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WAXMAN'S CANCER ACT RENEWAL LEGISLATION: MORE PLUSES THAN MINUSES; HEARING SCHEDULED FEB. 25

Congressman Henry Waxman (D.-Calif.), chairman of the House Health Subcommittee, has introduced his bill that would extend biomedical research authorities, including the National Cancer Act. It (HR 6522) preserves the Act and, for the most part, offers improvements sought by Cancer Program advocates.

The positive features of Waxman's bill include:

* Preservation of NCI's budget bypass authority, which permits the institute to send its budget request directly to the White House without alteration by NIH or HEW. (Continued to page 2)

In Brief

SEARCH COMMITTEE FINDS PROSPECTS UNCERTAIN ABOUT ELECTION, UNWILLING TO TAKE PAY CUT

NCI DIRECTOR search has made little progress, and it could still be months before a permanent appointment is made unless the search committee suddenly finds a top qualified person willing to take the job. The committee has interviewed a number of people only to find they were not interested because (1) the uncertainties of accepting a Presidential appointment from a President who might lose his job within the year; (2) they couldn't afford to take a salary cut, for a job that pays $50-70,000; (3) they would rather continue doing what they are doing now. The committee will keep trying to develop a list of at least two or three to submit to HEW Secretary Patricia Harris, whose choice will be accepted by President Carter. . . . **FRED HUTCHINSON** Cancer Research Center employees will vote on whether the Hutchinson Center Staff Assn. will have the right to represent them in dealing with center management, if the National Labor Relations Board certified authorization cards submitted to it. The association claimed it turned over more than the required 30 percent to the Board. If an election is held it will involve about 300 animal handlers, secretaries, research technicians, computer programmers and others. . . . **CHARLES LOWE** has been appointed acting director of the NIH Office of Medical Applications of Research. He replaces Seymour Perry, who now heads the National Center for Health Care Technology. . . . **COALITION OF CANCER** Issues' next meeting will be March 5 at the Lombardi Cancer Research Center, Georgetown Univ. Issues to be discussed include the move by the Assn. of American Cancer Institutes to get a line item in the NCI budget for cancer center core support; Assn. of Community Cancer Centers' concern about full funding of the Community Hospital Oncology Program; the Bayh-Chappell bill which would allow cancer patients to receive more timely disability insurance benefits; the funding level of the 1981 fiscal year NCI appropriations; concerns over the various proposals for NCI authorizing legislation; the interest by some organizations in pressing for more home care reimbursement.

WAXMAN'S BILL RETAINS ALL SPECIAL AUTHORITIES, PROVIDES DOLLAR LIMITS

(Continued from page 1)

* Retention of the Presidential appointments of the National Cancer Advisory Board and NCI director.

* Retention of the President's Cancer Panel.

* Increasing the amount in grants which can be awarded by the NCI director without concurrence of the NCAB from $35,000 to $50,000 for direct costs.

* Providing NCI the specific authority to award cancer center core grants for up to five years.

* Removing the $5 million limit on the size of center core grants.

Elements which some may consider negative include:

* Authorization levels for the next three fiscal years which most Cancer Program advocates will feel are too low—$1.074 billion plus $80.5 million for control in 1981; $1.22 billion plus $91.5 million in 1982; and $1.376 billion plus $103 million in 1983. A separate authorization for National Research Service Awards is included for all of NIH.

* No line item for cancer centers.

The American Cancer Society has asked that no dollar authorizations be included in the legislation. The ACS theory is that the levels have drifted too close to actual appropriations and have become ceilings rather than goals. ACS is recommending that NCI's appropriation for 1981 be $1.135 billion, too close for comfort to Waxman's $1.159 billion figure.

The Assn. of American Cancer Institutes determined that authorization figures are all right if they are high enough. It recommended totals ranging from about $1.5 billion in 1981 to $2.25 billion in 1983.

