CHACLER LETTER

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NCI DENIES GAO REPORT THAT BACKLOG STILL EXISTS, SAYS MOST WERE PUBLISHED AS RESEARCH RESULTS

The report on NCI's Carcinogenesis Testing Program by the General Accounting Office, the congressional agency charged with investigating Executive Branch activities, was typical of those filed by GAO on the Cancer Program:

• There were some valid criticisms, although most of the weaknesses GAO pointed out were ones of which NCI was well aware and in some cases had already corrected.

• There was considerable criticism based on cursory looks at problems with failure to take pertinent factors into consideration.

• It appears that GAO considers part of its job providing the congressman requesting an investigation (in this case, Henry Waxman, the California Democrat who made the request two years ago, before becoming chairman of the House Health Subcommittee) with some head(Continued to page 2)

In Brief

GORI TO RETURN AS HEAD OF SMOKING PROGRAM; WISCONSIN, AACI TO HONOR HAROLD RUSCH

GIO GORI, who still is technically the deputy director of NCI's Div. of Cancer Cause & Prevention, will return at the end of May from the "semi-sabbatical" he has taken to complete a master of public health program at Johns Hopkins Univ. He will resume one of his former tasks, as head of the Smoking & Health Program, but working out of Director Arthur Upton's office rather than DCCP as an associate or assistant director of NCI. Gori fell into some disfavor when he coauthored an article which claimed that a pack of modern cigarettes with average tar and nicotine content is no more dangerous to health than two pre-1960 cigarettes. Upton had to find another job for Gori anyway, since the then new DCCP director, Gregory O'Conor, wanted to select his own deputy. It's possible Gori and the smoking program may wind up in the proposed new Div. of Cancer Prevention, with Gori also being responsible for other prevention efforts. . . . HAROLD RUSCH, who has retired as director of the Univ. of Wisconsin Comprehensive Cancer Center, will become professor emeritus of the university at the end of June. The Assn. of American Cancer Institutes will hold its semiannual meeting in Madison June 24-26 and will honor Rusch at a dinner. . . . ANTHONY CURRERI, former director of the Div. of Clinical Oncology at Wisconsin, died suddenly May 3. . . . BERNARD FISHER, chairman of the National Surgical Adjuvant Breast Project and a surgeon himself: "I do not see surgeons demonstrating much willingness to participate (in clinical studies). That's sad. We're in a crisis situation. Suppose we find that chemotherapy and hormonal therapy don't work? Very few surgeons are willing participants in our segmental trials. It's a national tragedy that surgeons are not participating."

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NCAB Subcommittee
Tells Califano
To Keep Hands Off
Board Appointments
... Page 6

No Proof Fiber
Is Anticarcinogenic,
Newell Says, But
Diet Should
Include It Anway

... Page 8

GAO REPORT SAYS NCI DID NOT MONITOR ADEQUATELY BIOASSAY CONTRACTORS

(Continued from page 1)

line grabbing material, no matter how far a point had to be stretched. The media picked up Waxman's news release which stressed GAO investigators' claim that the infamous bioassay "backlog" of chemicals which had been tested but not reported still has not been cleared up, contrary to NCI's statements that it has. Neither Waxman nor the media bothered to report NCI's answer.

Following is GAO's summary of its investigation: The National Cancer Program emphasizes the importance of carcinogenesis activities and, in particular, the identification of carcinogenic hazards. NCI's appropriations and staff have increased significantly since the time the legislation was enacted. While NCI has devoted more resources to carcinogenesis activities, the proportion of its resources allocated for carcinogenesis in 1978 remained about the same as in 1972.

While staffing has not been a problem for the carcinogenesis research program, it has been a major problem for the testing program. Twenty of the 49 positions authorized for the testing program were vacant at the time of our field work—13 of these 20 vacancies were for scientific personnel. Recruiting certain types of scientists—toxicologists and veterinary pathologists—has been especially difficult; seven of the 13 scientific vacancies were for these two specialties.

