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Wittes, Group Chairmen Agree On Payment Per Case, Other Methods To Increase Patient Accrual

An aggressive program aimed at significantly increasing patient accrual to NCI supported clinical trials was outlined by Robert Wittes, director of the Div. of Cancer Treatment's Cancer Therapy Evaluation Program, during a meeting last week of chairmen and other representatives of
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In Brief

Saunders Retires As Dean of UT Graduate School At Galveston; Started Centers Program At NCI

PALMER SAUNDERS will retire Sept. 1 as dean of the Univ. of Texas Graduate School of Biomedical Sciences at Galveston. He will remain as professor in the Dept. of Pharmacology and Toxicology where he will pursue his research with computerized imaging techniques. Saunders went to Texas in 1974 after retiring as director of what was then NCI's Div. of Research Resources & Centers, which had program responsibility for all NCI grants. Saunders was encouraged by the late Kenneth Endicott, who was director of NCI in the 1960s, to start the Cancer Centers Program. "That program, buttressed by the National Cancer Act of 1971, is the bedrock of our National Cancer Program," Saunders said **RONALD PAIK**, health communications director for the Cancer Communication System at the Univ. of Hawaii Cancer Research Center, has been appointed to the National Heart, Lung & Blood Institute's ad hoc Committee on Cardiovascular/Pulmonary Disease Risk Factors in Minority Populations. . . "MANAGING YOUR Cancer Program: You and Your Patients," a workshop for physicians and health care administrators who want to develop or improve their cancer programs, is scheduled for Oct. 8-9 at Hilton Head, SC. The workshop is sponsored by Cancer CarePoint Inc. of Atlanta. **Gregory Lewis**, former member of the NCI Cancer Control Program staff and former executive with CDP Associates, is executive vice president of Cancer CarePoint. Contact Cancer CarePoint, 2394 Mount Vernon Rd., Suite 200, Atlanta 30338, phone 404/399-1812. . . . **NEW HOME** for NCI offices located in the Blair Building, in Silver Spring, and the Landow Building, in downtown Bethesda, is getting closer as the government concludes negotiations for an office building in Rockville. The annual rent is at the level that requires congressional approval, which is expected soon after Congress returns from the August recess.

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Reimbursement To Affiliates Seen As Key To Increasing Patient Accrual

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the clinical cooperative groups. After a day long discussion of the problem and potential remedies, Wittes presented his version of a consensus of those present, which included the following recommendations:

<>Per case reimbursement for affiliates

Wittes did not commit NCI to any specific amount, but the figure of \$900 a case was mentioned. During the discussion, one group representative suggested that \$500 to \$600 might be sufficient, and others said that all that might be needed was enough to pay for data managers. Wittes said the money would go from NCI to the groups, to be distributed to affiliates, with maximum flexibility permitted to group chairmen.

<>Bring the good performing Community Clinical Oncology Programs which have been left unfunded back into the system

A significant number of "stellar performers" did not survive the recent competition, according to one group chairman. Wittes agreed that unfunded CCOPs could provide a good resource of physician investigators and patients. They will be invited to join the groups as affiliate members, to align themselves with other affiliates such as the Cooperative Group Outreach Program (CGOP) members, or to reorganize as CGOPs, possibly with some temporary funding at first and then full status as a CGOP later.

Wittes said that much of the additional funding needed to implement these various strategies could be accomplished through administrative actions and would not require going through the RFA process.

Any CCOPs revived with DCT money will not be required to initiate the cancer control research portion of the program which was included in the recompetition.

<>Stepped up publicity of major new trials, directed at community oncologists and general practitioners, at patients and at the general population, with the assistance of NCI's Office of Cancer Communications and the public information offices of participating cancer centers

This was envisioned by some as an educational effort as much as a publicity campaign, selling the public and patients on the concept that clinical trials provide the best cancer treatment, describing the

protocols and what is involved, convincing physicians that they should participate.