Waxman's staff has pointed out that the proposed authorization level is 1.5 percent higher in 1981 than NCI's appropriation; however, it is only about 3 percent above the authorized 1981 level.

Waxman's bill is an improvement over the Senate bill (S. 988) proposed by Sen. Edward Kennedy, in some respects. Kennedy's bill did not increase the director's grant authority, did not lift the limit to five years on center grants, and left in the $5 million limit on core grants. It also retains all the special authorities for NCI, and it does not include dollar authorization limits.

The aspect of Kennedy's bill that worries some in the Cancer Program is the provision for a powerful new biomedical research council, which would be sort of a super Cancer Panel for all NIH. The new council would be charged with making budget recommendations, and ACS and others fear this might dilute NCI's budget bypass.

The Waxman bill provides only for an advisory committee to the NIH director.

Hearings on Waxman's bill started this week. The NCI portion is scheduled for Feb. 25, starting at 2 p.m. ACS, AACI and perhaps others have been invited to make statements, along with NCI Acting Director Vincent DeVita.

RANDOMIZATION WITH OPTIONS HELPS STIMULATE NSABP SEGMENTAL ACCRUAL

Use of "prerandomization" in selecting patients for one of the three arms in the National Surgical Adjuvant Breast Project segmental mastectomy study has helped to increase dramatically accrual to the point where the study now is a viable one.

The three arm clinical trial compares total (or modified radical) mastectomy vs. segmental mastectomy (with axillary dissection) vs. segmental (again with axillary dissection) plus radiation. During the first two years of the study, resistance by patients and their surgeons held entry to a discouraging level. NSABP Chairman Bernard Fisher called it "a tragedy."

After the randomization scheme was changed, however, accrual picked up immediately. There are now 545 patients in the study, which now is assured of enrolling enough to provide the necessary statistical base.

With the new scheme, once a patient is selected for prerandomization, she becomes part of the protocol regardless of the form of therapy she receives. She is then randomized to one of the three arms, after the study and each of the treatment methods has been thoroughly explained to her.

If she is randomized to the total mastectomy group, she may elect to stay in that group, or she may choose to switch to the segmental mastectomy group. Similarly, if she is randomized to one of the segmental groups, she may switch to the total mastectomy group.

To date, only 14 have chosen not to accept the therapy to which they were randomized. Nine opted to switch from total to segmental, and five the other way. No one randomized to the segmental plus radiotherapy group so far has refused the radiation portion of the treatment.

Norman Wolmark, NSABP executive medical officer, said, "Prerandomization was our second choice. We prefer to randomize in the normal manner. We felt we had to prerandomize to increase patient accrual."

Wolmark is not certain that the increase can be attributed entirely to prerandomization. A change in the attitude of surgeons may have helped. Perhaps more important, Wolmark feels, is the growing use of the two stage procedure. With the patient able to participate in treatment decisions, the surgeon is more obligated to explain the various alternatives, including entry into clinical trials.

Marvin Zelen, director of the Cancer Clinical Coordinating Center which provides statistical support for two Cooperative Groups, discussed with Cooperative Group chairmen last week aspects of prerando-

mization along the lines of an article he recently published in a scientific journal.

Zelen's plan would randomize half the eligible patients to a group which would receive the best standard treatment. The new therapy would not be available to them. The other half would be further randomized, after the study was explained to them and informed consent was obtained. Half of this group would be assigned to the experimental therapy, and the other half to the best standard treatment. Those in each group would have the option of switching to the other if they preferred that treatment to the therapy to which they were assigned.

The success of this plan depends on the proportion of patients who accept the assigned treatment, Zelen said. The greater the proportion who do not accept the assigned treatment, the greater the number of patients needed in the study to overcome the statistical bias.

Paul Carbone, chairman of the Eastern Cooperative Oncology Group, said he felt Zelen's plan was close to "the fine line of ethics."

John MacDonald, director of NCI's Cancer Therapy Evaluation Program, said, "It might be wise to consider piloting this method, to one group, or a pilot study with each group, before applying it across the board."