NCI stated that it was difficult to fill its scientific positions because the scientists lacked an opportunity to perform research, the testing program's future was uncertain, there was a shortage of toxicologists and veterinary pathologists and inadequate pay for Federal veterinary pathologists, and CSC lacked a job classification for toxicologists.

The vacant scientific positions primarily involved administrative duties dealing with extramural activities such as planning test projects, reviewing project proposals, and monitoring contracts. NIH's policy precludes scientists responsible for extramural activities from conducting intramural research. The associate director, Carcinogenesis Testing Program, stated that the lack of research opportunities for scientists has hindered recruiting efforts for the testing program. He added that scientists need to perform research to maintain and enhance their scientific skills.

An additional recruiting problem occurred because the secretary of HEW was considering alternatives to how the government should be organized to meet the nation's chemical testing needs; the future of the NCI testing program could have been affected by some alternatives. . . . This created a period of uncertainty during which NCI could not assure prospective employees about their job location or whether they would be working for NCI or another agency. The

secretary of HEW decided to create a National Toxicology Program in Sept. 1978. The program will consist of the relevant activities of several federal agencies, but these activities will remain within their respective agencies. While the testing program remains virtually unaffected by creating the National Toxicology Program, the secretary's decision has not eliminated the uncertainty of its future. . . .

Recruiting toxicologists and veterinary pathologists has been hindered because the demand for these specialties is high but the supply is limited. Toxicologists are in great demand both within and outside the government, primarily because a substantial amount of environmental health legislation has been enacted that requires this specialty. Hiring veterinary pathologists has been further hindered because there are large salary differences between the government and private industry.

NCI and others also claimed that recruiting toxicologists has been hindered because the Civil Service Commission has no toxicology job classification. CSC officials stated that other factors were more significant than this. They said the demand for toxicologists has increased because some legislation requires this specialty while the supply of toxicologists has been limited. They also said that NCI often failed to adequately justify why NCI's prospective employees should be considered above candidates CSC already had on its register. CSC officials also stated that other agencies have established training programs to fulfill its need for scientists. NCI recognized its need to establish training programs for toxicologists and veterinary pathologists in testimony before the Senate Appropriations Committee in 1977; NCI also testified that it had the legislative authority to initiate these programs. However, except for institutional support grants and fellowships-which do not require recipients to work for the government-NCI has not established any such training programs. Commenting on a draft of this report, NCI stated that a shortage of staff available to develop such programs, a subsequent determination that its legislative authority was questionable, and a shortage of funds prevented it from establishing training programs.

NCI attempts to identify the carcinogenicity of chemicals through bioassays; until 1974, NCI contracted directly with laboratories to perform them. However, staffing shortages caused NCI to contract with Tracor Jitco Inc., in March 1974 to manage NCI's bioassay activities. Pursuant to this arrangement, NCI no longer contracted directly with laboratories but contracted with Tracor Jitco, which subcontracted with laboratories to perform bioassays.

When NCI originally contracted with laboratories to conduct bioassays, NCI did not contractually require them to prepare bioassay reports. NCI decided detailed bioassay reports were needed in 1975, and it began the technical report series, which is the current method of publishing reports.

Terry has not ruled himself out as a candidate for the job he is holding on a temporary basis. "I haven't made a final decision on whether I want to be considered by the search committee," Terry said. "I'm thinking seriously about it."

Terry has headed NCI's Immunology Program for many years, holding the dual role as associate director of DCBD for immunology and chief of the Immunology Branch. That placed him in charge of both the intramural and contract supported research. With the reorganization, DCBD now administers both contracts and grants in immunology separately from the inhouse Immunology Branch.

Terry is faced with the decision of whether he wants to give up his career as a scientist and go permanently into administration, or return full time to the Immunology Branch. If he goes for the latter option, he would continue as interim head of the Centers Program until that job is filled.

Two other names have been mentioned as prospects for the resources, centers and community programs division—Stephen Carter, former DCT deputy director who now heads the Northern California Cancer Program; and Peter Greenwald, chief of the Bureau of Cancer Control in the New York State Dept. of Health.

