THE CANCER LETTER

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NATCHER SUBCOMMITTEE OPENS DOOR TO JUSTIFICATION FOR INCREASING CANCER PROGRAM 1982 APPROPRIATION

Congressman William Natcher, chairman of the House Appropriations Health Subcommittee, left the door wide open for an increase in the 1982 fiscal year budget for NCI above the Administration's request when the subcommittee heard NCI Director Vincent DeVita defend that request this week.

"If instead of the $1 billion, 25 million you are requesting, doctor,

(Continued to page 2)

In Brief

HHS REJECTS SOLE SOURCE AWARD FOR UTAH STUDY; REAGAN PROCLAIMS APRIL CANCER CONTROL MONTH

NCI HAS had to back down on the plan to award a sole source contract to the Univ. of Utah for an assessment of leukemia and thyroid disease in relation to nuclear test fallout when HHS ruled that justification did not exist for a noncompetitive procurement. NCI is seeking other qualified sources (see announcement inside) to determine if a competitive RFP will be issued. The National Cancer Advisory Board had approved the project as a sole source procurement, but only on a split vote after Board member Gale Katterhagen asked that it be made competitive (***The Cancer Letter,*** March 13). NIH contract officials also objected to a sole source award. . . . **PRESIDENT REAGAN**, in proclaiming April as "Cancer Control Month," said that "vigorous cancer research, directed to both treatment and prevention, must continue" but did not suggest that the federal government should increase its efforts to those ends. The proclamation noted that 805,000 Americans will be diagnosed as having cancer this year and that 134,000 will die who might have been saved by earlier diagnosis and treatment. "Cancer is one of the most manageable chronic diseases in our country," Reagan said. "We are approaching the day when, through surgery, chemotherapy and radiotherapy, half of the most serious forms of cancer can be cured. . . Vigorous cancer research directed to both treatment and prevention must continue.". . . **ROBERT GOLDBERGER**, NIH deputy director for science and former chief of the Laboratory of Biochemistry in NCI's Div. of Cancer Biology & Diagnosis, will leave the government at the end of June to become provost of Columbia Univ. and vice president for health sciences. . . . **ROBERT LEVY**, director of the National Heart, Lung & Blood Institute, also will become a vice president for health sciences, at Tufts Univ., where he also will be dean of the school of medicine. Levy will leave NIH in September. . . . **URSULA WALZ**, program analyst and information specialist in the Laboratory of Pathophysiology in the Div. of Cancer Biology & Diagnosis, died of cancer last week at age 56.

NATCHER TELLS DEVITA TO MAKE "RIGHT STRONG" STATEMENT ON ACCOMPLISHMENTS

(Continued from page 1)

suppose it was $3 billion you received?" Natcher asked.

DeVita, as an officer of the Administration has to defend its budget, and he plays that role absolutely straight. "There's not a direct relationship," he answered. "You can't buy ideas." However, he emphasized, the increase in Cancer Program appropriations in the early 1970s "allowed us to put more people to work."

"That's what I had in mind," Natcher said, although obviously he is not going to try for a $3 billion appropriation.

Pressed by Natcher for examples of accomplishments by the Cancer Program in the last four years, DeVita referred to mortality reductions under age 45 and in breast and rectal cancer, suggesting those reductions are due to new treatment, mostly with drugs, developed in recent years. He also referred to the new emphasis on prevention and said that it was made possible by NCI's support of epidemiology and basic research in the early years of the Cancer Program.

Natcher was not satisfied. "As far as money is concerned, this Committee has traveled a little faster than the Cancer Institute. The Committee feels you should have all the money you need." He asked DeVita to provide a statement for the record to include all accomplishments of the Cancer Program. "Make it strong. Amplify it. We need that kind of information to defend your budget when this bill gets to the floor of the House. Make it right strong," the Kentucky Democrat drawled.

Congressman Joseph Early (D.-Mass.) tried to help out. "NCI comes under attack more than any other institute at NIH," he said. "That is possibly because you have the highest level of spending, are the most visible, and maybe because of some mistakes that were made in the 1970s."