<>Other steps to make it easier for physicians and patients to participate in clinical trials and to remove "disincentives" to participation

These include improving and speeding up CTEP review of proposed protocols; expediting the writing of protocols, with better CTEP coordination of strategy development and planning, faster protocol generation within groups, and better group to group interaction, including use of electronic transfer; stepping up of discussions with the Health Care Finance Administration, Blue Cross/Blue Shield and other third party payers on reimbursement for patient care costs; maintaining a close monitoring of the Food & Drug Administration's "treatment INDs," the new procedure which permits sale of experimental drugs as last resort therapy and which some oncologists see as a threat to cancer clinical trials; discuss with HMOs and for profit hospital chains participation in clinical trials.

Assumptions On Increasing Accrual

"On the whole, the effort to hone down the cooperative group effort and concentrate on high priority areas has borne fruit," Wittes said in opening the discussion. He was referring to the discussions initiated with the groups two years ago, when he first proposed a series of drastic changes in the cooperative group program, then settled for an agreement to work for more intergroup collaboration, reducing the overall number of trials and zeroing in on seeking answers to major questions. "There has been a great increase in the quality and quantity of intergroup contact," he said. But the problem of slow patient accrual has remained. Wittes listed three assumptions presumably involved in consideration of efforts to increase accrual:

1. Maximizing accrual rates to important clinical trials is a good thing, provided that the data so obtained are of high quality.
2. For physicians already participating in the system, there is a substantial gap between the number of patients eligible for trials and the number actually entered.
3. There is a large reservoir of clinical trials participants among physicians who do not now participate.

Wittes said the gap between patients eligible and those participating was from 10

percent to 70 percent, according to information seen in the evaluation of CCOP. "There is room for improvement."

Paul Carbone, chairman of the Eastern Cooperative Oncology Group, said ECOG data show that only 15 percent of those eligible at member institutions are placed on protocols, with 10 percent at CCOP affiliates. Fifty percent of the time, physicians simply prefer not to enter their patients, Carbone said. "There is a large number of patients available. The reservoir is large."

"The question before the house is, "Why doesn't every physician want to participate in clinical trials?" Wittes said. He listed the following as obstacles to participation:

1. General aversion to clinical trials. "They don't want to be bothered." Also, many physicians are "impressed with the need to individualize therapy. They don't want to have their hands tied."

2. The time and trouble involved in obtaining informed consent, data management, complexity of protocols, and the cost to patients.

3. Randomization vs. the expectations of private patients.

4. Quality of the scientific question.

5. Alienation from the group system, possibly because of a perception that groups are "political," and because of a lack of community input.

Physicians can be placed in three groups, Wittes said--those who are "hard core" about not taking part in clinical trials, those who are wavering, "on the fence, and might be brought over, and those who want to but don't for various reasons." Those reasons might include problems with data management, cost of protocol related tests, "the discrepancy between protocol requirements and expectations of patients."

Wittes added, "Left out of this is lack of funding from us." The part that might play "is not clear," he said.

Two major elements in a program to increase accrual to high priority trials are, first, to identify those trials which are of high priority, and then, expect participation in those trials by all members of the NCI supported network, Wittes said. Those include the groups, CCOPs, CGOPs and centers, "provided they have no other viable ongoing trial of comparable importance."

High priority trials are those for diseases which are common or exploitable, in

which the question is of high medical importance, and in which treatment is likely to have an impact on mortality, Wittes said.

The high priority selection process should start first with CTEP making the identification, the cooperative group chairmen approving or rejecting it, with final ratification by the DCT Board of Scientific Counselors. "This puts the whole weight of the division behind it," Wittes said.

Enhancing, Enlarging

Ways in which the efficiency of present participants (in entering more patients than they do now) could be enhanced include, Wittes said:

1. Minimize protocol complexity, in their design, number of tests required and in data collection.

2. Monitor the ration of entered/eligible and set minimum performance standards.

3. Increase dollar support.

4. Use "technological fixes," including such things as video taped informed consents and computerized protocol prompts.

Ways in which the network include adding more universities as group members and centers, increasing the number of community participants, more involvement of large HMOs such as Kaiser Permanente and also the Veterans Administration hospitals, and bringing in the non-HMO for profit providers, such as the Hospital Corp. of America with its 400 hospitals.

