THE CANCER LETTER

Vol. 10 No. 8
Feb. 24, 1984

Subscription $150 year North America
$175 year elsewhere

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

DCT BOARD GIVES CONCEPT APPROVAL TO RECOMPETITION OF IN VITRO ASSAY FOR NEW DRUG SCREENING PROGRAM

Continuation and recompetition of the NCI supported effort to apply a human tumor colony forming assay to new drug screening was given concept approval last week by the Div. of Cancer Treatment Board of Scientific Counselors, following the recommendations of DCT staff and an ad hoc review committee. The Board had delayed approving the concept last June, calling for further tests of 14 compounds found to be active in the HTCFA and asking that pertinent data be reviewed by

(Continued to page 2)

In Brief

WYNDER TO RECEIVE DISTINGUISHED ACHIEVEMENT AWARD FROM ASPO; BROWN HEADS COUNCIL OF DEANS

ERNST WYNDER, president of the American Health Foundation, will receive the American Society of Preventive Oncology's Distinguished Achievement Award March 20 at ASPO's eighth annual meeting in Bethesda. Wynder will address the meeting on the topic, "Future Directions in Preventive Oncology".... **ARNOLD BROWN,** dean of the Univ. of Wisconsin Medical School and former member of the National Cancer Advisory Board, has been elected chairman of the Council of Deans of the Assn. of American Medical Colleges.... **CHARLES BALCH,** Univ. of Alabama (Birmingham), has been named the American Cancer Society Professor of Clinical Oncology. Balch also was recently elected president-elect of the Assn. for Academic Surgery.... **TOBACCO INDUSTRY'S** outrageous new advertising campaign claiming science has not demonstrated that cigarette smoking is hazardous to health ignores not only the massive weight of scientific evidence but also evidence turned up by scientists supported by the industry's Council for Tobacco Research. The Council says it has awarded nearly $84 million to independent scientists since 1954 for research aimed mostly at cancer, cardiovascular ailments and chronic pulmonary diseases. Many of the studies supported by the Council related only distantly if at all to tobacco, with such topics as "multitargeting with hybridomas on tumor cells" and "biology and molecular biology of the differentiation of a human monocytoid cell line." But the latest round of awards included a study of nicotine addiction on brain neurotransmitters and in an animal model of Parkinson's disease, and another on maternal smoking and blood concentrations of amino acids in umbilical arteries and veins. The awards, funded by tobacco manufacturers, growers and warehousemen, are made by an independent scientific advisory board. The Council says that more than 2,300 reports and articles have been published on research it has supported; a survey of those articles to determine which side of the issue they came down on would be very interesting.

HCTFA NEW DRUG SCREENING APPROVED FOR RECOMPETITION AT REDUCED LEVEL

(Continued from page 1)

a special review group. That group met last December and recommended that:

1. The contracts be recompeted to allow the screening of about 300 randomly selected compounds per year for three years (about one half the current funding level). Emphasis would continue on compounds found negative in the in vitro P388 colony forming assay, but evaluation also would be carried out on selected active compounds such as in vivo tumor panel actives and rationally designed compounds.

2. Contractors will be asked to pursue initial screening leads (dose response testing and in vivo tumor panel testing). The most promising (compounds with activity against a large spectrum of tumors or specificity against a particular histologic type of tumor) would be developed for clinical trials.

3. Assay improvements, such as medium development, will be pursued.

4. Contractors will compare the performance of the HTCFA for drug screening with a human tumor cell line project which was approved by the Board as a new initiative last year. Funds made available by reducing the HTCFA effort will support this project.

The program started with the award of contracts in 1980 to UCLA, Mayo Foundation, Cancer Therapy & Research Foundation of South Texas, and the Univ. of Arizona. It came to the Board last June for concept approval of recompetition, but when the decision was made to wait for more information, the contracts were extended for a year. A total of nearly $4 million will have been spent on the project when that fourth year expires next September. Staff estimated that the new streamlined effort will cost about $700,000 a year.

"Why reduce the funding?" Board Chairman Samuel Hellman asked. "I can understand not supporting this. I can understand supporting it. I can't understand reducing the budget."

Michael Boyd, director of the Developmental Therapeutics Program, said that the new effort would not need any more than that. DCT Director Bruce Chabner was a little more blunt:

"Some contractors performed better than others," Chabner said. "We didn't get much out of some of them. We don't need them."