"People do take shots at us because we are the biggest," DeVita said. "We also had some problems with contracts, but I'm proud to say that we've gone way beyond the criticism in correcting those problems."

"That message is not getting out to the public," Early said. "I'm not getting the real drive, the real push I should get from my constituents for more support for cancer research. Are you being too conservative in telling your story?"

"We try very hard to be radical in telling our story," DeVita said.

"You're not radical. Our chairman is more radical than you are," Early cracked, drawing laughs from everyone including the moderately conservative Natcher. "I don't think you get nearly enough recognition on where you are going. We need to convince everyone that you are spending that $1 billion wisely."

Silvio Conte (R.-Mass.) commented to DeVita that "we are fortunate to have you as director of the Cancer Institute." Conte, the top ranking Republican on the parent Appropriations Committee, expressed concern about adequate funding for NCI. "Has anyone asked you what impact the $25 million rescission (in FY 1981 appropriations) will have on the Institute?"

"No one has asked me," DeVita said.

"I'm asking," Conte responded.

DeVita described the cuts, about $14 million of which will come from institutional training grant support. "We will still be able to function adequately," he said.

"You feel comfortable with that?" Conte asked.

"I feel that it is our fair share of the available dollars."

Conte, Early, and Congressman Robert Livingston (R.-La.) all expressed interest in the status of interferon research and clinical trials and appeared satisfied with DeVita's answers—that two more years of clinical testing will be required to determine if it is a useful anticancer agent; that NCI is allocating enough money for interferon purchase and research; and that it is still promising despite early clinical results which have demonstrated it is not a "wonder drug."

Congressman Neal Smith (D.-Iowa) expressed concern about the salary differential between government and private sector professionals. DeVita said, "The government is lagging behind, and we are finding it increasingly difficult to attract people."

"In fact, we are beginning to lose people," NIH Director Donald Fredrickson commented.

Smith asked for comparative salaries received by radiotherapists. "I don't know any in private practice who are making less than $100,000," DeVita said. Top government pay for radiotherapists: $57,000.

Congressman Edward Roybal (D.-Calif.) was interested in comparative cancer incidence rates of minorities. DeVita said that the main data base for minorities is in the SEER program. "It has a good sampling for hispanics but not so good for blacks." DeVita said.

Roybal commented that Southern California hispanics have a lower cancer incidence than the overall population and asked if DeVita could offer any reason. DeVita said he felt it was due to diet factors.

Congressman David Obey (D.-Wisc.), a member of the subcommittee and frequent critic of NCI, did not attend the hearing.

The Administration last week changed directions again on what it intends to do about the 1981 (current) fiscal year budget.

President Reagan had changed the Carter Administration's rescission request for a number of agencies,

including about $13.5 million for NCI, into a deferral, and had increased it to about $17 million.

A rescission proposed by the President from an appropriation already approved by Congress and signed into law (as the 1981 appropriation has been for HHS through a "continuing resolution" which expires in June) can be made only if it is approved by both houses of Congress within 45 days. A deferral asked by the President goes into effect immediately and remains in effect until it is vetoed by either the House or Senate.

The White House changed Carter's rescission to a deferral in February, but last week (published in the March 25 *Federal Register*) switched back to a rescission. Thus, if both houses of Congress do not approve the request within 45 days of that date, the rescission is dead and NCI will get the nearly $1 billion approved by Congress in the continuing resolution.

The issue is complicated somewhat by the fact that the Carter rescission request ran out 22 days before it was changed to a deferral. HHS budget officers are considering the possibility that those 22 days could be subtracted from the 45, thus giving the Reagan rescission only 23 days before it dies unless acted upon first.

Another complicating factor is that the continuing resolution, enacted because a regular appropriations bill for HHS and a few other agencies had not been approved for FY 1981 when the fiscal year started, expires in June. A new continuing resolution will be required then, and the White House said it would seek another rescission to cover that period.

