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NCI Plans Conference To Reconsider Breast Cancer Screening In Women 40-49

NCI plans to take a fresh look at the controversial issue of whether women in their forties benefit from regular mammograms to screen for breast cancer, Institute Director Richard Klausner said.

The Institute has begun planning a consensus conference to be held later this year to evaluate new data from clinical trials, Klausner said to **The Cancer Letter**.

NCI would invite a panel of experts to Bethesda to evaluate data from Swedish studies as well as a meta-analysis published by US investigators earlier this year, Klausner said. Those data have become

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In Brief

Univ. of Texas Panel Selects Four Finalists For M.D. Anderson Cancer Center Presidency

FOUR FINALISTS for the presidency of M.D. Anderson Cancer Center have been selected by an advisory committee from a list of 71 applicants and nominees, the University of Texas Board of Regents said. The finalists are: **Charles Balch**, interim executive vice president for health affairs at M.D. Anderson; **Edward Copeland III**, chairman of the surgery department at University of Florida College of Medicine; **John Mendelsohn**, chairman of the medicine department at Memorial Sloan-Kettering Cancer Center; and **Andrew Von Eschenbach**, chairman of the urology department at M.D. Anderson. The regents plan to interview the finalists in May and select a successor to **Charles LeMaistre** at their meeting May 9. LeMaistre, M.D. Anderson president since 1978, announced last summer he would retire at the end of the fiscal year. Texas law requires that the names of finalists for a university presidency be made public 21 days before the regents fill the position. . . . **FRANK McCORMICK**, chief scientific officer of ONYX Pharmaceuticals Inc., of Richmond, CA, was selected to head the Cancer Research Institute at the University of California San Francisco, effective Jan. 1, 1997. McCormick will remain a consultant to the company on molecular oncology. He will also continue to serve as chairman of ONYX's Scientific Advisory Board. Prior to founding ONYX in 1992, McCormick was vice president of therapeutic research at Chiron Corp., and previously, held various positions at Cetus Corp. since 1982. . . . **THE WHITE HOUSE** is preparing to announce the President's intention to appoint several individuals to vacancies on the National Cancer Advisory Board, sources said.

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New Data From Swedish Trials Show Benefit For Screening

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available since NCI's 1993 decision to withdraw its support for screening women in their forties.

"The consensus conference would look at all of the data that is now available, specifically in light of the meta-analysis, and the new data from the five Swedish studies," Klausner said in an interview April 17.

Swedish investigators presented new data from five breast cancer screening trials at a scientific meeting held last month in Falun, Sweden. The data appear to show that women in their forties screened for breast cancer had a statistically significant reduction in their risk of dying from the disease, participants of the meeting said.

The purpose of the NCI consensus conference would not be to critique the Institute's 1993 statement, made under the former NCI director, Samuel Broder, Klausner said.

"I'm not interested in re-evaluating previous decisions by previous NCI directors," Klausner said to **The Cancer Letter**. "What I'm interested in is constantly evaluating the data, and acting on new data as new data becomes available.

"The discussion needs to be around the data and the evidence, and not around the gothic complexities of previous institutional decisions," Klausner said. "We have to get away from that. We're starting anew.

"My feeling is the previous business about signing on, signing off, [of guidelines] is just irrelevant," Klausner said. "What we want to do is, as soon as data is available, look at it, have the community evaluate it, and put together a committee to communicate the data and go to patients with it."

Klausner said he has spoken to the Swedish investigators and encouraged them to publish their results as soon as possible.

"From the reports, the Swedish data looked very impressive," Klausner said. "However, it is important that we analyze the data, and not just reports of the data."

Swedish Studies: 23% Reduction In Deaths

At the scientific conference in Falun, held March 21-22, Swedish investigators who conducted five clinical trials presented new relative risk estimates for the reduction in breast cancer deaths among women aged 40-49 invited to get a mammogram, versus those who were not invited.

Overall, women who received a mammogram had a 23 percent reduction in deaths from breast cancer, compared to those who did not receive a mammogram. The data were statistically significant.

In one trial, based in Gothenburg, Sweden, women in the screened group had a 41 percent reduction in deaths from breast cancer, compared to the unscreened group.

Edward Sondik, deputy director of the NCI Division of Cancer Prevention and Control, attended the Falun conference. "The Swedish investigators' presentation showed that point estimates of screening effectiveness have shifted from their earlier figures toward indicating a higher level of effectiveness and that the confidence intervals had narrowed," Sondik said to **The Cancer Letter**.