Mechanisms of affiliation could be through the groups, or directly with CTEP, Wittes suggested. "Centers and community physicians could affiliate with groups for high priority trials, even if they are not ordinarily part of the group system. Supporting funds, as required, would flow from NCI to groups to participants. These are much more likely to produce quality data for relatively simple studies. It could be facilitated by adoption of common intergroup forms and common toxicity criteria."

In the discussions two years ago, Wittes had suggested a system in what he now calls "promiscuous affiliation" of physicians with groups, with the physicians brought in for selected trials because of their interests and expertise. He mentioned that again but dropped it immediately. "I can hear the yells and screams about quality of data."

Affiliation directly with CTEP "might be used in two rather opposite circumstances--specialized trials of new approaches early in development, such as the LAK-IL-2 trial by

cancer centers; and by large, relatively simple studies."

The latter would be those whose aim is to examine effect of a treatment on a population basis, with broadest community participation possible. Characteristics of these studies would include nonrestrictive eligibility criteria, simple designs, minimal data reporting and mortality endpoints. They would not compete with groups, and group members and affiliates would not be eligible for participation. Quality assurance would be achieved through random sampling, and supporting funds would flow from NCI directly to participants.

NCI feels that the CTEP directed involvement of centers in the LAK-IL-2 trials was accomplished quickly and effectively, Wittes said at the end of the discussion, "I noted limited enthusiasm" for CTEP as a trials coordinator. He did not say the mechanism would not be used in the future, but it apparently will not play a role in the overall effort to enhance patient accrual.

"Money Will Be There"

Commenting that "cost is always an object," Wittes presented comparative per case costs of clinical trials (NCI's contribution) for FY 1985. For cooperative group members, the average was \$2,208, with a range of \$1,960 to \$3,647, For CCOPs, the average was \$1,582, with a range of \$1,275 to \$2,044. For CGOPs, the average was \$897 with a range of \$638 to \$2,484.

"Clearly, CGOPs were the most cost effective," Wittes said.

"We're in a position where we can exploit an increase in accrual. He said NCI Director Vincent DeVita and DCT Director Bruce Chabner agree. "I feel that the money will be there when we are ready for it."

Carbone agreed that CGOP "is a good mechanism to get people involved in clinical trials, at low cost. It is good training for CCOPs. But it has a high turnover, with 30 percent dropping out, and low accrual."

"Why do they poop out?" Wittes asked.

"Many never get started," Carbone answered. "They find they are too busy and did not realize how much time it takes. Also, there is normal turnover. People leave institutions, retire, do something else."

Charles Coltman, chairman of the Southwest Oncology Group, said he endorsed use of CGOPs as a mechanism to increase accrual. He added that "one of our major problems" is the NIH Office for Protection from Research Risks.

"There is a fellow there who is creating havoc. He is moving through the system, trying to bring everyone to his perception of compliance. If this continues, it will be destructive and force us to create an unbelievable number of new IRBs. This is a major impediment."

Coltman commented on the unfunded CCOPs. "Some of them are stellar players," doing work of "extraordinary quality. We are trying to bring some of them in as CGOPs. I would suggest that a portion of the CGOP budget be designated for unfunded CCOPs."

Coltman suggested that per case payment of \$500-\$600 "could be enough" for affiliates to hire data managers and pay for travel to group meetings. "We probably will not increase accrual from universities. Most of the patients are in the community."

"One of the problems we can do the most about immediately is the complexity of clinical trials," Emil Frei, chairman of Cancer & Leukemia Group B, commented. Also, "it makes a huge difference if (physicians in private practice) can get some help with data management." He suggested a pilot program involving four to five physicians, "hopefully relating to a center."

Frei questioned the assumption that the need is for a smaller number of phase 3 trials with more accrual. "I'm not sure that is true. With CALGB, accrual is not a limiting factor. We need to make sure the question being asked is correct. Most of the problems occur when the clinical trial deviates the most from clinical practice. I would rather accrue a small number to a good study."

"My emphasis might be different," Wittes responded. But he agreed that "if you try to entice community physicians into trials that are a radical departure and not relevant to their clinical setting, the effort is doomed. There are issues that can be handled in the community. If we set up a system to tap anything like the patient resources available, we do all the trials we want."