"I don't consider it radical or terribly innovative," Zelen said. "People are doing this kind of thing. What I consider radical is a physician giving experimental drugs with NCI providing the drugs, but without getting the data or any evaluation."

"We don't have to wait for the breast data," said Barth Hoogstraten, chairman of the Southwest Oncology Group. "Other groups are doing other things. It could be totally different for colon cancer."

Hoogstraten insisted that SWOG would use prerandomization "for studies where we have trouble getting patients."

"We're just saying it should not be adopted wholesale as a panacea," said Edwin Jacobs, associate chief of NCI's Clinical Investigations Branch.

"If the science is valid, and if it is ethical, something for local review boards to determine, NCI has no business interfering," commented John Durant, chairman of the Southeastern Cancer Study Group and head of the Cooperative Group Chairmen's Committee.

Giulio D'Angio, chairman of the Wilm's Tumor Study Group, said, "The fact that you're offering treatment B (the experimental therapy) means you want to improve on treatment A, that you think B will be better. The patient who is randomized to A could ask, 'You're not offering me the new treatment, which may be better.'"

"There may be a consensus that B has potential of being better," Zelen said. "But you don't know."

Durant summed up the discussion. "It is the sense of the chairmen that the Div. of Cancer Treatment should not hold up a protocol on the basis of the randomization method."

There was no objection expressed. Later, however, MacDonald told *The Cancer Letter* that DCT would continue to express concern (and presumably hold up a protocol) when patients are to be randomized to the control arm without being told they are being randomized. "I haven't seen any protocol like that, but I don't think we would approve it right now," MacDonald said.

"We're perfectly happy with the NSABP prerandomzation method," MacDonald continued. "The groups could come in with protocols using that method, and we would not object."

NCI ADOPTS GUIDELINES FOR PATHOLOGY REVIEW; GROUPS ACCEPT MCDIVITT PLAN

Problems which arose out of the pathology review in the Breast Cancer Detection Demonstration Project have convinced NCI that guidelines were needed for future studies in which pathology review is required.

The NCI Executive Committee has approved guidelines that were developed by a panel which included representatives of each national pathology organization, each NCI division, and two outside consultants.

The guidelines apply only to studies where review of pathology material is planned. They do not apply to studies already in progress, but only to those for which funding is requested.

The guidelines follow:

1. The following guidelines pertain to all NCI supported studies and projects requiring review of pathology material.

2. Such projects should include a pathologist as principal investigator or co-investigator.

3. Each division director in NCI has the following responsibilities in promoting appropriate practices with respect to pathology evaluations in all research projects in his/her respective programs:

a. Appointment of an appropriate staff person as a pathology coordinator, who shall serve as a member of the Pathology Working Group, and shall review projects within his/her division to determine whether the pathology section(s) of the project meet the guidelines promulgated by the Pathology Working Group.

b. Maintain, directly or through the pathology coordinator, proper liaison with the Pathology Working Group.

4. The Pathology Working Group should be composed of the division pathology coordinators and appropriate consultants. Meetings of the group will be held at least quarterly. The Pathology Working Group should promulgate and recommend guidelines and should make decisions on all matters brought before it.

5. Investigators, intramural and extramural, pro-

posing studies to be supported by NCI involving review of human pathologic material and should include the following information in their proposal:

a. How the pathologist investigator will interact with the contributing institutional pathologists, including the methods to be used to collect, review, report and exchange appropriate data.

b. The methods to be used to protect the patient; in (a) to code the information to insure proper compliance with the Freedom of Information and Privacy Acts.

c. Measures to insure that the mechanism for reporting results of pathology reviews to the contributing institutional pathologists conforms to usual ethical standards of medical practice, and is accomplished in a timely fashion so that the attending physician would be advised of the most current status.

Cooperative Group chairmen were cool to the proposal when it was presented to them last week by Dorothy Macfarlane, executive secretary of the Clinical Cancer Investigation Review Committee.