NCI RECEIVES MORE THAN 300 REQUESTS FOR COMMUNITY ONCOLOGY PROGRAM RFP

The new Community Hospital Oncology Program being developed by NCI's Div. of Cancer Control & Rehabilitation has stirred up more interest among community oncologists than anything DCCR has supported since the Community Based Cancer Control Programs.

The RFP for the three-tiered contract program became available early this month. Donald Buell, who heads up the program for DCCR, said there were more than 300 requests for the RFP (N01-CN-95457-45, *The Cancer Letter*, April 27). A preproposal conference is scheduled for June 18.

DCCR has earmarked funds to support as many as 10 contracts in each of three categories—multi-hospital cooperative (community wide) programs; small community programs; and single hospital programs.

Peer review will be conducted within each of those categories; proposals in one category will not be competing against those in the others, DCCR said.

Here's how the RFP describes each of the programs:

• Multi-hospital. This category is meant to include larger single communities or multiple geographically related small communities in which several hospitals admit cancer patients and which have surgeons, radiotherapists and one or more medical oncologists who can work together to develop a community wide program. This program is restricted to hospitals which have no major affiliation with a comprehensive cancer center or large university cancer program.

Limited Cooperative Group membership or participation as a satellite hospital of a Cooperative Group cancer control program is permitted. The participating hospitals must, as a group, see a minimum of 500 new cancer patients annually exclusive of early skin cancer. Six hospitals is felt to be a reasonable upper limit for this program. Those proposing a larger number of participating hospitals must provide justification. The principal investigator shall be a physician acceptable to the medical staff and administration of participating hospitals. The fiscal agent must be a community hospital or nonprofit organization. A university may not be the fiscal agent, nor may a university hospital receive direct funds under this program. Programs must establish consultative relationships with local medical schools as well as larger university comprehensive cancer centers.

In communities where a university has a significant cancer program and exerts a leadership role, a proposal in response to this RFP is inappropriate. Attention should instead be directed toward submission of a cancer control outreach grant proposal specific for community needs.

• Small community. This category includes single communities or multiple geographically related communities in which hospitals admit cancer patients but which have no practicing medical oncologists. In order to qualify, there must be a radiotherapy facility to serve the program and a functioning tumor registry. Such programs will be expected to establish close working relationships with a cancer center in order to draw upon necessary experience and expertise. The program however, is to be locally initiated, developed by and for the practicing community health care providers with the center acting as consultant.

If possible, a designated medical oncologist, surgical oncologist and consultant radiotherapist will travel from the center to the community to participate in tumor boards, make rounds, and advise in an ambulatory clinic on a regular basis. Under this program, the bulk of cancer care is delivered by the primary care physician-nurse oncologist team. This program is restricted to hospitals that have no major affiliation with a comprehensive or university cancer center. The participating hospitals must, as a group, see a minimum of 300 new cancer patients annually, exclusive of early skin cancer. The principal investigator shall be a community physician, acceptable to the medical staff and administration of the participating hospitals. The fiscal agent must be a community hospital or nonprofit organization. A university may not be the fiscal agent.

• Single hospital. This category will test the applicability of this model for cancer program development in large community hospitals which represent the major cancer care resource for their community. Some large private practice hospitals in this country admit over 500 cancer patients yearly. Although they may have house staff training programs, relationships

with university and comprehensive cancer centers are not well established.

Generally, trained radiation and medical oncologists practice in such hospitals, but where multidisciplinary care and referral patterns are not formalized, there is no assurance of a general high level of acceptable cancer care. Further, there may be no organized cancer education program for primary care physicians, oncology nursing, or cancer rehabilitative services. Because of the numbers of cancer patients seen, if a program compliant with the requirements of this RFP is developed and established in such a hospital, there should be significant patient benefit. The relative academic isolation of a large single hospital may be a reflection of a long standing private-academic or town-gown alienation. This RFP requires that close ties be established with a comprehensive or university center as a step which breaks this pattern. A Clinical Oncology Program, because it is initiated and funded within the private hospital which then seeks consultation with the center, is often much more acceptable to primary care physicians than a center initiated pro-

DCCR recognizes that this proposed program has the potential for strengthening the cancer program in a single hospital in a community while not resulting in benefits to cancer patients treated elsewhere in the same community. Sometimes a community is not ready to institute a community-wide clinical oncology program activity. Since the primary care physicians admit to multiple hospitals, once the benefits of COP management become apparent in a single hospital, the program becomes exportable. To quality as a participant in the Single Hospital Clinical Oncology Program, a hospital must justify its potential impact on the community. Further planning to this end will be required under the contract.

