

6. Are there sufficient existing guidelines and flexibility to allow for organizational changes to take place within the clinical trials program to adjust to changing times?

7. If we were starting the clinical trials program anew today, would we use the same organizational structure? If not, would geography and the existence of centers and control programs, not available in 1955, influence the organizational structure? If so, should we encourage a change in the organizational structure of the clinical trials program? If the answer is yes, how should such organizational changes be made and at what rate of speed?

Related to this subject is the question of optimal group size and number of groups, the mechanism for initiation of new groups and if and how proliferation of groups should be controlled.

C. The research instrument

1. Since all other institutes at NIH use the contract for clinical trials research, in order to focus their clinical trials, control expenditures, and avoid duplication, should DCT also use this mechanism exclusively?

2. If not, are we using the proper research instrument, or mix of instruments, for clinical treatment research to allow maximum freedom for investigator initiative, coordination and flexible adjustment to new opportunities? The options are the Cooperative Group grant (R10), the program project grant (P01), the regular research grant (R01), the consortium grant, the contract, the cooperative agreement, and a mixture of contracts and grants.

3. Clinical treatment research studies are often prolonged because of the indolent natural history of some human cancers and requirements for long followup period after treatment is terminated. Should clinical treatment research grants be approved routinely for five rather than three years, in order to avoid unnecessary paperwork and risk loss of the data base?

D. The review process

1. How can the review process for clinical treatment research be improved?

2. Is the peer review system, as currently constructed, biased against clinical treatment research for non-scientific reasons, i.e., budget, ethical considerations and logistical problems?

3. Do clinical treatment research projects, submitted as R01 grants, receive review comparable to those grants submitted as R10 or P01 grants?

4. Are the study sections that review other than coopera-

tive group grants adequately constituted to review clinical treatment research?

5. Do the CCIRC and other study sections give too much emphasis to form and logistics (patient accrual, mixture of investigators, data collection, etc.) rather than to the science of the clinical protocol—the therapeutic hypothesis under test?

6. Do we have need for a new or modified study section for cancer clinical treatment research grants submitted from individual investigators?

E. The role of the DCT staff

1. What is the role of DCT staff in encouraging and developing studies in gap areas? Are the current approaches, using input from disease discussion groups, disease oriented workshops, and DCT staff disease coordinators and drug monitors sufficient to identify and promulgate clinical trials in gap areas?

2. How can DCT staff meet regulatory responsibilities (to the FDA) and fiscal responsibilities (avoiding duplicate research trials and discouraging marginal clinical trials) without interfering with investigator initiative?

Summary

"It is my personal view that clinical trials often test fundamental therapeutic hypothesis," DeVita said. "At the very least, they represent the effector arm of a wide variety of preclinical research programs and they have clearly yielded important results. This review and these questions were promulgated primarily because of a firm belief that we face unusual opportunities to further reduce cancer mortality in the U.S. in a significant way in the next decade. To accomplish this end we all need to assure the most responsive organization possible. I congratulate all who are participating in the review for their healthy attitudes and willingness to review and be reviewed. We all look forward to the final report."

The committee appointed by board Chairman John Ultmann to collate and consider the reports and develop recommendations is chaired by Sydney Salmon, Univ. of Arizona. Other members are Rose Ruth Ellison, Columbia; Sharon Murphy, St. Jude's; and E. Carmack Holmes, UCLA.

Presentations by Cooperative Group members and others, with the accompanying board discussion, will appear in subsequent issues of ***The Cancer Letter.***

UPTON, OTHERS PRESENT MORE EVIDENCE OF CANCER PROGRAM ACCOMPLISHMENTS

NCI Director Arthur Upton presented a comprehensive statement of National Cancer Program accomplishments at the oversight hearings by Sen. Edward Kennedy's Health Subcommittee.

