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P.O. BOX 2370 RESTON, VIRGINIA TELEPHONE 703-620-4646

CONSTRUCTION NEEDS OVER NEXT FIVE YEARS TOTAL ESTIMATED $696 MILLION; NCI SHARE—$132 MILLION

A survey of cancer research construction needs conducted by NCI for the National Cancer Advisory Board has determined that a whopping $696 million worth of construction and renovation will be required

(Continued to page 2)

In Brief

NCAB STILL WITHOUT NEW APPOINTEES AS CARTER, CALIFANO DELAY DRAGS ON; KEELE TO U. KANSAS

NATIONAL CANCER Advisory Board met this week, once again without any of the vacancies filled which have been waiting action by President Carter for nearly a year. Carter also has not named a replacement for Benno Schmidt, chairman of the President's Cancer Panel. Although Board and Panel members are Presidential appointments, Carter has left it up to HEW Secretary Joseph Califano to select the nominees. Califano had the excuse, until Congress finally completed action on Cancer Act renewal, of waiting until any changes in makeup of the two bodies Congress might want to make could become law. It has now been four months since that legislation was completed; further delays are inexcusable. The terms of both the Panel chairman and the NCAB chairman, Jonathan Rhoads, expired a year ago, along with three other NCAB members. Carter and Califano thus missed the opportunity to exert their influence on the Cancer Program then, not that that has hurt the program any. Both Rhoads and Schmidt will be missed if they are not reappointed (they have continued their chairmanships, awaiting replacement), but it has not been fair to them nor to NCI and Cancer Program constituents to delay action so long. . . . **BERNARD KEELE**, special assistant to Centers Program Director William Terry, leaves NCI Jan. 19 to become director of scientific administration at the Univ. of Kansas in Kansas City. . . . **ROBERT MILLER**, chief of NCI's Clinical Epidemiology Branch and also director of the Office of International Affairs, has been named to succeed Guy Newell as head of the U.S. scientific group in the U.S.-Japan Cooperative Program. Director Arthur Upton praised Newell, his deputy, for his strong leadership in the program. . . . **EARLE BROWNING**, retiring in March as NCI financial management chief, also was praised by Upton as one whose "performance is legendary. He has earned enormous respect for his mastery of the budget and his superb presentations of budget details". . . . **WEST COAST** Cancer Foundation received such a heavy response from persons desiring to present papers at its symposium March 23-24 that it decided to offer a post session. Registrants may present scientific papers, reports on work in progress, or lead round table discussions. Symposium is on "Body Image, Self-Esteem and Sexuality in Cancer Patients." To submit papers or round table topics contact Robert Blomberg, WCCF, 50 Francisco St., Suite 200, San Francisco 94133.

REALISTIC NCI SHARE OF CONSTRUCTION COSTS ESTIMATED $26 MILLION A YEAR

(Continued from page 1)

over the next five years by the institute's grantees just to meet federal, state and local regulations and building and safety code requirements.

On a 50-50 matching basis, that would place NCI's share at $348 million, or $69.6 million a year. That figure is so wildly unrealistic in light of budget pressures being exerted on NCI that no one expects the institute to come up with anything close to that figure. NCI's budget for construction grants in the 1979 fiscal year is $12 million, and it probably will be less than that in 1980.

Donald Fox, chief of the Research Facilities Branch, presented the figures to the NCAB Subcommittee on Construction this week. Subcommittee Chairman Denman Hammond was scheduled to relay them to the full Board later.

Fox determined a more realistic set of figures in trying to establish NCI's obligation. Since 1972, peer review has approved 57% of the amount of construction funds requested, and NCI has awarded 38% of the amount requested. Those are averages over the eight years (through FY 1979)—percentages awarded range from 23% in 1978 to 61% in 1972.

Fox applied the 38% of the amounts requested to the figure estimated for the next five years, $348 million (50% of the total). NCI's support, if it follows the pattern established over the last eight years, would be $132.2 million, or $26.4 million a year.

Although $26.4 million a year is still more than twice the current budget, it cannot be considered completely unrealistic. Construction grants totaled more than $30 million a year from 1972 through 1975, with a high of $44 million in 1972. The cutback started with the leveling off of the budget in 1976 with NCI struggling to maintain respectable funding levels for research grants. Construction was cut back sharply, although not as much as it might have been. Congress rejected an attempt to reprogram $10 million from construction to research in 1977.