"Especially intriguing were the results from Gothenburg indicating a 40 percent reduction in breast cancer deaths at just about statistical significance," Sondik said. "However, no details on Gothenburg were presented, other than the overall result. Gothenburg had relatively few breast cancer deaths, but the results are still important.

"I hope the investigators publish these results quickly and that the community can meet and consider them in light of follow-up from other trials," he said.

Earlier this year, a group of US investigators published a meta-analysis of seven trials world-wide

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demonstrating that women in their forties who received screening mammography had a 24 percent reduction in death from breast cancer (Smart et al, Cancer 1995; 75:1619-1626).

"Confused A Whole Generation"

The controversy over whether women in their forties should get regular mammograms to screen for breast cancer divided the oncology and patient advocacy community when NCI withdrew its support for screening guidelines developed in 1988 with the American Cancer Society and other health organizations.

In the process, NCI angered many oncologists and patient advocates as much for the way the Institute handled the controversy as for the decision itself. The National Cancer Advisory Board had voted 14-1 in favor of a resolution urging the Institute not to change its breast cancer screening recommendations until further data became available.

However, in December 1993, NCI issued a "Summary of Scientific Fact," which made no recommendation about screening mammography for women in their forties, but affirmed that women 50 and over should get annual mammograms.

Less than one month earlier, ACS and 18 other professional and patient advocacy groups reaffirmed their support for the 1988 guidelines, which call for annual screening mammography and clinical breast examination for women over 50 and the same procedures every one to two years for women between the ages of 40-49 (**The Cancer Letter**, Nov. 26, 1993).

Ultimately, HHS Secretary Donna Shalala acknowledged that NCI might have handled the controversy more smoothly. "We tripped over ourselves and probably confused a whole generation of women," she said shortly after NCI issued its statement (**The Cancer Letter**, Jan. 7, 1994).

The new data give NCI no choice but to rescind the 1993 statement, said Daniel Kopans, director of breast imaging at Massachusetts General Hospital and associate professor of medicine at Harvard Medical School.

"We still have potentially thousands of lives being lost because women in their forties are not advised to get regular mammograms," Kopans said to **The Cancer Letter**. "I think NCI owes it to American women to move ahead quickly and get this resolved."

Kopans opposed NCI's statement in 1993.

"The people who made the decision at NCI based it on a flawed analysis comparing women aged 40-49 with everyone else," Kopans said. "Data have been inappropriately manipulated to create the appearance that there is a sudden change in breast density, recall rates, biopsy rates, and breast cancer detection rates that occurs abruptly at the age of 50. This is not supported by the scientific evidence."

NCI should not get caught up in the issue of who would pay for screening mammography for women in their forties, Kopans said. "We as a society may decide it is too expensive to provide screening for younger women, but women and their physicians should be given all of the analysis so they can make informed decisions," he said.

NCI's December 1993 Statement

Following is the full text of the NCI "Summary of Scientific Fact," released in December 1993:

"There is a general consensus among experts that routine screening every one to two years with mammography and clinical breast exam can reduce breast cancer mortality by about one-third for women ages 50 and over.

"Experts do not agree on the role of routine screening mammography for women ages 40-49. To date, randomized clinical trials have not shown a statistically significant reduction in mortality for women under the age of 50." (**The Cancer Letter**, Dec. 10, 1993).

Blues, Cooperative Groups Form Pediatric Network

The Blue Cross and Blue Shield Association, working with two NCI-supported clinical trials cooperative groups, has formed a Pediatric Cancer Network to provide subscribers to Blue Cross and Blue Shield Plans access to pediatric cancer treatment and clinical trials.

The network consists of 184 institutions deemed "centers of excellence." Most of the institutions belong to either the Pediatric Oncology Group or the Children's Cancer Group, two clinical trials cooperative groups supported by NCI grants.

The network was the result of discussions among the association, the cooperative groups, and other pediatric oncology experts, the Blues officials said in announcing the network April 11.

Studies have found that survival rates of children with cancer are about 20 to 40 percent higher if their treatment is coordinated by pediatric oncologists and delivered at multi-disciplinary cancer centers.

"We know that the odds for children with cancer can be greatly improved with highly specialized, multi-disciplinary care provided under the direction of pediatric oncologists," said Pat Hays, BCBSA president and CEO. "Our independent Blue Cross and Blue Shield Plans throughout the US will encourage physicians and their patients to use the Pediatric Cancer Network centers.

"We also encourage other managed care companies to adopt the model of the Pediatric Cancer Network," Hays said.