Upton's statement included progress in treatment of cancer, which was described in greater detail by the report compiled by the Div. of Cancer Treatment and submitted in writing to the subcommittee (***The Cancer Letter,*** March 23 and 30). That portion of Upton's statement is excluded from the following summary:

Cause & Prevention

The Bioassay Program has tested 247 chemicals, 104 of which were carcinogenic under the test conditions. Testing will continue, along with efforts to develop better interpretation of the tests in estimating risks to man.

About 50 environmental agents have been associated with increased occurrence of cancer in exposed persons, many of them associated with occupational exposure.

Intensive efforts are in progress to develop rapid and inexpensive lab tests of chemicals for carcinogenic potential.

Research on chemical carcinogenesis has led to a number of discoveries—that many chemicals are actually pre-carcinogens; that synthetic chemicals related to vitamin A, the retinoids, have potential for inhibiting development of epithelial cancers, resulting in clinical trials to determine its effectiveness; and that a potential exists for prevention of cancer by dietary means.

Detection & Diagnosis

The Breast Cancer Detection & Demonstration Project has demonstrated that x-ray mammography and physical examination in combination are effective in screening asymptomatic women age 50 and older to detect early breast cancer.

The uterine cervical cancer screening program conducted with 35 state and territorial health departments has demonstrated it is feasible to mobilize statewide health care systems to motivate high risk, hard to reach women to have the Pap test.

A large screening study of heavy cigarette smokers is evaluating the combined use of sputum cytology and chest x-rays for diagnosis of early lung cancer. Results thus far indicate that cancers can be found when they are small and presumably before they have spread. Lung cancer is so highly malignant, however, that further study is needed to determine whether treatment of these small cancers will lead to cure.

Research to improve early detection includes a major effort to identify and purify biological markers —antigens, enzymes or hormones produced by cancers. Carcinoembryonic antigens are useful as markers for monitoring response of colon cancer to treatment. A test for estrogen receptor protein in breast cancer tissue has been developed.

Machines are being developed to help read Pap test specimens, using laser beams. Use of x-rays has been greatly improved with use of new sensitive films and computers into radiologic diagnosis. Computerized tomography is a major advance.

NCI is involved in development of improved flexible fiberoptic endoscopes to examine inner organs. NCI is continuing research on noninvasive techniques for detecting breast cancer, such as ultrasound, thermography and biological markers.

Basic Research

Advances in the past two years using recombinant DNA techniques have increased the ability of scientists to produce enough copies of individual genes for

studies of how genes function.

An association was demonstrated between a defective DNA repair system and susceptibility to development of skin cancer caused by ultraviolet radiation. These results have increased our understanding of how radiation causes cancer and how cells are usually protected from radiation damage.

Investigators working with the Rous sarcoma virus have identified the protein product that is believed to be responsible for transforming the infected cells into cancer cells. This protein is not a part of the virus itself, but a product coded for by a viral gene. The identification of this transforming protein represents a milestone because it may help expalin the molecular mechanism of the cancer change. Moreover, it suggests that study of gene products of this sort may ultimately lead to the prevention, or even the treatment, of cancer.

Investigators have found that specific sites exposed on the membranes of virus-transformed cells can be masked experimentally, causing the cells to behave normally. These sites, which are exposed on cancer cells throughout the cell cycle are exposed on the surface of normal cells only during cell division. On the basis of such results, investigators have suggested that metastatic potential is determined by alterations in cancer cell membranes.

It is suspected that abnormal cells that develop regularly in the body can grow to a tumor mass only if they escape the action of the immune system. The main evidence in support of an immune surveillance mechanism is the higher incidence of certain types of cancer in ummunologically deficient animals and humans. Scientists have learned that the cells of the immune system interact with one another in an enormously complex network. New knowledge about suppressor, helper, and natural killer cells in the system has brought closer the development of highly specific procedures for helping the immune system destroy cancer cells.