The *Federal Register* publication may be confusing to some who saw it. It calls for cuts in Cancer Control, Cooperative Groups and cancer centers spending. Those are not new cuts, but represented reductions made previously. The budget status for research grants and training, as published in ***The Cancer Letter*** March 13, remains intact.

New cuts have been made, however, in the intramural research, direct operations and program management sections of that budget. NCI faced up to the fact that there is very little if any chance it will get a supplemental appropriation for 1981 to cover the cost of pay increases which went into effect last October. NCI had been assuming, in making up the budget projections, that it would get about $7 million from that supplemental.

Eliminating that assumption wipes $7 million from the $982.9 million total shown in the March 13 publication, leaving NCI with a total of $975.9 million.

The cuts were:

—$5 million from intramural research, leaving a total of $156,282,000.

—$700,000 from direct operations, leaving a total of $41,043,000.

—$600,000 from program management, leaving a total of $10,914,000.

A reduction of about $200,000 was made in Cancer Control, all from funds earmarked for staff salaries.

The White House may have determined that such strong support exists on Capitol Hill for budget cuts that it would have no problem getting the rescission approved. The HHS rescission, and possibly others, will go in as a package. Administration lobbyists are arguing that putting the cuts together is the only way they will survive the special interest lobbying efforts.

It might still be possible to get someone to offer an amendment striking the NCI cuts, either in committee (the Appropriations Committees have not yet reported out the rescission bill), or on the floor. To be successful, that would require a major, coordinated and immediate effort.

The prospect appears brighter for securing reasonable increases in the 1981 appropriations bills. Public witnesses still have an opportunity to make their cases before the House and Senate Appropriations Subcommittees.

ACCC ENTHUSIASTICALLY SUPPORTS NEW EFFORT IN COMMUNITY CLINICAL RESEARCH

The Assn. of Community Cancer Centers has enthusiastically endorsed the concept of an expanded, long term version of the Community Hospital Oncology Program as suggested by NCI Director Vincent DeVita (***The Cancer Letter,*** March 20 and 27).

ACCC President Herbert Kerman has appointed Edward Moorhead of Grand Rapids, director of the successful Community Oncology Program there, chairman of an ad hoc committee on clinical research to begin developing recommendations to submit to DeVita.

The committee will hold its first meeting April 29 at the Shoreham Hotel in Washington, during the AACR/ASCO meetings.

DeVita suggested that a long term version of CHOP, with the addition of requirements for participation in clinical research, might be a way to reverse the trend of dwindling numbers of cancer patients available for entry onto protocols while at the same time upgrading community cancer programs. He offered no further details and later said that he expected those would be developed through discussions with staff and others over the next six months.

In a letter to DeVita, Kerman said, "Personally, I view this as an important opportunity to serve the dual needs of research and quality patient care, and to involve the community as an active and equal partner in the National Cancer Program.

"The Board of Trustees and the membership of ACCC fully support the concept of community participation in national clinical investigations," Kerman continued. "To implement this I immediately established an Ad Hoc Committee on Clinical Research to be chaired by Dr. Edward Moorhead of Grand Rapids.

The committee plans to hold an initial planning meeting in conjunction with the upcoming ASCO meetings and will further consider developing plans for a workshop in the summer to develop specific recommendations on the requirements to carry out the program you have suggested.

"The needs of community physicians to participate in national clinical investigations are really modest in respect to personnel, facilities, and funding but without financial support there can be little, if any, participation. Entering their patients on national protocol studies which are supported either through the existing organization and methods or by expansion of these programs, including the national Cooperative Groups, the outreach network programs of the comprehensive centers, the regional programs, to the COPs and CHOPs should be the obvious mechanisms to implement this endeavor.

"It should also provide flexibility so that a wide spectrum of participation would evolve. Innovative approaches and local community initiated programs should allow for interaction and utilization of all possible existing resources, as well as provide an opportunity for further development."

Meanwhile, NCI announced the award of the 19th CHOP planning contract, to St. Luke's Hospital of Bethlehem, Pa., for $122,543. Four more awards remain to be announced.

