THE CANCER LETTER

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PANEL ANGERED BY UNREASONABLE SENATE COMMITTEE DEMANDS, WILL SEEK MEETING WITH HATCH ON PROBE

Members of the President's Cancer Panel, angered by unreasonable and sometimes abusive demands on NCI staff by Senate committee staff

(Continued to page 2)

In Brief

NCAB TO HEAR NCOG APPEAL; FDA MAY RENEGE ON NEW TOXICOLOGY PROTOCOL, HOLDS UP INDs

APPEAL OF the Clinical Cancer Investigation Review Committee's disapproval of the Northern California Oncology Group's grant will be heard May 18 by the National Cancer Advisory Board. NCI Div. of Cancer Treatment staff is supporting the request by NCOG to overturn the decision. The NCAB could accept the CCIRC minority report supporting NCOG; it could return the application to CCIRC or to an ad hoc committee for rereview; or it could accept the majority decision, which would put NCOG out of business. Best guess: NCOG will stay in business, by one of the first two routes. . . . **FOOD & DRUG** Administration is threatening to renege on its agreement to the new toxicology protocol it approved last year for preclinical testing of anticancer agents. In a memo from Bureau of Drugs Director Richard Crout to Stuart Nightingale, acting associate commissioner for health affairs, Crout said no more INDs would be approved for drugs coming through the new protocol until a meeting can be held with NCI representatives. The issue which concerns Crout is whether animal histopathology must be completed before phase 1 studies can start; the new protocol permits both to start simultaneously. Six or seven drugs are now nearing completion of toxicology studies on the new protocol, and apparently will not be permitted to go into phase 1 tests until the issue is resolved. . . . **MARVIN RICH**, executive vice president and scientific director of the Michigan Cancer Foundation for the past 10 years, will become director of the AMC Cancer Research Center & Hospital in Colorado Aug. 1. He will be responsible for all the laboratory and clinical work of the center. Rich played a key role in developing MCF to the point where it gained recognition from NCI as a comprehensive cancer center. . . . **HOWARD ANDERVONT**, member of NCI's original staff, first chief of the Laboratory of Biology and former editor of *JNCI*, died recently while vacationing in Florida. He was 83. . . . **OSHA'S 10TH** anniversary will be observed April 27-28 by "Friends of OSHA," led by representatives of organized labor, with a "vigil" on the Capitol steps, picketing of the White House, and a conference on budget and personnel problems in the Reagan Administration. William Terry, acting director of NCI's Div. of Resources, Centers & Community Activities, will participate in a seminar on cancer during the conference, in the AFL-CIO Building, 815 16th St. NW, Washington, April 28.

PANEL BECOMES MORE ASSERTIVE, TO SEEK MEETING WITH HATCH ON INVESTIGATION

(Continued from page 1)

investigating NCI contract practices, will ask for a meeting with Sen. Orrin Hatch (R.-Utah) in an attempt to cool the situation somewhat.

Hatch is chairman of the Labor & Human Resources Committee, the authorizing committee for health legislation. His staff has been conducting an investigation of NCI contracts as a followup to two departmental inspector general investigations conducted since 1978. The IG probes found a number of alleged deficiencies and led to several recommendations. NCI did not agree with all the findings, and the IG has not yet submitted its final reports.

NCI has been implementing extensive changes in contract management, including some of the IG recommendations. The changes have gone beyond problems brought up by the IG and other critics, however.

The Hatch probe was intended to determine how well NCI was addressing the deficiencies the IG said existed. It probably is premature, considering the fact that the reports have not been completed.

Director Vincent DeVita told the Panel at its meeting last week that the Hatch investigation has been disruptive. "Conclusions have been drawn that we're guilty " he said. "It may turn out to be a self-fulfilling prophecy, because if we stay in this mode, we can't do our job, and if we can't do our job, there will be deficiencies in our management."

According to the 1978 IG draft report, NCI was deficient in management of 54 of 1,500 contracts. DeVita said corrections of those problems have gone far beyond what was either required or expected.

DeVita said the Hatch committee has requested 50,000 documents in its probe, and providing them has cost NCI $40,000. Hatch's staff originally requested an additional 140,000 documents, but DeVita was able to talk them out of that, saving about $350,000.

Panel member Harold Amos suggested that the Panel arrange an appointment with Hatch, not to hamper the investigation but to talk to him about the methods being used. Panel Chairman Joshua Lederberg agreed, after DeVita said that such a meeting probably would be useful. "I don't know whether there has been any misfeasance here, but the investigation could be less disorderly," Lederberg said.