Cancer Control

Communication with community physicians, who are the first to see and treat more than 80% of cancer patients, is vital. Twenty-five networks linking community hospitals with cancer centers or major hospitals demonstrate the most effective therapies and other intervention methods for cancer of the breast, head and neck, and leukemia/lymphoma. NCI supports clinical oncology programs in which primary hospitals work with nearby community hospitals, outreach programs associated with the comprehensive cancer centers, and cancer control extensions of the Clinical Cooperative Groups.

Other NCI cancer control efforts include nursing oncology education, occupational education programs, pain control, field testing of hospice care for terminally ill cancer patients, centers for radiological physics to improve the quality of diagnostic and therapeutic radiology, studies on the psychosocial impact of cancer, and the six community based cancer control programs.

Upton's statement also described the massive efforts NCI has undertaken in information dissemination through publications, special projects such as the HEW DES task force, the International Cancer Research Data Bank, responses to more than 100,000 inquiries a year from patients, their families, and professionals, and the Cancer Information System.

He also referred briefly to the Cancer Centers Program, with the recognition now of 21 comprehensive centers (there were three when the Cancer Act was passed in 1971), and the support of 29 clinical centers and 19 basic science centers.

Emil (Tom) Frei, director of the Sidney Farber Cancer Institute, described progress in cancer treatment which supported the Div. of Cancer Treatment's presentation.

"Cancer is a highly complex clinical problem and because cancer is an abnormality in growth, it represents a very fundamental biological problem," Frei said. "Hence, progress in cancer prevention and treatment will require support for a broad range of basic and clinical scientific disciplines. The aforementioned progress in cancer treatment derives from both basic and clinical (applied) research. Rapid advances in our concepts, scientific methodology, and knowledge in basic and clinical research are in process and can be expected to impact increasingly on the prevention and treatment of cancer.

"Cancer is a vigorous disease and requires vigorous treatment. Surgery, radiotherapy, and chemotherapy may all be associated with unpleasant side effects. With emerging concepts in tumor biology and with more effective systemic treatment, mainly in the form of chemotherapy, it has become possible to improve the quality of life for the cancer patient. For example, radical mastectomy for breast cancer is being replaced by simpler procedures, and amputation of the extremity for bone cancer is being replaced in many patients by limb-preserving procedures.

"Nutritional studies have indicated that special dietary approaches can improve the sense of well being and quality of life for cancer patients. Similarly, we have developed techniques for reducing or treating certain side effects of chemotherapy such as the nausea and vomiting which occur with some drugs. Physicians, nurses, and paramedical personnel responsible for the care of cancer patients are developing increasing concern for, and effective means of, allaying some of the psychosocial consequences of cancer affecting patients and their families.

"The support for cancer research through NCI and the National Cancer Act of 1971 has resulted in a progressive and accelerating increase in our knowledge concerning the fundamental nature of cancer and in our ability to diagnose and treat this disease.

While we have made progress, we still have a long way to go. Support for cancer research through the National Cancer Institute has been, and will increasingly be, a sound investment towards control of the second most devastating public health problem facing the American people."

Grace Monaco, representing the Candlelighters, discussed problems affecting pediatric cancer patients and their families.

Of particular concern was the financial impact, especially for those families not living close to the major pediatric cancer centers. Monaco described a proposal by the Candlelighters for three levels of care:

"The proposal would work toward a guarantee that all children with cancer will have ready access to the most expeditious, safe and effective care available.

"Primary (Level I)—Located in the child's community, and providing home and outpatient/office health supervision with particular regard to normal growth and development, prevention of infectious disease, treatment of minor infections, liaison with school and community, and family counseling by professional and by peer group. This would be provided by a pediatrician, family practitioner, internist or pediatric oncologist.