Sydney Salmon, at the Univ. of Arizona, developed, with Anne Hamburger, much of the methodology for the assay. Salmon and his group have used the assay to predict clinical response to specific drugs for individual cancer patients. Salmon reported to the ad hoc committee that in 635 correlations of in vitro drug sensitivity test results with clinical responses involving patients with ovarian and melanoma tumors, the accuracy of the assay for predicting a clinical response was 71 percent, while accuracy for predicting clinical resistance was 91 percent. In a survival study of 16 patients with myeloma, the average life span was 48.5 months for patients who were sensitive in vitro to at least one of three agents used clinically and nine months for patients resistant to all three.

Salmon said those results indicate the assay should be useful in screening for new drugs. Only about five percent of the 10,000 compounds entered each year into the NCI screen are being identified by the in vivo P388 prescreen for additional testing, Salmon noted, and he expressed concern about what useful agents might be missed. At least one agent, tamoxifen, a fairly nontoxic drug useful in treating breast cancer, is missed by current screens. Salmon contended that HCTFA has the potential to identify agents with greater specificity for human cancer.

Dani Bolognesi, one of three Board members on the ad hoc committee (Paul Calabresi and David Goldman were the others), said committee members were "struck by the fact that the most active in HTCFA also were most active in the P388 in vitro assay. The question rose, why screen only P388 negatives? We suggested they look also at positives, and that has been built into the recommendations. The general consideration was that this is a useful assay and it might be able tp pick out some good compounds not otherwise seen."

Board member Max Cooper expressed the only serious reservations, contending that the assay has not been sufficiently developed to get valid answers from the study. But the vote to approve the concept was unanimous (the committee had voted 9-1 for approval).

Members of the ad hoc committee, in addition to the three Board members, were Michael Colvin, Johns Hopkins; Charles Erlichman, Ontario Cancer Institute; and NCI staff members Desmond Carney, David Johns, Robert Ozols, David Vistica, and Robert Young.

The Board also gave concept approval to addition of $160,000 to the contract with Meloy Labs Inc. for collection, storage, quality assurance and distribution of biological response modifiers, and to adding a similar amount to that estimated for recompetition of that contract, previously approved by the Board.

Meloy and Litton Bionetics Inc. are the present contractors for the project. The additional amount was made necessary by the rapidly increasing numbers of monoclonal antibody preparations available for clinical evaluation and demands for them by clinical investigators.

The Board also approved the concept of adding an additional year and $190,000 to contracts with Lawrence Berkeley Laboratory, Massachusetts General Hospital, Univ. of Pennsylvania, and M.D. Anderson Hospital for evaluation of treatment planning for particle beam radiotherapy.

DCT said the extension was needed to provide sufficient time to develop and submit a final report on the working group's achievements and recommendations for treatment planning; to analyze and score the 200 treatment plans resulting from this effort and to evaluate the role of CT scanning, 3-D calculations, inhomogeneity corrections and error analysis in treatment planning.

DEVITA SAYS TOP PRIORITY WILL BE MORE MONEY FOR CLINICAL TRIALS

One of NCI's top priorities during the 1985 fiscal year which starts next Oct. 1 will be to "loosen up some more money for clinical trials," Director Vincent DeVita told members of the Div. of Cancer Treatment Board of Scientific Counselors last week.

DeVita pointed out that the budget for the clinical cooperative groups has increased from $22 million in 1974 to the $45 million proposed for FY 1985. He acknowledged that there has been very little increase for the past three years. "Dr. (Bruce) Chabner (DCT director) brought this up at our recent retreat, as a serious problem. Everyone, including the Executive Committee, agreed that it is."

DeVita said that NCI's goal of reducing cancer mortality by 50 percent by the year 2000 is based half on "better application of what we know about treatment" and half on better application of present knowledge about prevention. He cited a 15 percent difference in treatment survival nationally and that achieved "in the best institutions. PDQ should help reduce that difference."

Among items brought to the Board's attention by Chabner were:

* National Cooperative Drug Discovery Groups, the new program to form multidisciplinary groups, with academic and industry participation, which will search for creative new approaches in anticancer drug development. This program was initiated by the Board on the recommendation of Alan Sartorelli, at that time a member of the Board. Sartorelli is chairman of the committee which is reviewing the applications.

Chabner said that 13 applications have been submitted, with 43 individual institutions involved. Review has been scheduled for April 4-6. DCT has earmarked $2 million for the first year of the program, but "it looks as if we have more than $2 million worth of very good groups," Chabner said. "We are considering adding more." That decision and others involving final allocations from the 1984 budget will be brought to the Board at its June meeting.

The drug discovery groups will be supported through cooperative agreements.

