DRS 1/11/88

THE CANCER LETTER

Vol. 14 No. 2

Jan. 8, 1988

Subscription: $175 year North America, $190 year elsewhere

P.O. Box 2370 Reston, Virginia 22090 Telephone 703-620-4646

Rauscher To Leave ACS When It Moves To Atlanta; Gadberry To Retire In March; Other VPs Stay On

Frank Rauscher, who gave up his job as NCI director in 1976 to become senior vice president for research of the American Cancer Society, has decided not to remain with the

(Continued to page 2)

In Brief

OMB Misses Deadline On 1989 Budget, Blames Late Action On '88 Money Bill; Raney Heads AACE

LATE APPROVAL of 1988 fiscal year appropriations, coming just before Christmas, probably will lead to the same thing for FY 1989. The White House Office of Management & Budget notified Congress this week that it was impossible to submit the 1989 budget proposal Jan. 4, as required by law. OMB Director James Miller said the budget would not be ready before mid-February, noting that the late completion of the current budget made it impossible to arrive at "responsible" figures for 1989 before then. That means the appropriations committees can't start their hearings before late February in a year in which there will be recesses for the two presidential nomination conventions along with pressure to recess for the campaign. . . . **BEVERLY RANEY**, Charlottesville, VA, has been elected president of the American Assn. for Cancer Education. He succeeds Sidney Saltzstein. **James Newsome**, Chapel Hill, NC, is president elect. **Samuel Brown** remains as secretary, and **B.J. Kennedy** succeeds John Horton as chairman of the Advisory Committee. . . . **AWARDS, HONORS** wrap up for 1987: **Luther Brady**, chairman of radiation oncology and nuclear medicine at Hahnemann Univ. Hospital and chairman of the Radiation Therapy Oncology Group, received the Gold Medal Award from the American Society for Therapeutic Radiation & Oncology; **Kenneth Olson**, emeritus professor of medicine, Albany Medical College, and **David Wood**, emeritus professor of pathology, Univ. of California (San Francisco), received the Margaret Hay Edwards Award from the American Assn. for Cancer Education; **Howard Skipper**, president emeritus of Southern Research Institute, and **John Gooch**, associate director of environmental sciences research there, received awards from M.D. Anderson and the Univ. of Alabama, respectively. Skipper received the Jeffrey A. Gottlieb Memorial Award, while Gooch was named the 1987 chemical engineering outstanding fellow; **Isaiah Fidler**, chairman of cell biology at M.D. Anderson, delivered the Ernest William Goodpasture Lecture at Vanderbill Univ.

Rauscher To Leave ACS, Two Thirds Of Staff Won't Move To Atlanta

(Continued from page 1)
Society when the headquarters is moved this year from New York to Atlanta.

Rauscher thus becomes the most senior of the casualties brought on by the controversial decision to leave New York, but he is not alone. It appears now that about two thirds of the Society's 300 plus staff members will not go, although they do not have to make a final commitment until the end of January. ACS officials have told Atlanta sources that they will recruit locally to fill about 200 positions.

Staff changes brought on by the move, along with recent and impending retirements, will constitute the most extensive shakeup in the Society's history. "We'll need a map and a program just to go from one office to another," one staff member cracked.

The shakeup starts at the top. Robert Gadberry, who took the position of executive vice president on an interim basis when Lane Adams retired, plans to retire himself in March. A national search to fill that key job has been under way.

Arthur Holleb, senior vice president for medical affairs, retired last year but has been continuing on a month to month basis while the search has gone on for his successor.

Irving Reimer, vice president for public relations, plans to retire in January, 1989.

The other vice presidents have all decided to make the move: Diane Fink, professional education; John Laszlo, research; Morton Bard, service and rehabilitation; James Bell, finance; Don Henry, annual crusade; Michael Heron, creative services; Allan Erickson, public education; and Lowell Lueptow, deputy executive VP.

Alan Davis, vice president for public affairs, moved his office to Washington DC last year and will remain there.

The majority of the public relations department will move to Atlanta, but the media office will remain in New York.