DIANE FINK TO LEAVE NCI, WILL BECOME ACS VP FOR SERVICES, REHABILITATION

Diane Fink, NCI associate director for medical applications of cancer research, will become the American Cancer Society's vice president for service and rehabilitation on June 15.

The programs she will administer for the Society range from home care and transportation to comprehensive rehabilitation. Assistance is provided to some 450,000 cancer patients annually.

Fink, who served from 1974 to 1979 as director of NCI's Div. of Cancer Control & Rehabilitation, currently is responsible for programs of consensus development, diet and nutrition, and smoking and health. She joined NCI in 1971 after obtaining her medical degree at Stanford Univ. and completing her residency at San Francisco Veterans Administration Hospital.

The ACS patient service programs are highlighted by information and referral activities which help individual families to benefit from all community resources. The Society has pioneered self-help programs in which recovered cancer patients offer psychological support to those suddenly confronted with a need for adjustment to cancer therapy.

These include ostomy programs for patients who have undergone intestinal surgery, laryngectomy programs to teach alternate speech techniques to patients whose voice boxes have been lost to cancer, and Reach to Recovery programs for women treated for breast cancer.

The job Fink has been performing at NCI was created for her when she left DCCR two years ago. The smoking and nutrition elements probably will be broken up and placed in the appropriate program divisions, with some coordination from the Div. of Resources, Centers & Community Activities. The medical applications/consensus development function will be retained in the NCI director's office, and Director Vincent DeVita will look for someone to fill that job. Since it is a Senior Executive Service position, filling it will require the search committee–national advertising procedure required for SES, unless DeVita can find a Public Health Service commissioned officer for it.

PREVENTIVE ONCOLOGY ANNOUNCEMENT WITHDRAWN; TO BE MODIFIED, REISSUED

NCI has withdrawn the program announcement for Preventive Oncology Academic Awards issued last year, with plans to reissue it after some modifications provided the Div. of Cancer Cause & Prevention Board of Scientific Counselors gives its concept approval.

Grant applications generated by the announcement last year fared very well, with 19 approved by study sections, some with very good priority scores, and eight of them will be funded.

Donald Luecke, chief of DCCP's Special Programs Branch, said the announcement, which included May 1, 1981 as the deadline for the next round of applications, was withdrawn because modifications are being considered and that deadline was too close to permit consideration of modifications by the division's Board.

Luecke said he was pleased with the first round of applications, and that they apparently stimulated considerable interest on the part of young investigators. Priority scores for the eight funded grants ranged from 146 to 219.

The grants, principal investigators and major areas of interest are:

Norman Breslow, Univ. of Washington, $47,641 (direct costs), environmental and occupational cancer, education.

Seymour Grufferman, Duke Univ., $58,719, multiple myeloma, rhabdomyosarcoma, epidemiology.

Richard Love, Univ. of Wisconsin, $46,415, familial breast cancer, genetic factors in cancer, biometry.

Seth Rudnick, Univ. of North Carolina, $44,710, environmental and occupational cancer studies, clinical trials.

Diane Russell, Univ. of Arizona, $75,390, mechanisms for inhibition of neoplastic growth by vitamin

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Diane Russell, Univ. of Arizona, $75,390, mechanisms for inhibition of neoplastic growth by vitamin

analogs, clinical applications.

David Shottenfeld, Memorial Hospital, $48,990, nutrition and cancer, occupational exposure.

Jeanne Stellman, Columbia Univ., $52,458, environmental and occupational carcinogenesis.

Jerome Yates, Univ. of Vermont, $57,855, bladder and colorectal cancer studies, breast cancer and associated risk factors.

TOBACCO RESEARCH COUNCIL AWARDS 24 NEW GRANTS, TWO STUDYING INTERFERON

Twenty-four new grants for smoking and health studies were awarded last year by the Council for Tobacco Research. The grants, plus renewals of numerous ongoing projects, totaled more than $5.5 million and brought the council's research funding to nearly $64 million.