Eligible single community hospitals must see at least 500 new cancer patients each year, excluding early skin cancer, and can not have a major affiliation with a university cancer program or comprehensive cancer center. All facilities and specialists for multidisciplinary cancer management must be available, including at least one medical oncologist. A hospital in a community where other hospitals admit significant numbers of cancer patients must present and defend a rationale why the community would not be better served by a community-wide cooperative program. Limited cooperative group membership or participation as a satellite of a cooperative group cancer control outreach program is permitted. The principal investigator must be a community physician acceptable to the medical staff and administration.

The RFP asked that prospective applicants not contact administrative offices of the seven existing Clinical Oncology Programs, upon which much of the new program is based, "as that would create an unacceptable burden on their time."

However, directors and other representatives of

some of these programs are on the program of a three-day "National Seminar on Community Cancer Care" June 1-3 in Indianapolis. These include Blen Becker and Korth Bingham, Blue Mountain Oncology Program; Judy Holaska and Robert Post, Allentown COP; Edward Moorhead and Thomas Tucker, Grand Rapids COP; Robert Pannoni, San Jose COP; and several representatives of the host Methodist Hospital of Indianapolis COP.

Buell will also be on the program, so there should be plenty of opportunity for prospective applicants to discuss the new RFP with people in the business. Contact William Dugan or Donna Minnick, program chairmen, at Methodist Hospital, P.O. Box 1367, Indianapolis 46206.

Indiana Sen. Birch Bayh is also scheduled to address the seminar.

The RFP commented that the new model, based on the experience of the pilot clinical programs, "is grounded in the principal that community programs are most successful when planned and developed by those who will use and be most affected by the program. Therefore, it is an important requirement under this approach that community cancer care providers plan the program. Because of the importance of such 'participatory planning' in the acceptance and ultimate success of the program, 18 months are allowed for the planning phase. Under this approach, multidisciplinary management guidelines are to be developed for the most frequently seen cancers. Site specific guidelines for staging and medical management are to be developed by committees including primary care physicians who are responsible for at least 75% of cancer admissions to the participating community hospitals.

"Further, the guidelines must have appropriate multidisciplinary input including pathology, surgery and its subspecialties, radiation therapy, and medical oncology. Guidelines should reflect optimum criteria of community cancer management and should receive independent validation. In government funded programs the community developed guidelines are independently validated through peer review and by NCI program, staff. Similarly, site specific nursing care and rehabilitation guidelines are to be developed by appropriately constituted committees of community cancer care providers. Where multiple hospital cooperation is required, the model specifies a consortium committee to advise in the development and operation of the program. The committee must include highlevel representatives who can speak for the participating hospitals such as the chief of staff, key administrators and a member of the board of trustees.

"Since the model is designed for community hospitals that have no major affiliations with a comprehensive or university cancer center, it specifies that such relationships must be developed or existing relationships strengthened. Community programs should seek needed consultation and advice, drawing upon

the expertise available in such centers. Appropriate referral patterns should be developed for patients requiring the specialized care of a center. Conversely, followup care and appropriate investigational care should, whenever possible, be made available in the community."

MOPP AT 15 YEARS: MAJOR CONSEQUENCE IS BIG DECLINE IN HODGKIN'S MORTALITY

"The dramatic fall in cancer mortality under age 30 is largely due to the effect of treatment of Hodg-kin's disease and early childhood malignancies, but please note that we are even beginning to see an early reduction in mortality in patients less than the age of 60 with cancer," Vincent DeVita said in the annual meeting of the American Society of Clinical Oncology last week.