Paul Carbone, chairman of the Eastern Cooperative Oncology Group, said his group did not agree with the proposals. Barth Hoogstraten, chairman of the Southwest Oncology Group, said they were "explosive."

The group chairmen considered briefly the report on proposed clinical trial pathology improvements submitted more than a year ago by an ad hoc group headed by Robert McDivitt (*The Cancer Letter*, Jan. 12, 1979). Those recommendations said each group should (1) establish a pathology discipline committee; (2) the chairman of that committee be appointed a member of the group's executive committee; (3) pathology disease/organ specific committee chairmen be members of each group's disease/organ specific committee.

The McDivitt recommendations also called for establishing an intergroup pathology executive committee and that its chairman be an ex officio member of the Cooperative Group Chairmen's Committee.

Cooperative Group Chairmen's Committee Chairman John Durant commented, "Pathologists have asked for treatment as full partners. We have had enough time to consider the report, and I haven't heard any disagreement. It is time to add to the funding problems of Cooperative Groups by accepting pathologists as full partners."

The chairmen agreed without dissent.

INTERFERON RESULTS "PROMISING," ACS WILL COMMIT ADDITIONAL $3.4 MILLION

The American Cancer Society, which already has invested $2.4 million in interferon research, announced that it has allocated an additional $3.4 million for further study of the substance.

Saul Gusberg, professor of gynecology at Mt. Sinai School of Medicine in New York and ACS national president, reported that early research with interferon "has been promising enough to warrant expansion of the Society's clinical trials."

He said, "More extensive work is necessary to determine whether interferon will ultimately prove useful in the treatment of cancer. The unprecedented size of the Society's appropriations for interferon is due to the very high cost of the material. There is little expectation that much less expensive material will become available for research purposes in less than two to three years."

Interferon costs as much as $30,000 per patient, sometimes more.

"If there's the slightest possibility that it might prove helpful to future cancer patients," Gusberg said, "we feel that every effort must be made to check it out. The exciting promise of a new family of natural substances with antiviral and antitumor activity demands nothing less than a full dress, prompt, carefully planned and carefully controlled clinical trial."

Controlled clinical testing with interferon supplied by ACS currently is in progress at 10 U.S. medical centers. For its initial $2 million outlay the Society obtained enough of the substance to treat approximately 150 patients. "Although preliminary results have been good," Gusberg declared, "it's still too early to draw conclusions. In order to determine interferon's effectiveness, we'll have to study these patients over a longer period of time and add more patients to the testing group.

"That there is great promise there is little doubt. That we have made but a small beginning is equally true. That research means lack of knowledge of the ultimate outcome is the code with which all scientific investigators live.

"At this point we're still very early into this research and must await data concerning final tumor response and any possible long term side effects. Precise knowledge of dosage, dosage timing, coordination with other types of treatment such as surgery, radiotherapy and chemotherapy, and possible immune effects must be obtained before we can know the place of the interferons in clinical cancer therapy."

Only leukocyte interferon is being used in the ACS clinical testing program. Scarcity of the material has resulted in slow progress for the current research, Gusberg said. "Material is just trickling in, and until better production methods are devised we'll be forced to continue at a slow pace."

Virtually all of the Society's original investment in interferon was for purchase of the material. Research institutions participating in the clinical trials have contributed the necessary facilities and personnel.

In addition to buying interferon, ACS has invested over $100,000 in laboratory attempts to increase its supply. These grants have included $50,000 to Sloan-

Kettering and $50,000 to the New York Blood Center.

Although the newly announced funds will be used primarily for the purchase of additional material, it is expected that substantial amounts will go into related patient studies as well as into projects aimed at purifying the material and increasing its production.

Four cancer sites are now being studied with ACS support—melanoma, multiple myeloma, cancer of the breast and lymphomas other than Hodgkin's disease. Gusberg said that supplementary funding probably will make it possible to add other types of cancer to the clinical trials list.

