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## NCI TO SEEK CONCEPT APPROVAL FOR CONTINUING GROUP OUTREACH PROGRAM; FIVE CCOP PROPOSALS REREVIEWED

The staff of NCI's Div. of Resources, Centers & Community Activities will ask the division's Board of Scientific Counselors for concept approval to continue the Cooperative Group Cancer Control (outreach) Program at the Board's meeting in October.

The outreach program, which supports the clinical cooperative groups affiliation with community hospitals, was initiated in 1976 and has been very successful in bringing community patients into clinical trials. Two years ago, when the Community Clinical Oncology Program was in its

*(Continued to page 2)*

*In Brief*

### CANCER RESEARCH INSTITUTE TO SUPPORT AIDS GRANTS, WITH MAXIMUM OF $70,000 EACH; DEADLINE IS OCT. 1

**CANCER RESEARCH** Institute, a nonprofit organization in New York which commits its resources to immunological approaches to cancer, will support a program for research on acquired immunodeficiency syndrome. James Siegel, executive director, said CRI has allocated $350,000 to start the program, to be awarded in maximum grants of $70,000. Funding will be sought from other sources to expand the program. Deadline for grant applications is Oct. 1. Proposals will be selected by the institute's Scientific Advisory Council. Lloyd Old, associate director of Sloan-Kettering Institute, is medical director of the advisory council. CRI's address is 133 E. 58th St., New York 10022, phone 212-688-7515. . . . **CIGARETTE SMOKING** is not related either to tumor recurrence or length of survival in bladder cancer, Roswell Park Memorial Institute investigators have reported. However, Arthur Michalek and colleagues Michael Cummings and Edson Pontes found in a study supported by NCI that in a group of 302 patients with bladder cancer, current cigarette smokers averaged nine years younger at diagnosis than persons who had never smoked, and five years younger than ex-smokers. Ex-smokers were significantly younger at diagnosis than never-smokers. "These results suggest that cigarette smoking may promote tumor growth in patients with bladder cancer," the investigators concluded. The study has been submitted for publication to *Preventive Medicine*. . . . **AACR/ASCO MEETING** in 1984 will be in Toronto, Houston in 1985, Los Angeles in 1986 and Atlanta in 1987. Starting with Houston, future meetings will be held only in cities with major convention centers, due to the size of the two organizations. Other cities mentioned as future possibilities include Seattle, New Orleans, San Francisco, Boston, Baltimore, Cincinnati, Minneapolis, Chicago, and Honolulu. The Oncology Nursing Society will continue trying to schedule its annual congress in the same cities, except when ASCO/AACR go to a state that did not ratify the Equal Rights Amendment.

## DRCCA STAFF CONCLUDES OUTREACH, CCOP CAN COEXIST; CONTROVERSY OVER MONEY

*(Continued from page 1)*

developmental stages, NCI considered phasing out the cooperative group outreach program on the theory that the CCOP would supplant it. The original outreach contracts were expiring then, and the DRCCA Board agreed to continue the program for another two years. Board members agreed that by then it might be easier to determine if the program should be continued indefinitely, coexisting with CCOP or, if the latter failed, supplanting it.

Now that the first round of CCOP awards has been made, DRCCA staff has come to the conclusion that there is a place for both programs.

About 30 cooperative group satellite hospitals were successful in competing for CCOP awards, either on their own or as members of consortia. They were receiving approximately $200,000 a year through the cooperative groups and will have to give that up when they start receiving their CCOP support. The disposition of that $200,000 has been a point in controversy between NCI and the groups.

NCI executives had thought that the money going to outreach satellites turned CCOPs would be returned to DRCCA to help make up the $10 million which had been committed to CCOP. The cooperative groups argued that the money should be returned to them, to be used to fund new satellites. DRCCA staff is leaning to the groups' position, particularly if the groups would agree to use that money to bring some of the approved but unfunded CCOP applicants into the outreach program. Whether the NCI Executive Committee can be sold on that remains to be seen.