The survey was broken out into four categories—facilities for clinical research, standard research labs, labs in which biohazard containment is required, and animal research facilities.

The survey asked for estimates of current needs and for needs over the next five years (not including current). The current and future estimates for each of the four categories:

Clinical Research—current need, $82 million ($64 million for inpatient areas, $18 million outpatient); five year estimate, $191 million ($114 million inpatient, $77 million outpatient). Total clinical research—$191 million.

Standard research labs—current needs, $107 million; five year estimate, $213 million. Total for standard research labs, $320 million.

Biohazard facilities—Current needs, $35.5 million; five year estimate, $65.5 million. Total for biohazard facilities, $101 million.

Animal research facilities—Current needs, $33.1 million; five year estimate, $50.9 million. Total for animal research facilities, $84 million.

Fox agreed with Hammond that many of these figures are "soft." The clinical, standard and biohazard figures involved projections based on returns from substantial majorities but not all of the institutions receiving survey questionnaires. The animal facility survey resulted in 100% response (86 questionnaires sent), and the figures thus were more firm.

The clinical and standard lab survey questionnaires were sent to 107 institutions which have NCI funded program project grants, center core grants, cooperative clinical research grants (not Cooperative Groups), and construction grants, and those who have previously applied for construction funding. The projected figures were based on returns from 68 institutions, although by this week, responses from 100 had been received. Thirtyfour of the institutions indicated a need for financial assistance for clinical research facility improvements, and 60 for standard lab activities.

The biohazard survey included questionnaires to member institutions of the Assn. of American Cancer Institutes. Thirtysix of 59 responded, and 13 of the 36 expressed no need for assistance in meeting biohazard requirements.

The biohazard questionnaire was also sent to 172 NCI R01 grantees, with 141 responding. Thirtyone expressed no need.

Those responding to the biohazard questionnaire indicated a need for a total of 357,595 square feet of space, which was projected to 540,065 square feet to include those that did not respond.

The animal facilities survey asked the question, "Are all your animal facilities adequate under current NIH guidelines?" Fiftyfour responded yes, 32 no. It also asked, "Do present facilities provide adequate biohazard and chemohazard containment for current research involving animals?" (And the same question for usage anticipated in the next five years). Fiftythree responded that current facilities were adequate in those respects, but 59 said they would not be adequate for the next five years.

The animal facilities survey went to institutions with NCI funded core grants, active construction grants, those previously applying for construction grants, and those with major cancer research programs.

The clinical research facilities survey asked the question, "Are improvements needed to your present clinical research facilities in order to meet current HEW guidelines?" and "Do your present facilities provide sufficient space for clinical research activities anticipated for program expansion during the next

five years?" Sixteen responded that clinical research facilities do not now meet HEW guidelines, and inpatient needs include a total of 700 beds. Nineteen indicated future needs for program expansion, with inpatient requirements including 800 beds.

CENTERS SUBCOMMITTEE CONSIDERS NEW PROPOSALS FOR COMPREHENSIVE STATUS

Cancer centers desiring official recognition by NCI as comprehensive cancer centers would be required to have a core grant before such recognition could be considered under new proposals developed by Centers Program staff.

The requirement for a core grant would be added to the 10 "characteristics" which the National Cancer Advisory Board presently uses to determine if a center is "comprehensive." The staff proposal also would require that an evaluation for geographic impact be made in considering recognition for comprehensiveness.

The staff proposals were included in recommendations submitted this week to the NCAB Subcommittee on Centers on how the Board and NCI should go about withdrawing comprehensive recognition from a center which has given evidence it may no longer deserve that status. The issue came up when the Colorado Regional Cancer Center failed to get its core grant renewed last year. That coincided with completion of the review of most of the comprehensive centers on how well they have been living up to the Board's characteristics.

Colorado's problems and the failure by some centers to adequately fulfill a significant number of the characteristics, as shown in the review, led to the question, "What do we do about it?" Recognition withdrawal should at least be held out as a doomsday possibility, some have argued; there is no other enforcement mechanism available.

The subcommittee suggested to the Board last year that loss of a core grant should be considered a "flag" warning that a center recognized as comprehensive may no longer really be comprehensive. The subcommittee suggested that this should trigger a site visit by NCI staff, Board members and other nongovernment reviewers if a center fails to get a core grant within two years after losing one. The reviewers and Cancer Centers Program staff would then recommend to the Board and NCI director whether comprehensive recognition would be withdrawn.