ACS announced its first financial commitment in August of 1987. The program launched at that time is now in progress at the following institutions: Univ. of Texas M.D. Anderson Hospital & Tumor Institute; Sloan-Kettering Institute for Cancer Research; Mt. Sinai School of Medicine; Columbia Univ. College of Physicians & Surgeons; Roswell Park Memorial Institute; Yale Univ. School of Medicine; Johns Hopkins Oncology Center; Univ. of Wisconsin Center for Health Sciences; Stanford Univ. Medical Center, and UCLA Center for the Health Sciences.

MOST OF NCI CARCINOGENESIS TESTING PROGRAM WILL MOVE TO NORTH CAROLINA

It is now all but official: the major portion of NCI's Carcinogenesis Testing Program will be moved to Research Triangle Park, N.C.

Richard Griesemer, associate director of the program, told ***The Cancer Letter*** that about three-fourths of the staff positions eventually would be transferred to North Carolina where the National Toxicology Program is headquartered.

David Rall, NTP director, is also director of the National Institute of Environmental Health Sciences. Although Rall maintains a small office at the NIH campus in Bethesda, it seemed obvious from the inception of NTP that if Rall was going to manage it, the major elements would be moved to NIEHS sooner or later.

The Carcinogenesis Testing Program is the largest single element of NTP, with a 1980 budget of $45.6 million out of NTP's total budget of $68.8 million.

Most NCI staff members of the testing program objected at first to being moved, and Rall said that no one would be forced to go. The North Carolina contingent would come from those willing to make the move plus those recruited to fill vacancies, he said.

Griesemer said that is still the policy. There seems to have been a change in attitude by many staff members, however. A majority have now indicated willingness to make the move. The most important factor in the attitude change probably is acceptance of the situation—the program was going to be headquartered in Research Triangle Park, it no longer will be an actual functioning part of NCI, and staff members serious about their careers in the program had better go where most of the action will be.

Research Triangle Park is located in a scenic area between Raleigh and Durham. Three major universities are nearby—Duke, Univ. of North Carolina and N.C. State—with all the academic and cultural opportunities that implies.

The beautiful new NIEHS building with superb lab facilities will be completed within 18 months and certainly will be envied by those remaining in the increasingly overcrowded labs at NIH.

Government employees, upon being transferred from Washington to the "field," sometimes get the effect of a pay increase even when their salaries stay the same, due to a lower cost of living than exists in the D.C. area. But that depends on where the "field" is.

"They shouldn't expect the cost of living to be any lower here," an NIEHS staff member and former Washington resident said. "We've caught up with you." He did say that housing costs are still significantly lower in the communities surrounding Research Triangle Park than in metropolitan Washington.

The draft of a recruitment plan for the NCI-NTP contingent, a plan still subject to modification, called for five members of the Toxicology Branch, three of the Pathology Branch, six of the Technical Information Resources Branch, one from Griesemer's office and not more than six secretaries to remain in Washington. Everyone else would go to North Carolina.

The draft said that "Program (staff) estimates that NCI/NTP will have 341 chemicals in various stages of testing by September 1980. About 10 percent slippage in estimates is expected as some chemicals are withdrawn from testing and substitutes provided, some are tested in multiple tests, and some require retesting. When a steady state is reached at the rate of 100 per year, Program will have to deal with 534 chemicals at a time, including 125 in the pretesting phase, 325 in actual animal experiments, and 84 in review and report phases. Seven more toxicologists will be required to meet this need in FY '81."

The recruitment plan draft mentions a new category of staff in the Toxicology Branch, the chemical manager.

"The principal role of the toxicologists (including pharmacologists and physiologists) is to serve as chemical managers," the draft said. "These staff members will be responsible for the design, conduct, analysis and reporting of toxicologic and carcinogenic experiments. It is estimated that a full time work load is approximately 24 chemicals for each scientist and that 10 toxicologists are required therefore to manage 240 test chemicals. These individuals also have primary responsibility for experimental design and data evaluation committees, monitoring of experiments, site visits (both pre and post award)

to 25 contractor laboratories (at least four visits per year per lab), and interagency liaison on their chemicals and tests."