NCI senior staff members, incidentally, are meeting this week in a "retreat" in which final disposition of FY 1983 funds and early funding plans for FY 1984 are being made. The CCOP-outreach issues may be thrashed out then.

Another issue to be resolved is how many additional CCOP awards will be made. The 59 already announced consumed, with indirect costs and the support required for research bases, $8 million. That leaves $2 million from the total NCI Director Vincent DeVita committed to the program.

DRCCA has said that the left over money would be used to fund additional CCOPs to achieve better geographical distribution. That means some of the applicants who did not achieve priority scores under the 250 payline, and who are located in the Southwest and South, may be funded after all. DRCCA would especially like to have CCOPs in Oklahoma, Texas, New Mexico and Mississippi.

DRCCA also intends to make a few more awards to correct some obvious deficiencies in the review of CCOP applications. Five are being rereviewed because of "serious misunderstandings" on the part of reviewers, as pointed out in rebuttal letters. Some of the reviewers clearly misinterpreted data in the proposals, according to the rebuttals.

If another 10-15 CCOP awards are made and if the 30 departing outreach satellites are replaced, proponents of both programs probably will be satisfied, for the moment.

**"Final Agenda: How to Survive CCOP."**

That's the title of a seminar produced by Elm Services Inc. July 31-Aug. 6 for the successful CCOP applicants. The 59 which have received awards so far were sent invitations, although all which were approved may attend, according to Lee Mortenson, Elm president.

The program includes sessions entitled:

"How to succeed as a CCOP administrator," with a panel consisting of Mortenson, Thomas Tucker, administrative director of the Kalamazoo CHOP and CCOP; and Ann Welch, administrative director of the Cincinnati Tri-State CHOP and CCOP.

"Lessons from the COP, CHOP and cancer control satellite programs, with Paul Anderson, director of the Southern Colorado Cancer Program; Mortenson, Tucker, and Welch.

"The national CCOP evaluation," with Mortenson and Anderson.

"Clinical research and clinical trials," presented by Albert LoBuglio, director of the Univ. of Alabama Comprehensive Cancer Center.

"Data management, the local administrator's perspective and the research base perspective," by Jennifer Guy, administrative director of the Columbus CCOP. Guy and LoBuglio will be on a workshop panel on current data collection plans.

"How to effectively manage your federal cooperative agreement," by William Goldwater, collaborative programs policy officer at NIH.

"New institutional review board requirements for CCOP," by Charles McCarthy, director of the NIH Office for Protection from Research Risks.

"New federal audit requirements," by Raymond Weiss, chairman of the CALGB data audit committee.

"NCI's clinical research program and the responsibilities of investigators in drug usage and toxicity reporting," by Robert Wittes, director of the Cancer Therapy Evaluation Program in NCI's Div. of Cancer Treatment.

"Your role as a federal contractor," by Eugene Miller, controller and administrative director of the Franklin Institute. (CCOP awards are cooperative agreements, which are administered as grants but with some of the restrictions which apply to contracts.)

"Computerizing your cancer program," by Mortenson and Donna Wicker, data base manager of

NCI's International Cancer Research Data Bank.

"Major problems and opportunities confronting principal investigators of community research programs," by Rodger Winn, chief of oncology at St. Barnabas Medical Center, and Anderson.

"How to be a full participant in clinical trials and clinical research," by Charles Coltman, chairman of the Southwest Oncology Group, and Larry Wickerham, associate chairman of the National Surgical Adjuvant Breast & Bowel Project.

"Your legal and ethical obligations as a principal investigator," by Mortenson.

"The National CCOP Network, helping each other to survive," by William Dugan, president of the Assn. of Community Cancer Centers.

"How the bureaucracy works, a special presentation," by John Yarbro, president elect of ACCC.

Mortenson will present a discussion on the ramifications of the impending Diagnosis Related Group reimbursement system, and will arrange appointments for seminar attendees with congressional staff to discuss DRG exceptions. The entire day of Aug. 4 has been set aside for the briefing and congressional visits.