DeVita commented that there have been contract management practices he has not liked, "but I don't think there's been anything criminal going on."

"My impression of the Hatch staff is that they are interpreting," Amos said. "We could do more. Instead of standing on presumed impotence, we should make an effort to change their method of investigating. Dr. Lederberg, you're a prominent figure in the scientific world. You have a right to be heard. We haven't been as active as we might be. We shouldn't sit on our hands."

Lederberg cautioned against the Panel expressing an opinion on the substance of the investigation because the members have not looked at the specific contracts being investigated.

"If you would like to take a month off, you can look at the documents they are investigating," DeVita said.

"It isn't out of the question that we might look more closely into these matters," Lederberg said.

Panel member Bernard Fisher agreed that a meeting with Hatch should be requested. "Since we don't work for NCI, we can request a meeting as an independent group."

The President's Cancer Panel was established by the National Cancer Act of 1971 as a means of calling attention to the White House problems in the Cancer Program which need attention at high levels. Former Panel Chairman Benno Schmidt, who had the confidence of the Nixon and Ford Administrations, succeeded in doing just that, although to a lesser extent with the Carter White House. He also did not hesitate to go to Congress and the public when he felt it was appropriate.

Lederberg thus far has not been as aggressive. If he does succeed in getting Hatch's staff off DeVita's back, it will be the first accomplishment of the Panel since Schmidt's departure.

Rep. Albert Gore (D.-Tenn.), chairman of the House Science & Technology Subcommittee, has indicated that he will investigate the flap between NCI and FDA over the latter's charge that NCI was slow in reporting kidney toxicity of methyl CCNU (***The Cancer Letter***, April 10).

DeVita described the issue for the Panel, including NCI's position that it followed precisely steps in its agreement with FDA for reporting toxicities and that FDA staff apparently are not familiar with that agreement.

The Gore investigation also may get into the matter of the new toxicology protocol, which streamlined preclinical testing of new drugs but which FDA now is threatening to change (see "In Brief," this issue).

Gore tentatively plans to hold hearings this fall.

DeVita told the Panel that the ratio of R01 to P01 grants will be examined during a staff retreat in the near future.

Although P01s (program projects) account for only 5 percent of the total number of NCI grants, they get 30 percent, or $110 million, of the money for research grants.

Staff members will discuss whether it would be better to spend more on R01s, less on P01s.

DeVita said that NCI will try to determine how many investigators are supported by P01s, how much

is spent per investigator, whether center core grants can support some P01 work where both kinds of grants exist at the same institution.

If the existing levels are appropriate and most efficient, the statistics will help defend the status quo to NIH, DeVita said.

"We need to develop some methodology to deal with this," Lederberg said. "Let's not just rely on what's in our heads."

DEVITA SEEKS BETTER WAYS TO DEVELOP PRIORITIES IN BYPASS, "REAL" BUDGETS

Vincent DeVita, frustrated by the growing gap between NCI's unique "bypass budget" and the real world as it exists in the NIH-HHS budget which goes to Congress, is thinking about changing the system.

The bypass budget is a creation of the National Cancer Act of 1971, permitting NCI to submit its fiscal request each year directly to the President without alteration by NIH or HHS. In practice, the White House ignores the bypass and instead, deals with the budget developed by NIH and department financial officers. That budget cannot exceed the total amount of money the White House allots the department and NCI's bypass budget is not considered in that allocation. When the NIH and HHS people split it up among the institutes, NCI in recent years has not even received a proportional share of available increases.

Congress intended for the bypass budget to be a message to the President, and to Congress, on what NCI determined its needs to be be. President Nixon said in signing the Act that the Cancer Program "will get all the money it needs," a promise neither he nor his successors have kept.

The National Cancer Advisory Board and the President's Cancer Panel have a hand in developing the bypass budget, but they get to see the NIH-HHS version of NCI's budget only after it is submitted to Congress. Thus, most of the priorities which are reflected in the real budget are determined by DeVita and his staff, with some very significant alterations imposed by the chain of command through NIH, HHS, and the Office of Management & Budget at the White House.

DeVita does not consider that process satisfactory. In particular, he does not favor the method used in recent years to arrive at bypass budget figures. "Our usual way is to deal with growth," he told the President's Cancer Panel last week. "When we devised the bypass budget last year, we decided that NCI should have an overall five percent growth, plus 10 percent for inflation."