Some Board members objected to parts of the subcommittee's recommendation and asked it to make further studies. This week's suggestion was in response to that directive.

The staff recommendation that centers seeking comprehensive recognition initially should have a core grant followed the logic that, if a center could lose its status as a result of losing its grant, new ones should not be qualified without a core grant.

Subcommittee Chairman William Shingleton said the suggestion, as well as the requirement for geographic impact evaluation, needed further consideration by the committee. He did not plan to ask the Board for action on the recommendations at this meeting.

The staff proposal follows:

"I. For initial recognition, a center would apply to the Cancer Centers Program and, after presenting information concerning eligibility, the center would be site visited by a team of Cancer Centers Program staff and a suitable group of nongovernment advisors. This group will make a recommendation to the director of the Cancer Centers Program. This recommendation and the site visit report will be presented to the NCAB Subcommittee on Centers by the program director or his designee in closed session. The program director will present a separate report if there is a discrepancy between his own recommendation and that of the nongovernment advisory group. The recommendations of the advisory group, the Board subcommittee, and (if necessary) the director of the Cancer Centers Program, will be presented as a single report by the Cancer Centers Program director to the full NCAB in closed session. The NCAB shall make a recommendation to the director of the National Cancer Program, and he will make the final decision concerning recognition.

"II. Criteria for recognition will be those of the NCAB, modified to include the requirement that a center must have a core grant and that there shall be an evaluation for geographic impact. It is proposed that the site visit team will vote priority scores for each of the characteristics but that the chracteristics will be weighted to reflect the importance of research or research potential.

"III. If recognition is not recommended, a center may submit a new application two years from the time of notification of failure to achieve recognition.

"IV. If recognition is recommended by the director of the NCP, recognition shall continue in perpetuity, or until one of the following occurs:

"A. The center loses its core grant. Under this circumstance, the center has approximately two years from notification of loss of grant to again acquire a funded core grant. For example, an institution that is notified of core grant disapproval following the May 1979 NCAB meeting must receive new grant approval by the May 1981 NCAB meeting, and receive funding before the end of FY 1981. If this does not occur, a site visit to evaluate for continued comprehensive recognition will be initiated by the Cancer Centers Program staff and carried out as rapidly as possible. In no case will this review be deferred more than three months after the two year period. The recommendations of the site visit team and of the Cancer Centers Program director will be handled in the same way as in the recognition process, with the final decision concerning loss of recognition

to be made by the director, NCP.

"If a comprehensive center is supported by two core grants, loss of either core grant starts the two year clock for comprehensive reevaluation.

"B. The center loses its core grant and indicates that it will not seek to obtain another funded core grant within the two year period. As soon as the Centers Program is notified, review for comprehensiveness will be initiated.

"C. Cancer Centers Program staff determine that the comprehensive nature of the center is in doubt and that a site visit should be carried out. The Centers Program would notify the center and initiate a site visit. The details of this procedure would then be as in IV A."

RALL SAYS NTP TO INITIATE LONG TERM TESTS ON 50-75 COMPOUNDS THIS YEAR

The new National Toxicology Program headed by National Institute of Environmental Health Sciences Director David Rall will initiate long term tests on 50-75 compounds during this fiscal year and short term tests on an addition 400-500, Rall told the National Cancer Advisory Board this week.

NCI is contributing about half the program's $41 million budget, through its Carcinogenesis Testing Program which remains technically within NCI but will work under Rall's direction.

The new program is charged with developing an annual plan which spells out in detail which chemicals are to be tested, how they will be tested, research opportunities and program needs, Rall said. The first annual plan will be completed in six weeks, he told the Board.

Rall reports to an executive committee which consists of the heads of four research agencies–NCI, NIH, National Institute of Occupational Safety & Health, and NIEHS (which of course is himself), and four regulatory agencies–FDA, Environmental Protection Agency, Occupational Safety & Health Administration, and Consumer Product Safety Commission.

The program also will have a board of scientific counselors, organized along the line of traditional NIH boards with nongovernment scientists making up most or all the membership. The board's job will be to assure a high degree of scientific quality, Rall said. It has not yet been appointed.

Rall said he expects over the next three to five years to develop and validate a series of tests of increasing complexity, duration and expense. If a compound passes the initial stages of this sequential series of tests with flying colors, it will generally be presumed not to pose an unreasonable risk of injury to health, he said. He estimated that 80-85% of chemicals will pass the first stages of the sequential series of tests. Suspicious results would require further testing, culminating in a full scale two year, two species lifetime rodent tests. He added that he believes that any chemical which is produced in large quantities, or any chemical to which a significant human population will be exposed, should promptly undergo full scale testing.