The draft points out that "the workload on the Pathology Branch is formidable, with an average of two toxicologic studies and two carcinogenic studies to be evaluated each week. The weekly number of tissue sections submitted to NCI/NTP will be about 40,000.

"To meet this need, the Program has elected to utilize a core of pathologists supplemented by pathology support contracts."

A new branch, Genetic Toxicology, will be developed out of an activity now located in Griesemer's office. The draft said that scientists are needed to develop each of the sub areas—cell transformation, submammalian mutagenesis, mammalian mutagenesis, DNA damage and repair, and gene markers and products.

The matter of staff positions is still a sore point with both NTP and NIEHS.

In the FY 1980 appropriations bill, Congress directed that 28 new slots be given to NTP and another 55 to NIEHS. In a brief interview recently (*The Cancer Letter*, Feb. 1), Rall said that the Office of Management & Budget had released the 28 NTP positions.

That was news to NCI, which ought to have been the first to know since those are still carried as NCI slots and they will be filled by people who are NCI employees, at least on the books. OMB also denied that it had released the positions.

OMB has resisted directives by Congress dealing with new positions and has obtained a ruling from the comptroller general that Congress can establish position ceilings for Executive Branch agencies but cannot order that positions be filled up to those ceilings.

Rall was out of the country this week and not available for comment. It was assumed that his comment on the release of the positions was based on unofficial assurances from OMB that they would be. In any case, both NIEHS and NTP are proceedings with plans to recruit for those positions.

At last week's meeting of the Clearinghouse on Environmental Carcinogens Risk Assessment/Data Evaluation Subgroup, Subgroup member Michael Shimkin asked, "Is this the last meeting of this group?"

Clearinghouse Chairman Arnold Brown said, "I suspect it is. The charter runs out in May."

But Griesemer commented that the carcinogenesis testing segment of NTP would continue to need advice from nongovernment scientists relating to evaluation and risk assessment. "We need the Clearinghouse or something else," Griesemer said. He suggested that NTP's Board of Scientific Counselors might want to recommend extending the Clearinghouse charter.

Griesemer told the Subgroup that "NTP is on course" and is "proceeding very well." He noted that at the NTP Board of Scientific Counselors recent meeting, three issues were addressed:

—Chemical selection. Considering that a number of research and regulatory agencies are interested in that issue, "How do you go about selecting chemicals for testing, and setting priorities?" Board Chairman Norton Nelson appointed a subcommittee to study this question, with Marjorie Hornung of Baylor as chairman. Clearinghouse members Joseph Highland, Sheldon Samuels and Verne Ray have been invited to participate in those discussions.

—Data processing and management needs will be evaluated by a subcommittee chaired by Mortimer Mendelsohn.

—Peer review of reports and release of data. Nelson will chair this subcommittee himself and has asked Brown to join in the discussions.

Another activity of the Board, Griesemer said, will be technical review of various testing activities. "We hope that groups of nongovernment people will participate in such things as pathology review, chemical analysis, diet. We're looking to ensure that standards are set and met."

Ray commented that the Clearinghouse Experimental Design Subgroup "never came to fruition. Is there a group looking into experimental design?"

Griesemer acknowledged that "we badly need advice" in that area. . . . There will be some mechanism to address experimental design, likely a subcommittee of the Board of Scientific Counselors. We need to address conceptual design issues."

NCI CONTRACT AWARDS

Title: National Cancer Consultative Program for Hospitals, 20-month renewal
Contractor: American College of Surgeons, $735,146.

Title: Support for Cancer Surveillance System, continuation
Contractor: Fred Hutchinson Cancer Research Center, $691,493.

Title: Tumor registry training program and allied activities, continuation
Contractor: Univ. of California (San Francisco), $142,997.