Rauscher told **The Cancer Letter** that he made his decision after extensive discussions with his family. "We just don't want to leave the northeast," he said. Rauscher and his wife, Peg, live in Connecticut. "Our kids all are only 20 minutes away, and my father is two hours away in Pennsylvania." His mother died last year.

Rauscher will be 57 this year. "If I am every going to make a change, now is the time," he said. "So I'm looking." Possibilities include foundations, research institutes, and industry.

ACS executives and board members knew that the move would cost them some staff; those who supported the switch felt they had to do it anyway. Gadberry has estimated that the eventual saving in operating costs will range from $5 million to as much as $9 million a year.

The Society's new headquarters building will be located on four and a half acres donated by Emory Univ. and the Robert W. Woodruff Foundation, which also is giving ACS $1 million to help pay moving costs. Construction of the 155,000 square foot building is expected to start next month, with completion scheduled for early next year. It is being designed by Heery International and constructed by the Holder Corp.

NCI Expands Extramural Trials Of LAK/IL-2 To 20 More Cancers

NCI has announced that the extramural clinical trials of interleukin-2 and lymphokine activated killer cells (LAK/IL-2) are being expanded to include more than 20 additional cancer sites. The new studies will be carried out at the six cancer centers which have been conducting the LAK/IL-2 trials with advanced kidney cancer and melanoma.

Added to the trials will be acute leukemia; chronic, accelerated and blast phase chronic myelogenous leukemia; chronic lymphocytic lymphoma; cutaneous T-cell lymphomas; Hodgkin's disease; cancers of the anus, bladder, breast, cervix, endometrium, esophagus, head and neck, liver (primary), lung, ovary, pancreas, prostate, stomach, and testes; multiple myeloma; bone and soft tissue sarcomas; and mesothelioma.

The expanded trials at the six centers are funded through 1991 at an annual cost of $3.5 million.

Steven Rosenberg, chief of surgery with NCI's Clinical Oncology Program who developed the LAK/IL-2 regimen, summarized experiences with 137 patients in a presentation at the fourth international symposium of the French Assn. for Cancer Research in Bethesda last month.

Approximately 10 percent of patients with renal cell cancer and melanoma will undergo

complete regression; another 20 percent will have partial regressions. "If we consider patients who have minor regressions, between 25 and 50 percent, about half of all patients with renal cell cancer will show responses. About 40 percent of patients with melanoma will have minor responses," Rosenberg said.

Rosenberg and his colleagues have been searching for various agents that can enhance LAK/IL-2 activity. He has received approval for a combination of alpha interferon and IL-2; and another combination, tumor necrosis factor and IL-2. He also received approval for a phase 1 study of granulocyte monocyte colony stimulating factor (GM-CSF).

Another potential method to improve what Rosenberg calls "adoptive immunotherapy" is to find more potent cells for use in adoptive transfer, he said. "We recently observed that the addition of IL-4, a new lymphokine, to IL-2 makes a super LAK cell, a LAK cell four to five times more potent than the standard IL-2 induced LAK cell. We're now studying this in animal models."

A complete report on Rosenberg's presentation, which also included more details on the first patients to receive his new regimen of tumor infiltrating lymphocytes (TIL) with IL-2 and cyclophosphamide, appeared in the December issue of **The Clinical Cancer Letter.**

Patients entering the new trials may have received prior chemotherapy but not certain immunologic therapies. Treatment requires support in an intensive care unit and patients must have normal heart, lung, liver and kidney function and no significant medical problems except their cancer. Patients with metastasis to the central nervous system are not eligible.

The participating centers, investigator and they physician/patient contact person (if that is not the investigator) are:

Albert Einstein College of Medicine, Bronx, NY, Peter Wiernik, 212/920-4826.

New England Medical Center, Boston, David Parkinson, Michael Atkins and James Mier; Ann Baldyga, 617/350-8501.

Loyola Univ. Medical Center, Maywood, IL, Richard Fisher; Linda Sticklin, 312/531-3311.

Univ. of Texas Health Science Center (San Antonio)/Audie Murphy VA Hospital, Geoffrey Weiss; Sharon Huegele,512/694-5186.

Univ. of California (San Francisco) Cancer Research Institute, Anthony Rayner; Mary Rose, 415/476-4765.

