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FDA BLOCKS NINE MORE INDs; COOPERATIVE GROUP CHAIRMEN, DEVITA BLAST "LACK OF EXPERTISE"

Chairmen of the Clinical Cooperative Groups joined NCI Div. of Cancer Treatment Director Vincent DeVita in a bitter denunciation of the Food & Drug Administration's latest series of "outrageous" actions which are holding up nine investigational new drug applications.

Their fire was directed primarily at Robert S.K. Young, FDA's youthful and relatively inexperienced group leader for oncology who

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In Brief

UICC PUBLISHES INTERNATIONAL DIRECTORY OF CANCER CENTERS; HSAs STILL WORRY NCI

CORRECTION: The increased risk of breast cancer for women exposed to radiation from the Hiroshima and Nagasaki A-bomb blasts is estimated at 5.5% *per rad* for women age 10-19 at time of exposure, and 1% *per rad* for women over 35 at exposure. ***The Cancer Letter,*** Dec. 10, quoted NCI statistician Charles Land as reporting the increased risks, but left out the per rad qualifier. The lowest dose at which an effect was shown among A-bomb survivors was 17 rads. . . . **LUCIUS SINKS** is the new chief of the Div. of Pediatric Oncology at Georgetown Univ. He was formerly at Roswell Park Memorial Institute. . . . **ENVIRONMENTAL CARCINOGENESIS** conference will be held at the Shamrock Hotel in Houston Jan. 12-13. Rulon Rawson, of the M.D. Anderson Extramural Programs Div., is chairman. The program includes mechanisms of chemical carcinogenesis, detection in the lab and in the human population, and opportunities for prevention. . . . **INTERNATIONAL DIRECTORY** of specialized cancer research and treatment establishments has been compiled and published by the International Union Against Cancer. The directory was a project carried out by the UICC committee on international collaborative activities, headed by R. Lee Clark, Univ. of Texas, and S. Eckhardt, Budapest. Its 600 pages contain data on about 500 establishments in 50 countries. For $30, it may be obtained from UICC, 3 rue du Conseil-General, CH-1205, Geneva, Switzerland. . . . **POTENTIAL THREAT** to awarding of contracts and grants posed by Health Systems Agencies continues to worry NCI executives and their advisors. The issue now is what Cancer Program activities will be subject to HSA review, and if so, what if anything should be done to gain exemption. John Kalberer, program planning officer in the Div. of Research Resources & Centers, said that HEW had determined that cancer control, construction and centers activities are subject to HSA review. "Now we're being told (by the HEW planning office and by the Health Resources Administration which will oversee HSAs) that all of our programs may be under HSA," Kalberer said. "That's a clearly predictable development," Benno Schmidt commented.

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FDA HOLDS UP MORE INDs; NCI DEVELOPS NEW POLICY ON DISTRIBUTION OF DRUGS

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has been primarily responsible for the problems with INDs for the past year and a half.

Barth Hoogstraten, chairman of the Southwest Oncology Group, opened up on Young at the recent meeting of cooperative group chairmen. Young was not present.

Hoogstraten said that extensive phase I and phase II studies with rubidazone had been completed when, "to my utter disgust," FDA ordered the studies stopped. "Young took it upon himself to criticize the way our protocols were put together," Hoogstraten said. "It's outrageous. Our protocols were drawn up by 20 experts, and were reviewed by some of the most competent people in the field. Young is just one man, with comparatively little experience in that field. One man is directly interfering with the operation of the group, nitpicking over language."

Franco Muggia, director of DCT's Cancer Therapy Evaluation Program, commented that Young had asked the Southwest Group why it had lumped all forms of leukemia into one protocol.

"That's none of his business," Hoogstraten said. "It would be sheer nonsense to have separate protocols for each leukemia."

DeVita said that Young "doesn't have the expertise" to make such demands. "He doesn't have the right. He has overstepped his bounds. It shows a lack of appreciation for the complexity of phase I and phase II trials."

NCI is trying to work out the problems "through normal channels," DeVita said, "but I hate to have to solve the same problems two, three, four or five times. . . . This action, by one man without the expertise, is interfering with thousands of investigators."

Young was on vacation and was not available for comment.