The association represents 63 locally operated, independent Blue Cross and Blue Shield Plans, which together insure one in four Americans.

About 8,000 to 12,000 new cases of cancer are diagnosed each year in children. The network expects to see about 2,000 to 3,000 of those patients, according to David Tennenbaum, the association's managing director for specialty networks.

In addition to treatment, the network plans to generate medical outcomes data. "By pooling our knowledge and evaluating our outcomes, we'll continue to see the kinds of breakthroughs that offer children with cancer real hope," Hays said.

NCI, Pediatric Oncologists Commend the Blues

NCI said the network's formation would help ensure that children with cancer receive the care they need at specialty centers.

"We are particularly pleased that the Pediatric Oncology Group and the Children's Cancer Group have helped establish the foundation of the Blues' Pediatric Cancer Network," Robert Wittes, director of the NCI Division of Cancer Treatment, Diagnosis and Centers said. "These groups and their member institutions are the very definition of excellence in care.

"More than that, the clinical trials of these two groups over the past several decades have constituted the principal engines of progress for pediatric cancer in the US and have moved the state-of-the-art in treatment upward to its present level," Wittes said. "The improvement in results of childhood cancer therapy is one of the major success stories of 20th century medicine."

The formation of the network "will assist the two pediatrics groups in realizing their mission of developing fully successful treatment for all children with cancer," he said.

Archie Bleyer, chairman of the CCG, said the cooperative group centers are "delighted and honored" to be members of the network. "I think this is an exciting opportunity," Bleyer said to **The Cancer Letter**. "It's one of the first times that a company has come to our patients and said, 'We want to support you, we trust your physicians, your nurses. We know the cost of care can be catastrophic, but we want to take that risk.' If that's not exciting, I don't know what is."

"The Pediatric Cancer Network is a first for the insurance and managed care industry, and we welcome this strategic alliance with our cooperative group," said Sharon Murphy, chairman of POG. "The network will help us further our mission of advancing the clinical science of pediatric oncology and of assuring optimal survival and quality of life for our patients."

The network also received statements of support from several members of Congress, including Sens. Christopher Dodd (D-CT), Bill Frist (R-TN), Connie Mack (R-FL) Mike DeWine (R-OH), Reps. Bill Archer (R-TX), and Scott Klug (R-WI).

The Network Model

Membership in the network is open to hospitals that meet selection criteria derived from current POG and CCG standards, as well as standards of the American Academy of Pediatrics and the American Society of Pediatric Hematology/Oncology.

Institutions belonging to either cooperative group are deemed to meet the network's criteria, but must go through a separate process to be designated. About 90 percent of the POG and CCG institutions have joined the network, Tennenbaum said to **The Cancer Letter**.

"Our intention is to invite other institutions who meet the quality criteria to join, rather than being limited to those that happen to be in the cooperative groups," Tennenbaum said. "Maybe with time those cooperative group members that did not to join would decide to join."

According to the network model, 80 percent of the child's care, from definitive diagnosis to the completion of active treatment, would be delivered in a network center. A board-certified pediatric oncologist would coordinate every phase of the child's treatment with a team of specialists and caregivers.

The remaining 20 percent of the child's care, which includes early diagnosis and post-treatment care, would be provided by the family's own physician under the direction of the center.

The Blues plans would reimburse for network-provided care, whether or not it involved clinical trials, Tennenbaum said.

"As we came to understand the cooperative group structure and the particulars of pediatric cancer, we learned that 80 to 90 percent of children's cancer care is offered in clinical trials, whether that is phase I, II or III," Tennenbaum said to **The Cancer Letter**. "So we didn't view the network as a clinical trials policy initiative; we simply see it as a delivery system.

"The vast majority of care is not controversial," he said. "If a child was involved in a phase I trial, it is possible that a particular BCBS plan would have some concerns, or want to make sure there was informed consent."

According to a statement, the network defined three levels of care:

"Level I care is generally provided by the primary care physician in the community. When the physician has a suspicion of cancer, the patient will be referred to the Pediatric Cancer Network.

"Level II: Often, the initial diagnosis and treatment of pediatric cancer must be provided in a hospital. This care will be provided in a Pediatric Cancer Network center with the multi-disciplinary team needed for effective management. This care includes definitive diagnostic evaluation, e.g., biopsies and staging of cancer, active treatment and surveillance for complications and recurrences; and follow-up once a year after five years for late effects of treatment. Some children may need to return to their communities to receive continuing treatment on an outpatient basis. This continuing care will be provided under the direction of a pediatric oncologist.