City of Hope National Medical Center, Duarte, CA, James Doroshow, 818/359-8111.

New Jersey Takes A Slice of DOE For Development of Cancer Center

Add the Center for Molelcular Medicine & Immunology in New Jersey, with its go-getter director, David Goldenberg, to those who have managed to slice off a little federal money for cancer research from the budget of the Dept. of Energy.

Last week, **The Cancer Letter** reported that Loma Linda Univ. in California received $8.5 million from DOE's 1988 fiscal year appropriations for development of a proton beam demonstration cancer treatment center. LLU is working with Fermi National Laboratory on the project. Fermi is supported by DOE, and the department enthusiastically endorsed the project. It was pushed through the House Appropriations Committee by Congressman Jerry Lewis, whose district includes Loma Linda, and Lewis made sure that it remained in the compromise bill approved by the House and Senate.

Goldenberg took a slightly different route, and DOE did not particularly like it. The New Jersey center received $3 million through DOE last year and another $7.5 million in the appropriations bill just completed for FY 1988. Goldenberg plans to ask for $7.5 million more in FY 1989 for a total of $18 million, which will be matched by state and private contributions ($10 million state, $8 million private).

The money is being used to develop a 750,000 square foot facility which Goldenberg said would focus on monoclonal antibody imaging and therapy. Radiolabel imaging, with MRI and CT equipment, will be included.

Goldenberg hopes that his center will be developed into a major resource for the National Cancer Program and eventually compete for recognition from NCI as a comprehensive cancer center for New Jersey.

Those prospects apparently did not impress DOE officials. When Victor Braren, a member of the National Cancer Advisory Board, asked at a recent meeting of the Board about an item in the DOE budget for a New Jersey Cancer Center, Energy's ex-officio representative on the Board expressed outrage.

"That's strictly a pork barrel thing," said James Robertson, from DOE's Office of Health & Environmental Research. "It came entirely through Congress. No request was submitted to DOE."

Goldenberg has heard criticism on the matter. In response to a comment that his

money was being taken from other DOE research programs, "I said that I don't mind if it comes at the expense of nuclear weapons research and development."

Goldenberg gave credit to the New Jersey congressional delegation, particularly Representatives Robert Roe, chairman of the Science, Space & Technology Committee, and Peter Rodino, chairman of the Judiciary Committee; and Sen. Frank Lautenberg. He also mentioned Sen. Bill Bradley and Rep. Bernard Dwyer.

Nearly 3,000 Certified As Oncology Nurses; 852 Passed Exam In October

Eight hundred fifty two registered nurses passed the certification examination administered last October by the Oncology Nursing Certification Corp. in Atlanta, Boston, Chicago, Houston and San Francisco. That figure represented 82 percent of those who took the exam.

Roberta Scofield, president of the certification corporation which is an affiliate of the Oncology Nursing Society, said that RNs from 47 states and Puerto Rico participated in the October tests. Those who received certification included staff and head nurses, clinicians, educators, supervisors, clinical nurse specialists, and assistant directors or directors of nursing.

The majority of those certified work in hospitals or clinics with nurses also representing schools of nursing, community or public health nursing, private group practice, office nursing and comprehensive cancer centers.

Certification for oncology nurses was introduced at the 1986 ONS congress in Los Angeles, where 1,384 registered nurses passed the exam. Almost 3,000 nurses are now certified in oncology.

Oncology nursing certification is available to nurses who have a current RN license, three years experience as an RN within the last five years, and a minimum of 1,000 hours of oncology nursing practice within the last three years.

Testing will be held this year May 4 in conjunction with the 13th ONS congress in Pittsburgh, and on Oct. 15 in Phoenix, New Orleans, Minneapolis, New York and Seattle. RNs interested in taking the exam should contact the Oncology Nursing Certification Corp., 1016 Greentree Rd., Pittsburgh, PA 15220, or phone 412/921-7373.

Maxine Singer Receives Top Civil Service Award From President Reagan

Maxine Singer, "one of the great biochemists in the world" in the words Alan Rabson, was one of 58 members of the federal government's Senior Executive Service to receive the Distinguished Presidential Rank Award, the country's highest civil service prize, last week from President Reagan.