This first series of tests will include tests designed to answer the following questions, Rall said:

–Does the chemical persist in the body?

–Does the chemical stimulate certain critical enzyme systems?

–Does the chemical damage DNA or DNA replication or promote cellular proliferation?

–Does the chemical show evidence of damage to the neurological system, the immunological system, the reproductive system, the developing fetus or newborn, the liver or kidney, proliferating cellular systems such as the bone marrow and intestinal tract mucosa?

–Does the chemical alter normal histology after a brief but intensive chemical exposure?

A negative response to each of these is good–but not conclusive–evidence that the chemical will be reasonably safe, Rall said. Positive responses will require further study, but the knowledge gained in these tests will permit a more focused investigation.

Rall said that as the sequential testing procedures are phased in, he plans to test many more chemicals in future years.

"It will be critical to validate this test system. The NTP must test chemicals of known toxicity and known nontoxicity to insure that the system performs as we expect."

Development of this toxicology testing system must be based on the best fundamental science in these fields and it must bae made practical and functional by those scientists willing to turn the fruits of fundamental research into useful applications, Rall said.

The NTP is unique in that these talents are available to it, he added. It couples the basic research competence of the NIH to the most pragmatic needs of the regulatory agencies. The executive committee represents the full spectrum from fundamental research to toxicity testing mandated by urgent regulatory needs, Rall noted.

Rall commented that one objective of the NTP will be to test chemicals for the full range of toxicological effects, not only for their ability to cause cancer but to cause other serious effects such as damage to the nervous system, to the endocrine system, etc. But as the program develops, the major contribution will be the development and validation of new test methods, he said. These methods will hopefully provide industry and the regulatory agencies with test methods that can be used to test products before they are marketed; test methods that will be much more efficient than available today. They will be less expensive, take less time to perform, and predict for human toxicological effects with greater precision, he predicted. "Further, we will understand better what test

results mean, their strengths and weaknesses, and how they can be applied to man. Such information will be of particular importance to the medical profession."

NCAB Chairman Jonathan Rhoads, referring to estimates that 10,000 new compounds enter the environment each year, asked Rall if he felt that testing a few hundred chemicals a year met the needs.

"I have two answers to that question," Rall said. "With the fiscal crunch we all face, like every other program manager I think we need more money. I think the number of compounds we can test is inadequate. On the other hand, the Toxic Substances Control Act does put more burden on industry (for premarket testing of new compounds), so that in the long term, the number we are testing may be adequate. In the short term, they may be a gap, until there is complete implementation of the Act."

Rall said that FDA's National Center for Toxicological Research in Pine Bluff, Ark., "is a superb facility. Some very critical compounds will be studied there, when more than regular testing is desired—such as when we want to ask questions on the influence of diets, or fiber, the duration and timing of exposure, to make results more useful."

In response to Board member Bruce Ames' question on whether NCTR will develop extramural programs, Rall said that is being considered.

COURT ACTION FORCES CPSC TO REOPEN POLICY ON CARCINOGEN REGULATION

The Consumer Product Safety Commission published last year (***The Cancer Letter***, July 21) an "interim statement of p olicy and procedure for classifying, evaluating and regulating carcinogens in consumer products." A clarification of the commission's intent was published in the Dec. 28 *Federal Register* and the period for comments was reopened.

The interim statement established a classification scheme under which the commission, on the basis of a review of existing data, would provisionally assign substances to one of three categories based on the type and quality of data available concerning a substance's carcinogenic potential. The Commission would publish the provisional classification and solicit public comment on its correctness and on the validity of the underlying scientific principles relevant to the classification.

Comment also would be solicited on the manufacture and use of the substance in consumer products, consumer exposure to it, and the potential for ingestion, inhalation, or absorption of the substance into the human system.

In its classification, the Commission said that on the basis of comments it received, it agreed that the category to which a substance is assigned would have no binding legal effect on the substance or products containing the substance.

The Commission was in the process of considering the first provisional classification of a substance when a lawsuit was filed in a U.S. district court in Louisiana by several chemical manufacturers. The suit raises procedural and substantive objections to the interim statement and its implementation. The court issued a preliminary injunction probiting the Commission from provisionally classifying any substance under the interim policy, pending a final decision in the case.