James Holland, chairman of the Cooperative Group chairmen's committee, suggested that FDA's actions could constitute "malfeasance in office" by the FDA commissioner. "If we're back to square one with FDA, after trying to resolve the problem at the level of the FDA commissioner and NCI director, perhaps it is time to go to a higher level."

"We're not back to square one on everything," DeVita said, noting that FDA had agreed to NCI's plan for drug distribution and for monitoring and reporting clinical trials. "But we are with INDs. Last time, they held up six INDs, then disgorged them all at once when pressures were brought on them. If they do that again, it will really make it difficult for the staff to handle all nine INDs."

FDA's obstinacy is certain to add impetus to the effort to sell Congress on removing from the agency authority over clinical research of anticancer drugs. At least one amendment along that line will be offered in the renewal of the National Cancer Act.

DCT has changed somewhat its policy on distribution of investigational drugs to physicians, limiting some drugs for release only to clinical investigators who provide protocols for review and approval. Five drugs at present will still be given to "qualified registered investigators" upon submission of a written request. Drugs in phase I testing will be given only to investigators who are part of the DCT collaborative programs of new drug testing.

Muggia released a "statement of policies regarding drug distribution for non-peer reviewed clinical research." The statement follows:

"The Investigational Drug Branch oversees clinical trials involving 169 drugs for which DCT now holds the IND notice. This means that for each drug the toxicities, results and individual patient data must be monitored and reported at yearly intervals to FDA. Unexpected untoward reactions must be reported immediately.

"At the present time, the Investigational Drug Branch is receiving between 300 and 400 protocols per month from independent investigators, large institutions, regional cancer centers, and cooperative cancer study groups. This tremendous number of protocols and necessary drug monitoring, plus 400-500 telephone calls requesting information on drugs or drug supply per month, presents a serious overload to the staff whose main function is to monitor drug studies which would lead to a drug efficacy determination in support of a new drug application. In order to comply with FDA requirements and to achieve these goals, we have to follow the strict policies detailed below:

* "1) Group 1: Because of their proven efficacy, certain drugs including BCNU, MeCCNU, daunomycin, 5-azacytidine, and streptozotocin will be available to qualified registered investigators (submitting Form 1573). To obtain the drugs, a written request must be sent to this office stating the purpose of the drug request. You will be requested to register and the drug will be sent. You are required to use the drug only as suggested by the guidelines and only for the conditions in which clinical efficacy has been shown, as set down in the guidelines.

"2) Group 2: Protocols using any drugs still in investigational stages, besides the five listed above under group 1, will be available only to clinical investigators provided a proper protocol is submitted in review and approved. Single drug and single disease protocols which fit into an overall plan of development of the drug toward an NDA are most likely to be accepted. These protocols must be of research value, leading to publication, and help in development of toxicity and effectiveness data for the drug. Reporting of data back to the Investigational Drug Branch is mandatory at six month intervals. No drug will be distributed until the protocol has been reviewed by a committee at the IDB.

"3) Group 3: Drugs in phase I testing will only be available to physician investigators who are part of the DCT collaborative programs of new drug testing.

"4) The staff of the Investigational Drug Branch is not here to serve as consultants for patient care. It is suggested that physicians contact the cancer center nearest them for expert consultation.

"5) The Investigational Drug Branch will continue to be available to answer questions on the investigational drugs. However, cooperative group members and their affiliates are requested to channel all their requests through their respective New Drugs Committee Chairmen.

"We request your understanding and help in enforcing these policies. It has become detrimental to clinical research and the early approval and efficient monitoring of, perhaps, effective investigational drugs to dilute the efforts through a myriad of protocol studies, few of them yielding reliable information. Investigators seeking to participate in clinical research for the benefit of their patients are encouraged to seek an affiliation with cooperative groups or centers where investigational drugs are incorporated into their studies, or to seek their own IND with FDA in special cases.

"These policies will be instituted immediately and subject to periodic revisions as experience with given drugs warrants them."

FDA COMMITTEE TO CONSIDER POLICY ON COMBINATIONS, NDA FOR TAMOXIFEN

FDA's Oncologic Drugs Advisory Committee will meet Jan. 13-14 to consider among other things the touchy question of a policy for regulating experimental use of drug combinations in cancer chemotherapy.