"Level III is high specialized care for rare cancers requiring specific expertise, such as retinoblastoma, and for complex treatments such as bone marrow transplants and stereotactic radiosurgery. This level of care is provided at network centers with a demonstrated expertise in the disease or treatment modality."

Follow-up care is to be provided by the primary care physician. After five years of treatment, the network center will provide annual monitoring for long-term complications.

Tennenbaum said the Blues Association is working with oncologists to define Level III care.

The Blues Association is considering the development of other specialty networks, some of which could involve adult cancer treatment, Tennenbaum said.

"We are trying to think about how we can best promote the quality of care for adult cancers," Tennenbaum said. "We are asking what subsets of cancers would lend itself to the model of the Pediatric Cancer Network."

Claims Payments Not Guaranteed

David Tubergen, executive officer of CCG, said the formation of the network will not in itself solve the problem of individual insurance plans making a decision not to pay for care of patients involved in clinical trials.

"The Blue Cross and Blue Shield Association is at best a federation, and has nothing to do with paying the claims," Tubergen said. "The association is recommending the network organizations to its members. What will happen in individual BCBS plans is yet to be seen."

Phase II and III trials may not present any problems, but plans might balk at paying for phase I studies, he said.

However, Tubergen said, the network's formation is only the beginning of an ongoing process. "We think it is a step in the right direction, and a recognition of the value clinical research plays."

Tubergen said CCG is interested in beginning discussions with other insurers.

ORI To Begin Investigation Of Fisher, 2 Others At NSABP

The HHS Office of Research Integrity has made an apparent effort to rekindle its investigation of Bernard Fisher and two other researchers at the National Surgical Adjuvant Breast & Bowel Project.

In a memorandum marked "confidential," an ORI official instructed the cooperative group to prepare for the arrival of the investigators who would probe the allegations of knowing use of fraud-tainted data by the three researchers.

Under ordinary circumstances, a document of that sort would have remained confidential. However, ordinary circumstances have been scarce in the NSABP controversy.

Thus, the March 21 letter from John Dahlberg, a

senior investigator with the ORI Division of Research Investigations, to Walter Cronin, deputy director of the NSABP Biostatistical Center, became part of the public record, as an exhibit to a motion filed by Fisher's Washington attorneys.

Fisher is in the process of suing the ORI and NCI for their handling of the NSABP controversy, and, according to an April 15 filing by his attorneys, the government's resumption of the investigation constitutes a violation of an injunction that prohibits retaliation.

Thus, Fisher's attorneys argue, ORI and NCI should be held in contempt of court.

"If it looks like a duck, quacks like a duck, and lays eggs like a duck, it's probably a duck," said Robert Charrow, an attorney with the Washington firm, of Crowell and Moring. "In this case, I believe it's retaliation, which is prohibited by a court order."

The Dahlberg letter offered a detailed overview of the status of the government's investigation of Fisher as well as Lawrence Wickerham, NSABP Deputy Director for Administration, and Carol Redmond, the cooperative group's former chief biostatistician.

According to the letter, the investigation focused on the data from 99 patients from St. Luc Hospital in Montreal whose records were found discrepant in a related investigation of St. Luc researcher Roger Poisson.

"The purpose [is] to endeavor to determine which data from 99 subjects with falsified and fabricated eligibility data from the St. Luc study may have been included in ... reports and manuscripts," Dahlberg wrote.

The ORI reviewed publications and manuscripts submitted since February 1993, the date of issuance of the agency's report on St. Luc, Dahlberg wrote.

"Our current analysis has led us to the identification of four papers and submitted manuscripts where it appears that one or more of the 99 St. Luc subjects may have been included in the study," he wrote.

The four papers listed in the letter are:

— "The Benefit of Leukovorin-Modulated 5-FU as Postoperative Adjuvant Therapy for Primary Colon Cancer; Results From NSABP Protocol C-03."

The paper's authors include Norman Wolmark, now NSABP chairman as well as Fisher, Wickerham and Redmond. The paper was published in the Journal of Clinical Oncology, 11:1879-1887, 1993.

— "Conservative Surgery for the Management of Invasive and Noninvasive Carcinoma of the Breast; The NSABP Trials."

The paper, which lists Fisher as the lead author, was published in the Journal of Surgery, 18:6349, 1994.

— "The NSABP Breast Cancer Prevention Trial of Tamoxifen in Women at Increased Risk for Breast Cancer."