The court said the Commission violated the Administrative Procedure Act in issuing the interim policy statement by making it effective on the date of publication without prior notice and an opportunity for comment.

The court viewed the statement of policy as a conclusive statement of the Commission's views on fundamental questions of scientific and regulatory policy and as an attempt to foreclose consideration of such questions in later individual proceedings.

"The Commission is issuing this clarification to clearly indicate that its intention in issuing the interim statement of policy and procedure is not to foreclose consideration of any fundamental issues involved in the regulation of potential carcinogens in consumer products, nor to deny to any interested person the right or opportunity to participate in the regulatory process," the Commission said in its latest statement. In summary, the Commission said:

"The Commission reemphasizes that it will fully analyze all public comments it receives on the classification criteria and the underlying scientific principles set forth in the interim statement of policy and procedure and will make any necessary changes before it issues a final statement. In addition, when operating under the policy the Commission will publish each classification of a substance as a provisional (or proposed) classification before it issues a final classification. The public will be able to comment on any of the scientific principles upon which the classification is based, both as to their validity and application to the particular substance in question.

"The Commission will evaluate and address all comments before issuing a final classification. Finally, in any subsequent rulemaking proceeding concerning the substance, the public will be able to comment on all information and date on which a proposed regulation is based, including the scientific principles underlying the finding of risk of injury. Again, the Commission will analyze and address all comments before it issues a final regulation. Any final regulation must be supported by substantial evidence on the record.

"Thus, there will be several stages of any proceeding to regulate a substance as a carcinogen where the principles and assumptions underyling the Commission's decision are subject to the informed reflection and genuine dialogue which the District Court in *Dow Chemical, U.S.A. v. CPSC* held as necessary to comply with the APA.

"While the Commission is prevented by the preliminary injunction from implementing the interim statement of policy and procedure through the provisional classification of substances about which a question of safety has been raised, it is continuing to carry out its statutory responsibility to receive and screen information concerning possibly carcinogenic substances, set priorities for the evaluation of consumer products containing such substances, and carry out other internal activities, independent and separate from the statement of policy and procedure, related to addressing possible hazards associated with carcinogenic substances in consumer products.

Comments on the interim statement are due by Feb. 26. They should be sent to the Secretary, CPSC, Washington D.C. 20207.

NCAB GROUP WORRIES ABOUT CHANGES BY CONGRESS IN BOARD'S MAKEUP

The National Cancer Advisory Board, perhaps given a message by Congress last year when the Cancer Act renewal permitted Congress to spell out some changes in the makeup of the Board, decided last year to take a close look at how it operates and what it might do better.

Board member William Baker, president of Bell Telephone Laboratories, was appointed chairman of a subcommittee to consider the situation and come up with recommendations.

The subcommittee met two weeks ago, and some members expressed concern over the congressional changes which added as ex officio members the heads of several regulatory agencies and the Secretary of Labor. They also criticized the requirement that five Board members be persons knowledgeable in environmental causes of cancer. They felt thse changes might move the Board away from its attention to research, particularly basic research.

Board Chairman Jonathan Rhoads went out of his way to welcome the new ex officio members (with most of them being representatives of the agency chiefs, not the chiefs themselves. David Rall, NIEHS director, was the only agency head to represent himself). Director Arthur Upton echoed Rhoads' welcome.

Baker, however, in his report to the Board this week did not attempt to play down the subcommittee's concerns.

"On the one hand we are creatures of the legislature," Baker said. "On the other, we don't approve of some of the things Congress has approved and we feel responsible to point it out."

Baker said he was "pleased to find that this Board has a vertebrae. We have encouraging evidence that this one has a spine."

The subcommittee's chief recommendation was that the Board should have a hand in planning the agenda for its meetings. It suggested that a subcommittee be established to work with NCI staff in developing agendas.

Baker said the subcommittee agreed that some "additional mechanism" was needed to deal with Congress. "Board members should be available for consultation with Congress and other political forces."

Finally, the subcommittee suggested that the Board should pay more attention to NCI's intramural scientific programs and should have more extensive reports from the institute's labs and clinics.

DCT ANNOUNCES NEUTRON THERAPY RFP, NEW COMBINATION THERAPY TOXICITY TESTS

NCI officially kicked off its expanded clinical neutron therapy program with the announcement of the availability of the RFP for development of new facilities and expanded clinical trials (see RFPs Available, page 6).