* The neutron therapy program. DCT awarded contracts in 1979 for development of three new clinically dedicated neutron facilities, at Fox Chase, UCLA and Univ. of Washington. The first two were to be constructed by Cyclotron Corp. of Berkeley, the Washington facility by a Scandanavian firm. Another neutron facility had previously been started at M.D. Anderson, also built by Cyclotron, with grant support from NCI. NCI also has supported neutron treatment studies with existing facilities at Fermi Lab in Chicago and the Cleveland Clinic.

The Fox Chase facility is now complete and clinical trials have started, Chabner said. One problem has been that Fox Chase has only one functioning DT tube. Those tubes last about a year, and plans were made to purchase another from Cyclotrong.

The M.D. Anderson facility "is virtually complete, and they have been able to treat some patients. They have some problems, but they are solvable," Chabner said.

The UCLA neutron generator is 75 percent complete. "Fermi and the Cleveland Clinic neutron facilities are functioning and present no specific problems," Chabner said.

There is a major problem at UCLA, however. Last year, Cyclotron filed under the Chapter 11 bankruptcy provisions. The firm continued to operate, and NCI had hoped that it would be able to complete the UCLA project. "We had firm guidelines and put in only the amount of money warranted by progress," Chabner said. However, two weeks ago, Cyclotron went into Chapter 7 bankruptcy, "which means essentially the demise of the corporation."

The 75 percent finished UCLA neutron generator "is not worth much as it is," Chabner said. Efforts are under way to finish the job by either hiring Cyclotron employees, bringing in another company, or through another company buying out Cyclotron. Whatever, no more NCI money will be put in until a reliable source has been lined up, Chabner said.

Fox Chase is trying to find some way to get the three DT tubes which have been 90 percent finished by Cyclotron. "We hope to convince one of the national labs to finish them," Robert Goodman, member of the Board and PI on the Fox Chase project, said.

Chabner said the clinical studies at the six institutions "need to be reorganized under a common funding mechanism. This Board made it clear that we have to get some clear answers from this program.

These are not to be pilot studies. We felt that the best way for coordination and cohesion would be through the contract mechanism. We can exercise more coordination, more involvement and direction with contracts. In many ways these studies represent something like phase 1 and 2 drug trials."

Chabner said that with a limited number of patients available, "we need to have a well ordered, well planned approach." Protocols, he suggested, should be developed by a working group, not by NCI staff. The working group would "operate under its own steam." He asked the Board to help form a working group, "help us work out the details."

Board Chairman Samuel Hellman appointed members Karen Fu, Carol Portlock, M.M. Elkind, and Rodrigue Mortel and former Board member Simon Kramer to the working group, with Fu as chairman. She is professor of radiation oncology at the Univ. of California (San Francisco). Elkind is chairman of the Dept. of Radiology & Radiation Biology at Colorado State Univ. Portlock is professor of medical oncology at Yale and Mortel is chairman of the Dept. of OB-GYN at Hershey Medical Center. Kramer, former chairman of the Radiation Therapy Oncology Group, is one of the pioneers in radiation therapy.

Board member Brigid Leventhal suggested that some money be made available for patient travel, rather than expand the number of institutions participating in the program.

"We have six, and there are some indications that others may want to participate," Chabner said. "There are others with cyclotrons and particle machines, and they may want to do clinical trials. My concern is that if they do, it should be as part of a working group." Although no plans have been made to include non-U.S. institutions, Chabner said that it might be considered.

* NMR contracts. An RFP for clinical evaluation with $1.2 million set aside for funding was approved by the Board in June, 1982. The RFP was issued later that year, but "the review process was a little longer than most," Chabner said. "We expect awards to be made this May. There were a number of good applications, and as usual there is insufficient money to cover them all. We expect to make three awards."

ACCC 10TH ANNIVERSARY MEETING TO CONSIDER IMPACT OF DRG SYSTEM

Members of the Assn. of Community Cancer Centers will convene in Washington March 7-11 for their 10th annual meeting, with the theme, "A Decade of Progress; a Decade of Challenge." Foremost on their minds this year will be the impact of DRG reimbursement.

ACCC has demonstrated considerable political clout in the 10 years since a handful of community physicians met in Denver to put together an organization which could help them organize cancer programs and at the same time help carry their message to the halls of Congress and NCI.

The annual meeting always starts off with a day long blitz of Capitol Hill, and this time, the blitzers will have blood in their eyes. They hope to rally congressional support for legislation directing the Health Care Finance Administration, which has ignored their concerns about DRGs, to establish a new DRG category for clinical trials.

Michael Maher, director of the Office of Reimbursement Policy at HCFA, will be one of the speakers at a session on the impact of prospective reimbursement on community cancer programs.