Two studies on interferon were among the new g rants. One was a pilot project to see whether smoking affects the level of this protein in normal persons and in cancer patients. The other will study the interplay of natural killer cell activity and interferon in tumor development. Most of the studies are in the areas of cancer, pulmonary disease and heart ailments.

Recipients of new grants, their institutions and the titles of their projects:

Harry Antoniades, Center for Blood Research, Boston. "Human platelet-derived growth factor: relationship to human atherosclerosis."

Bernard Babior, Tufts-New England Medical Center Hospital. "Studies on the mechanism of activation of the respiratory burst in neutrophils."

Debajit Biswas, Harvard School of Dental Medicine. "Effects of nicotine and benzo(a)pyrene on normal and ectopic hormone production."

J. Mark Braughler, College of Medicine, Northeastern Ohio Universities, Rootstown. "The alteration of guanylate cyclase by nitric oxide."

Rebecca Bryson, San Diego State Univ. "Interactive effects of nicotine, testosterone and estradiol on weight change, food consumption and activity of male and female rats under high and low protein diets."

William Carter, Hahnemann Medical College & Hospital, Philadelphia. "The interplay of immunosurveillance and interferon induction in tumorigenesis."

Paul Hamosh, Georgetown Univ. Schools of Medicine & Dentistry. "Cigarette smoke and lipoprotein remodeling by the lung."

Robert Hoffman, Univ. of California (San Diego) School of Medicine. "Methionine dependence, methylation and oncogenic transformation."

Don Lapenas, Univ. of Vermont School of Medicine. "The association of inorganic dust deposition with pulmonary neoplasia in tobacco users."

Philip LeQuesne, Northeastern Univ., Boston. "Oxygenated sterols: Their role in atherosclerosis and neoplasia."

Fabian Lionetti, Boston Univ. School of Medicine. "Neutrophil mediated injury to tissues."

Jerald Mitchell, Wayne State Univ. School of Medicine. "Nicotine induced suppression of embryo growth."

Jay Nadel, Univ. of California (San Francisco). "Mechanisms of airway hyperreactivity."

Ronald Rasmussen, Univ. of California (Irvine). "Correlation of cellular and biochemical events in the lungs of mice exposed to cigarette smoke or lung toxic chemicals."

John Repine, Univ. of Colorado Health Sciences Center. "Basic mechanisms of lung injury from inhaled oxidants; elucidation of the role of hydroxyl radical using dimethylsulfoxide."

Hanoch Slor, Tel Aviv Univ., Israel. "The use of specific antibodies to monitor the formation and removal of benzo(a)pyrene adducts from DNA of damaged human cells in vivo and in vitro."

Dennis Smith, Wellesley College. "Autonomic control of pulmonary surfactant in the adult lung."

Timothy Springer, Harvard Medical School. "Studies of macrophage subpopulations and differentiation using monoclonal antibodies."

Lynn Taussig, Arizona Health Sciences Center. "Effects of age, sex and disease on the growing human lung."

Stephen Vatner, Harvard Medical School, New England Regional Primate Research Center. "Direct effects of nicotine on brain circulation."

Ake Wennmalm, Karolinska Institute, Sweden. "Nicotine as inhibitor of prostaglandin bioformation: localization of the inhibitory step and characterization of the cardiovascular implications."

Alvin Winters, Veterans Administration Medical Center, Bay Pines, Fla. "Effects of smoking on the inherent interferon levels in control and cancer patients: a pilot study."

ACS PLANS NEW STUDY ON LIFESTYLE, ENVIRONMENTAL FACTORS IN DISEASE

A big new epidemiology study which will involve one million Americans as subjects and thousands of volunteers collecting data is being considered by the American Cancer Society, ACS President Edward Scanlon said last week.

The six year study follows one initiated by ACS under the direction of E. Cuyler Hammond in 1959. Known as the Cancer Prevention Study, that effort enlisted more than one million subjects in a search for clues to the environmental causes of cancer and other diseases.