The announcement says that "DCT (The Div. of Cancer Treatment) is planning to award one or more contracts." However, DCT's Board of Scientific Counselors had recommended development of two additional facilities, and the division has budgeted funds for two, provided the proposals do not exceed the estimates.

Spirited competition from several institutions for the contracts is anticipated. DCT is allowing 90 days from the availability of the RFP for submission of proposals, twice the usual time. A conference for those competing for the contracts is scheduled Feb. 15 to assist them in developing their proposals.

DCT's Developmental Therapeutics Program announced another major contract effort with an RFP to investigate toxicity from antitumor drugs in combination with other treatment modalities and other drugs. They will involve preclinical studies using mice and large animals.

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.

RFP NCI-CM-9782

Title: *Clinical neutron therapy program*
Deadline: *Approximately April 15*

The Div. of Cancer Treatment is soliciting proposals from organizations capable of developing the necessary resources to conduct clinical trials on

cancer patients through the use of clinically based, neutron therapy treatment devices.

This project will include 1) procurement of a high Linear Energy Transfer (LET) neutron generator capable of demonstrating specific performance characteristics; 2) construction of a suitable facility to house the device; and 3) conduct of clinical trials designed to evaluate its capabilities relative to conventional radiotherapy.

Each offeror will be required to demonstrate 1) past and current capability for undertaking complex clinical trials in radiation oncology; 2) ability to acquire the necessary facilities and equipment to undertake this program; 3) the current availability of an experienced and trained staff to administer the program; 4) the ability to access a minimum of 300 new patients per year for treatment and followup in the neutron therapy clinical trials. A close proximity to existing ancillary facilities and equipment normal to conventional radiation therapy will be an important consideration for this procurement.

DCT is planning to award one or more contracts for this program and each is to be modeled after a currently approved and funded program in clinical neutron therapy under development at M.D. Anderson Hospital. Each contract awarded under this RFP will be for a time period of up to 10 years.

Any contract awarded will be subject to HEW regulations relative to the use of human subjects in research projects. A pre-proposal conference is scheduled for Feb. 15, 1979.

Contracting Officer: Stephen Gane
Cancer Treatment
301-427-8125

RFP NCI-CM-97263

Title: *Study on the Toxicity and Pharmacology of Combinations of Antitumor Drugs*

Deadline: *Approximately March 1*

The Developmental Therapeutics Program, Div. of Cancer Treatment, NCI, is seeking a contractor to investigate and define the toxicity resulting from the administration of an antitumor drug in combination with another treatment modality. This may be another antitumor drug, an agent designed to modify the metabolism or disposition of the antitumor drug, a physical agent, for example, radiation, heat, etc., immunostimulants or biological response modifiers. The specific objectives of the program which the contractor shall exert its best efforts to obtain are:

1. To conduct preclinical evaluation of the toxicity of a combined treatment modality where at least one of the two agents is an established antitumor drug.

2. To determine the schedule(s) of the two agent combination in mice which results in the least toxicity and, if possible, the maximal therapeutic effect. The second of a two agent combination may be a physical agent, an immunostimulant or a biological modifier of the antitumor drug. When the schedule and appropriate dose levels have been determined, the investigation of the combination toxicity in beagle dogs and/or monkeys will proceed. The dose levels and schedules to be investigated in the large animals will be determined by extrapolation from the preliminary mouse studies conducted above above and in consultation with the project officer.

3. To determine in large animals (dog and/or monkeys) the four defined dose levels for the combination according to the currently defined doses resulting from DCT protocol toxicological evaluation of a single agent. These are, (a) highest nontoxic dose, (b) toxic dose low, (c) toxic dose high, and (d) lethal dose. For the present studies the term "combination" should should be substituted for "dose" and represent the fixed ratio arrived at in the mouse studies. In addition, complete and clinical chemistry determinations will be performed as needed. While it is not possible to specify which modalities will be investigated in advance it is expected that individual projects will not take less than one or more than two years to complete. The longer projects will be of a more complex nature and the actual time needed to complete a given study will be estimated by the government in advance of its initiation.

This prospective study of combined modality toxicity in animals is of great importance for disclosing unexpected toxicities which may be encountered when clinically unexplored combination regimens are used. The selection of a drug and combination modality will be made solely by NCI; contractors should be prepared to provide the support services needed to undertake any studies of the type described in this statement of work. The antitumor drugs and other chemicals studies will be furnished by the government. Protocols for administration of the antitumor drugs and the combinations will be agreed upon jointly by the project officer and contractor.