For registration and other information, contact Elm services, 11600 Nebel St. Suite 201, Rockville, Md. 20852, phone 301-984-1242.

## NCI SUGGESTS ALTERNATIVE TO 5,000 GRANTS; AACR CONSIDERS ISSUES GROUP

The issue of whether NIH should continue to support the fixed number of 5,000 new and competing renewal grants no matter what the budget level is developing into a major controversy which, in the main, pits NCI against the other institutes.

"We at NCI are not in favor of that, largely because it is now thought that regardless of any level of budget, we can continue to support a fixed number at a smaller and smaller dollar level," NCI Director Vincent DeVita said in addressing the American Assn. for Cancer Research at its recent annual meeting.

Those who think that way—the Office of Management & Budget and some NIH executives, among others—are willing to sacrifice programs other than those supported by R01 and P01 grants, and are willing to take continued reductions in R01 and P01 grants, in order to continue funding a fixed number. Although DeVita did not say so, one reason why opposition has developed at NCI to that philosophy is the fear that it tends to reduce some of the pressures on the White House and Congress for increasing the NIH budget.

NCI has offered a proposal which DeVita said "is not the most popular one at the moment" at NIH. "We have proposed a system for giving priority to the research project pool by giving an algorithm of sorts to a fixed cost of living increase regardless of the NCI budget, increasing it proportionately as we get increases. It would never fall below the stability level of a fixed cost of living increase. This is under debate at NIH."

DeVita suggested that AACR members join in the debate.

NIH's practice of allocating smaller percentage budget increases to NCI than to the other institutes, or when cuts are made, allocating larger percentage increases to NCI, continues to rankle DeVita.

"If in fact we are supporting the best science; if in fact, as Dr. (Gerald) Mueller (AACR president) implied, all of biology is tied into cancer research; if in fact we are well managed, then we don't deserve to be penalized because we're large. It seems to me the experiment started in 1971 has worked and perhaps that should be the overriding consideration."

The problem at NIH is the "general attitude that NCI should pay back increases received between 1971 and 1976," DeVita said. "Our increases after that either covered only inflation, or we had no increases at all. I will modestly say that we are the best managed institute on campus, yet we are 12th of 12 in NIH priority, because of our size, not science. Our science is second to none. As a group, we need to address this issue more and more."

The number one priority, DeVita said, is to support basic research. "I do believe that at any given level of budget, we have to support some application of research. If we don't, the public gets cranky, Congress gets cranky. If Congress gets cranky, we get less money for research."

DeVita said there is some confusion among scientists about the NCI budget growth. "Between 1971 and 1983, the R01 pool as a percentage of NCI's budget increased from 24 to 40 percent." The P01 pool stayed relatively the same, going from 16.9 to 16.5 percent. The intramural program increased only from 10 to 11.9 percent. "The biggest share of our resources support the primary instrument for supporting basic research." Clinical trials account for 10 percent of the budget, the same level as in 1971. Cancer centers receive 8 percent, a figure not comparable since the centers program did not exist in its present form in 1971, DeVita said.

As for the percentage spent on resources, "You can't do clinical trials without drugs," DeVita said. "We've never spent more than $40 million a year on drug development. That now is $28 million. Thirty-six percent of our budget went for resource and development contracts in 1974, the peak year (for that category). That is down to 16 percent in 1983."

DeVita's remarks were made at the AACR business meeting. Earlier, the members had agreed, at least in principle, to recommendations by a committee chaired by John Laszlo to form a permanent Scientific and Public Affairs Committee.

"Members are interested in becoming more active in matters that pertain to public education and those governmental affairs that impinge on cancer research," Laszlo said. "This is a change from earlier positions of the association."

The committee's charge would include informing itself on "matters that affect cancer research with respect to funding, public policy, and legislative initiatives; to develop strategies that represent the broad goals of AACR; to establish functional liaisons with selected associations which have paid lobbyists and be prepared to assist these associations with expenses incurred as the result of our liaison."

A further recommendation, Laszlo said, was to "select those items which AACR would pursue separately and those to which it would lend its prestige to other health related agencies pursuing similar goals."