Singer is chief of the Laboratory of Biochemistry in NCI's Div. of Cancer Biology & Diagnosis. Rabson, DCBD director, nominated her for the award.

NCI Director Vincent DeVita said that Singer "has made major contributions to understanding what is sometimes called nonsense or junk DNA." One such DNA which she calls "Line 1" represents five percent of all human genetic material, which research has shown to be of significance in human disease.

Singer has been at NIH 29 years, since receiving her PhD at Yale.

The Distinguished Presidential Rank Award carries with it a cash prize of $20,000. Singer is the first NCI staff member to receive the top award. She, along with Eli Glatstein, chief of the Radiation Oncology Branch in the Div. of Cancer Treatment's Clinical Oncology Program, and Max Gottesman, chief of Biochemical Genetics in DCBD, had previously won the Merit Award, the second highest prize in the civil service.

Other NIH SES members who received the award last week were William Raub, NIH deputy director; and David Davies and Gary Felsenfeld of the National Institute of Diabetes & Digestive & Kidney Diseases.

OCC Proposes Patient, Physician Clinical Trials Education Plan

One of the most vexing and frustrating problems facing cancer clinical investigators is that they have been able to recruit only a few thousand patients a year for clinical trials, despite the fact that the total number of Americans diagnosed each year with cancer is now approaching one million.

"That is a national disgrace," NCI Director Vincent DeVita has said. It has resulted in stretching accrual in colon cancer studies, for example, to three years or more. With 150,000 patients to choose from, accrual in those trials should be completed in a year, DeVita insists.

The changes being implemented in the

clinical cooperative groups, with emphasis on intergroup studies of high priority protocols (**The Cancer Letter**, Dec. 4), are aimed specifically at stepping up the pace of accrual. Cooperative group chairmen and staff members of the Div. of Cancer Treatment's Cancer Therapy Evaluation Program have agreed there are other steps that can be taken. One of them is to involve NCI's Office of Cancer Communications in an effort to educate cancer patients and physicians on the merits of participating in clinical trials.

Katherine Crosson, OCC staff member, reported on the "Clinical Trials Accrual Project Education and Promotion Plan" at the recent meeting of group chairmen. The report follows, with some editing to conserve space:

DCT has set a goal of increasing patient entry to NCI sponsored clinical trials twofold by 1992. DCT wants to place initial emphasis on patient recruitment into the following trials:

*Adjuvant trials for stage 1 breast cancer (number of patients to increase from 200 to 400).

*Adjuvant trials for colon-rectal cancer (recruit 750 new colon cancer patients and 150-200 new rectal cancer patients).

*Adjuvant trials for bladder cancer.

If these increments in accrual rates across NCI sponsored clinical trials are attained, cancer patients would realize some important benefits: increased numbers of participants would allow researchers to expand the number of trials being run, shorten the time span of any particular trial, and ultimately move therapeutic results out of the experimental stage and into routine physician practice more rapidly.

Critical information gaps concerning factors affecting patient enrollment in and physician referral to clinical trials have inhibited the development of strategies to increase patient accrual. A review of the recruitment literature produced little information in two key areas: factors that motivate individuals to enroll and to maintain participation in clinical trials, and factors that motivate physicians to refer patients to clinical trials.

To gather additional information in these areas, OCC and DCT in 1985 performed an assessment of the educational needs of patients who were considering clinical trials enrollment. Responses from potential participants revealed a basic problem: many simply do not understand the concept of clinical trials. Also, respondents stated that they fear being used as "guinea pigs" in an investigator's research. To complicate matters, stress (resulting from the illness itself or from pressure to make treatment decisions) impedes a patient's ability to understand explanations of risks and advantages of clinical trials participation. Respondents did, however, mention this positive factor: they feel that participation in clinical trials could benefit others as well as themselves.

Physicians in this study expressed concerns about issues such as referring patients to a system of impersonal care, explaining risks and advantages of partici- pation in a manner that allows informed consent, the quality of the research being performed, and the costs of the trial to the patients and to themselves.