That method, considering the mood of the Administration and economic realities, is "unrealistic," DeVita said. "Maybe we should talk about programs in the bypass budget, not figures."

Although the NCAB and its Subcommittee on Planning & Budget do have an opportunity for comments and suggestions in the makeup of the bypass budget, which is presented to the Board at its May meeting, the opportunity for influencing significantly priority development is limited.

When he was director of the Div. of Cancer Treatment, DeVita eagerly sought advice of the DCT Board of Scientific Counselors in establishing priorities, right down to specific projects as well as broad areas of policy. He rarely went against that advice.

DeVita would like for the NCAB to play a similar role in developing institute priorities, especially through the budget process. While it would be relatively simple for the Board to become more involved in drawing up the bypass budget, it would not be so easy in dealing with the NIH-HHS verson of NCI's budget.

The White House does not permit public disclosure of its budget figures before they are submitted to Congress. Administrations past have learned that when dollar totals suggested for specific programs become known while the budget is still being developed, incredible pressures can be generated by special interest groups. If the NCAB is given any opportunity to discuss the NIH-HHS budget in development and to make recommendations on it, it would be in closed meetings. Board members would be warned against permitting leaks, but leaks invariably will occur.

While it might pose some difficulties, it would be possible for the NCAB to participate in drawing up the "real" NCI budget.

DeVita suggested to the Panel that if the bypass budget were closer to the real budget in dollar levels, it might be more useful in that it would more easily permit priorities established by the Board in the bypass to be carried over to the real budget. "The bypass is developed before we interact with Building 1 (NIH headquarters)," DeVita said. "The question we have to ask is, would our priorities have been the same for this year if we had known what our budget would be? I'm not sure they would have been."

He also claimed that a rapprochement of the two budgets would better enable him to defend the priorities in the bypass, since they would be presented in a more realistic context.

Tailoring the bypass to meet the limits imposed by NIH and HHS, however, is exactly what Congress did not want with the bypass authority, and Panel members expressed concern.

Harold Amos commented that if certain programs are ever conceded expendable or reducible in difficult times, they will never be retrievable. "For instance, if the indirect costs and institutional allowances are removed from the National Research Service Awards, we may never get those funds back."

"Why does the bypass have to be unrealistic?" Panel Chairman Joshua Lederberg asked.

"I regret the departure of Mrs. (Mary) Lasker (from the NCAB)," Amos said. "She would bring us the realistic 'don't give up' attitude."

Amos insisted that NCI should not agree with NIH on a budget reduction. Using as an example an episode from the recent Senate Appropriations subcommittee hearing on NCI's budget (*The Cancer Letter*, Feb. 27), Amos said it was an instance of congressional support for an increase above the Administration's request. Sen. Harrison Schmitt (R.-N.M.), subcommittee chairman, showed great knowledge of and interest in construction supported by NCI, Amos pointed out. NIH Director Donald Fredrickson did not adequately answer Schmitt's questions, Amos claimed. "Schmitt knows about construction because of his experience at NASA," Amos said. "He should have been better answered."

DeVita said that construction is a good example of how working with the budget from the angle of priorities instead of percent growth could protect the real interests of NCI. "We could show the department the sacrifices we are willing to make in order to get some construction money."

Lederberg, summarizing the discussion, said that when the budget is cut below NCI's request, "there needs to be a clear presentation of what we're giving up."

NIH ADOPTS CARCINOGEN GUIDELINES, OFFERS COPIES TO EXTRAMURAL LABS

NIH has adopted its own "Guidelines for the Laboratory Use of Chemical Carcinogens" and will require that they be followed in the NIH intramural laboratories. The guidelines contain "recommendations and requirements governing the use of chemical carcinogens. . . as well as guides to researchers in their selection and use of safeguards that will allow full usage of chemical carcinogens while at the same time minimizing exposures to laboratory personnel," the NIH announcement said.

NIH is offering copies of the guidelines for use outside the government. "The guidelines provide an excellent approach to working safely with carcinogens, and we encourage all investigators in the extramural community who are working with chemical carcinogens to review these guidelines," NIH said.

Copies may be obtained from NIH, Div. of Safety, Bldg 13 Rm 2E43, Bethesda, Md. 20205.

ACCC CLINICAL RESEARCH GROUP MEETS

The Assn. of Community Cancer Centers Clinical Research Committee will meet April 29, 4 p.m., in the Shoreham Hotel, Washington D.C. The committee will discuss the proposed development of a new, modified community oncology program as suggested by NCI Director Vincent DeVita at the annual ACCC meeting last month. The meeting will be open.