The association should "avoid embarrassing conflicts of interest with other organizations (which may attempt to) use our prestige to further goals not approved by AACR," Laszlo said.

"The president (of AACR) should be prepared to make public policy statements at the annual meeting to media which might include the types of concerns described above." That recommendation included a suggestion that a press conference be held at the annual meeting, to include the president, members of the board and others, "which summarize in a balanced way some of the major areas of research."

Mueller said that the recommendations constituted a proposal "in a developmental stage," and asked for the members' approval to take them to the Board of Directors "to formulate a mode of action, which will be brought back to the membership at a later time." The members agreed.

## AACI TO BECOME MORE AGGRESSIVE IN DEVELOPING NATIONAL ISSUES, LEADERS

Members of the Assn. of American Cancer Institutes approved recommendations of an ad hoc long range planning committee committing the organization to a more active role in developing national programs related to cancer research and control, including recruitment of new lay and scientific leaders.

AACI President John Durant presented the report of the planning committee at the association's recent annual meeting at AMC Cancer Research Center in Denver. Other members of the committee were Palmer Saunders, John Ultmann, Timothy Talbot, and Sydney Salmon.

Durant said the committee agreed that AACI has achieved "considerable legislative impact at the congressional level, largely through the interaction of John Grupenhoff with the board and membership." Grupenhoff, of the firm Endicott & Grupenhoff, represents AACI in Washington.

"Lines of communication between AACI and NCI have been opened," Durant said. "A tangible result has been the satisfactory recent resolution of the issue of flexibility in staff investigators' salaries (paid from center core grants)."

However, Durant said, the committee agreed that recent AACI meetings "tend to be repetitious, boring, and poorly attended, and attended by persons of secondary importance at cancer centers.

"There is a need to provide university based centers a greater voice and make the organization more responsive to their needs," Durant continued. "There is a great need to develop an active rather than a reactive program which meets the needs of the cancer community in general. If such needs are met, it was agreed, the needs of AACI would automatically be addressed. Such an approach would necessitate involving individuals not necessarily now active in AACI."

Suggestions for implementing a strategy to meet those issues included:

—Identification and recruitment by AACI of lay and scientific leaders "who would take a national role equivalent to that played by such people as Lee Clark, Mary Lasker, Sidney Farber, and Benno Schmidt."

—AACI should develop its own "terse, carefully worked position papers on issues of substantial importance. A suggested plan would be to address a subject of concern with a symposium from which a position paper would be prepared and published, much as the National Academy of Sciences would. It would then be used to promote the ideas expressed in the highest councils of the United States as regards decision making and priority setting."

The committee suggested sample topics for those position papers, including:

- National needs for renewal of scientific facilities and equipment required for cancer research.
- A program for meeting changing needs of clinical and research training in disciplines related to cancer.
- An assessment of the scientific opportunities available over the next decade with some attempt at broad prioritization of them.
- An AACI definition and plan for cancer control.
- A plan to assess cancer care in the U.S. by describing its characteristics and identifying which of these are associated with better survival under what circumstances. Recommendations regarding optimal care could then be made. "This would be constructed along the lines of the NCI supported patterns of care study in radiation therapy," Durant said.

"These projects are only five among many possible," Durant continued. "It was recommended that we settle on no more than two at a time and work

on them until complete. In general, it was believed that the activities of the organization should center around developing the means for our members to:

- "Learn about and influence science planning in depth. This is defined as trying to learn what will be needed in the way of resources and then how to secure such resources. Resources include facilities, equipment, trained personnel, and money.
- "Learn about and improve management problems. What are the contemporary issues? How do we solve them? Some of these include how centers work in universities, how we cope with patient care reimbursement issues, how do we raise funds, how do we relate to industry.

"Many other issues exist. Our organization should help its membership become leaders in solving these problems," Durant concluded.