DeVita, director of NCI's Div. of Cancer Treatment, developed with his colleagues the MOPP chemotherapy for advanced Hodgkin's disease in 1964 (he was a clinical associate at that time). They had first experimented with a combination they called MOMP—cyclophosphamide, vincristine, methotrexate and prednisone.

"As we developed our own experience with procarbazine, we thought the results were superior to methotrexate and incorporated procarbazine into the next program (MOPP), in 1964," DeVita said. MOPP included nitrogen mustard, vincristine, procarbazine and prednisone.

It turned out to be one of the most significant advances ever in the treatment of cancer, particularly important in the development of combination chemotherapy. DeVita's lecture included a 15-year update of the MOPP study results.

"The major consequence of the development of MOPP chemotherapy for Hodgkin's disease is the demonstration that drugs can cure patients with advanced disease," DeVita said. Another consequence was that the "long term effects of chemotherapy on the gonads, the immune system, and the carcinogenic effect of this drug therapy are important subjects to consider, as we strive to decrease the morbidity of effective treatments.

"However, I wish to remind you that dead patients don't complain of side effects, which is why I have put the cure of the disease as the first and most important consequence."

A third major consequence of the success of the MOPP program "was the provision of a tool to construct complete therapeutic experiments in humans with Hodgkin's disease—the combination of effective local and systemic treatments; radiation therapy plus drugs in this case."

Also, DeVita continued, "if you can cure advanced stages of Hodgkin's disease with drugs, why not early stages? Again, posing this question required confidence in the capacity to cure patients with advanced disease with drugs and a need to improve on the re-

sults of radiotherapy of early stages of the disease. Both exist today."

DeVita discussed the early development of chemotherapy, starting with the work of Howard Skipper and his colleagues at Southern Research Institute which demonstrated that "the cytotoxic effect of cancer drugs followed first order kinetics and that the tumor killing effect of drugs in the rodent leukemia 1210 model could be readily quantitated, opened up clinical chemotherapy and led to the exploration, in the mouse model, of nuances of dose response effects, scheduling, and the use of drugs in combination, all of which spilled over into clinical protocols when the tools of the trade, the drugs, existed to make it possible."

A "critical mass" of biologic data plus availability of some new drugs "gave us some clearcut goals to aim for in the development of the MOPP drug combination program," DeVita continued. These were:

"First, we attempted to avoid dose limiting host toxicity, seen with sharp escalation of doses of single drugs, that were known to have steep dose response curves. We did this by using the agents that were available, in combination, to achieve additive, or, hopefully, even synergistic antitumor effects while still using standard doses. The availability of two vinca alkaloids allowed us to select the less marrow toxic vincristine, in preference to vinblastine, although the former drug was thought to be less effective than vinblastine when used alone.

"Because human tumors could be presumed to grow more slowly, and divide less uniformly than the L1210 model, prolonged administration of chemotherapy for six months was also a goal.

"We hoped, as in rodent models, that the use of drugs in combinations would circumvent resistance to drugs by preventing its development or by exposing the heterogeneous population of tumor cells to multiple agents.

"Finally, we aimed at cure, not palliation. I say this boldly now, but I must tell you that in 1963 speaking of curing advanced cancers with drugs was considered somewhat bizarre and required a modicum of courage in an academic environment."

Referring to the MOMP study, DeVita said, "I well remember how radical we thought this treatment was. All patients were hospitalized for the entire course of the treatment. The early patients were even put on precautionary isolation procedures.

"It is interesting to note that 80% of patients treated with MOMP had a complete remission and 42% of a small group with Stage III disease remain free of disease to this day, indicating that the use of methotrexate was probably beneficial, since the use of the other three drugs, in combination by others, has, even today, not proven to be beneficial for patients with advanced Hodgkin's disease.

"Emboldened by the absence of disasters with the use of MOMP therapy, we increased the duration of

24.5

treatment to six months but reduced the use of prednisone to cycles 1 and 4 only.