NCI ADVISORY GROUP, OTHER CANCER MEETINGS FOR MAY, JUNE, FUTURE

72nd Annual Meeting of the American Assn. for Cancer Research—April 27-30, Washington D.C. Sheraton Hotel. Dr. Frederick Philips, AACR, MSK Cancer Center, 1275 York Ave., New York NY 10021.

17th Annual Meeting of the American Society of Clinical Oncology—May 1-2, Washington D.C. Sheraton Hotel. A. Van Horn III, ASCO, 435 N. Michigan Ave., Suite 1717, Chicago 60611.

6th Annual Congress of the Oncology Nursing Society—May 4-6, Baltimore Convention Center. Nancy Berkowitz, ONS, 701 Washington Rd., Pittsburgh 15228, 412-344-3899.

13th European Tumor Virus Group—May 10-14, Bornholm, Denmark.

7th Latin American Cancer Congress—May 10-15, Sao Paulo, Brazil. Contact Dr. Charles Sherman, Univ. of Rochester Medical Center, 160 Elmwood Ave., Rochester, N.Y. 14642, phone 716-473-7172.

Society of Surgical Oncology—May 11-15, annual meeting, Boston.

UICC Clinical Cancer Chemotherapy Course—May 11-16, Jakarta.

Epidemiology Course on Chronic Diseases with Emphasis on Cancer—May 11-30, Ndola, Zambia.

Symposium on Safety Assessment of Artificial Sweeteners—May 12-13, Washington D.C. Holiday Inn-Smithsonian. Write: International Study Center, 503 Grasslands Rd., Valhalla, N.Y. 10595.

Hematologic Problems in Cancer Patients—May 14, Roswell Park continuing education in oncology.

National Cancer Advisory Board Subcommittee on Planning & Budget—May 17, NIH Bldg 31 Rm 11A10, 7:30 p.m., open.

National Cancer Advisory Board—May 18-20, NIH Bldg 31 Rm 6. Open May 18, 8:30 a.m.—3:30 p.m., and May 20, 8:30 a.m.—adjournment. Closed May 19.

NCAB Subcommittee on Special Actions—May 18, NIH Bldg 31 Rm 6, 3:30 p.m., closed.

Management of Hazardous Chemical Wastes in Research Institutions—May 20-21, Washington D.C. Holiday Inn-Smithsonian. Write: 1981 NIH Research Safety Symposium, Environmental Control & Research Laboratory, Frederick Cancer Research Center, P.O. Box B, Frederick, Md. 21701, phone 301-663-7167.

2nd International Meeting on Radio-oncology—May 21-23, Baden/Wein, Austria. Contact K. Karcher, Vienna Univ. Klinik, Radiotherapy and Radiobiology, Alsestr. 4, 1090 Vienna.

Conference on Pain Management for Practicing Physicians—May 21, Detroit Engineering Society, 110 Farnsworth St. Sponsored by Wayne State Univ. Gertrude Levin Pain Clinic and the Comprehensive Cancer Center of Metropolitan Detroit. Ramon Evans, director of the Smythe Pain Clinic, Toronto, will speak on "Dilemmas in Diagnosis;" John Ingla, director of the Levin clinic, on "Cancer and Therapy;" and Dietrich Blumer, chairman of the Dept. of Psychiatry, Henry Ford Hospital, on "psychological Diagnosis and Psychological Mechanisms;" John Gilroy, chairman of the Dept. of Nuerology at Harper-Grace Hospitals, on "Neurological Diagnosis;" Robert Ho, director of the Neurosciences Intensive Care Unit at Harper-Grace, on "Neuro Surgical Management of Pain," and Eli Brown, president of the American Society of Anesthesiologists, on "Drug Management." For registration information, call 313-577-1848.

International Seminar on Management of Superior Pulmonary Sulcus Syndrome (Pancoast Syndrome)—May 25-26, Stresa, Italy. Contact V. Ventafridda, Fondazione Floriani, Vicolo Fiori 2, 2012 Milan, Italy.