**The first initiative AACI will undertake in its new aggressive stance will be to initiate a collaborative effort by centers on new diagnostic techniques.**

Richard Steckel offered the suggestion that a network be established to look at the fast developing new diagnostic methods. "I'm not particularly wedded to diagnostic studies, but it does seem to be a target of opportunity," Steckel said. "There are no cooperative clinical studies in diagnosis." He suggested nuclear magnetic resonance, with about 50 installations due to be established in the U.S. during the next year, as a prime candidate. "Or it could be nonimaging, such as monoclonal antibodies with tracers."

Steckel suggested that a workshop or a series of workshops be organized, to include center directors and scientists involved in those areas. "One might be on NMR, one perhaps on a new modality."

Jerome Yates, who heads the Centers & Community Oncology Program in NCI's Div. of Resources, Centers & Community Activities, agreed to work with AACI representatives in developing a workshop proposal which he will present to the division's Board of Scientific Counselors for concept approval in October.

"The possibilities are tremendous," Yates said. "I would like to move relatively rapidly."

NMR is "new, virgin territory," Steckel said. "There is not much research to go on yet, but there will be. Most centers are planning to develop NMR facilities. But NMR is only the tip of the iceberg."

"We had a cooperative group doing CAT scanning for brain tumors," Nathaniel Berlin said. "I can tell you the mistakes I made. The science will vary rapidly. We didn't dream anyone would put in a contrast agent."

"I don't want to develop another CCPDS," Yates said, referring to the Cancer Center Patient Data System established for centers which an NCI review determined was not being used enough, resulting in the cutoff of funds. "We want to involve centers completely in planning the program. . . . I would prefer to start with a focused program, measurable and discrete."

Sydney Salmon commented that "we should concentrate now on NMR and ultrasound." Michael Brennan pointed out that perhaps some centers may not want to consider NMR only for diagnosis, but that it also has potential for research.

## NEW PUBLICATIONS

"Manual for Staging of Cancer," edited by Oliver Beahrs and Max Myers. Second edition, by the American Joint committee on Cancer. Includes all currently available information on the classification and staging of cancer at various anatomic sites. J.B. Lippincott Co., Harper & Row Inc., East Washington Square, P.O. Box 1430, Philadelphia 19105, $17.50 paperback.

"The Biology of Nasopharyngeal Carcinoma," edited by M.J. Simons and K. Shanmugaratnam. UICC workshop proceedings. Hans Huber, 76, Langgassstrasse, 3000 Bern 9, Switzerland, $18 (36 Swiss francs).

"Tumor Prostheses for Bone and Joint Reconstruction," edited by Edmund Yee-Su Chao, and John Ivins. Workshop proceedings on design and application. Thieme-Stratton Inc., 381 Park Ave. South, New York 10016, $62.

"Oncogenes and Retroviruses: Evaluation of Basic Findings and Clinical Potential," edited by Timothy O'Connor and Frank Rauscher. Proceedings of a workshop held at Roswell Park Memorial Institute in September 1982. Alan R. Liss Inc., 150 Fifth Ave., New York 10011, $34.

"Computed Tomography in Radiation Therapy," edited by Clifton Ling, Charles Rogers, and Robert Morton, $45.

"Advances in Polyamine Research (Vol. 4), edited by Uriel Bachrach, Alvin Kaye, and Ralph Chayen, $49.

"Pathobiology Annual, 1982," edited by Harry Ioachim, $60.

"Role of Medroxyoprogesterone in Endocrine Related Tumors, Vol. 2," edited by L. Campio, Della Robustelli, G. Cuna, and R.W. Taylor, $24.

## NCI CONTRACT AWARDS

TITLE: Development of parenteral dosage forms for clinical investigation
CONTRACTORS: Univ. of Arizona, $356,758; Univ. of Kansas (Lawrence), $563,866; Univ. of Kentucky, $335,122.

TITLE: New fermentation antineoplastic drug acquisition, evaluation development and screening
CONTRACTOR: Warner Lambert Co., Ann Arbor, Mich., $4,112,840.

## 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, 8300 Colesville Rd., Silver Spring, Md. 20910. RFP announcements from other agencies will include the complete mailing address at the end of each.