It is anticipated that one award will be made for a three year period.

Contract Specialist: Otis Parham
Cancer Treatment
301-427-8125

RFP NCI-CM-97254

Title: *Storage and distribution of chemical and drug samples*

Deadline: *Approximately Feb. 26*

An organization not affiliated with chemical or pharmaceutical organizations is needed to provide support services related to the storage and distribution of bulk and chemical drugs used as potential antitumor agents in the screening program. Approximately 350,000 samples are being stored by the current contractor. On an annual basis, it is estimated that the contractor will be required to receive, store and ship approximately 15,000 new samples, ship approximately 20,000 refill materials and weigh approximately 20,000 return samples.

The services must provide for receiving, inventory, distribution and storage of these materials. Specifically, the candidate organizations must have the capability to: 1) receive, weigh and store bulk chemicals and drugs; 2) provide and maintain accurate and current inventory records, portions of which are computerized; 3) provide safety and security measures as prescribed by the project officer or as required by all applicable government regulations pertaining to handling of dangerous drugs, hallucinogens, etc.; 4) including necessary licensing package and ship chemicals and drugs and related documents; 5) provide daily pickup and delivery services; 6) provide staff capable of interfacing with inventory computer operations.

This project requires the immediate availability of 8,000 square feet of space located within a 10 mile radius of NIH.

Technical equipment requirements include: adequate air conditioning, hoods, balances, dry box, freezer (approximately 700 cubic feet), refrigerator (approximately 400 cubic feet), safe, computer terminals, etc. The principal investigator must have a bachelor of science degree in chemistry, preferably organic, experience in supervising an operation of this nature, and must devote 100% of his time to this contract.

It is anticipated that one award will be made as the result of this RFP. It is also anticipated that award will be for a three year incrementally funded period of performance. The budget is planned to be level for the three year period with an anticipated effort of 14 man years for the first year.

Contract Specialist: Daniel Abbott
Cancer Treatment
301-427-8125

RFP NO1-CN-95446-05

Title: *Approaches to cancer patient management: A synopsis of the network program experiences*

Deadline: *Approximately March 20*

Preparation of monographs on cancer network demonstration project experiences as a comprehensive approach to cancer patient management. The Div. of Cancer Control & Rehabilitation wishes to synthesize the information and experiences of 16 prototype cancer network demonstration projects to facilitate the transfer of the current knowledge, skills, and technology gained from the projects in a meaningful, concise, operational form for members of the health professional community who are interested in implementing the network concept as a system of health care delivery.

The purpose of this procurement is to review the lessons learned from the different network projects and documents the process information and available data on patient outcome in order to prepare a synopsis for health professionals who wish detailed information on developing network programs. The project objective is to prepare a digest which brings together the currently available information on establishing site-specific treatment and care networks for cancer patients.

Two monographs shall be prepared—one for the breast cancer network demonstration projects (10) and one for the head and neck cancer demonstration projects (6). Monographs shall include a compilation of the educational materials the network prepared for the public and health professionals. Offerors may submit a proposal for the preparation of one or both monographs. If the offeror wishes to submit a proposal for both monographs each monograph must be proposed separately. For evaluation purposes, proposals for the head and neck and breast projects will be evaluated separately.

The anticipated period of performance of this requirement is 18 months. Offerors should demonstrate familiarity with the network concept as employed in the health care field and knowledge of the cancer site addressed and have experience in the methods of intervention employed. Should two different contractors be selected for the individual monographs, collaboration between the two contractors will be required. Also, a cooperative and coordinated effort with network personnel is an essential element of this project. For prospective offerors desiring background information for proposal preparation, a reading room with appropriate materials will be made available by DCCR.

Contracting Officer: Helen McEvan
Control & Rehabilitation
301-427-7984

NCI CONTRACT AWARDS

Title: Plateletpheresis services
Contractor: Community Blood & Plasma Service, Birmingham, Ala., $1,780,012.

Title: Development, management and support services to the Diet, Nutrition and Cancer Program
Contractor: Enviro Control Inc., $620,012.

Title: Computer-aided prediction of metabolites for carcinogenicity studies
Contractor: Univ. of California (Santa Cruz), $85,096.

The Cancer Letter _Editor Jerry D. Boyd
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