"Secondary (Level II)—The pediatric cancer care facility, usually connected with a children's hospital located close to the child's community and providing outpatient and inpatient care for the particular disease and its complications. This would include administering anticancer drugs according to protocol; maintaining treatment records, and managing moderately severe infections, bleeding episodes, anemia, nutritional and metabolic disorders. This would be provided by a pediatric hematologist/oncologist or a pediatrician with additional training or experience in pediatric oncology. Also, this facility should provide access to childlife specialists, psychosocial support by professional or peer group as well as undertaking an education program directed to medical and nursing students, graduate trainees, and practitioners.

"Tertiary (Level III)—A regional children's cancer center. This would be accessible to provide confirmation or correction of initial diagnosis, subcategorization and staging, complete evaluation of the child's needs through discussion among team members and with child and family, assignment to protocol study with consent of child and parents, initiation of therapy, conduct of any phase I experimental treatment, basic and clinical research relevant to children's cancer, and training of oncologists in research and practice. The child and/or his specimens and findings would be periodically sent to the center for reassessment, change in therapy, investigative studies not available at the secondary level and documentation of disease course."

Jack White, director of the Howard Univ. Cancer Center, presented figures showing the disproportionate increase in cancer rates among blacks. The cancer death rate among black males was less than 50% of that for white males in 1920; by 1975 the mortality rate for black males was 20% higher than for white males, White said.

"There is a tendency to attribute these changes to advanced stages of the disease when first found in the black population and to defects in the health services they receive," White said. "There are reasons to believe that other factors are probably more important and these seem to be largely environmental."

Jonathan Rhoads, chairman of the National Cancer Advisory Board, pointed out that NCI is turning down about seven of 10 approved research projects because of funding limits. "How much progress in cancer research has been lost in this way no one knows."

Cancer Program Is Saving More Lives Than Polio Vaccine, Garb Points Out

Solomon Garb, chairman of the Citizens Committee for the Conquest of Cancer and one of the early leaders in the effort that resulted in the National Cancer Act of 1971, submitted this statement to the Kennedy Subcommittee:

"Sometimes a simple comparison can be more revealing than complicated analyses. Since a number of people have compared the cancer program to the conquest of polio, I will use the same comparison.

"In the 10 years before the use of polio vaccine, the average number of young Americans dying of polio each year was 1,750. With our increased population, we can estimate that if not for the polio vaccine, about 2,500 young Americans would die of polio this year. Probably an equal number would suffer devastating paralysis like that requiring an iron lung. Altogether, then, the polio vaccine will save about 5,000 young Americans from death or devastating paralysis this year.

"From among the many accomplishments of the cancer program, let us look at four cancers that also strike young Americans—acute lymphocytic leukemia of children, Hodgkin's disease, cancer of the testis, and primary bone sarcoma. If not for the cancer program, the five year cure rate for these would be close to zero. Because of the cancer program, the five year cure rate for patients afflicted this year will be over 50%—better than half. The number of young Americans who will be afflicted with one of these cancers this year is 15,050. The lives of at least 7,500 will be saved by the cancer program, just with these four cancers!

"In summary, in 1979, polio vaccine will save about 5,000, while the cancer program will save more than 7,500 (with those four diseases alone). We are winning the fight against cancer."

Benjamin Byrd, past president of the American Cancer Society, called for a redefinition of cancer control, with emphasis on application of diagnosis and treatment research through cancer centers.

MEMBERS OF SENATE, HOUSE LABOR-HEW APPROPRIATIONS SUBCOMMITTEES LISTED

Senate and House Appropriations subcommittees are continuing their hearings on the fiscal 1980 money bills, with the markups (subcommittee recommendations for each line item in the budgets) to come later in the spring.

Those wishing to contact members of the Senate Labor-HEW Appropriations Subcommittee may do so by writing to the individual senator, Senate Office Building, Washington D.C. 20510. Members of the subcommittee are:

Democrats—Warren Magnuson (Wash.), chairman; Robert Byrd (W. Va.), William Proxmire (Wisc.), Ernest Hollings (S. Car.), Thomas Eagleton (Mo.), Birch Bayh (Ind.), Lawton Chiles (Fla.), Quentin Burdick (N. Dak.), and Daniel Inouye (Hawaii). Republicans—Richard Schweiker (Pa.), Charles Mathias (Md.), Mark Hatfield (Ore.), Lowell Weicker (Conn.), and Harrison Schmitt (N. Mex.).