FDA staff (primarily Group Leader Young) had previously suggested that the agency might require separate INDs for many new combinations, sparking considerable debate among committee members (***The Cancer Letter***, Sept. 3). That item is on the agenda again, along with a discussion on conflict of interest in oncologic drugs (FDA did not explain), effectiveness standards for new drug applications, and a report on ICI United States' NDA for tamoxifen.

Tamoxifen is an antiestrogen for breast cancer therapy. The company, which has marketed the drug in Europe since 1973, contends that it has the same response rate as other hormonal therapies but with fewer side effects. ICI United States representatives will present their case for approval of the NDA to the committee on Jan. 14.

The first hour of the two day meeting starting at 9 a.m. Jan. 13 will be an open public hearing, in which anyone may present data, information or views, orally or in writing, to the committee. The meeting will be open the rest of the day, through 4 p.m., and from 9:15 a.m. to 2:30 p.m. Jan. 14. The meeting will be closed from 9–9:15 a.m. Jan. 14 for discussion of INDs, with the closure required "to protect trade secret data," FDA said.

UCLA FINALLY GETS RECOGNITION AS COMPREHENSIVE CANCER CENTER

It is now official–the UCLA Cancer Center is the 19th Comprehensive Cancer Center.

NCI Acting Director Guy Newell, perhaps risking the wrath of Congress, which wants broader geographic distribution of comprehensive centers, and of the Office of Management & Budget, which wants to limit the number of such centers to 21, announced the recognition of UCLA last week.

"There is no question that UCLA meets these criteria" for comprehensive cancer centers, Newell said. "In fact, the excellence of its programs and the breadth of its activities required its recognition."

If OMB has its way (and its policies may change after Jan. 20), there will be only two more comprehensive cancer centers recognized by NCI despite the fact that more than 20 other institutions are attempting to build to that status. Recognizing two centers in one city probably will draw some additional heat from congressional interests who have already criticized the uneven distribution of centers.

Newell said that although Los Angeles is the first city to have two recognized comprehensive cancer centers, "the recognition of UCLA is consistent with NCI's policy of recognizing only institutions where excellent cancer research and control programs already exist and where the center's activities meet the National Cancer Advisory Board's criteria for comprehensiveness."

Among these criteria are requirements that comprehensive centers have high quality, interdisciplinary capabilities in cancer diagnosis and treatment; an environment of excellence in basic science; an organized cancer detection program; a statistical base for the evaluation of results; leadership in developing community programs; and training programs related to both fundamental and applied research.

UCLA will complement the activities of the USC/LAC Comprehensive Cancer Center in serving Southern California and Southern Nevada, which have a population of more than 13 million people, Newell said.

Richard Steckel is director of the UCLA Cancer Center. Joseph Cullen is deputy director of the center and executive for cancer control.

Denman Hammond, director of the USC/LAC Center, said that there are many areas of cancer research, patient management and professional and public education in which the two Los Angeles-based centers are collaborating already. "Now I foresee greatly expanded opportunities for sharing the responsibilities and the goals of a Comprehensive Cancer Center," Hammond said. The USC/LAC center was recognized as comprehensive in June, 1973.

NCI support for UCLA is $9.6 million active as of this date. This includes $3.1 million for 17 contracts in cancer prevention, biology, diagnosis, treatment and control; $2.6 million for 37 research grants; $2.7 million for five center research and support grants; $210,000 for a cancer control grant in health behavior; $212,000 for two clinicaleducation grants, and $723,000 for eight training grants.

In addition, UCLA received an NCI award of $5,062,500 in June 1975 to construct a portion of a 17-level building, the Jonsson Cancer Center. This facility, to be a focal point of cancer research activities at the university, will be built on the eastern side of the UCLA Medical School campus. Construction is scheduled to be completed in 1980. The upper levels will be for cancer research, while the lower floors, which will house the School of Nursing, will be financed by state and other federal funds.

Biocontainment facilities for research involving viruses and cancer-causing chemicals will be contained in the new building. Other areas will contain laboratories for research in medical and surgical oncology, tumor immunology and viral oncology. A clinical area on the eighth and ninth floors will have examination rooms and offices for outpatient clinical studies.