**RFP NCI-CM-37544-07**

TITLE: Development and manufacture of solid oral dosage forms

DEADLINE: Approximately Oct. 17

The Pharmaceutical Resources Branch of the Developmental Therapeutics Program, Div. of Cancer Institute, NCI, is seeking a contractor to provide staff and a facility for the manufacture and production of solid oral dosage forms for investigational use in man. The products prepared will be used for NCI sponsored clinical trials throughout the world.

The contractor selected must prepare all products in accord with FDA's Current Good Manufacturing Practices regulations and NCI's product specifications. The contractor selected shall be experienced in the preparation of solid oral dosage forms for human use.

As a minimum requirement, the contractor's facility must be registered and approved by the FDA for the manufacture of solid oral dosage forms. The contractor must be currently engaged in the manufacture and production of oral tablets and hard gelatin capsules. The contractor will be required to have operational equipment and capabilities for all production and quality control tasks at the time of contract award.

The government will provide the new drug substance and the contractor shall provide all other materials used in the manufacture, testing, packaging and labeling of the formulated solid oral dosage products. The annual workload estimates for development and production are, respectively, 1,040 hours of technical staff time and six production assignments. Most development projects will involve the preparation of solid oral dosage forms requiring only familiarization studies with an existing formulation. Small batch development (preproduction) runs will be required before each new production.

Contractor will be responsible for quality control testing of all formulation components including the active ingredient, excipients. container closure system as well as the finished product. Contractor will not be responsible for the shelf life surveillance of the dosage form since a separate contract resource will perform this task. All products will be labeled and packaged according to specifications supplied by the government. Label preparation may be subcontracted, but labeling must be performed at the contract site.

It is anticipated that the government will award a single contract on an incrementally funded basis. Each increment will be for a period of one year and the total contract will be awarded for a five year period.

**RFP NCI-CM-37595-07**

TITLE: Development and production of parenteral dosage forms

DEADLINE: Approximately Sept. 19

The Pharmaceutical Resources Branch of the Developmental Therapeutics Program, DCT, NCI, is seeking a contractor to provide staff and a facility for the manufacture and production of solid oral dosage forms for investigational use in man. The products prepared will be used for NCI sponsored clinical trials throughout the world.

Contractor selected must prepare all products in accord with FDA's Current Good Manufacturing Practices regulations and NCI's product specifications.

Contractor selected shall be experienced in the preparation of sterile freezedried dosage forms and sterile liquid filled products. The capability to develop and manufacture other pharmaceutical dosage forms, i.e., sterile suspensions, dry fills, large volume parenterals, etc., is desirable, but not essential.

As a minimum requirement, contractor's facility must be registered and approved by FDA for manufacture of sterile parenteral pharmaceuticals. The Contractor must be currently engaged in sterile parenteral manufacturing involving freeze drying, liquid filling and ampuling. The contractor will be required to have operational equipment and capabilities for all production and quality control tasks at the time of contract award.

The government will provide the new drug substance and contractor shall provide all other materials used in the manufacture, testing, packaging and labeling of the formulated solid oral dosage products. Annual workload estimates for development and production are, respectively, 1,040 hours of technical staff time and 10 production assignments. Most development products will involve preparation of sterile freezedried products requiring only familiarization studies with an existing formulation. Small batch development (preproduction) runs will be required before each new production. Approximately eight freeze dried productions and two liquid filled productions wil be required annually. Contractor will be responsible for the quality control testing of all formulation components including the active ingredient, excipients, container closure system as well as the finished product.

Contractor will not be responsible for the shelf life surveillance of the dosage forms since a separate contract resource will perform this task. All products will be labeled and packaged according to specifications supplied by the government. Label preparation may be subcontracted, but labeling must be performed at the contract site.

It is anticipated that the government will award a single contract on an incrementally funded basis. Each increment will be for a period of one year and the total contract will be awarded for a five year period.

CONTRACT SPECIALIST
FOR ABOVE 2 RFPs: Helen Kelly
RCB, Blair Bldg. Rm. 228
301-427-8737

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