"Today I can report that the ACS is considering plans to do another large study," Scanlon said at the annual Science Writers Seminar sponsored by the So-

ciety. "There are new things to investigate in our life habits that may influence the incidence of cancer, either up or down."

Scanlon said that Lawrence Garfinkel, who replaced Hammond as ACS director of epidemiological studies, will run pilot projects in nine ACS divisions. The first was scheduled to start this week in Tampa. Other cities in the pilot group will be Syracuse and Melville, N.Y.; Oakland, Minneapolis, Chicago, Newton, Mass.; Dallas, Little Rock and Salt Lake City.

"Some questions will be the same as those asked 20 years ago to extend the observations, but there will be many new ones as life styles have changed and suspected carcinogens are different," Scanlon said. "We are now exposed to new consumer products and drugs, for example. And we've come to wonder just what the effect is of caffeine in coffee or cola drinks. Are the newer low tar, low nicotine cigarettes really less hazardous, and if so, by how much? Has the birth control pill had either harmful or possibly protective effects on cancer risks in women? What is air pollution doing, or what long term effects may there be from low levels of radiation? Which industrial chemicals, including consumer products and chemicals from occupational exposure, are truly dangerous? Why are black men and women so much more susceptible to certain forms of cancer? Is our water safe enough? Is hard water different from soft water in carcinogenesis? What elements in our foods may be hazardous? This is a terribly tough question to resolve, partly because most of us cannot remember what we had for breakfast, lunch or dinner just a few days ago, much less what our food preferences were 10 or 20 years ago when our diet may have initiated a cancer.

"Only large scale, long term studies can provide answers to such questions. Once the new questionnaire is refined and proven, the plan is to have ACS volunteers again go into homes around the country, and enlist the support of another million people. Followup on these million people will go on for at least six years. By then we may have a solid basis for eliminating some cancer hazards, and be able to reduce the risks of other diseases as well.

"Only a voluntary organization like the American Cancer Society can, from a practical point of view, undertake such a prodigious task. Our federal government could not afford the expense of hiring the thousands of people—68,000 ACS volunteers performed the first study—to conduct the interviews, do the followup, track down the people who inevitably will move from their original homes, compile the data, make the computer analyses, and perform all the other tasks involved. ACS volunteers, as they have so often, will contribute their time and effort, but Larry Garfinkel estimates that even with this help the costs may still come to $10 million. However, the new cancer prevention study will be worth it in terms of learning facts that save lives from cancer, and perhaps laying some fears to rest.

"The Cancer Prevention Study is, of course, only one of many opportunities facing the ACS, particularly at this time when government funds for cancer research may be reduced. As a nation, we need to keep training bright young investigators; we need to continue supplying services to cancer patients; stimulate research; and to foster clinical application of new discoveries.

"Looking back 10 years, you can appreciate the remarkable progress. At least 13 types of cancer, most affecting young children, now are highly curable. Each type claims relatively few victims, but the collective effect is significant. More than half of the children with lymphocytic leukemia now are surviving five years; not long ago all of them soon died. Eighty percent of children with osteogenic sarcoma are surviving, without amputation of the affected limbs in most cases. Hodgkin's disease, when detected early, is curable in more than 75 percent of patients. Choriocarcinoma, the malignant tumor in the womb that can occur after pregnancy, is virtually one hundred percent curable with drugs.

"The brilliant development of monoclonal antibodies promises a precise new tool for discovering hidden cancer cells, and for carrying curative drugs or radiation just to those cells, because they have the marker or antigen against which the antibodies were fashioned. Interferon is showing some effects against major tumors, and now pure interferon is being made in the laboratory at far less cost than that obtained from human blood.

"There are beginnings now of specific vaccines against some cancers. As those of you who were here last year may recall, researchers reported early trials of vaccines against four types of lung cancer, and their project is continuing. Dr. Baruch Blumberg, of Philadelphia, reported a vaccine against hepatitis B virus, which may also be effective against liver cancer.

"The American Cancer Society will fulfill its commitment to persist in its efforts until the ultimate solution is found."