Div. of Cancer Cause & Prevention Board of Scientific Counselors–May 28-29, NIH Bldg 31 Rm 4, 9 a.m. both days, open.
Malignant Melanoma–May 29-30, Hellenic Cancer Society, Thessalonika, Greece.
Large Bowel Cancer Review Committee–June 1-2, O'Hare Holiday Inn, Chicago. Open June 1, 1:30-5 p.m., June 2, 8–8:30 a.m.
Assn. Francaise pour l'Etude du Cancer–June 1, Paris. Annual meeting. Proffered papers on recent research on cancer. Federation Nationale des Centres de Lutte contre le Cancer, 101 rue de Tolbiac, 75654 Paris.
Div. of Resources, Centers & Community Activities Board of Scientific Counselors–June 4-5, NIH Bldg 31 Rm 8, 8:30 a.m. both days, open.
Pancreatic Cancer Review Committee–June 4-5, New Orleans Tidewater Place. Open June 4, 8:30 p.m.–10 p.m., June 5, 8 a.m.–adjournment.
Associazione Italiana di Oncologia Medica–June 4-6, Turin. Annual meeting on all aspects of medical oncology. S. Monfardini, Associazione, Via Venezian 1, 20133 Milan.
Progress in the Management of Upper Gastrointestinal Cancer–June 6, Roswell Park continuing education in oncology.
Congress of European Nuclear Medicine Society and World Federation of Nuclear Medicine and Biology–June 7-13, Pisa. Nuclear medicine in diseases of the breast and lungs. P. Rigo, Institut de Medecine, 66, bd de la Constitution, 4000 Liege, Belgium.
Cancer Control Grant Review Committee–June 8-9, NIH Bldg 31 Rm 7, open June 8, 8:30–9 a.m.
Bladder Cancer Review Committee–June 10-11, Hershey Lodge & Convention Center, Hershey, Pa. Open June 10, 1-1 :30 p.m.
Div. of Cancer Treatment Board of Scientific Counselors–June 11-12, Chevy Chase Holiday Inn, 5220 Wisconsin Ave. Open June 11, 8:30 a.m.–4 p.m.; June 12, 8:30 a.m.–adjournment.
Therapeutic Advances in Solid Tumor Oncology–June 12, Univ. of Alabama (Birmingham). The physicians' program will include discussions of adriamycin and cytoxan as adjuvant treatment for breast cancer by Stephen Jones; adriamycin by infusion technique for breast cancer, by Robert Benjamin; combination of radiotherapy and chemotherapy for limited extent oat cell cancer of the lung, by Robert Oldham; high dose regimens for extensive oat cell lung cancer, by Lawrence Einhorn; adjuvant management of ovarian cancer, by Anthony Greco; management of testicular cancer, by Einhorn; and adjuvant chemotherapy of advanced head and neck cancer, by William Maddox. A concurrent session will be held for oncology nurses, with presentations on nausea and vomiting, extravasation, venous access, alopecia, sperm banking, psycosocial, hospice and bone marrow transplantation. Contact Dr. John Durant, 205-934-5077, for registration.
Assn. of American Cancer Institutes–June 21-23, Duke Univ. Comprehensive Cancer Center, semiannual meeting.
Conference on Biostatistics in Clinical Oncology–June 21-26, New York. Contact Valerie Miké, PhD, Biostatistics Laboratory, Memorial Sloan-Kettering Cancer Center, 1275 York Ave., New York 10021.
FDA Oncologic Drugs Advisory Committee–June 25, Parklawn Bldg., Rockville, Md.
Parents, Patients & Professionals: Expanding Horizons Together–June 26-28, The Candlelighters Foundation 1981 Conference. Washington Univ., St. Louis. Write to Candlelighters St. Louis Chapter, Box 451, Wentzville, Mo. 63385, or phone conference coordinator, Cheryl Moellenhoff, 314-625-3052 after 6 p.m. central time.

FUTURE MEETINGS

Gynecologic Oncology Group–July 23-25, Sheraton-West Hotel, Indianapolis. Business meeting. Contact John Kellner, group manager, GOG Headquarters, 1234 Market St., Suite 430, Philadelphia 19107.
"The Oncology Team: A Diverse But Unified Force"–Sept. 21, Fox Chase Cancer Center. Second annual seminar sponsored by the Delaware Valley Chapter of the Oncology Nursing Society. Seminars are scheduled on nursing research, developing models for linking hospital and home care, adolescents with cancer, family systems, and sexuality and the cancer patient. Roundtable discussions will be on alternate forms of cancer treatment–what is the nurse's role?, hospice care, developing an oncology unit, symptom control and nutritional support, new techniques for chemotherapy administration, symptom management of the GI tract, patient support group, ethical considerations, means of professional education, implementation of ONS standards of care, and rehabilitation.
Second National Seminar on Community Cancer Care–Sept. 25-27, Hyatt Regency, Indianapolis. Sponsored by the Clinical Oncology Center and the Graduate Medical Center at the Methodist Hospital of Indiana. Contact Office of Continuing Medical Education, Methodist Hospital of Indiana Inc., 1604 N. Capitol Ave., Indianapolis 46204.