A special session has been scheduled on "ACCC's DRG Research Plan, HMOs, and PPOs," by Robert Clarke and Lee Mortenson. Workshops sessions will include one on "Maximizing Your Community Cancer Program in the Face of DRGs."

James Holland, chairman of the Dept. of Neoplastic Disease at Mt. Sinai School of Medicine and one of the country's leading figures in clinical cancer research, will speak March 11 on the topic, "Future Development in Cancer Management: The next 10 years."

John Yarbro, who will assume the ACCC presidency from William Dugan during the meeting, will speak at the Saturday luncheon on "Science, Politics, Money and Change."

On March 12, following the meeting, ELM Services Inc. will hold an all day meeting on the Community Hospital Oncology Program Data System, with sessions on the national cancer data base, DRG features, concurrent abstracting, and research applications. Contact ELM at 301-984-1242.

NCI ADVISORY GROUP, OTHER CANCER MEETINGS FOR MARCH, APRIL, FUTURE

Div. of Cancer Etiology Board of Scientific Counselors—March 1-2, NIH Bldg 31 Rm 10, closed 9-11 a.m. March 1, open 11 a.m.-adj. March 1 and 8:30 a.m.-adj. March 2.

Gastrointestinal Oncology—March 1-2, Hoffmann Auditorium, Memorial Sloan-Kettering Cancer Center, New York. Contact Charlene Landis, CME Conference Planner, MSK, 1275 York Ave., New York 10021, phone 212-794-6754.

Infusion Cancer Chemotherapy—March 1-3, New England Deaconess Hospital, Boston. Contact Dept. of Continuing Education, Harvard Medical School, 25 Shattuck St., Boston 02115, phone 617-732-1525.

UCLA Winter Oncology Conference—March 1-3, Miramar-Sheraton Hotel, Santa Monica. Contact Health Sciences, UCLA Extension, PO Box 24901, Los Angeles 90024, phone 213-825-7257.

Oncology Nursing Conference—March 1, Hilton Hotel, Daytona Beach, Fla. Caring for the patient with advanced cancer. See next item for contact.

Cancer Conference—March 2-3, Halifax Hospital Medical Center, Daytona Beach. Dedication of the new Regional Oncology Center. Contact Ken Mead, Coordinator, Cancer Conference, PO Box 9054, Daytona Beach 32020, phone 904-258-1544.

Cancer and AIDS—March 2-4, Sheraton Palace Hotel, San Francisco. 19th annual San Francisco Cancer Symposium. Contact West Coast Cancer Foundation, 50 Francisco St., Suite 200, San Francisco 94133.

Cancer Clinical Investigation Review Committee—March 5-7, NIH Bldg 31 Rm 10, open March 5 8:30-9 a.m.

Cancer Control Grant Review Committee--March 5-6, NIH Bldg 31 Rm 8, open March 5 8:30-9 a.m.

Mediators in Cell Growth & Differentiation--March 6-9, Houston. 37th annual Symposium on Fundamental Cancer Research, sponsored by Univ. of Texas M.D. Anderson Hospital. Contact Office of Conference Services, Box 131, MDA, 6723 Bertner Ave., Houston 77030, phone 713-792-2222.

Decade of Progress, Decade of Challenge—March 7-11, Hyatt Regency Capitol Hill, Washington D.C. Assn. of Community Cancer Centers 10th anniversary meeting. Contact ACCC Executive Office, 11600 Nebel St., Rockville, Md. 20852, phone 301-984-9496.

Ultrasonics in Medicine--March 7-12, Strasbourg, France. 5th European Congress. Contact F. Weill, Dept. of Radiologie, Viscerale, C.H.U., 2 Place, St. Jacques, 25000 Besancon, France.

Breast Cancer: Diagnostic & Treatment Options—March 8, Roswell Park continuing education in oncology. Contact Gayle Bersani, Cancer Control Coordinator, RPMI, 666 Elm St., Buffalo 14263, phone 716-845-4406.

President's Cancer Panel—March 9, Southern Research Institute, Birmingham, Alabama, 9 a.m., open.

Developmental Therapeutics Contract Review Committee—March 12, NIH Bldg 31 Rm 8, open 8:30-9 a.m.

3rd International Conference on Cancer Nursing—March 12-25, Melbourne, Australia. Contact National Hospice Organization, 2344 Nicollete Ave., Suite 150, Minneapolis 55404.

Cancer Education Review Committee—March 15-16, Holiday Inn Crown Plaza, Rockville, Md. Open March 15, 8:30-10 a.m.