Charles Moertel, chairman of the North Central Cancer Treatment Group, said that experience with the intergroup colorectal study which is nearing completion suggests to him that "I'm not sure we want to go any faster, and in fact it could be harmful. There are logistic problems that you solve as (the trial) evolves. I shudder to think what would happen if we had 300 patients the first month, which we could have if the resources

are there the way you are talking about. It could affect the quality. There are bugs that have to be worked out. If you spread out to get 2,500 patients, there would be more dropouts, and it would dilute the importance of therapeutic results."

Moertel suggested the emphasis might be on smaller trials, "perhaps more original, perhaps against the grain. We don't want to lose them."

"There isn't a lot of feeling out there that the system is stifling creativity," Wittes said. "If we can harness anything like the number of patients available, we could get 50 to 60,000 bowel cancer patients instead of the piddling 1,000."

"In this particular issue, I feel the question will be answered faster with a smaller study," Moertel said.

Slow Protocol Approval

"That's one intergroup study which ran so well," Wittes said. "If you decide to increase the power by increasing the number, there is no problem." He insisted that quality can be maintained when accrual is increased.

Moertel brought up an issue involving CTEP protocol review. The intergroup colorectal study will end in September, and no new study has been approved to follow it. If there is now new protocol ready, "the surgeons will lose interest. We'll have to start all over again getting them involved. We tried to have a protocol in place, but I'll bet you it will not be approved for a year."

"That is a problem, at multiple levels," Wittes agreed.

"In the olden days, you would keep study A open until study B was ready," Coltman said.

"One of the strengths of multidisease groups is that you can turn attention to something else," Carbone said.

"But there are still questions to ask in colorectal cancer," Coltman insisted.

Wittes said that the early end of the intergroup study (it had been scheduled to go through December) had something to do with the fact that a new protocol has not yet been approved.

Moertel brought up the issue of FDA's "treatment IND."

"That will create havoc for us," he said. "We get a drug to a phase 3 study, and it will then be available for marketing under the treatment IND. "Anyone on a street corner can buy the drug and give it to his patient. The guy across the street, who is not

involved in clinical trials, can say, 'I have this drug, and you won't have any problems with a protocol, or with randomization.'"

"We spent an extraordinary amount of time on this last spring," Wittes said, referring to negotiations with FDA, which modified its original proposal at NCI's insistence. "The current law has a great deal of potential for harm to clinical trials, although a lot less than originally proposed. A lot depends on how drug sponsors and FDA react. Irresponsible distribution could cause the whole clinical trials system to come crashing down. But I do see a desire for dealing with this responsibly. It does not have to be destructive."

"It can't help but be destructive to some extent," Coltman said.

"That's not an absolutely foregone conclusion," Wittes said. "The real issue is how quickly can we get drugs approved. There will always be a time lag between when you know a drug works and when you can get it approved for marketing. It is not clear that treatment INDs will be approved in a destructive way. Pharmaceutical companies don't want to harm clinical trials."

Moertel said that NCI's PDQ service might also harm clinical trials, used with the treatment IND. "The physician across the street can say, 'I have access to the drug, and the details on how to use it (obtained through PDQ). You don't need to go into a clinical trial.'"

Mixed Signals

Bernard Fisher, chairman of the National Surgical Adjuvant Breast & Bowel Project, said that "it is difficult enough now to convince the scientific community that clinical trials are a scientific endeavor. I agree with what Tom (Frei) said. We must not interfere with the scientific aspects for expediency. It is naive to think we can get an early fix on what is wrong.

"We're getting mixed signals relative to putting patients on clinical trials," Fisher continued. "There is great emphasis on trying to disseminate information to practicing physicians on what to do for patients who don't go on clinical trials, at consensus conferences, meetings, etc. One of the places we're doing that is at ASCO. Hordes of physicians swarm there looking for something to take home. They miss the point. Even some of the presidents of ASCO are not clinical trials people (Coltman, sitting next to Fisher, is president elect of ASCO)."

Fisher agreed that OPRR "is a major stumbling block," and added, "many of the demands put on us by NCI do not do anything to help us put patients on clinical trials.