In 1972 the university received an NCI grant of $3,139,537 toward the construction of a seven-floor cancer facility within its Molecular Biology Institute, established in 1965. This research institute contains many of UCLA's cancer-related basic science laboratories.

NCI has provided longterm support for UCLA's programs in tumor immunology and molecular biology. Cancer virus research is prominent in the basic science work funded by NCI at UCLA. UCLA scientists also are participating in NCI-supported organ site programs for cancers of the colon, bladder and pancreas, and the NCI's Clinical Cooperative Group for gynecologic cancer. A joint inter-institutional program in radiotherapy and radiobiology to serve UCLA and several of its major affiliated teaching hospitals has been initiated.

In a joint effort, the UCLA Comprehensive Cancer Center, USC/LAC Comprehensive Cancer Center, the American Cancer Society and the Drew Postgraduate Medical School in Los Angeles are developing a community-based cancer control program called Community Cancer Control/LA for a defined population in Los Angeles of 4 million people.

At the time the National Cancer Act was passed in 1971, three institutions were recognized as having comprehensive cancer centers: the Univ. of Texas System Cancer Center–M.D. Anderson Hospital & Tumor Institute, Houston; Memorial Sloan-Kettering Cancer Center, New York City; and Roswell Park Memorial Institute, Buffalo.

The other 14 institutions or groups of institutions with recognized comprehensive cancer centers are: Sidney Farber, Boston; Yale Univ., New Haven; Fox Chase-Univ. of Pennsylvania, Philadelphia; Johns Hopkins, Baltimore; Georgetown Univ./Howard Univ., Washington, D.C.; Duke Univ., Durham; Comprehensive Cancer Center of the State of Florida, Miami; Univ. of Alabama, Birmingham; Illinois Cancer Council, Chicago; Univ. of Wisconsin, Madison; Mayo, Rochester, Minn.; Colorado Regional Cancer Center Inc., Denver; Fred Hutchinson Cancer Research Center, Seattle; and Ohio State Univ., Columbus.

L.A. COUNTY NEARS CRUCIAL DECISION ON MONEY FOR USC/LAC CENTER BUILDING

The USC/LAC center is still sweating out a long-delayed and extremely crucial decision by the Los Angeles County Board of Supervisors. The Board is scheduled to vote Jan. 11 on whether or not it will provide $38 million, the county's share of constructing a cancer hospital and research institute.

At the November election, L.A. County voters cast 57% of their ballots in favor of a bond issue to finance the county's share. It was less than the two-thirds required for that type of bond, but the Supervisors agreed to look for some other way to get the bonds sold.

"You can say that 1 million people voted to increase their taxes to pay for a new cancer hospital, or you can say it failed to get two-thirds approval," said Denman Hammond, director of the center, who prefers the first option. Hammond said that the annual cost of operation of the facility and debt service on $38 million in bonds would amount to about $3.5 million a year and would cost the owner of a $40,000 home a total of $1.56 annually.

NCI awarded USC/LAC an $11.9 million construction grant three years ago, contingent on the availability of local funds to complete the project. The university provided another $6 million. Both the NCI and university funds will be withdrawn if the county does not come up with its share.

The building will cost $41 million, with another $6.5 million in architect's fees and site preparation. Hammond is asking the county to provide $30 million toward that figure, plus another $8 million to equip the building.

The county's chief administrative officer has prepared a report in which he recommended that the county proceed with the project. The report said the money could be provided without exceeding the county's fiscal capacity or jeopardizing its excellent bond rating.

RADIOTHERAPY MORTALITY INCREASE REPORT CHALLENGED BY SEYMOUR LEVITT

Seymour Levitt, head of the Dept. of Therapeutic Radiology at the Univ. of Minnesota Medical School, objected to one of the claims by Jan Stjernsward of the Swiss Institute for Experimental Cancer Re-

search, reported at the "Report to the Profession on Breast Cancer." Levitt's letter follows:

"In ***The Cancer Letter*** of Dec. 3, 1976, you quote Dr. Stjernsward as stating that there is an increased mortality correlated with the use of radiotherapy in eight of nine randomized trials. Dr. Stjernsward has made this statement before.

