THE CANCER LETTER

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CONTINUING PROGRESS REPORTED ON BREAST CANCER TREATMENT; MAMMOGRAPHY CONTROVERSY COOLED

This week's "Report to the Profession" on breast cancer did not offer any reports of startling breakthroughs nor turn up any new items of major controversy. But it did present evidence of continuing progress, particularly in treatment, and it cooled somewhat the controversy over mammographic screening.

The use of mammography, particularly in the NCI-American Cancer Society sponsored demonstration program at 27 screening centers around the U.S., has been a red hot issue all year. Evidence that breast x-rays may increase the risk of breast cancer caused NCI to recommend against annual mammograms for asymptomatic women under age 50.

Critics in general went along with the new NCI guidelines. John Bailar, the NCI staff member who opened up the controversy 18 months ago when he publicly criticized the demonstration program after opposing it within NCI, acknowledged the improved situation in his presentation Monday. (Continued to page 2)

In Brief

UNIV. OF NEW MEXICO LOOKED OVER AS POSSIBLE COMPREHENSIVE CENTER; MISSOURI ASKS DELAY

NCI STAFF and a National Cancer Advisory Board site visit team looked over the Univ. of New Mexico Cancer Center as a possible new comprehensive center. The team's findings will be reported to the Board in January. Columbia Univ., another prospective comprehensive center, will be visited in March. The Missouri Cancer Program, which had requested a Board site visit, withdrew that request. . . . JOHN HOGNESS, president of the Univ. of Washington, resigned from the National Cancer Advisory Board to accept a position on the National Science Board of the National Science Foundation. New NCAB members at this month's meeting were Mrs. Marie Lombardi, widow of football coach Vincent Lombardi, and Gerald Wogan, MIT. . . . NEW POSITIONS written into the appropriations bill for NCI by Congressman David Obey have been released by the Office of Management & Budget. The Environmental Epidemiology Branch, headed by Joseph Fraumeni, will get 17, and "carcinogenesis" will get 60. Obey's intention was that all 60 would go into the Carcinogenesis Program in the Div. of Cancer Cause & Prevention, but DCCP Director James Peters said "there's no way we can absorb that many." Some of the new slots will go to other divisions, all of which have programs dealing with carcinogenesis one way or another. . . . ROSWELL PARK investigators Enrico Viadana, Irwin Bross and Lorne Houten report that statistical analyses of occupation-associated risks show that chemical fume inhalation increases risks of stomach, esophagus and larynx cancers. They said that "people who inhale chemical fumes are at considerably greater risk of developing cancer than people whose work involves combusion products."

CRITICS COOLED, STRONG CASE MADE FOR MAMMOGRAPHY SCREENING PAST 50

(Continued from page 1)

"Improvements include reduction in radiation exposure (at least in some centers), guidelines from NCI and ACS on screening women under 50, changes in the consent form signed by screenees in the program, and a marked increase in both professional and public awareness of the need to balance the clear benefits of screening with its risks," Bailar said. "It is likely that future improvements will in time further define and extend the optimum range and application of breast cancer screening programs."

Bailar acknowledged that "there is no reasonable doubt that earlier detection of breast cancer can reduce mortality. There is also no reasonable doubt that x-ray mammography carries a risk of causing breast cancers at some future time. Both benefits and risks can be estimated with satisfactory precision. In terms of breast cancer mortality, adding mammography to a program of annual breast examinations of average U.S. women seems to be of questionable value under age 55, but beneficial to older women. Consideration of risks and benefits other than breast cancer survival or mortality would probably put the breakeven point at a slightly higher age. However, the breakeven point is closely related to the average radiation exposure of breast tissue, and screening might well begin as early as age 50 in a few centers now using optimum techniques and equipment."