"We realized long ago that we would be defunct if we had to rely on universities for patients," Fisher continued. "I want to emphasize that it is not institutions that participate in clinical trials, it is individuals." But he observed that cancer centers now are "increasingly anxious to participate."

Fisher admitted problems at cooperative group headquarters involving CCOP and CGOP grants. "It is an administrative nightmare." An example is the requirement for information on where patients come from. "That is important to know, but it results in deviation of manpower away from other group activity."

Fisher and others expressed concern over increased administrative problems caused by the cancer control requirement in the new CCOP grants. But Moertel said, "I think cancer control activities, the way we have defined them, have enhanced treatment research. They have generated a lot of enthusiasm, not only among physicians but also among the nurses, social workers and others. They feel like they are more a part of the action. Cancer control protocols need to be designed as complementary."

James Cox, chairman of the Radiation Therapy Oncology Group, had some suggestions for increasing patient accrual.

"Anything that makes available to the investigator that which is not available to practicing doctors increases accession." He mentioned drugs and data management as examples, 3D tumor displays and 3D dosimetry aids for radiation oncologists. "I don't know what you could do for surgeons."

Cox suggested that steps could be taken to enhance the prestige of physicians and institutions participating in clinical trials. Wittes at first countered with the comment that "the purpose of clinical trials is to answer questions, not enhance the prestige of individuals or institutions." But that suggestion led to the notion that appropriately applied publicity at local levels, announcing participation in important new studies, could not only help with accrual but also encourage physician participation by making known their roles.

James Anderson, CALGB, noted that use of a "circuit riding data manager" has helped his group in patient accrual by taking some of

the burden off community participants.

William Shapiro, Brain Tumor Study Group, suggested that efforts to convince patients of the value of participating in clinical trials should be made. "We need to do a better job of informing the public that:

"1. Supposedly the best available care is in clinical trials.

"2. Expertise in their own illness is more readily available in clinical trials.

"3. The newest drugs or techniques are there, although they may not necessarily get it."

Shapiro noted that one advantage, that free or lost cost care could be offered to patients enrolled in trials, "has dwindled. Some of the money in clinical trials should go to the patient," either by offering free care or by paying some of the patient's expenses.

"That's a terrific idea," Wittes responded. "Do you have any idea where we can get our hands on \$30 billion?"

"Talk to the guys with the dollars," Shapiro said. "Congress, or DeVita."

Reduce Disincentives

"I don't take exception to that position," Wittes said. "If (money can't be found) to cover all the costs, we should at least try to reduce the disincentive."

Thomas Lad, Lung Cancer Study Group, mentioned PDQ as a disincentive made available by NCI. "PDQ provides computer access to recipes. Maybe the best way to encourage patients to go onto clinical trials would be to do away with PDQ."

"Would you have NCI take the position that it should restrict information?" Wittes asked.

"No, but they can read the literature and go to meetings," Lad responded.

"Read the National Cancer Act," Wittes said. "It requires dissemination of information." He noted that NCI had been making available hard copies of PDQ data.

"Which NCI turned off," Moertel said.

Jerome Yates, associate director of the Div. of Cancer Prevention & Control, said that DeVita had taken the position that PDQ information is available on computers and that distributing hard copies, which soon are out of date, could have liability aspects.

Teresa Vietti, chairman of the Pediatric Oncology Group, said "The idea of some publicity from NCI directed to the general population and to general practitioners is extremely important."

In a discussion of the merits of expanding the base (more affiliates, more physician participants) vs. "squeezing the system," as Wittes called efforts to increase the ratio of entered/eligible, Wittes urged the groups to consider that "it is cheaper to squeeze the system for all it is worth than to increase the number from nonparticipants."

Roger Winn, M.D. Anderson, countered, "I think it would be easier to bring in new groups rather than squeeze the present system. We would do better to get in more CCOPs and more CGOPs."

Yates supported that view. "In the CCOP evaluation, those that increased accrual did so by adding other hospitals and not by squeezing."