Cancer Preclinical Program Project Review Committee--March 15-16, NIH Bldg 31 Rm 6, open 9-9:30 a.m.

Gynecologic Oncology—March 15-17, Hyatt Regency Hotel, Baltimore. J.D. Woodruff Symposium, sponsored by Johns Hopkins Medical Institutions. Contact Susan Bavaro, Office of Continuing Education, Turner 22, 720 Rutland Ave., Baltimore 21205, phone 301-955-6046.

Impact of Biotechnology on the Immunobiology of Cancer--March 15-16, Chapel Hill. 8th annual Cancer Research Center Symposium. Contact Pam Upchurch, Cancer Research Center, Box 30, McNider Bldg, Univ. of North Carolina, Chapel Hill 27514.

Human Values & Cancer—March 15-17, New York. 4th National Conference. Contact Dr. Diane Fink, American Cancer Society, 777 Third Ave., New York 10017.

American Radium Society—March 18-22, Hotel Del Coronado, San Diego. Contact Sally Polek, American Radium Society, 925 Chestnut St., Philadelphia, Pa., 19107, phone 215-574-3179.

1984 Mid-Atlantic Central Cancer Registry Conference--March 19, Hilton Hotel, Philadelphia. Operations of registries, applications of registry data in cancer control. Contact Pamela Peters, American Cancer Society, Philadelphia Div., 21 S. 12th St., Philadelphia 19107.

American Society of Preventive Oncology--March 20-21, Holiday Inn, Bethesda, Md. Eighth annual meeting. Topics include applied intervention trials, methodologic issues in intervention trials, radiation carcinogenesis and risk assessment, and ethnic, endocrine, and nutritional factors in the epidemiology of breast cancer. Contact Rose Anderson, Memorial Sloan-Kettering Cancer Center, 1275 York Ave., New York 10021, phone 212-794-6580.

Adjuvant Therapy of Cancer—March 21-24, Tucson Convention Center. 4th International Conference, sponsored by Univ. of Arizona Cancer Center. Contact Mary Humphrey, Conference Coordinator, UACC, Tucscon 85724, phone 602-626-6044.

Clinical Cancer Program Project Review Committee—March 29-30, NIH Bldg 31 Rm 10, open March 29, 8:30-10 a.m.

Cancer Center Support Grant Review Committee—March 29-30, NIH Bldg 31 Rm 6, open March 29 8:30-9:30.

Appraisal of Interstitial Brachytherapy--March 30, Hoffmann Auditorium, Memorial Sloan-Kettering Cancer Center. Annual Brachytherapy Oncology Update. Contact Charlene Landis, CME Conference Planner, phone 212-794-6754.

Diagnosis & Treatment of Neoplastic Disorders: Medical, Surgical & Radiotherapeutic Aspects—April 5-6, Johns Hopkins Medical Institutions. Tenth annual symposium. Contact Office of Continuing Education, Johns Hopkins Univ. School of Medicine, 720 Rutland Ave., Baltimore 21205, phone 301-955-6046.

Management & Theory of Pain in Cancer Patients—April 5-7, Four Seasons Hotel, Houston. Contact Office of Conference Services, M.D. Anderson Hospital, 6723 Bertner Ave., Houston 77030, phone 713-792-2222. 3 Bertner Ave., Houston 77030, phone

Cervical Neoplasia--April 6-7, Stouffers Hotel, Houston. Contact Office of Conference Services, Box 131, M.D. Anderson, 6723 Bertner Ave., Houston 77030, phone 713-792-2222.

Breast Cancer: An International Seminar—April 8-14, Edinburgh. Contact Courses Dept., The British Council, 65 Davies St., London W1Y 2AA. The British

President's Cancer Panel—April 9, Univ. of Southern California, Mayer Auditorium. 9 a.m., open.

Cancer Therapeutic Program Project Review Committee--April 9-10, NIH Bldg 31 Rm 9, open April 9, 9-9:30 a.m.

Breast Cancer Task Force—April 9-11, NIH Bldg 31 Rm 10, 8 a.m. each day, all open.

In Vivo Effects of Interleukin-2--April 10, Frederick, Md. Contact Martha Harshman, Biological Response Modifiers Program, Bldg 567 Rm 135, NCI-FCRF, Frederick 21701.

Vertebrate Animals in Health Research—April 11-12, National Academy of Sciences, Washington D.C. Scientific and public issues on lab animals in health research and related animal welfare issues. Contact Office for Protection from Research Risks,

Bldg 31 Rm 4B09, NIH, Bethesda, Md. 20205, phone 301-496-7005.