"We began to administer MOPP gingerly in the outpatient department where now it is used routinely. MOMP and MOPP were given in the now familiar 28 day cycles because of one other solid piece of information available at the time. Full recovery of blood counts took about 28 days. If a complete remission was attained after six cycles, all further treatment was discontinued and the patients were followed and restaged at intervals.

"In the interval between February 1964 and April 1975, 198 patients with advanced stages of Hodgkin's disease were treated with the MOPP program as their primary form of treatment. As of April 1979, 184 of the 198 patients have been followed at least five years; 137 at least eight years and 79 patients beyond 10 years.

"All but 32 of these patients had received no treatment prior to referral to NCI; 32 patients received local x-ray therapy only and had relapsed with a more advanced stage at the time of referral.

"The capacity to attract previously untreated patients to a center investigating a new approach to treatment played an important role in our ability to carry out this study successfully.

"Not included in these 198 patients are a group of 26 patients heavily pretreated before referral. This latter group of patients taught us our first lesson, that exposure to prior chemotherapy compromised a patient's ability to achieve a complete and durable remission with MOPP. This fact has now been amply confirmed by others.

"Eighty percent of 198 patients attained a complete remission, a fourfold increase over that achievable with single agents, a fact that has also now been confirmed in other studies. The mean time to complete remission was three months, but no two patients were the same. Response times varied widely. The range of the number of cycles needed to attain a complete remission was from 1 to 11 cycles.

"In contrast to the negative impact of prior chemotherapy, previously alluded to, there was an interesting positive trend noted with the 32 patients who had received prior radiotherapy. All but two of these patients, or 94%, attained a complete remission compared to 78% of previously untreated patients. While this difference is not quite significant, the p value is 0.065

Other aspects of the study included:

- Sixty-eight percent of patients who attained complete remission were continuously relapse free five years after end of all treatment; only four relapses have occurred beyond four years—at 52, 77, 88 and 90 months. Relapse free survival at 10 years is 63.4%.
- Twenty-three patients died of other causes while in apparent CR. Fifteen were autopsied, and 14 were completely free of Hodgkin's disease evi-

dence. The other may have had microscopic evidence but the diagnosis was unclear. "These data provide further confidence that patients in clinical remission for long periods of time are truly free of their tumor," DeVita said.

- The most important single factor affecting relapse free survival was B-symptoms and the second histology, especially those patients who had the lymphocyte depleted variety of nodular sclerosing Hodgkin's disease or no minor histopathologic classification.
- Because one-third of the patients were relapsing, NCI designed a clinical trial to assess the impact of further treatment on those who achieved a complete remission. Patients in CR were randomized to intermittent MOPP, intermittent BCNU or no further treatment. The study was discontinued after five years because there appeared to be no benefit from maintenance therapy.
- It soon became apparent, however, that relapsing patients were not necessarily resistant to MOPP. Fifty-nine percent achieved a second CR after retreatment. The duration of the initial CR determined the likelihood of a second long remission. Median survival of all patients following their first relapse exceeded four years when retreated with MOPP.
- Adverse effects of MOPP therapy included long term sterility in a majority of male patients; amenorrhea in about 50% of females.
- Since drugs used in MOPP are among the most immunosuppressive agents yet developed, there was concern about effects on patients who were inherently immunosuppressed. DeVita found that "there appears to be no tendency for patients in long remissions after MOPP chemotherapy to correct the deficiency in numbers of T-cells." He concluded that the immunologic defect of T-cell function in Hodgkin's patients antedates treatment; immunologic status at diagnosis does not affect initial response or relapse free survival; defect in T-cell persists even after curative therapy; the persistent T-cell abnormality may not be related to treatment, but an uncorrected residual of disease process; and the immunosuppressive effects of treatment are of no consequence if the treatment works.
- Patients treated either with extensive radiotherapy alone or MOPP alone are at slightly higher risk of second tumors, but it is of borderline significance. However, for those who had both MOPP and radiotherapy, the increased incidence of second malignancies is 15 fold, almost entirely due to myelocytic leukemia. At 10 years, it may be as much as 5%, which DeVita said may outweigh the benefits.