Mark Nisbit, Childrens Cancer Study Group, revealed how CCSG does its squeezing. "If the percentage of pediatric patients at a hospital drops under 90, you can be darn sure Denny Hammond (CCSG chairman, who was not at the meeting) will be on the phone wanting to know why."

Wittes summarized the discussion. "I don't see why we can't devise strategies" to increase accrual. "I don't see why it would not be healthy to increase the flow of patients to clinical trials. I can't accept that the system is at optimal size."

Year 2000 Goal Focus of Fox Chase Symposium; Bonadonna To Keynote

A two day symposium focusing on progress in cancer research is scheduled for Sept. 15-16 in the Center Building auditorium at Fox Chase Cancer Center in Philadelphia. Speakers at the conference, titled "Toward 2000--Oncology Today," will focus on current research and future implications of that research in achieving the goals set for the Year 2000 by NCI, reducing cancer mortality by 50 percent.

Topics to be discussed include new developments in photodynamic therapy, current trends in new drug development, the role of intraoperative radiation therapy and hepatitis B as a model for cancer prevention. Other lectures will focus on the significance of oncogenes in carcinogenesis, current surgical approaches to advanced colon cancer, and the role of cancer control in cancer care. The conference also will feature workshops on current therapeutic approaches to major cancer sites, such as lymphoma, testicular cancer, metastatic breast cancer

and small cell lung cancer.

Gianni Bonadonna, director of the Dept. of Medical Oncology at the Instituto Nazionale Tumori in Milan, will deliver the keynote address, "Curative Treatment for Stage 2 Breast Cancer."

NCI CONTRACT AWARDS

Title: Maintenance of the NCI Drug Information System
Contractor: Fein-Marquart Associates, \$299,989

New Publications

"Learn About Leukemia," 32 page coloring book for children with leukemia. Free from the Leukemia Society of America, 733 Third Ave., New York 10017.

"Repertoire des travaux de recherche fondamentale et clinique en oncologie au Quebec," listing over 350 research firms, plus researchers' names, protocols and other information designed to allow better communication between researchers and physicians. Free from Fondation Quebecoise Du Cancer, 801, rue Sherbrooke est, Bureau 300, Montreal, Qc H2L 1K7, Canada.

"Cancer Chemotherapy: Advances in the Management of Nausea and Vomiting," a 15 minute film available free from A.H. Robins, Attn: Pharmaceutical Div., PO Box 11391, Richmond, VA 23230.

"Primary Care of Cancer: Recommendations for Screening, Diagnosis & Management," edited by Edward Mortimer, Joseph Robinson and Stephen Smookler. Published by the Case Western Reserve Univ. School of Medicine to provide primary care physicians with a readily accessible compilation of all currently recommended procedures (screening, diagnosis, management) for the 28 most common types of cancer. Emphasis on prevention and detection, encourages referrals to specialists. Single copies, \$15, 25-49 copies, \$13 each, 50-99, \$11, and 100 or more, \$10. Office of Community Health, Case Western Reserve Univ. School of Medicine, 2119 Abington Rd., Cleveland 44106, phone 216/368-3660.

"Treatment of Early Breast Cancer: Conservative Surgery with Radiation," a 26 minute videotape available in either beta or VHS. Radiation Oncology Dept., Georgetown Univ. Medical Center, 3800 Reservoir Rd NW, Washington DC 20007, Attn: Radiation Medicine Education Video, \$295.

"Chemotherapy of Gynecological and Breast Cancer," edited by M. Kaufmann. S. Karger AG,

Basel, PO Box Postfach, CH-4009 Basel, Switzerland, \$15.50.

"Tumor Markers and Their Significance in the Management of Breast Cancer," edited by Thomas Dao, Angela Brodie and Clement Ip. Alan R. Liss, 41 East 11th St., New York 10003, or phone 212/475-7700, \$36.

"Commentaries on Research in Breast Disease," edited by R.D. Bulbrook and D. Jane Taylor. Alan R. Liss, address above, Vol 1, \$29; Vol. 2, \$28; Vol. 3, \$42.

"Dietary Fat and Cancer," edited by Clement Ip, Diane Birt, Adrienne Rogers and Curtis Mettlin. Alan R. Liss, address above, \$130.