House members may be contacted by writing to the individual congressman, House Office Building, Washington D.C. 20515. Members of the subcommittee are:

Democrats—William Natcher (Ky.), chairman; Daniel Flood (Pa.), Neal Smith (Iowa), Edward Patten (N.J.), David Obey (Wisc.), Edward Roybal (Calif.), Louis Stokes (Ohio), and Joseph Early (Mass.). Republicans—Robert Michel (Ill.), Silvio Conte (Mass.), George O'Brien (Ill.), and Carl Pursell (Mich.).

RFPs AVAILABLE

Requests for proposal described here pertain to contracts planned for award by the National Cancer Institute, unless otherwise noted. Write to the Contracting Officer or Contract Specialist for copies of the RFP, citing the RFP number. Some listings will show the phone number of the Contract Specialist, who will respond to questions. Listings identify the respective sections of the Research Contracts Branch which are issuing the RFPs. Address requests to the contract officer or specialist named, NCI Research Contracts Branch, the appropriate section, as follows:
Biology & Diagnosis Section and Viral Oncology & Field Studies Section—Landow Building, Bethesda, Md. 20014; Control & Rehabilitation Section, Carcinogenesis Section, Treatment Section, Office of the Director Section—Blair Building, Silver Spring, Md. 20910.
Deadline date shown for each listing is the final day for receipt of the completed proposal unless otherwise indicated.

SOURCES SOUGHT

Title: *Centers for Radiological Physics Coordination Program*
Deadline: *April 30 (for qualifying responses)*

NCI proposes to contract with the American Assn. of Physicists in Medicine to provide a coordination program for the Centers for Radiological Physics (CRP) located throughout the country. The primary objective of the CRPs is to ensure uniform high quality of radiological physics review services at clinical facilities where the Div. of Cancer Control & Rehabilitation supports operations involving diagnostic and therapeutic radiology.

The mission of the coordination program also will be to insure utilization of accepted procedures, establish methods to evaluate the CRPs and evaluate the impact on cancer control, monitor existing linkage for communication to the medical physics community and encourage on a national scale improvement in the quality of radiological physics. It is preferred but not mandatory for the contractor to provide an office in the metropolitan Washington area staff with two full time medical physicists, necessary support staff, and additional consultants in medical physics as required.

Organizations desiring to be considered must meet the following criteria:

Nationally recognized in the field of medical physics and must have accesss to the medical physics community; access to nationally recognized experts in the fields of medical physics, health physics, and radiology; full time scientific and management staff with a demonstrated record of experience in a related activity.

Responses should not include cost or pricing information. Concise responses directed specifically to the points mentioned above are requested. An RFP will be sent to qualified respondents. Unqualified organizations will be notified in order to save them the expense and effort of submitting proposals. It should be noted, however, that this procedure does not preclude any organization from requesting an RFP and submitting a proposal.

Organizations responding to this announcement must submit eight copies of letters describing their qualifications.

Contracting Officer: James Cavanagh
Control & Rehabilitation
301-427-7984

RFP NCI-CN-95458-05

Title: *Training programs for maxillofacial prosthodontists and maxillofacial dental technicians*
Deadline: *Approximately June 20*

The Div. of Cancer Control & Rehabilitation is soliciting proposals from institutions that are either accredited by the Council on Dental Education of the American Dental Assn. or those institutions that can present in their proposal documentation that such accreditation is forthcoming. This procurement provides for the implementation of comprehensive training programs for maxillofacial prosthodontists in the specialized techniques used in protective shield-

ing, functional and cosmetic restoration requisite for rehabilitation of the head and neck cancer patient.