Tumors Involving the Skin--April 12, Roswell Park continuing education in oncology.

Oncology Update 1984--April 14, Sheraton Grande Hotel, Los Angeles. Contact Ann Richards, Administrative Director, Northridge Hospital Medical Center, 18300 Roscoe Blvd., Northridge, Calif. 91328, phone 213-885-8500.

Gynecological Malignancies--April 25, Wright State Univ., Dayton. Annual Nicholos J. Thompson Cancer Update. Contact Mary Fisher, Postgraduate Medicine & Continuing Education, Wright State Univ. School of Medicine, P.O. Box 927, Dayton, Ohio 45401, phone 513-429-3200 Ext. 377.

Ethics for a Categorical Institution--April 26-27, Shamrock Hilton Hotel, Houston. Contact Office of Conference Services, M.D. Anderson Hospital, 6723 Bertner Ave., Houston 77030, phone 713-792-2222.

FUTURE MEETINGS

National Tumor Registrars Assn.--May 15-18, Hotel Continental, Chicago. Tenth annual meeting. Computers and tumor registry applications, current cancer concepts, fundamental and advanced tumor registry application, central registry organization and management. Contact Suzanna Hoyler, American College of Surgeons, 55 E. Erie St., Chicago 60611, phone 312-664-4050.

Regional Breast Cancer Symposium--May 21-22, Kansas City, Kan. Contact Jan Johnston, Office of Continuing Education, Univ. of Kansas Medical Center, 39th & Rainbow Blvd., Kansas City, Kan. 66103, phone 913-588-4480.

Scripps Cancer Symposia--Oct. 18-20, Sheraton Harbor Island Hotel, San Diego. Eighth annual cancer symposium for physicians and fourth annual cancer symposium for nurses, sponsored by Scripps Memorial Hospital Cancer Center. Contact Nomi Feldman, Conference Coordinator, 3770 Tansy, San Diego 92121, phone 619-453-6222.

Cancer Chemo-Sensitivity Assay--Oct. 21-25, Hyatt Regency Hotel, Long Beach, Calif. Sponsored by Long Beach Community Hospital Llewellyn Bixby IV Hematology-Oncology Laboratory. Contact Mrs. Mickles, phone 213-498-1000 Ext. 3600.

Seventh Annual San Antonio Breast Cancer Symposium--Dec. 7-8, San Antonio. Deadline for abstracts of proffered papers on the experimental biology, etiology, diagnosis and therapy of breast cancer are due by June 1. Contact Terri Coltman RN, Cancer Therapy and Research Center, 4450 Medical Dr., San Antonio 78229, phone 512-690-0655. Medical Dr., San

Cancer Chemo-Sensitivity Assay--Oct. 21-25, Hyatt Regency Hotel, Long Beach, Calif. Sponsored by Long Beach Community Hospital Llewellyn Bixby IV Hematology-Oncology Laboratory. Contact Mrs. Mickles, phone 213-498-1000 Ext. 3600.

Seventh Annual San Antonio Breast Cancer Symposium--Dec. 7-8, San Antonio. Deadline for abstracts of proffered papers on the experimental biology, etiology, diagnosis and therapy of breast cancer are due by June 1. Contact Terri Coltman RN, Cancer Therapy and Research Center, 4450 Medical Dr., San Antonio 78229, phone 512-690-0655.

PROGRAM ANNOUNCEMENT

NCI Clinical Investigator Award

Application receipt dates: June 1, Oct. 1, Feb. 1

NCI announces the availability of Clinical Investigator Awards for the purpose of developing physician researchers in basic and applied cancer sciences. The initiation of this award is intended to encourage recently trained, highly qualified physician investigators to undertake careers in cancer research. The award is prompted by the chronic shortage of physician investigators, particularly surgical oncologists, therapeutic radiologists, diagnostic radiologists, preventive oncologists, physiatrists, nutritionists, and epidemiologists. It is expected to facilitate the awardee's transition to independent basic or applied research. The award will enable successful candidates to investigate for up to three years a defined cancer problem under the guidance of an active researcher who has the knowledge, background and research experience required to be a mentor in that field.

A. Candidate Eligibility

The award is designed to provide intensive, supervised research experience for physicians. Thus, candidates are restricted to those holding the MD or DO degree. A candidate will not qualify if he/she is in any of the following categories:

—A person having more than seven years of post-doctoral experience at the time of award.

--A person having previous independent NIH research support or its equivalent from another source.

--A person having less than two years total postdoctoral clinical experience at the time of award.

—A person holding a PhD or comparable research degree.