NCI CONTRACT AWARDS

Title: Incorporation of two additional alteration/renovation/maintenance/upgrading projects necessary to support the research program at Frederick Cancer Research Center
Contractor: Litton Bionetics, $113,545.

Title: Long-term followup of the Breast Cancer Screening Project participants
Contractor: St. Joseph's Hospital, Houston, $652,389.

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. NCI listings will show the phone number of the Contracting Officer or Contract Specialist who will respond to questions. Address requests for NCI RFPs to the individual named, the Blair Building room number shown, National Cancer Institute, 8300 Colesville Rd., Silver Spring, Md. 20910. RFP announcements from other agencies reported here will include the complete mailing address at the end of each.

RFP NCI-CM-17387

Title: *Statistical support for the Gastrointestinal Tumor Study Group*

Deadline: *Approximately May 15*

The Div. of Cancer Treatment, NCI, requires an organization possessing the capabilities and facilities necessary to perform the following:

This contract will provide statistical support for the GITSG, a group of approximately 15 contractors with 2,500 patients currently on procotol with an annual accrual of 500 patients. There are 10 currently active protocols and four in followup. These protocols currently involved include phase 2 evaluations of single drugs, combinations of drugs in gastric and pancreatic cancer, phase 3 evaluations in gastric cancer, and adjuvant and combined modality trials. The contractor shall perform the following:

1. Review proposed protocols to ensure that the clinical investigations will be efficient, scientifically valid, and unambiguous.
2. Prepare and maintain randomization materials and implement randomization procedures.
3. Monitor ongoing studies to determine serious toxicity.
4. Request, collect, inventory, edit, enter, process, and analyze all data for studies in preparation of semi-annual statistical reports and for special meetings.
5. Assist study chairmen in the publications resulting from GITSG studies.
6. Maintain full documentation on computer systems, operations, and programs used by the GITSG statistical center.
7. Assist study chairmen in the design and analysis of ancillary studies.
8. Design review, and distribute forms for all studies.
9. Provide for radiation therapy quality control. This shall be performed by a medical doctor, fully trained in radiation oncology experienced with radiation quality control in cooperative clinical trials.
10. Special tasks requested by NCI, the GITSG executive committee, or individual participating group members.

This project is to have a five year period of performance requiring five staff years of effort per year.

This project has been set aside totally for small business concerns. In order to be eligible for consideration for this project, an offeror shall not have more than 500 employees.

Contracting Officer: Harold Thiessen
RCB Blair Rm 228
301-427-8737

SOURCES SOUGHT

Project Number NCI-CO-14348-41-S

Title: *Assessment of leukemia and thyroid disease in relation to fallout in Utah*

Deadline for capability statement: *April 23*

NCI proposes to contract with an organization to conduct, in collaboration with NCI, a current assessment of both leukemia and thyroid disease in relation to radioactive fallout resulting from atmospheric weapons testing conducted by the U.S. government. Considerable public concern has been expressed about the possible health effects of such fallout in Utah from weapons tests conducted between 1950 and 1962 at the Nevada test site.

The importance of leukemia in past studies of radiation effects and in the recent mortality analysis of childhood cancer in Utah justifies some further efforts to explore the possibility of excess leukemia in "high exposure" areas. An appropriate study might be either (1) case-control in design, with cases ascertained from vital and medical record information, but with extension to leukemias at all ages, or (2) a cohort study providing a contrast between "high exposure" and "low-exposure" groups defined on the bases of existing isodose curves. In the case-control study, the leukemia cases would be ascertained for all residents of Utah between 1950 and 1980, and from such sources as the Utah cancer registry, mortality records. A parallel control group of comparable age and sex would be required. The cohort study samples would be traced as to mortality through the vital record system of the state, the cancer registry, and the records of the Church of Jesus Christ of Latter-Day Saints.