ADVISORY GROUP, OTHER CANCER MEETINGS FOR JUNE, JULY

National Seminar on Community Cancer Care—June 1-3, Indianapolis Hyatt Regency, sponsored by the NCI Clinical Oncology Program, Methodist Hospital Graduate Medical Center, Assn. of Community

Cancer Centers, ACS Indiana Div., and Community Hospital of Indiana-

Prostatic Cancer Review Committee-June 1, Roswell Park, open 8:30-

Consensus Development Conference on Management of Primary Breast Cancer-June 5, NIH Masur Auditorium, 8:30 a.m., open.

Bladder Cancer Review Committee-June 7-8, Des Plaines, III. Royal Court Inn, open June 7, 8:30-10:30 a.m.

Large Bowel Cancer Review Committee-June 7-8, Houston Prudential

Bldg., open June 7, 7:30-8 p.m.

FDA Oncologic Drugs Advisory Committee—June 7-8, Parklawn Bldg, 5600 Fishers Ln., Rockville, Md., Conference Rm G, 9 a.m. both days, all open.

Cancer of the Colon-Rectum-June 9, Roswell Park continuing education in oncology.

Clinical Cancer Education Committee— June 11-12, NIH Bldg 31 Rm 6, open June 11, 8:30-9 a.m.

American Cancer Society Board of Directors-June 11-15, Minneapolis

Hodgkin's & Non-Hodgkin's Lymphoma: Multifocal Aspects in the Clinical Spectrum-June 14-15, Wilmington, Del. Sheraton Brandywine

Cancer Control Intervention Programs Review Committee-June 14-15, Landow Rm A, open June 14, 8:30-9 a.m.

Charged Particle Radiotherapy - June 24-28, Canadian Assn. of Radiologists. Vancouver.

Clinical Cancer Investigation Review Committee-June 25-27, NIH Bldg 31 Rm 8, open June 25, 8:30-10 a.m.

Cancer Special Programs Advisory Committee- July 11-12, NIH Bldg 31 Rm 9, open July 11,9-10 a.m.

Century of Mammalian Genetics & Cancer: 1929-2029-A view of Mid-Passage - July 17-20, Jackson Laboratory 50th anniversary symposium, Bar Harbor, Maine.

President's Cancer Panel-July 25, NIH Bldg 31 Rm 7, 9:30 a.m., open.

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

RFP N01-CP-95626

Title: Open formula diet for rodents

Deadline: June 25

NCI Div. of Cancer Cause & Prevention is issuing this sources sought announcement to locate prospective proposers interested in providing feed for rodents in bioassay tests.

There is no RFP available at this time. Upon receipt and evaluation of the proposals, a determination will be made from the interest shown if an RFP should be developed. Proposals will be technically

evaluated to determine capabilities and potential sources for solicitations.

The objective of the Bioassay Program of the National Toxicology Program is to provide open formula diet for rodents to contractor laboratories located in all parts of the United States. These diets will be made in large batches. An average of 25, 35, 45, 55 and 65 tons of feed for years 1, 2, 3, 4 and 5 respectively will be needed. The diets will be routinely assayed for nutritional composition and for chemical contamination.

All information submitted shall address the following areas: The proposer must have previously produced open formula rodent diets. Include names, professional qualifications, specific experience of key personnel and percent time of their availability for this project. A description of the specific facilities available at this time for the conduct of the work, and/or a discussion of facilities which might be available within nine months should be included. Include any other pertinent data that would enhance understanding and evaluation of the information submitted.

Contract Specialist: J. Roland Castle

Carcinogenesis 301-427-8764

RFP N01-CO-95464-09

Title: Evaluation of the effectiveness of cancer education

Deadline: Approximately July 10

NCI is requesting proposals for a new procurement from offerors interested in developing a methodology for providing a systematic evaluation of the effectiveness of a grant program which provides support to schools of medicine, dentistry, public health and their major affiliated hospitals for improved cancer education activities.

In order to conduct such a project, it will be necessary to review cancer education objectives and methods of their achievement as carried out in such institutions, to review guidelines for the grant program as developed by the NCI, and to define, with the help of experts, minimally acceptable and optimal cancer education programs in various institutions. A methodology should then be developed which would enable NCI to assess the status of the grant program at any time by means of special documentation procedures.