Many of the treatment procedures for patients with cancer of the head and neck result in serious functional and cosmetic impairments which require lengthy and complicated restoration procedures. Cooperative efforts between surgeons and maxillofacial prosthodontists and other specialties are required for the rehabilitation and functional restoration of these patients. There is a shortage of maxillofacial prosthodontists and dental technicians required for the rehabilitation and functional restoration of these patients.

Objectives of this procurement:

A. To provide for the training of additional prosthodontists in the use of maxillofacial prosthetics for rehabilitation of patients with cancer of the head and neck.

B. To provide for the training of additional maxillofacial dental technicians in the fabrication of prosthetic devices and appliances necessary to the rehabilitation of patients with head and neck cancer.

Contracting Officer: Shelby Buford
Control & Rehabilitation
301-427-7984

RFP NO1-CP-95615-56

Title: *Chemical services support for carcinogenesis bioassay testing*

Deadline: *June 12*

NCI is interested in establishing a contract to provide chemical procurement, analyses, storage, repackaging and distribution services in support of the activities of the Carcinogenesis Testing Program. The contractor will serve as an analytical resource for the program, performing analyses of chemicals for identity, assay and stability; formulation of protocols for chemical mixes; analysis of feed samples for toxic components; and analysis of dose-feed samples. Special tasks will also include isolation and identification of impurities and other analytical problems.

It is expected that approximately 18 professional man-years per year will be needed for this project.

NCI is also interested in initiating a contract to establish a facility (chemical repository) for the safe storage, repackaging and distribution of bioassay chemicals. It is expected that approximately one professional man year per year will be needed for this project. A 60 month cost reimbursement completion type contract is anticipated for an effective pursuit of this project.

Contract Specialist: Ann Peale
Carcinogenesis
301-427-7574

RFP NCI-CM-97287

Title: *Operation of an animal virological diagnostic laboratory*

Deadline: *Approximately April 27*

The successful offeror will operate virus serum diagnostic laboratories for NCI. Serum samples are submitted by contract animal suppliers and testing laboratories. The importance of these services cannot be overemphasized since NCI will use these profiles to evaluate the technical ability of individual rodent suppliers.

The successful offeror will supply services, qualified personnel, material, equipment and facilities not otherwise provided by the government under the terms of the contract to perform the following procedures: (1) test animal serum for four to nine viruses depending on the animal being tested; (2) monitor tumor samples for 15 viruses; and (3) produce extromelia vaccine. Respondents must demonstrate experience and expertise in performing viral serological diagnosis of laboratory rodents.

Proposals must detail the type of test to be used and reasons for using each. Experience with receiving and analyzing experimental rodent and human tumors is of importance to the project. The ability to produce extromelia vaccine must be demonstrated in detail. Key personnel and the principal investigator must demonstrate experience in the areas of viral serology, tumor viral diagnostic techniques, and in the production of vaccines will be very important to this project.

Proposals must demonstrate that the facilities and equipment are adequate for the performance of this contract which includes on an anual basis (1) 65,000 serum virological tests; (2) 15,000 tumor virological tests; (3) production of 100,000 units of extromelia vaccine.

It is anticipated that award will be for three years, incrementally funded, periods of performance.

Contracting Officer: Daniel Abbott
Cancer Treatment
301-427-8125

RFP 210-79-0036-0000

Title: *Co-carcinogenicity of foundry particulates*

Deadline: *Approximately May 25*

NIOSH is soliciting proposals from organizations interested in assessing the co-carcinogenic activity and compare the fibrogenic potential of particulate samples supplied by the government.

National Institute for Occupational Safety & Health
5600 Fishers Ln. Room 8-29
Rockville Md. 20857
Attn: Michael Stitely, Contracting Officer

The Cancer Letter _Editor Jerry D. Boyd

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