"We have demonstrated and will soon publish data which demonstrates that his claims are without foundation. It is important to point out that under no circumstances has there been any statistically significant evidence that radiation therapy has a correlated increased mortality.

"This is not to imply that the modern radiotherapist advocates indiscriminant use of radiotherapy in each patient with breast cancer. Each patient, of course, must be evaluated separately."

Levitt cited two articles which are in the process of being published:

Levitt, S.H., and McHugh, R.B.: *Radiotherapy in the postoperative treatment of operable cancer of the breast. Part I.* Critique of the clinical and biometric aspects of the trials. Cancer, in press.

Levitt, S.H., McHugh, R.B., and Song, C.W.: *Radiotherapy in the postoperative treatment of operable cancer of the breast. Part II.* A re-examination of Stjernsward's application of the Mantel-Haenszel method. Evaluation of the effect of the radiation on immune response and suggestions for post-operative radiotherapy. Cancer, in press.

ACCC TO TACKLE CANCER ACT CHANGES, HSA PROBLEMS; 10 WORKSHOPS PLANNED

Efforts to develop policy on recommendations for changes in the National Cancer Act and on Health Systems Agencies will be made by members of the Assn. of Community Cancer Centers at their third annual meeting Jan. 28-30 in Arlington, Va.

Two policy committees will meet Jan. 28. Robert Frelick will chair the meeting dealing with renewal of the National Cancer Act. Specifically, the group will consider how the Act as amended can stimulate more responsive communication between communities and NCI. One consideration will be establishing a seat on the National Cancer Advisory Board for a community representative.

The policy committee considering the HSA problem will be chaired by David Johnson. The committee will hear an overview of the act which authorized HSAs and will discuss appropriate strategies for ACCC to deal with them.

Delegate members will vote at the business meeting Jan. 30 on resolutions developed by the two committees.

Plenary sessions on Jan. 29 will include:

—Psycho-social considerations in cancer care, with Abraham Brickner, Michigan Cancer Foundation, as moderator. Melvin Krant, Univ. of Massachusetts, will be keynote speaker, and panelists will be Mila Tecola, Georgetown Univ.; Wendy Schein, NCI; and Joann Vettese, Michigan Cancer Program.

—Allied health personnel and the team concept of cancer care, with John Nelson, Northeast Florida Cancer Program, as moderator. Panelists will be Charles Vogel, Florida Comprehensive Cancer Center; Viola Harrell, Univ. of Miami; and Patricia Porcher, St. Vincent's Medical Center, Jacksonville.

—Relationship between cancer centers and community programs, with John Yarbro, Missouri Cancer Program, as moderator. Panelists will be Robert Cooper, Univ. of Rochester Cancer Center; Stephen Carter, Northern California Cancer Program; and John Carpenter, Univ. of Alabama Comprehensive Cancer Center.

Ten workshop sessions will be conducted Jan. 29:

—Tumor boards and registries. David Wishart, St. Peter Hospital, Olympia, Wash., discussion leader, with Robert Connell, Blue Mountain Oncology Program, Pendleton, Ore., and Bruce Smith, Veterans Administration, Washington, D.C.

—Clinical oncology unit. Vogel will be discussion leader, assisted by Cooper.

—Administrative concepts of marketing and developing a cancer program. Robert Clark, Community Hospital of Indianapolis, will be discussion leader, assisted by Carter.

—Ambulatory care for the cancer patient. Leslie Whitney, Delaware Cancer Program, will be discussion leader.

—Current allied health professional concepts for continuing education in cancer. Elsa Brown, Medical College of Ohio, discussion leader.

—Clinical investigation in the community. James Luce, West Coast Cancer Foundation, discussion leader, assisted by Carpenter.

—Enterostomal therapy. Patricia Porcher, St. Vincent's Medical Center, Jacksonville, discussion leader.

—Clinical nurse oncologist. Harrell will be discussion leader.

—Leadership profiles—the role of the change agent in developing community cancer programs. Gale Katterhagen, Tacoma General Hospital and ACCC president, will be discussion leader, assisted by Yarbro.