"Current Concepts and Approaches to the Study of Prostate Cancer," edited by Donald Coffey, Nicholas Bruchovsky, William Gardner, Martin Resnick and James Karr. Alan R. Liss, address above, \$130.

"Recent Advances in AIDS and Kaposi's Sarcoma," edited by H. Schonfeld. S. Karger AG, Basel, PO Box Postfach, CH-4009 Basel, Switzerland, \$113.50.

"Childhood Cancer and the Family," by Mark Chesler and Oscar Barvarin. Brunner/Mazel Publishers, 19 Union Square, New York 10003, \$30.

"European Journal of Cancer & Clinical Oncology," edited by H.J. Tagnon. Pergamon Press, U.S. office, Fairview Park, Elmsford, NY 10532, \$480, 12 issues.

"Leukemia Research," edited by Terry Hamblin and Peter Reizenstein. Pergamon Press, address above, \$395, 12 issues.

"Eyelid Tumors: Clinical Diagnosis and Surgical Treatment," edited by Jay Older. Raven Press, 1185 Avenue of the Americas, New York 10036, phone 212/930-9500, \$74.50.

"Hormonal Manipulation of Cancer: Peptides, Growth Factors and New (Anti) Steroidal Agents," edited by Jan Klijjn, Robert Paridaens and John Foekens. Raven Press, address above, \$59.

RFPs Available

Requests for proposals described here pertain to contracts planned for award by the National Cancer Institute unless otherwise noted. NCI listings will show the phone number of the Contracting Officer or Contract Specialist who will respond to questions. Address requests for NCI RFPs, citing the RFP number, to the individual named, the Blair building room

number shown, National Cancer Institute, NIH, Bethesda MD 20892. Proposals may be hand delivered to the Blair building, 8300 Colesville Rd., Silver Spring MD, but the U.S. Postal Service will not deliver there. RFP announcements from other agencies will include the complete mailing address at the end of each.

RFP NCI-CP-EB-85604-21

Title: Support services for radiation and related studies

Deadline: Approximately Oct. 15

The Radiation Epidemiology Branch, Epidemiology & Biostatistics Program of NCI's Div. of Cancer Etiology, is seeking a contractor to provide support services for the conduct and management of epidemiologic investigations of cancer directed by the REB alone or in collaboration with other investigators.

This will replace current contracts with Westat Inc., which are scheduled to expire June 29, 1988. The principal activities can be classified as follows:

1. Liaison, whereby the contractor assists in the coordination of multicenter studies and helps facilitate cooperation between NCI and its collaborators.
2. Development of study materials, including questionnaires, abstract sheets, coding forms, manuals of field procedures and other documents.
3. Identification of study subjects, including location of cancer patients and/or their relatives, selection of controls through such methods as random digit dialing and acquisition of appropriate study population rosters or files.
4. Training of interviewers, abstractors and other field personnel.
5. Field supervision and management.
6. Interviewing of study subjects.
7. Abstracting and coding relevant medical and other records.
8. Obtaining biologic specimens and arranging for the appropriate laboratory tests on them by designated laboratories.
9. Data preparation and processing, including editing and preparing information in format suitable for computer analysis.
10. Quality control and standardization so that appropriate and valid data result.

The concept from which this RFP was derived was approved by the DCE Board of Scientific Counselors at its last meeting and reported in the July 10 issue of **The Cancer Letter**.

This project will be for a five year period with the anticipated award scheduled for June 30, 1988.

Contracting Officer: Barbara Shadrick
RCB Blair Bldg Rm 114
301/427-8888

RFP NCI-CM-87224-30

Title: Preclinical pharmacology investigations of anti-AIDS agents

Availability of this RFP, previously announced as late June (**The Cancer Letter**, May 29) has been changed to late August. The deadline for proposals has been changed from July 20 to approximately Oct. 1.

Also, the anticipated number of awards has been changed from "more than one" to "at least three awards." The period of performance has been changed from 60 months to 36 months.

Contract Specialist: Elsa Carlton
RCB Blair Bldg Rm 224
301/427-8737

The Cancer Letter — Editor Jerry D. Boyd

Associate Editor Patricia Williams

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