The paper lists Redmond as the lead author, and Fisher, Wickerham and Cronin among co-authors.

According to Dahlberg's letter, the manuscript was withdrawn from consideration from the journal Cancer in March 1995.

However, sources said to **The Cancer Letter** that the manuscript was, in fact, withdrawn a year earlier.

—"The Role of Thymidylate Synthase Expression in Prognosis and Outcome to Adjuvant Chemotherapy in Patients with Rectal Cancer."

The paper's lead author is P.G. Johnston, an NCI researcher. Co-authors include Fisher, Wolmark and Bruce Chabner, then director of the NCI Division of Cancer Treatment.

ORI is interested in the manuscript submitted to the New England Journal of Medicine in October 1993, but rejected by that journal.

Subsequently, the authors learned that a pathology sample from one of the 99 St. Luc patients was included in the original version of the paper.

As a result, the paper was reanalyzed and ultimately published in the Journal of Clinical Oncology in December 1994. The article contained no data from discrepant patients from St. Luc, sources said.

"We wish to visit your facility and review the process by which that data used for the particular figures, tables and textual comments were extracted from the database," Dahlberg wrote.

"The determination that one or more of the 99 St. Luc subjects were included in any of these papers is only one step in ORI's investigation of the matter [which] does not establish that scientific misconduct occurred," Dahlberg wrote. "Once the facts have been established, it will be necessary to interpret them in the context of the purpose of the publication and the rationale for how the data was [sic.] obtained and interpreted."

Dahlberg urged that the impending visit be kept confidential and that only the staff members who would need to assist the investigators be informed

about it. "We ask that you advise the involved staff not to discuss the visit or the subject matter with anyone," Dahlberg wrote.

Case Unusual From The Outset

"It's a bizarre letter on several counts," said Suzanne Hadley formerly an NIH scientific misconduct investigator who worked on the staff of Rep. John Dingell (D-MI) at the time of his investigation of the NSABP.

"The most striking aspect of it is that on the one hand ORI appears to be saying that it has established that four papers contain data on the St. Luc 99 patients. On the other hand, they are saying that they would like to come to Pittsburgh to establish whether these papers contain data on the St. Luc 99.

"Has ORI established it or has it not? What in the world has ORI been doing over the past two years?"

Hadley said she was surprised that the letter was addressed to Cronin rather than to NSABP Chairman Wolmark or the University of Pittsburgh General Counsel.

Dahlberg's letter indicates that Louis Popper, Pitt's general counsel, was intended to receive a copy. Wolmark's name does not appear on the cc list.

The NSABP investigation has departed from ORI policy from the outset.

For one thing, the initiation of the investigation, usually a confidential matter, was announced by HHS Undersecretary for Health Philip Lee in an interview with The New York Times.

The official "complainant" against Fisher, then NSABP interim chairman and principal investigator Ronald Herberman, was apparently never informed by the ORI that his name figured on the complaint.

"[We] had no thought or intention to raise the issue about possible scientific misconduct on the part of Dr. Fisher or others," Herberman, director of the University of Pittsburgh Cancer Institute, said to **The Cancer Letter**. "I was very surprised to learn that I was listed as the complainant when I was deposed in regard to Dr. Fisher's law suit." (**The Cancer Letter**, Oct. 20, 1995).

Generally, misconduct cases are referred to specially formed "inquiry panels" comprised of peers of the respondents.

Such panels are usually formed early in the case, said sources familiar with ORI practice and procedures. However, sources close to the case said they were unaware of an inquiry panel being formed in the NSABP case.

Also, early in the controversy, NIH and NCI, in cooperation with ORI, placed warning flags in the government databases containing papers that include Fisher as an author.

The flags, removed following a court order, stated "Scientific Misconduct—Data to be Reanalyzed."

Now, as a result of the apparent rekindling of the misconduct investigation, Fisher's attorneys are claiming that the government has violated the provisions of a March 1995 injunction that also called for removal of the warning flags from the government databases (**The Cancer Letter**, March 24, 1995).

Though the injunction did not address the continuation of the ORI investigation, it did prohibit "retaliation."

"ORI has no legitimate reason whatsoever to resurrect this investigation," the April 15 motion by Fisher's attorneys stated. "There is certainly no `new' evidence that Dr. Fisher committed any wrongdoing related to the Poisson affair. Indeed, there never was evidence to initiate this investigation in the first place.

"[The] evidence points to one unmistakable conclusion, [ORI and NCI are] attempting to punish Dr. Fisher for continuing with this litigation," the motion said.