VAN POTTER WINS BRISTOL-MYERS AWARD FOR DISTINGUISHED CANCER RESEARCH

Van Rensselaer Potter, who first demonstrated that all cancer cells are not biochemically alike, has received the fourth annual Bristol-Myers Award for Distinguished Achievement in Cancer Research.

Potter was also the first to suggest that sequential administration of anticancer drugs might be useful in cancer chemotherapy. This theory had a direct and immediate impact on treatment of cancer in humans.

Potter is professor of oncology at the McArdle Laboratory for Cancer Research at the Univ. of Wisconsin. The award includes a $25,000 cash prize.

"Van Potter has applied basic biochemical concepts to a wide range of cancer studies," said Alan Sartorelli, professor and chairman of the department of pharmacology at Yale Univ. and chairman of the award selection committee. "He is a particularly insightful and imaginative researcher who has synthesized broad concepts and pointed to important new areas of investigation."

"Professor Potter has made a number of observations on the biochemistry of cancer that have changed the course of cancer research," said Henry Pitot, director of the McArdle Laboratory. Pitot nominated Potter for the award.

In accepting the award, Potter said:

"My professional career also benefitted from my good fortune to land at the Univ. of Wisconsin as a graduate student under Professor Conrad Elvehjem. I returned to that university after a period of study abroad to become a member of the McArdle Laboratory for Cancer Research. My association with Professor Harold Rusch, the first director, for the past 41 years, and for nearly as long with Professors James and Elizabeth Miller, has been a source of continuous inspiration and encouragement. My association with our second and present director, Dr. Henry Pitot, for

the past 20 years, has had the same kind of impact, although for only half as long.

"With gratitude for my family, and with gratitude for my colleagues at the McArdle Laboratory, I accept the Bristol-Myers Award with pride, and, I hope, without hubris. Let us be aware that our successes in research have left us still unable to deal with much of the suffering and death caused by cancer."

Contract Awards

TWO MORE CHOPs ANNOUNCED

Two more contracts for NCI's Community Hospital Oncology Program have been awarded, bringing the total so far to 20. NCI's Div. of Resources, Centers & Community Activities plans to support 23 CHOPs.

The latest CHOP awards were to St. Luke's Hospital of Bethlehem, Pa., for $122,543; and St. Paul Hospital of Dallas, for $111,096. The first round of 23 awards are for 18 months of planning. Those who develop successful plans will be supported for an additional two years for implementation.

Other contract awards announced by NCI are:

Title: Support of Institute of Laboratory Animal Resources

Contractor: National Academy of Sciences, $108,000.

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-CP-FS-11006-51

Title: *Support services for a mortality study of workers exposed to formaldehyde*

Deadline: *May 19*

The Div. of Cancer Cause & Prevention, NCI, Environmental Epidemiology Branch, is seeking technical, managerial, and clerical support to conduct a followup mortality study of 5,000 to 10,000 workers with exposure to formaldehyde. Occupational groups likely to be included in this study are formaldehyde producers, resin makers, film coaters, plastic laminant makers, textile manufacturers, and plywood manufacturers.

The study is a collaborative effort between the dustries to workplace exposures as determined by job titles, work locations, type of exposure, and length of exposure. The duration of this contract is expected to be three years, to be funded annually, and to begin approximately July 1981.

Prospective contractors must have had experience in conducting all phases of cohort mortality studies, including design of data collection documents; abstracting, keying, editing, updating, and recoding of data; tracing of individuals to determine their vital status; creating and manipulating data files; developing estimates of historical workplace exposures; and obtaining death certificates for deceased subjects.

Special consideration will be given to respondents who have, and can document, previously established contacts with companies producing or using formaldehyde that will be immediately useful in conducting and completing this study. For the past year, Westat Inc., of Rockville, Md., has been assisting NCI in locating suitable companies to study through a contract with the FI and is expected to submit a proposal.