Offerors should be experienced in both the development and analysis of educational curricula of institutions of higher learning in the medical and dental professions. They should have familiarity with the mechanisms of evaluation of education programs and curricula in these institutions. They should have some experience and capability in the development and implementation of data analysis systems for education programs directed toward physicians and dentists. They should also have familiarity with specific programs of cancer education in medical and/or dental schools and should have a background in the clinical aspects of oncology. They should have some experience in arranging and the conduct of large meetings and workshops, and expertise in documentation of the outcome of such meetings.

Contract Specialist: Gloria Dahl

Office of Director 301-427-7984

RFP NCI-CP-FS-91030-67

Title: Nonmelanoma skin cancer survey in New

Hampshire and Vermont Deadline: Approximately July 10

The Div. of Cancer Cause & Prevention of NCI, Field Studies & Statistics, is seeking support services for a nonmelanoma skin cancer survey in New Hampshire and Vermont.

It is essential that the respondents be experienced in population-based registries, have expertise in the field of medical abstracting with proficiency in dealing with medical records of patients newly diagnosed with cancer and a project director with expertise in epidemiological methodology, who also has established ties with the medical community. Respondents must have an office and facilities already established in New Hampshire or Vermont at the time this RFP is published.

Contract Specialist: Dorothy M. Coleman

Viral Oncology & Field Studies

301-496-1781

RFP N01-CO-95462-09

Title: Preparation and updating of clinical protocol summaries

Deadline: Approximately July 10

This was previously announced under RFP N01-CO-95448-09 which is cancelled in its entirety; inquiries should be made referencing the new number above.

NCI is requesting proposals for a new procurement consisting of four main activities: (1) the collection of new clinical protocols and the preparation of summaries; (2) the preparation of a compilation of protocol summaries on an annual basis; (3) the preparation of an updated, on-line computer file of these protocol summaries currently housed at the National Library of Medicine (NLM) in Bethesda, Md. and known as "Clinprot" and (4) the updating of protocol summaries already in the file.

At the present time, these activities are divided between two existing procurements. One pertains primarily to immunotherapy protocols, the other primarily to chemotherapy protocols. Within one month of the award of this contract, the successful offeror will receive, from the two current contractors, the file of existing protocol summaries, either as computer tape or hard copy, all protocol documents from which completed summaries have been prepared and also all protocol documents for which summaries have yet to be prepared.

Special requirements:

1. Project director must have extensive experience in managing biomedical information projects that are relevant to this contract. An advanced degree in a biomedical subject area would be very desirable.

2. Senior staff members who will prepare the summaries must have at least a B.S. degree in a biomedical area plus additional experience in analyzing/abstracting biomedical information. The extent of relevant biomedical training and experience will be a major factor in the rating criteria.

3. The proposed staff should be able to deal with routine technical questions as they arise. More complex/difficult questions can be referred either to the projec officer (who will pass them on to an appropriate expert) or to the individual who developed the protocol. For these reasons, in-depth clinical expertise is not required. However, the offeror must specify how proposed staffing arrangements and technical approach will ensure a high level of accuracy in the protocol summaries.

4. Arrangements for preparing protocol summaries from a small number of documents written in other languages (primarily German, Italian, French and Spanish) must be required.

5. In addition, offerors must demonstrate that they have the highly qualified data processing staff and experience necessary for entering the summaries on magnetic tape in a format which will be acceptable as input to the MEDLARS system at the National Library of Medicine.

6. Because of the weekly and bi-weekly meetings necessary with the project officer, and fast turnaround time for certain deliverables, preference will be given to offerors within a 50 mile radius of the Washington D.C. area. If, however, offerors outside the prescribed area believe they can meet the specific requirements and remain within the competitive range, all consideration will be given to their proposals.

Contract Specialist: Gloria Dahl

Office of the Director

301-427-7984

The Cancer Letter _Editor Jerry D. Boyd

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