The thyroid gland, particularly in children, is known to be extremely sensitive to the carcinogenic effects of ionizing radiation. The most likely pathway by which radioactive fallout could affect the thyroids of Utah residents is through the ingestion of radioactive iodine contained in milk from cows grazing in high-fallout areas. Therefore, it is reasonable to anticipate that excess thyroid cancer may have occurred among persons who, as children, drank milk produced in high-fallout areas at the time of weapons testing.

A milk distribution table for each residential community studied, showing the distribution by source of the milk consumed in the community at times when a fallout hazard was considered present, is a prerequisite for any study of thyroid cancer risk as-

sociated with fallout from the Nevada Test Site. With such a table, accompanied by a series of maps giving estimated isodose contours of radioactive iodine, present in cattle forage at different times, and taking account of seasonal variation in the consumption of stored fodder instead of grazing, it should be possible to quantify average thyroid doses from radioactive iodine, by time and place of residence. In studies using personal interviews, it may be possible to further refine dose estimates on an individual basis, by distinguishing between milk from dairies and milk from family cows, for example. Without such dosmetry, it will be very difficult to conclude that any variation in thyroid cancer rates is causally related to fallout.

Given some measure of dose, studies of thyroid cancer risk can be separated into clinical studies, involving medical examination of thyroid glands of persons in two or more exposure categories, and so-called "paper" studies, in which incidence information is obtained from tumor registries, death certificates, and other records. The clinical approach should yield a more complete ascertainment of thyroid disease than the paper approach, but consideration of the cost and logistics of examination, may limit the number of persons examined.

If the incidence of thyroid nodules, rather than cancer, were the health outcome of interest, a clinical study of adequate power should be possible. Thyroid nodule incidence is also known to be increased by radiation exposure. Among fallout victims in the Marshall Islands the evidence for increased nodularity is stronger than it is for thyroid cancer.

With a "paper" approach it should be possible to study reported thyroid cancer among substantially all the Utah population who were children during the testing period. A case-control study, in which exposure would be determined for thyroid cancer cases obtained from tumor registries and other records and for appropriate controls, would be less expensive and have greater statistical power than any feasible cohort study in which persons known to have lived in various high dose and low dose areas as children would be examined for the incidence of thyroid cancer or thyroid nodules. Both approaches would require a statewide dosimetry effort based on milk consumption and distribution. With the case-control approach, more refined dosimetry, based on questionnaires or interviews, should be feasible.

Interested sources are invited to submit qualifications to conduct an assessment of both leukemia and thyroid disease in relation to fallout in Utah.

Source information previously submitted to this office or any other office will not be considered. Interested organizations must submit information on:

1) Organizational structure and background.
2) Qualifications of professional personnel.
3) Specific prior experience in epidemiological research on effects of radioactive fallout or low-level radiation exposures.
4) Availability of qualified personnel and facilities necessary to undertake the work involved.
5) Access to data for sources described above or other sources, such as indicated by letters of agreement.
6) Any other pertinent information.

Only those sources deemed qualified for the work under consideration will be invited to submit proposals when and if a request for proposals is initiated.

This is not a request for proposal, but a request for a detailed statement of capabilities. Responses should not include cost or pricing information. Respondents should limit their responses to 25 pages or less. Ten copies of the capability statements must be submitted to:

Contract Specialist: Diane Smith
RCB Blair Bldg Rm 327
301-427-8877

RFP N01-CP-15764

Title: *Development and validation of a multiple endpoint mutation system in cultured mammalian cells*

Deadline: *May 29*

The National Toxicology Program organizes and conducts a comprehensive interagency testing and research program focused on determining potential human health hazards due to environmental exposures to chemicals. The cellular and genetic toxicology component of NTP supports these effects through the development of establishment of in vitro and short term test systems with predictive value for potentially hazardous chemicals.

The purpose of this procurement is to develop, define and test a protocol (or series of protocols) using mammalian cells in culture to determine the frequencies of chemically induced gene and chromosomal mutations. The possibility of determining other genetically related endpoints such as sister chromatid exchange, DNA damage and repair and aneuploidy should be considered.

Contract Specialist: Susan Hoffman
RCB Blair Bldg Rm 2A01
301-427-8774

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