Personnel required include (a) a data manager, with at least three years of directly related experience who will serve as the principal investigator and will supervise all aspects of the data collection and followup (100% time for years one, two and three); (b) two or more industrial hygienists with three to five years experience in developing historical workplace exposure scales and in conducting walkthrough surveys to detect and pinpoint the location of occupational exposures (a total of 3½ person-years will be required through the duration of this three year project); (c) a computer programmer with at least three years experience in various aspects of writing, debugging, and documenting computer programs (30% time for years one, two and three); and (d) abstractors, coders, keyers, and clerical help as necessary to complete the study.

Contract Specialist: Daniel Jones
RCB Blair Bldg. Rm 114
301-427-8888

RFP NCI-CP-FS-11019-51

Title: *Support services for a case-control study of brain cancer and occupation*

Deadline: *May 26*

The Div. of Cancer Cause & Prevention of NCI, Field Studies & Statistics Program, Environmental Epidemiology Branch, desires to contract with an organization that is highly experienced in conducting medical-type case-control personal interview studies, including data collection and computer processing of data. This will be a three-year support (resource) contract, with no independent research by the contrac-

among white males from areas of the United States where the petroleum refining and chemical industries are heavily concentrated. Specifically, the study aims to (1) clarify the role of occupational exposures in the etiology of cancers of the brain and central nervous system, particularly among workers in the petroleum refining and chemical industries; and (2) investigate other factors that may contribute to elevated risk of brain and CNS cancer (e.g., family history, other occupational and environmental factors).

Organizational requirements. (a) Experience. The respondent should be highly experienced in locating and interviewing (in person) patients or next of kin and in processing and editing collected data. Organizations having only nonmedical survey and interviewing experience will not be acceptable, as medical case-control interviewing experience is mandatory. All experience entries will be verified by NCI during evaluation.

(b) Location. The organization should be headquartered *either* (a) in the Washington, D.C. metropolitan area, so as to facilitate frequent and convenient consultations with the NCI project officer, *or* (b) in one of the major areas of the U.S. where petroleum refining and chemical industries are heavily concentrated and would be a likely source of cases for this study. No other location will be acceptable because it would increase travel expenses.

(c) Computer facility. The organization should have access to data processing equipment and facilities in order to produce a clean magnetic tape of all data collected. Alternatively, the respondent may use the NIH computer facility by remote access.

(d) Personnel. The project director (bachelor degree only, to spend only 25% of time for year 1, and 10% of time for yeares 2 and 3), should have had three years experience in supervising the conduct and management of medical-type case-control interview studies with appropriate data processing experience. The computer programmer (20% of time in year 1, and 50% of time in years 2 and 3) should have had five years of experience writing and debugging programs in at least two languages and experience using statistical packages. Field manager(s) (two person-years only) will direct interviewing in each geographic region in which interviews are conducted; they, along with abstractors, interviewers, and coders need not be selected before award. Travel. Key personnel should be able to travel to the geographic areas likely to be selected for study to personally monitor field operations as necessary.

Contractor's duties. The contractor will (a) assist in identifying geographic areas in which petroleum refining and chemical industries were heavily concentrated in the past; (b) assist the project officer only after award in obtaining cooperation from state vital records offices; (c) ascertain 600 cases of brain and/or CNS cancer among males over age 30 who died within the past two years; (d) select an appropriate control for each case according to criteria specified by the project officer; (e) obtain death certificates; (f) assist in obtaining hospital records and pathology reports to confirm the diagnosis for each case; (g) hire and train appropriate field personnel; (h) locate and personally interview available next-of-kin of cases and of controls; (i) maintain quality control of all aspects of the work; (j) process accumulated data as required; and (k) provide the NCI project officer with required computer tape(s), files, and reports.

Contract Specialist: Daniel Jones
RCB Blair Bldg Rm 114
301-427-8888

RFP NCI-CP-FS-11022-63

Title: *In vitro radiosensitivity and DNA repair in genetic syndromes and families at high risk of malignancy*

Deadline: *May 26*

Objectives: The Div. of Cancer Cause & Prevention of NCI, Clinical Epidemiology Branch, desires to contract with an organization that is highly experienced in conducting in vitro tests or assays of radiation sensitivity and DNA repair in human fibroblasts. This organization will (a) collaborate with NCI personnel in a research and resource (support) study of the role of abnormal cellular response to radiation and radiomimetic agents in cancer families and in patients with genetic disorders that predispose to malignancy, and (b) evaluate the role of host-susceptibility and host-environmental interaction in cancer etiology.

Duration. The duration of this contract is expected to be three years, and will begin approximately June 1981, unless delayed by contract processing or review procedures.