Many critical questions remain. Do various demographic groups view clinical trials in the same manner? Will similar recruitment strategies work for these various groups? What do current clinical trials participants identify as the primary reason for their participation? For patients who considered participation but declined, what was the strongest factor that kept them out? Do gatekeepers to clinical trials participation (physicians and other health professionals who refer patients or influence patients' decisions) understand the nature of these trials and feel comfortabale explaining them to their patients?

OCC proposes a two part education and promotion plan. Part 1 strategies will focus on increasing the understanding and awareness of clinical trials in several target groups. Implementation of part 1 strategies should yield short term gains in patient accrual and should lay the foundation for future increments.

Part 2 proposes a longer term approach to the goal of increasing patient accrual. The purpose of part 2 activities is to expand the knowledge base concerning costs and benefits of clinical trials participation from the point of view of the patient and the gatekeeper. This will facilitate development of more refined strategies to increase both patient enrollment and physician referral. For example, we may discover that the term "clinical trial" sounds too scientific, impersonal or threatening to patients. In that case, a new expression that sounds less forbidding and more inviting might be

developed and tested.

The rest of the report focuses on part 1.

An education and promotion plan is proposed that is targeted to patients, families, physicians and other key health professionals to:

*Increase public awareness (including cancer patients and their families) and understanding of the concept of clinical trials and the availability of high priority clinical trials.

*Increase awareness among physicians (both primary care physicians and oncologists) of the benefits of clinical trials to their patients and to themselves, the availability of specific trials for their patients, and the professional interactions that will occur when they enroll patients in clinical trials.

*Increase awareness of the benefits of clinical trials to other health professionals who can heighten the awareness of prospective patients. These professionals would include oncology nurses, pharmacists, social workers, patient educators and physician assistants.

Educational and promotional efforts in part 1 will be targeted primarily to patients, their families and the general public and will include:

1. Addition of a statement about clinical trials to all OCC patient education publications. The Patient Education Program staff is continually reviewing and revising the inventory of print materials that have been developed for cancer patients, their families and the general public. A generic statement about clinical trials will be developed and the statement will be added when any publication is due for reprinting or revision.

2. Development of a fact sheet on clinical trials that is modeled after the publication, "What Are Clinical Trials All About?" OCC will continue to produce and promote the pamphlet version of that publication, and will aslo produce that information as a fact sheet. It will be graphically designed to invite reading and will be easy to understand. It will be available through the Cancer Information Service, physician offices, hospitals and clinics. An aggressive distribution plan to stimulate widespread dissemination will be implemented.

3. Placement of general articles about clinical trials in popular magazines and newspapers and as television feature stories. Publications such as Parade, Reader's Digest, Family Circle and Ladies' Home Journal are read widely, especially by females. The placement of articles in these publications, especially those articles based on a personal story or testimonial, will help to increase the awareness and understanding of clinical trials among the general public. These articles will be distributed in such a way as to result in a continuous stream of stories, not just a one time dissemination.

Each institution participating in a trial could write and submit articles for local publication. In addition to print media, electronic media could be investigated as possible outlets for feature stories about clinical trials.

An additional possibility for clinical trials promotion in the media is to develop a seminar about clinical trials for reporters in cities that have sophisticated cancer treatment facilities. This seminar would explain the concept of clinical trials, publicize availability of particular trials, and perhaps feature success stories.

Celebrities also could be asked to appear in radio and TV public service announcements that describe and promote enrollment in clinical trials.

4. Promotion of clinical trials and clinical trials investigators through local media.

Many clinical trials investigators have commented that positive local publicity about clinical trials could serve both to educate the public and to increase patient accrual. For example, press releases from NCI (regarding awarding of grants, publication of an important paper, or presentation of results at a national or international meeting) could enhance the stature of the investigator in his or her community and could trigger an increase in referrals to clinical trials. Publicity for important administrative decisions (such as establishment of a CCOP or the refunding of a cooperative group or cancer center core grant) could have the same effect.

5. Consultation with cancer center marketing directors regarding innovative patient recruitment strategies.

Marketing directors or directors of patient recruitment at major cancer centers could be a good source of innovative recruit-ment strategies. These individuals will be identified and contacted, and strategies they suggest will be reviewed to determine their applicability to increasing patient accrual in clinical trials.