Candidates should have broad clinical training, should demonstrate individual competence in clinical activities, and should show research potential in the chosen area of interest. Candidates must provide evidence of a serious intent for engaging in research and/or academic careers.

Only U.S. citizens, nationals or permanent residents may be presented as candidates for this award.

B. Institution Eligibility

The sponsoring institution must have a strong, well established research program in the candidate's area of interest, and experienced faculty members in the clinical and basic departments relevant to the candidate's proposed training. The institution must include a plan for the candidate's research and academic development. Only domestic institutions are eligible.

C. Preceptor Eligibility

The candidate's primary preceptor must be a competent investigator in the area of the candidate's proposed research activity. The preceptor must be active currently as an investigator, and must be prepared to provide personally much of the candidate's research supervision. The award is intended to provide an intensive, supervised research experience for the successful candidate.

The Clinical Investigator Award is made for a

maximum nonrenewable and nontransferable period of three years. Support is based upon a full time, 12 month appointment. The award will provide salary support not to exceed $30,000 annually from NCI funds for the three year period. The actual salary must be consistent with the established salary structure of the grantee institution for persons of equivalent qualifications, experience and rank. This salary may be supplemented by the grantee institution in conformance with PHS policy. Up to a total of $10,000 annually will be provided for supplies, equipment, travel, etc., which are necessary for pursuit of the awardee's research program. Funds will be provided for the reimbursement of indirect costs at a rate not to exceed eight percent of the total allowable direct costs. When requested, the grantee institution's share of the fringe benefits may be paid as a direct cost (if not treated as an indirect cost) on that portion of the employee's salary provided by the NCI Clinical Investigator Award.

It is expected that the candidate will spend at least 75 percent of his/her time in research during the period, with the remainder being divided among other activities such as teaching, pertinent clinical training, research training, and academic studies. An appropriate sponsor must assume responsibility and provide guidance for the research development in the chosen areas.

Institutions may apply for awards on behalf of named individuals meeting the above criteria. It is not essential for the applicant institution to commit itself in the application to eventual placement of the candidate on its permanent, full time faculty, but it is expected that institutions will choose candidates who will be able to meet the criteria for making that decision. Evidence of commitment to the candidate's research development must be provided by the institution.

Candidates for this award may not concurrently apply for a Research Career Development Award, an Academic Award, or a New Investigator Research Award.

Sponsors must provide their concept of a development and research plan for the candidates, updated CVs with a complete bibliography and research support; and letters indicating willingness to provide guidance and support for the award's duration.

Candidates must provide a full description of the proposed research and career development plan for the three year period of the award. The candidate must be prepared to commit full time to the objectives of this award.

Candidates must agree to inform NCI annually for a period of 10 years subsequent to completion of the award about academic status, publications, and research grants or contracts received.

Applications will undergo initial merit review in the Grants Review Branch of NCI's Div. of Extramural Activities. Secondary review will be by the National Cancer Advisory Board. Criteria for review include:

--The candidate's potential for a career in independent research.

--The candidate's commitment to a research career.

--The eligibility of the candidate as defined above.

--The overall merit of the candidate's three year plan for research and the development of research skills.

--The quality of the candidate's clinical training and experience.

--The institution's ability to provide quality facilities, resources, and opportunities necessary to the candidate's research development.

--Presence of highly trained faculty in clinical and basic science departments relative to the area of study.

--The ability and plans of the sponsors who will provide the candidate with guidance necessary for career development in research.

Applicants should obtain copies of the program guidelines from Sami Mayyasi, PhD, Program Director, Clinical Investigator Awards, Div. of Cancer Prevention & Control, Blair Bldg Rm 717, Bethesda, Md. 20205, phone 301-427-8898. Applications, on PHS Form 398, should be sent to the NIH Div. of Research Grants as indicated on the instructions in the application kit. Questions should be directed to Mayyasi.

Vascular and Lymphatic Invasion in Breast Cancer

Application receipt dates: March 1, July 1, Nov. 1

The Breast Cancer Section of the Organ Systems Program in NCI's Div. of Cancer Prevention & Control sponsors both fundamental and clinical research grants and contracts in a continuing effort to improve ability to diagnose and to estimate prognosis in breast cancer. In the past several years, it has been shown that vascular and/or lymphatic invasion is an important correlate to survival. This announcement is intended to encourage submission of investigator initiated research grant proposals designed to facilitate the identification of intravascular and intralymphatic tumor growth in histological sections.