—Psycho-social group therapy for patients and staff. Abraham Brickner, Michigan Cancer Foundation, will be discussion leader, assisted by Krant, Vettese and Schein.

The schedule for Jan. 30 includes election of officers and presentation of the annual ACCC award. A plenary session will follow on developing a community cancer program, with Gerald Kallas, Community Cancer Center of Milwaukee, as moderator. Panelists will include David Goldenberg, Ephraim McDowell Cancer Research and Treatment Network, Lexington, Ky.; Jake Henry, Southwest Texas Medical Hospital; and Joseph Kraut, O'Connor Hospital, San Jose.

Diane Fink, director of NCI's Div. of Cancer Control & Rehabilitation, will speak at the Jan. 29 luncheon, followed by Congressman Tim Lee Carter, ranking minority member of the House Health Subcommittee.

Lily Engstrom, CDP Associates, who conducted a study of the impact of HSAs on the cancer program, will discuss that problem in relation to community cancer programs at the closing luncheon Jan. 30.

ATLAS SHOWS CANCER MORTALITY RATES FOR NONWHITES; AVAILABLE FROM NCI

A new geographical study of cancer death rates among the nonwhite population in the United States further supports a relationship between environmental factors and cancer risks, NCI reported this week.

The *Atlas of Cancer Mortality Among U.S. Nonwhites: 1950-1969* describes cancer death rate patterns which often were similar for nonwhite and whites, NCI scientists indicated. Further study will be necessary before many of the specific reasons for these patterns can be identified, they said.

The atlas is a companion publication to the *Atlas of Cancer Mortality for U.S. Counties: 1950-1969,* which describes geographic patterns for cancer among whites. Authors of both volumes are Thomas Mason, Frank McKay, and Robert Hoover, William Blot and Joseph Fraumeni Jr., of the NCI Environmental Epidemiology Branch.

As with their previous publication, the NCI scientists believe the new atlas should be used to identify communities or regions where investigations into possible environmental factors may prove most fruitful.

The similarity in geographic patterns of cancer for whites and nonwhites was particularly striking for cancers of the breast, colon, rectum and esophagus, which showed generally high rates in the North and low rates in the South. Cancers of the larynx, bladder and ovary also had above-average rates in the North.

For lung cancer, both white and nonwhite males experienced high rates in northern areas; however, the pattern of high lung cancer rates for white males along the Gulf and Southeast Atlantic coasts was much less pronounced among nonwhites. For esophageal cancer, on the other hand, rates among white and nonwhite males were high in the urban North, but only nonwhites showed an excess in southern coastal areas.

For both whites and nonwhites, cancers of the uterine cervix had above-average rates primarily in rural areas of the South. Among nonwhites this reflects the higher cervical cancer rates among Black women, the scientists indicated.

The major U.S. nonwhite groups are Blacks, American Indians, Chinese and Japanese. To compare cancer rates among these groups and Whites, the NCI scientists also tabulated national death rates for each race. Compared to other racial groups, Blacks experienced high rates for cancers of the mouth and throat, esophagus, stomach, pancreas, larynx, lung, bladder and cervix, and multiple myeloma (a bone marrow cancer). American Indians experienced more cancers of the gallbladder, bile ducts and liver; Chinese had high rates for cancers of the nasopharynx (inner passages of the nose); and Japanese had increased stomach cancer rates.

Single copies of the atlas are available free of charge from the Office of Cancer Communications, NCI, Bethesda, Md. 20014.

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. Some listings will show the phone number of the Contract Specialist, who will respond to questions about the RFP. Listings identify the respective sections of the Research Contracts Branch which are issuing the RFPs. Their addresses are:
Biology & Diagnosis Section—Landow Bldg
Viral Oncology & Field Studies Section—Landow Bldg
Control & Rehabilitation Section—Blair Bldg
Carcinogenesis Section—Blair Bldg
Treatment Section—Blair Bldg
Office of the Director Section—Blair Bldg.
The Landow Bldg is located in downtown Bethesda, and the Blair Bldg in Silver Spring, Md., but the correct mailing address for both is the same as the NIH main campus, Bethesda, Md. 20014.
All requests for copies of the RFPs should cite the RFP number. The deadline date shown for each listing is the final day for receipt of the completed proposal unless otherwise indicated.