Additional activities will be developed

based on market research and needs assessment. Activities for patients, families and the general public will include:

1. Development of a promotional poster for each of the high priority clinical trials, to be placed in hospitals, cancer centers and physician offices.

2. Inclusion of a generic statement about clinical trials in all PDQ patient information file statements.

Activities for physicians and health professionals will include:

1. Placement of articles in professional journals and newsletters regarding clinical trials.

Health professionals, particularly primary care physicians, oncologists and oncology nurses and social workers, are the gatekeepers to patients who are eligible for clinical trials. Articles placed in professional journals will help to educate gatekeepers about the importance of clinical trials for advances in cancer treatment, for achievement of the Year 2000 goal for cancer control, and for their patients' prospects for control or long term survival of the disease. Articles will help to increase willingness to refer patients to experimental protocols and to acquaint health professionals with how to do so. Promotion and placement of articles in local publications will also be encouraged through networking with cancer centers, cooperative group members, and other NCI funded clinical resources (e.g., CCOPs).

An additional possibility is the development of a direct mail piece targeted to selected clinicians (e.g., internists, FPs, OB/GYNs) advising them in a personalized way of the urgency of increasing patient accrual, especially in the priority trials.

2. Active participation through scheduled presentations and exhibits at professional society meetings. Although approaches to primary care physicians will be made, most efforts will be targeted to various oncology specialists.

3. Inclusion of a statement in the PDQ file on clinical trials regarding the importance of patient accrual to the high priority trials.

4. Development of program resources and materials for physicians based on market research and a needs assessment survey.

5. Developoment and distribution of orientation materials on clinical trials for use in oncology training programs.

Process and outcome evaluation measures will be developed to assess the success of planned promotional activities in reaching the target audiences. For example:

*Information will be collected on what types of audiences received the clinical trials fact sheet and the number distributed.

*The number of articles placed in professional journals and public media outlets and estimated readership/viewership will be monitored.

*Enrollment in NCI trials can be tracked through NCI data sources to determine if expected outcomes are being achieved.

Charles Moertel, chairman of the North Central Cancer Treatment Group, suggested some of OCC's proposed efforts could help conserve physicians' time. "If you provide them with professional, solid materials for their patients, it could reduce their work."

Emil Frei, chairman of Cancer & Leukemia Group B, suggested that care be given "to how you deal philosophically with the issue that clinical trials very often is the best clinical care."

OCC has encountered that problem in the past. The NIH Office for Protection from Research Risks is skeptical about too much emphasis on clinical trials as the best cancer care because of the potential impact on informed consent.

"Are there any hangups about advertising that a physician in a given area is a card carrying participant in clinical trials?" Moertel asked. If it would help sell the idea that that physician is highly qualified, "it would double accrual overnight."

Charles Coltman, chairman of the Southwest Oncology Group, saaid there were no hangups as far as he knew. CTEP Director Robert Wittes said that identification of an institution as an affiliate of NCI could help.

"How many patients do you need to put on a trial before you get the card?" Bernard Fisher, chairman of the National Surgical Adjuvant Breast & Bowel Project asked.

Teresa Vietti, chairman of the Pediatric Oncology Group, suggested that oncology nurses should be considered as important gatekeepers.

Frei noted that another important issue is that of third party support for patients on clinical trials.

Coltman, who is president elect of the American Society of Clinical Oncology, said that it is his intent to focus on clinical trials during his term.

RFPs Available

Requests for proposals described here pertain to contracts planned for award by the National Cancer Institute unless otherwise noted. NCI listings will show the phone number of the Contracting Officer or Contract Specialist who will respond to questions. Address requests for NCI RFPs, citing the RFP number, to the individual named, the Blair building room number shown, National Cancer Institute, NIH, Bethesda MD 20892. Proposals may be hand delivered to the Blair building, 8300 Colesville Rd., Silver Spring MD, but the U.S. Postal Service will not deliver there. RFP announcements from other agencies will include the complete mailing address at the end of each.