Pathologists have always had difficulty in distinguishing intravascular or intralymphatic breast tumor growth, even with the use of special histochemical methods, such as elastic tissue stains. These stains are of no use in differentiating tumor growth in venules, capillaries or lymphatics, since these small vessels do not have elastic tissue. Larger vessels, such as veins and small arteries which have an elastic lamina often cannot be distinguished from mammary ducts, especially in the areas of periductal elastosis. Furthermore, vascular or lymphatic channels may be difficult to recognize because of fibrosis, which often occurs in breast cancer, shrinkage artifacts from fixation, or inflammation which obscures the vascular space.

Thus in order to improve the detection and quantitation of vascular and lymphatic invasion, especially in stage 1 cancers, the Breast Cancer Section is interested in 1) developing histochemical, immunohistochemical or other histologic methods that could be used routinely and that would differ-

entiate intravascular and intralymphatic extension from the remainder of the tumor mass, or 2) determining other histologic factors that would correlate with the extent of invasion. With further clinical pathological studies, it should be possible to determine if these methods can provide a useful estimate of prognosis and even serve as a guide for therapy.

Mechanism of support will be the traditional research grant. Applications will be received by the NIH Div. of Research Grants and reviewed by a DRG study section.

Cancer Education Program

Application receipt dates: June 1, Oct. 1, Feb. 1

The Cancer Education Program R25 grants (formerly Professional Oncology Education Program or Clinical Cancer Education Program) announces the continuing receipt of grant applications. Those interested in preparing applications should request copies of the most recent program guidelines, including review criteria, from Olga Joly, DDS, ScD, Program Director, Cancer Education Program, Blair Bldg Rm 722, Bethesda, Md. 20205, phone 301-427-8855.

Cooperative Agreements for Cooperative Group Outreach Programs

The RFA for the recompetition of the Cooperative Group Outreach Program is now available. The program received concept approval from the Board of Scientific Counselors of NCI's Div. of Cancer Prevention & Control, with a total of $5 million set aside to fund from five to eight awards (The Cancer Letter, Oct. 28, 1983). The program has been supported through contracts but will be recompeted as cooperative agreements. Applications will be accepted only from the 18 cooperative groups supported by NCI's Div. of Cancer Treatment. For copies of the RFA, contact Dorothy MacFarlane, MD, DCPC, NCI, Blair Bldg Rm 7A05, Bethesda, Md. 20205, phone 301-427-8708.

RFPs AVAILABLE

Requests for proposal 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. 20205. 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-CM-47663

Title: Clinical Development of Anticancer Agents

Deadline: Approximately May 21

The Cancer Therapy Evaluation Program of NCI's Div. of Cancer Treatment is seeking organizations with the capabilities and facilities to provide phase 1 pharmacokinetic and phase 2/3 clinical evaluations of investigational new drugs which are developed through the DCT Drug Development Program and are sponsored to the Food & Drug Administration under an investigational new drug application held by DCT. Specifically, the organization shall:

1. Perform phase 1 studies which define the acute toxicities of new anticancer agents in patients with advanced cancer, and define the dose of each agent which can be safely given in subsequent phase 2 studies of drug activity; and perform pharmacokinetic studies during phase 1 studies which provide information on the pharmacologic characteristics (absorption, distribution, metabolism, and elimination) of selected antitumor agents, and explore the potential uses of pharmacokinetic analysis for optimizing scheduling and dose escalation procedures in a phase 1 trial.

2. Perform phase 2/3 studies which determine the spectrum of activity of new agents across a variety of human cancers in patients with minimal prior therapy; and establish the role of a new compound, alone or in combination, in selected human cancers compared to standard therapy.

It is planned to make multiple awards. Proposals to conduct phase 1 clinical pharmacokinetic studies may be made with or without proposals for phase 2/3 clinical studies and vice versa. Phase 1 and phase 2/3 studies are currently being performed by several institutions under existing DCT contract programs. Purpose of this RFP is to recompete these efforts. Contracts will be awarded for a period of five years.

All patients for these studies must be treated at the offeror's own institution.

Offerors who propose phase 1 and pharmacokinetic studies must demonstrate an adequate patient accrual rate within the offeror's institution to provide 50-60 evaluable patients per year to phase 1 studies. NCI anticipates that each contractor must be able to perform two to three completed phase 1 studies per year.

It is estimated that each contractor will perform pharmacokinetic studies on approximately 25 to 30 of these patients per year.

Offerors who propose phase 2/3 studies must demonstrate an adequate patient accrual rate within the offeror's institution to provide at least 200 evaluable patients per year for phase 2/3 studies.

Contracting Officer: Shelby Buford
RCB Blair Bldg Rm 228
301-427-8737

The Cancer Letter _Editor Jerry D. Boyd

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.