Title: Population based cancer epidemiology research center in Iowa, continuation
Contractor: Univ. of Iowa, $281,460.

Title: Detroit SSMA population based cancer registry, continuation
Contractor: Michigan Cancer Foundation, $391,625.

Title: Bovine leukosis survey of Florida
Contractor: Univ. of Florida, $27,500.

Title: Immunoprevention spontaneously occurring neoplasia, continuation
Contractor: Microbiological Associates, $30,000.

Title: Epidemiological investigation of cancer in Utah, continuation
Contractor: Univ. of Utah, $463,033.

Title: Establishment and development of a Connecticut cancer epidemiology program, continuation
Contractor: Yale Univ., $122,455.

Title: Studies of HLA genetic markers of immune response to cancer viruses
Contractor: UCLA, $76,170.

Title: Studies of the interrelationships of viruses, genetics and immunity in the etiology of human cancer
Contractor: UCLA, $344,650.

Title: In vivo screening program
Contractor: Institute Jules Bordet, Brussels, $1,984,054.

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 Biological Carcinogenesis & Field Studies Section—Landow Building, Bethesda, Md. 20205; Control & Rehabilitation Section, Chemical & Physical 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-CO-05513-48

Title: *Statistical analysis and quality center (SAQC) for the centralized cancer patient data system (CCPDS)*
Deadline: *April 14*

NCI has a requirement for a Statistical Analysis & Quality Control Center (SAQC) which collects and disseminates data from the Centralized Cancer Patient System. The CCPDS is a standard system for registering persons, with reportable malignant neoplasms, who are patients of comprehensive cancer centers throughout the United States.

Thirty-eight items of information are collected on each patient. The contractor will be expected to plan, develop, update, implement and operate a SAQC for the CCPDS. This will include development or adaptation and operation of a computerized system to deal with uniform acquisition, quality control, storage, retrieval and analysis of basic cancer patient data from initially 21 comprehensive cancer centers.

In addition, the contractor will be expected to develop proposals for expansion of the CCPDS, including development of special studies as an adjunct to the minimal cancer patient dataset, and develop a description of appropriate analytical capabilities which would be a necessary component of an expanded data collection and processing center.
Contracting Officer: Linda Waring
Office of Director Section
301-427-8747

AMENDMENT: DEADLINE CHANGES

RFP NCI-CM-07342-22

Title: *Quick reaction task orders for phase I and II clinical trials involving pediatric patients*
New Deadline: *March 17*

The synopsis appeared in the Jan. 4 issue of ***The Cancer Letter.***

RFP NCI-CM-07362

Title: *Operation of genetic production center for rodents in biocontainment environments*
Deadline: *March 24*

The synopsis which appeared in the Jan. 18 issue of ***The Cancer Letter*** announcing the availability of RFP NCI-CM-07362 is hereby cancelled and the following substituted therefore:

Develop and maintain colonies of inbred and outbred rodents of required genetic characteristics, and with defined microflora. Some of the tasks include substitutions and additions of strains and stocks, and the production of large numbers of rodents in barrier environments.

Successful offeror(s) must have an existing facility with, as a minimum, an absolute filtration system, mechanical cage washing machines, auxiliary generators, autoclaves (steam sterilizers) with sufficient capacity for large numbers of caging equipment, and large volumes of animal food and bedding. Offerors must have a minimum of three years experience in pedigreeing procedures with inbred rodents. Respondents must be capable of demonstrating a minimum of two years experience in the maintenance of barrier type facilities. Evidence for this experience shall include a minimum continuous period of three years in the production and distribution of laboratory rodents for biomedical research; and a minimum two years in maintenance of barrier enclosed production colonies.

To accomplish the needs of the program as described, the following task levels are required. The isolator cage levels of each task are those that allow the maximum production efficiency for the rat and mouse strains needed. The listed ratios of isolator to barrier cages are the only ones which will be considered at this time.