RFP NO1-CO-75383-04

Title: *Technical support services for the International Cancer Research Data Bank (ICRDB) program*

Deadline: *Approximately Feb. 28*

This project involves multi-faceted tasks in support of the ICRDB Program (e.g., monitoring services and products, preparing documents and presentations, evaluating, promoting, and assisting in various operational aspects of the program).

The organization selected must be prepared to engage in a wide awway of technical biomedical information activities in order to carry out the objectives of the program in promoting and facilitating the exchange of cancer-related information on a world-wide basis. The organization must exhibit capabilities for but not limited to: Technical information system monitoring and evaluation, controlling the quality of ICRDB services and products; preparing and assisting in questionnaire development and user surveys; preparing professional briefings, handling exhibits and technical meetings/seminars, collecting information on technical activities in the cancer field, promoting

and disseminating ICRDB products and services, developing methodologies for responding to requests for various types of information; and other activities as needed by the program.

Contract Specialist: Pat Eigler
Office of the Director
301-427-7984

RFP NCI-CP-FS-71010-55

Title: *Biomedical computing software services in support of the clinical and diagnostic trials program*

Deadline: *Approximately Jan. 30*

This procurement is 100% set aside for small business. The Div. of Cancer Cause & Prevention of NCI is seeking biomedical computing software services in support of statistical projects being conducted by the Clinical and Diagnostic Trials Section. This includes the analysis of large sets of medical data often involving complex statistical analysis, sophisticated data handling and analytic techniques, and extensive plotting by digital computer. The facilities of the NIH Div. of Computer Research & Technology will be used for all computer processing. The contractor's support will include a senior analyst, senior programmer and a journeyman level programmer to work in close cooperation with the staff of the section. A minimal amount of data coding and keypunching support is also required.

Contract Specialist: Fred Shaw
Cause & Prevention
301-496-1781

RFP NO1-CP-75885-62

Title: *Preparation of Carcinogenesis Abstracts, Vols. 15, 16 & 17*

Deadline: *March 8*

NCI is interested in establishing a monthly secondary journal which will be distributed on a subscription basis by the successful offeror. Each issue will contain 300 abstracts and 300 citations which will refer to the current scientific literature that describes the most significant carcinogenesis research world wide.

Contract Specialist: Dorothy Britton
Cause & Prevention
301-427-7914

RFP NCI-CM-77139

Title: *Synthesis of radiosensitizers and their preliminary biological evaluation*

Deadline: *Approximately March 15*

The objective of the project is to synthesize chemicals that will selectively radiosensitize hypoxic cells in combination with radiotherapy. This is based on the assumption that hypoxia limits the effectiveness of the radiation in the treatment of some solid tumors. The ideal chemical for this application would be expected a) to mimic completely the radiosensitizing effect of molecular oxygen at nontoxic levels, b) to be slowly eliminated from tissues and c) to diffuse rapidly into the hypoxic regions of tumors after administration.

It is expected that the synthesizing group should have the capabilities needed to conduct limited in vivo and/or in vitro studies which would guide the synthetic approach in the direction of increasingly selective compounds. Considerable understanding and awareness of the problems in the area are essential and relevant experience must be clearly documented. Chemical experience in the proposed chemical area is required.

Laboratories are to be equipped with modern equipment and facilities for synthesis and analysis of the compounds. Library resources must be adequate and readily available. Fully characterized three to five gram samples will be prepared for follow-up to the radiosensitizer study and for evaluation in experimental tumor systems.

It is anticipated that one contract of five technical man-years per year will be awarded for a period of three years. The principal investigator should be trained in medicinal chemistry at the PhD level, from accredited schools and be familiar with the synthesis of compounds having potential as radiosensitizers. He must be named and available to the project a minimum of 60% of his time. Other chemical technical supporting personnel are required to be trained chemists and they must devote at least 50% and preferably 100% of their time to the project.

It is essential that the team have appropriate technical capability to evaluate the potential radiosensitizing effect of materials which are synthesized.