Fisher's attorneys also objected to what they described as continued involvement of ORI investigator Barbara Williams in the case. Williams was a designated agency witness in Fisher's suit under the Privacy Act, a law that prohibits the government from improper disclosure of information about individuals.

Last January, Judge Ricardo Urbina of the US District Court for the District of Columbia heard oral arguments in the Privacy Act case (**The Cancer Letter**, Jan. 19). His decision is pending.

The ORI investigators were expected to arrive in Pittsburgh on April 18, sources said.

Barton Seeks GAO Inquiry Of FDA Foreign Inspections

Rep. Joe Barton (R-TX) last week requested an investigation of FDA program for inspection of pharmaceutical facilities located outside the US.

In a letter dated April 10, Barton, chairman of the Subcommittee on Oversight and Investigation of the House Committee on Commerce, requested that

the US General Accounting Office investigate the FDA foreign inspections program.

Many cancer drugs are manufactured outside the US, and, according to critics, the agency has been ineffective in monitoring the manner in which these drugs are produced (**The Cancer Letter**, Aug. 18, 1995).

"The [subcommittee] has been investigating the FDA foreign inspection program," Barton wrote in a letter to Charles Bowsher, US Comptroller General. "As part of this effort, the subcommittee seeks GAO's assistance in obtaining additional information on foreign inspections in preparation for possible hearings in the near future.

"In particular, the subcommittee requests that GAO obtain and examine information about how FDA foreign inspections are conducted, managed and supported," Barton wrote.

A copy of the letter was obtained by **The Cancer Letter**.

Seeks Information On Etoposide

In a development related to Barton's investigations of FDA, the House Member recently requested that FDA provide the subcommittee with all documents on the use of the generic version of the drug etoposide.

Last year, researchers at H. Lee Moffitt Cancer Center reported that they stopped using the generic version of the drug in a high dose regimen. At that time, they prepared an abstract describing their experience with the generic (**The Cancer Letter**, May 5, 1995).

Subsequently, the Moffitt researchers prepared another abstract, summarizing their data and submitting it to FDA, Barton wrote to the agency Commissioner David Kessler. The letter, dated March 6, cites an article in the March 1 issue of FDA Week, a Washington newsletter.

Barton requested a copy of the most recent Moffitt abstract as well as all FDA materials on generic etoposide.

ONF Invites Applications For Fatigue Research Grants

The Oncology Nursing Foundation invites applications for a multi-institutional research project on cancer-related fatigue.

The $500,000, three-year grant is part of the Fatigue Initiative through Research and Education project.

The principal investigator must be a registered nurse actively involvedin some aspect of cancer patient care, education and/or research.

Projects targeted at explaining fatigue mechanisms, developing clinical assessment tools, and/or designing intervention strategies will be given funding priority.

Application deadline is Nov. 1.

A required letter of intent is due Sept. 16. The letter of intent must include the names and institutional affiliations of all the members of the research team, a list of potential research sites, and the tentative focus of the grant.

To request an application, contact the Oncology Nursing Society, Research Department, 501 Holiday Dr., Pittsburgh, PA 15220-2749, tel: 412/921-7373, fax: 412/921-6565, e-mail: res_ons@nauticom.net.

RFP Available

RFP NCI-CM-77014-28

Title: **Analysis of anti-cancer and anti-AIDS chemical and pharmaceutical formulations**

Deadline: Approximately July 12

The Pharmaceutical Resources Branch of the NCI Developmental Therapeutics Program, Division of Cancer Treatment, Diagnosis and Centers, is seeking contractors experienced in the analytical assessment of bulk pharmaceutical substances and clinical drug products to provide analytical services. Analytical information generated under these contracts will be used for preclinical and clinical development of the drug candidates. Data provided in the analytical reports will be supplied to the FDA as part of the Investigational New Drug filings for anti-tumor and anti-AIDS agents. It is anticipated that three cost-reimbursement, completion type contracts will be awarded for a base period of three years, with two one-year options for each contract. The proposed contract represents a recompetition of contracts held by Midwest Research Institute, Research Triangle Institute, and SRI International. Contractors will be expected to have operational equipment and capabilities.

Contract specialist: Carolyn Barker, NCI RCB, TCS, 6120 Executive Blvd., EPS Rm 603 MSC 7220, Bethesda, MD 20892-7220, tel: 301/496-8620, fax: 301/496-6699, e-mail: barkerc@rcb.nci.nih.gov.