Requirements:

1. Organization—The organization to be considered must have a minimum of 10 years experience in studying the biological effects of radiation, and have a core staff of highly experienced consultants in radiation who can provide expertise as needed.

2. Resource (support) aspects—The support aspects of this contract pertain to the conduct of laboratory assays connected with screening procedures to identify abnormal radiation responses in individuals who are under study by the Family Studies Group. These assays are as follows:

a. Examination of fibroblast cell lines for mycoplasma contamination.

b. Quantification of in vitro colony formation of human skin fibroblasts after exposure to γ-radiation, tomonochormatic UV-radiation (both near and far wavelengths), and to radiomimetic chemicals such as bleomycin, N-methyl-N'-nitro-N-nitroquanidine, and 4-nitro-quinolone 1-oxide.

c. Repair replication assay of DNA repair.

d. Alkaline elution assay and alkaline sucrose gradient technique to assess DNA repair.

e. Techniques to determine the molecular basis of abnormal radiation responses, including at least two enzymatic assays to measure the ability to execute rejoining of a single strand break and excision repair of gamma-modified bases.

f. Additional assays as necessary to further study abnormal cell lines, including bromouracil photolysis for measuring repair patch size.

3. In the research aspects, the organization's personnel will undertake studies to identify the cellular mechanisms which underlie the abnormal cellular radiation responses. They will develop a protocol for each specific study, and will provide expertise in the analysis of all the results.

Personnel

The respondent should have on its staff an established senior cell biologist in this field to serve as principal investigator (project director) and a qualified associate cell biologist to serve as project manager. The principal investigator must have the following qualifications: (a) a PhD or MD degree or their equivalent, with major study in radiation biology; (b) minimum of five years experience in the conduct of of research projects on radiation sensitivity and DNA repair, including the required assays; (c) at least five years experience in the organization, interpretation, and analysis of such data, resulting in original research reports and papers dealing with these assays and DNA repair on human fibroblasts, published mostly under first authorship in reputable, leading scientific journals over the past five years; (d) at least three years experience in directing and managing the conduct of projects centering about these assays; (e) at least three years experience in studies of family cancer; and (f) be able to devote 10% to 25% of time for the duration of the project.

The associate cell biologist should have (a) a PhD or MD degree or equivalent in radiation biology; (b) minimum of three years experience in radiation sensitivity and DNA repair; (c) publications in these assays and DNA repair over at least three years; (d) three years experience in studies of family cancer, and (e) must devote 100% of time to work on this contract.

In addition, a half-time assistant cell biologist with qualifications comparable to those of the associate cell biologist, must be available for this contract, and also two to three laboratory technicians who are already trained and experienced in the conduct of these assays. All required personnel must already be in the employ of the respondent. Additional personnel needed should be justified. The same key personnel will work on both the support and research aspects of the contract and will devote a definite percentage of time to each.

Equipment—The respondent must have on hand by the due date of this announcement all the equipment which is necessary to carry out the work of this contract. The U.S. government will not provide funds to purchase the basic equipment for this project.

Location—There are no specific geographic requirements for the location of the contractor's main laboratory, except that it must be close enough to assure receipt of shipped cells in a viable condition following dispatch of cells by air from the Washington D.C. metropolitan area.

Contract Specialist: Donna Rothberg
RCB Blair Bldg Rm 114
301-427-8888

RFP N01-CO-14346-41

Title: *Budget formulation and fiscal projection model*

Deadline: *May 26*

Provide ADP support to NCI for year years in the enhancement, maintenance and operation of a fiscal project model used in preparing and analyzing institute budgets. This research effort is to be performed in close collaboration with NCI staff. The contractor's facility must be within a 25-mile radius of the NIH headquarters, Bethesda, Md.

Contract Specialist: Diane Smith
RCB Blair Bldg Rm 332
301-427-8877

RFP N01-CP-15770-50

Title: *Toxicology and carcinogenesis bioassays*

Deadline: *June 22*

The National Toxicology Program is interested in obtaining proposals from bioassay laboratories capable of performing toxicology and carcinogenesis bioassays in laboratory animals for the purpose of obtaining data, which would aid in the meaningful prediction of the toxicity/carcinogenicity potential of chemicals to man.

The experimental protocol will involve two major tasks: Task I—prechronic tests and Task II—chronic tests. A master agreement (basic ordering agreement) is to be used for this award.

Contract Specialist: Dave Monk
RCB Blair Bldg Rm 2A01
301-427-8774

The Cancer Letter _Editor Jerry D. Boyd

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