RFP NCI-CP-85613-59

Title: Production of purified recombinant viral proteins
Deadline: Approximately March 15

The Div. of Cancer Etiology is recompeting this ongoing project which is currently being performed by Repligen Corp. Under this proposed acquisition the contractor shall provide milligram quantities of purified recombinant proteins from cloned genes of HIV-1, HIV-2, HTLV-1, HTLV-2, HBLV and simian immunodeficieny virus (SIV). These proteins will be utilized:

1. To carry out structural studies using X-ray crystallography and nuclear magnetic resonance.
2. To study immune response in various animal species and to test the development of neutralizing antibodies against HIV and SIV.
3. To prepare monoclonal and polyclonal antibodies against various antigens.

A three year contract is anticipated.
Contract Specialist: Christine Virts
RCB Blair Bldg Rm 114
301/427-8888

RFP NCI-CM-87248-22

Title: Storage and distribution of clinical drugs for AIDS
Deadline: Approximately March 5

The Pharmaceutical Resources Branch of the Develop-mental Therapeutics Program of NCI's Div. of Cancer Treatment is seeking a contractor to store and dis- tribute clinical drug products and keep adequate records of such distribution in support of clinical trials sponsored by the AIDS Treatment Branch of the National Institute of Allergy & Infectious Diseases.

The project will involve the receiving of drugs from various sources, storage of the products under specified conditions, repackaging and subsequent shipment to authorized investigators in the United States. In some cases, packages of clinical products may require relabeling in order to provide medication supplies suitable for dispensing to individual patients in blinded clinical studies.

Manual and computerized data processing systems will be used for various recordkeeping and repository functions. The contractor must possess an Environmental Protection Agency toxic waste generator permit and the necessary state and local permits for generation and transportation of toxic waste drugs.
Contracting Officer: Elizabeth Moore
RCB Blair Bldg Rm 216
301/427-8737

RFP NCI-CM-87253-48

Title: Production of monoclonal antibodies for treatment of human disease--master agreement
Deadline: Approximately March 5

NCI is seeking to identify those institutions with the capacity and expertise to generate cell clones capable of large scale production of murine-human monoclonal antibodies.

Institutions identified as scientifically and technically qualified will be awarded certification of eligibility to compete for future master agreement orders.
Contracting Officer: Thompkins Weaver
RCB Blair Bldg Rm 212
301/427-8737

RFP NCI-CN-85073

Title: Evaluation of chemoprevention agents by in vivo screening assays
Deadline: Approximately March 4

The required services will be defined by master agreement orders issued during the three year period of performance. This is a recompetition of the entire pool of master agreement holders. All master agreement holders must requalify to be eligible to compete for future master agreement orders (MAOs).

Pursuant to the MAOs, the contractor shall conduct in vivo screening studies in laboratory animals (primarily rats and mice) using gavage and other routes of administration to administer the designated chemopreventive agents in animal models using any carcinogenic mechanism (that is consistent with the evaluation criteria), such as the administration of carcinogens, promoters, hormones, irradiation, cells, or other carcinogenic agents.

This research will be provided under cost reimbursement and/or fixed price MAOs. Offerors will not be considered eligible for award unless they can conduct specific individual MAOs in accordance with FDA good laboratory practice regulations in facilities that are operated in compliance with the NIH guide for care and use of laboratory animals, the Animal Welfare Act, and the U.S. government principles for utilization and care of vertebrate animals used for testing research and training.

It is estimated that up to four task orders per year will be issued pursuant to the master agreement contracts.
Contracting Officer: Charles Lerner
RCB Blair Bldg Rm 2A07
301/427-8745

NCI CONTRACT AWARDS

Title: Performance of protocol toxicology studies
Contractors: Southern Research Institute, $3,616,955; Springborn Life Sciences Inc., $3,697,789

Title: Support for cancer Surveillance, Epidemiology & End Result (SEER)
Contractors: Connecticut Dept. of Health Services, $1,107,565; Fred Hutchinson Cancer Research Center, $1,786,364

Title: Iso-antigenic typing of mouse strains
Contractor: Northwestern Univ., $779,672

Title: Maintenance of a rodent production center
Contractor: Taconic Farms Inc., $670,340

The Cancer Letter _Editor Jerry D. Boyd Associate Editor Patricia Williams
Published forty-eight times a year by The Cancer Letter, Inc., P.O. Box 2370, Reston, Virginia 22090. Also publisher of The Clinical Cancer Letter.