Contract Specialist: Jack Palmieri
Cancer Treatment
301-427-7463

RFP NO1—CM-77133

Title: *Procurement of human hematopoietic tissue cell lines and related technical services*

Deadline: *Approximately Feb. 10*

The Developmental Therapeutics Program, Div. of Cancer Treatment, requires research support services as follows:

1. Provision of large quantities of short- and long-term cultured human leukocytes.
2. Provision of "byproducts" from the procurement and growth of blood cells, particularly conditioned medium (spent culture fluid) and blood plasma.
3. Testing conditioned medium harvested from leukocytes or from selected monolayer cultures furnished by the government for sustaining growth of myeloid leukocytes in tissue culture, particularly from the blood or bone marrow patients with myelogenous leukemia.

It is anticipated that the contract will require approximately five technical man-years of effort per

year. It is estimated that the contract will be awarded for a three year period.

Contracting Officer: Stephen R. Gane
Cancer Treatment
301-427-7463

RFP NCI-CM-77142

Title: *Synthesis of nucleosides and related derivatives for cancer chemotherapy studies*

Deadline: *Approximately Feb. 18*

Synthesis of unique nucleosides, including but not limited to C-nucleosides, nucleosides containing novel bicyclic and tricyclic bases, and analogs of biologically important transition state nucleosides. The objective of the project is to provide nucleosides of unusual types which may be of value in cancer chemotherapy.

Experience in the proposed chemical area is required. Laboratories are to be equipped with modern equipment and facilities for synthesis and analysis of compounds. Library resources must be adequate and readily available.

Fully characterized one to three gram samples will be prepared and submitted to NCI for antitumor evaluation.

It is anticipated that one contract of six technical man-years per year will be awarded for a period of three years. The principal investigator should be trained in medicinal chemistry at the PhD level, from accredited schools and experienced in the synthesis of nucleosides for biochemical uses. He must be named and available to the project a minimum of 60% of his time.

All other technical supporting personnel are required to be trained chemists. They must devote at least 50% and preferably 100% of their time to the project. It is also desirable to maintain collaborative studies in the nucleoside area between the synthesis group and an established biologist interested in cancer chemotherapy.

Contract Specialist: W.T. Harris
Cancer Treatment
301-427-7463

RFP NCI-CB-74139-39

Title: *Growth of normal and tumor virus cells*

Deadline: *Feb. 9*

Grow normal and tumor virus cells. Organizations submitting proposals should be within 30 miles of the main NIH campus.

Contracting Officer: T. Weaver
Biology & Diagnosis
301-496-5565

CONTRACT AWARDS

Title: Mass screening for breast cancer by electronic infrared pattern recognition
Contractor: Univ. of Oklahoma Health Sciences Center, $416,480.

Title: Studies in a predictive transplantable animal mammary tumor model
Contractor: Mason Research Institute, $169,500.

Title: Investigation of estrogen binding and estrophile proteins in human breast cancer
Contractor: Worcester Foundation for Experimental Biology, $135,000.

Title: Regulation of gene expression in mouse mammary cancer
Contractor: Baylor College of Medicine, $96,036.

Title: Immunologic assessment of high risk cancer families
Contractor: Litton Bionetics, $121,948.

Title: Immunological studies on the relationship of embryonic antigen to virus-induced tumor antigens
Contractor: Duke Univ. Medical Center, $41,745.

Title: Support services for investigational new drug reports
Contractor: Information Planning Associates, $90,195.

Title: Establish and maintain a blood serum bank
Contractor: Mayo Foundation, $100,458.

Title: Cervical cancer screening program
Contractor: State of Nevada, Div. of Health, $130,809.

Title: Technical support services for the Office of Cancer Communications, OD
Contractor: Small Business Administration, $99,515.

Title: Incorporation of seven alteration/renovation projects as necessary for the performance of the cancer research program being conducted at the Frederick Cancer Research Center
Contractor: Litton Bionetics, $342,037.

Title: Support services for the Div. of Cancer Research Resources & Centers
Contractor: Capital Systems Group Inc., Rockville, Md., $141,942.

Title: Expansion of Georgia cervical cancer screening program
Contractor: Georgia Dept. of Human Resources, $141,209.

Title: Clinical oncology program
Contractor: Butterworth Hospital, Grand Rapids, Mich. $150,000.

The Cancer Letter—*Editor* JERRY D. BOYD

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