Task 1. Approximately 1,225 mouse cage equivalents maintained as foundation colonies in associ-

ated flora isolators. Approximately 2,000 mouse cages maintained under strict barrier conditions as pedigreed expansion colonies.

Task 2. Approximately 1,250 mouse cage equivalents maintained as foundation colonies in associated flora isolators. Approximately 4,000 mouse cages maintained under strict barrier conditions as pedigreed expansion colonies.

Task 3. Approximately 2,200 mouse cage equivalents maintained as foundation colonies in associated flora isolators. Approximately 4,000 mouse cage equivalents maintained under strict barrier conditions as foundation and colonies in associated flora isolators.

Task 4. Approximately 850 mouse cage equivalents maintained as foundation colonies in associated flora isolators. Approximately 4,000 mouse cage equivalents maintained under strict barrier conditions as foundation expansion colonies.

Task 5. Approximately 3,550 mouse cage equivalents maintained as foundation colonies in associated flora isolators. Approximately 13,500 mouse cage equivalents maintained under strict barrier conditions as foundation and expansion colonies.

Due to size of this effort and special requirements, it will be necessary that barrier production be performed on at least three facility sites which are located at least 50 miles apart. With the exception of Task 1 only one task will be awarded to any one contractor location.

It is anticipated that five awards will be for three year incrementally funded periods of performance.

Contracting Officer: Daniel Abbott
Cancer Treatment
301-427-8737

RFP NCI-CM-07343-22

Title: *Quick reaction task orders for clinical trials of biological response modifiers*

New Deadline: *March 17*

The synopsis appeared in the Jan. 4 issue of ***The Cancer Letter.***

RFP NCI-CM-07341-22

Title: *Quick reaction task orders for phase II clinical trials*

New Deadline: *March 17*

The synopsis appeared in the Jan. 4 issue of ***The Cancer Letter.***

Contracting Officer for above 3 RFPs: Harold Thiessen
Cancer Treatment
301-427-8737

RFP-GENS-3

Title: *Preclinical toxicologic studies of antineoplastic agents*

Deadline for submission of qualifications: *March 10*

Studies utilizing the protocols, (excluding monkey studies) and requirements of "Procedures for Preclinical Toxicologic Evaluation of Cancer and Chemotherapeutic Agents: Protocols of the Laboratory of Toxicology" (Cancer Chemotherapy Reports, Part 3, Volume 4, No. 1, January 1973).

In order to qualify, firms must have experienced and qualified personnel, as well as facilities/equipment for the studies, described in the above referenced document. Specific requirements are: (1) an investigator with experience in toxicologic evaluations using beagle dogs and mice, (2) a qualified staff capable of undertaking the required pathologic evaluations; (3) facilities for holding and treating up to 60 dogs and 400 mice at one time, (4) suitable clinical chemistry and hematology capability, (5) facility should be able to conduct studies under GLP adherence, (6) overall capacity to completely evaluate at least three antineoplastic agents undergoing lethality and toxicity studies in mice and toxicity studies in dogs, plus compound identify and purity analysis and blood compatibility testing, or an equivalent mix of studies in a one-year period.

Small and small disadvantaged businesses are especially encouraged to reply, although this is not a 100% small business set aside procurement.

Battelle Toxicology Program Office
Suite 810, 8330 Old Courthouse Rd.
Vienna, Va. 22180

RFP NIH-NIAID-MIDP-80-22

Title: *Immune interferon standards*

Deadline: *May 7*

The Microbiology and Infectious Diseases Program, National Institute of Allergy & Infectious Diseases has a requirement to produce standards for mouse immune interferon and human immune interferon. The contractor will be required to prepare these standards, characterize and standardize these standards, and supervise a collaborative titration to determine potency. The contractor should have demonstrable experience in this area.

Chief, Contract Management Branch
National Institute of Allergy & Infectious Diseases, NIH
Westwood Bldg, Room 707
5333 Westbard Ave.
Bethesda, Md. 20205
Attn. Sara Spencer

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