Sam Shapiro, Johns Hopkins Univ., reported new data derived from the Health Insurance Plan of Greater New York study, the study which originally encouraged NCI and ACS to proceed with the demonstration project. Shapiro said that new data support earlier reported benefits of screening. During the nine years following date of entry there were 128 breast cancer deaths in the control group as compared with 91 in the study group. "The impact of the screening program continues to be confined to women 50 years of age and over with no benefit at ages 40-49," Shapiro said. The fact that there was no reduction in breast cancer mortality among women under 50 "is of major importance," he said. "The possibility that under different screening conditions (e.g., with current mammography equipment) a benefit would be found needs to be investigated. There is a clear need for rapidly determining whether a new randomized trial is the only way to answer the question and whether experience in the 27 NCI-ACS demonstration centers can provide useful data.

"Another critical issue," Shapiro continued, "concerns the incremental value of mammography in a screening program. Over an eight-year period after diagnosis, breast cancer cases that were positive only on mammography when screened had a case fatality rate of 14%; this compares with 32% for cases positive only in the clinical examination and 41% for cases positive on both modalities. Excluding mammography would have reduced the benefit of screening by an estimated one third.

"It is concluded that the increment in risk resulting from radiation exposure in mammography does not offset the benefits of screening above 50 years of age. Below that age, although the risk increment is small, the risk-benefit balance is negative because of the absence of a demonstrated benefit.

"Based on current findings in the HIP study," Shapiro concluded, "there appears to be strong support for periodic screening at ages 50 years and over with clinical examination and mammography. To justify screening under 50, new information from other studies is required."

NCI acting director Guy Newell, Div. of Cancer Control & Rehabilitation Director Diane Fink, ACS President and Cancer Panel member Lee Clark, and Benjamin Byrd, chairman of the ACS Breast Cancer Task Force, presented updated results reported by the 27 project centers when they defended the program at a press conference.

Through last June, the centers reported, out of a total of 270,000 women enrolled in the program:

–A total of 1,768 cancers have been found.

–Of that number, 1,544 were found by the screening program, and 224 (referred to as "interval" cancers) were found either by the women on self examination or by physicians not involved with the program. Those could be cancers the screening program could have missed by error, or they could be ones that became detectable only after one screening and before the next (a year apart).

–Of the 270,000 enrollees, data is available on 260,281. There were 203,826 who were asymptomatic, 55,087 with symptoms. Symptoms were defined as lumps or masses, nipple discharges, or past history of breast disease (1,368 with past histories were enrolled who had had mastectomies and with a remaining breast apparently disease free at time of enrollment).

Newell said that lowering the exposure to one rad, which NCI ordered last July, has not resulted in reducing the number of cancers found in the program. "It's about the same rate we had before, and the image quality is holding up," Newell said.

Byrd said the fact that the program recommended 10,800 biopsies and that reports have come in on only 5,800 of those is "startling. We're just beginning to see the pattern of the yield, with 47% yet to come." Most of that difference represents delay in data retrieval, although some might involve patients reluctant to seek medical care, some might involve "doctors unwilling to operate on the basis of x-rays alone. Some like to operate only on something they can feel," Byrd said.

Arthur Holleb, ACS vice president for medical affairs, said there has been a 10 to 40% drop off in the number of women receiving mammograms at the

centers since the controversy arose last summer. But some of them are starting to come back, he reported.

Fink noted that x-ray machines at all 27 centers are now set to deliver 1 rad or less exposure, "including those that might have been up a little above that."

FCRC COMMITTEE LIMITED TO REVIEWING BASIC SCIENCE PROGRAM, NEW PROPOSALS

Members of the Temporary Review Committee for the Frederick Cancer Research Center found out last week exactly what it was that NCI wanted them to do.

At their first meeting in September, NCI had expected them to look over the workscope the staff had written for the RFP to recompete the FCRC contract, held by Litton Bionetics since the center was opened in 1972. The committee instead insisted that it should go into the broad philosophy guiding NCI use of FCRC and look closely at the scientific quality of all operations there (*The Cancer Letter*, Sept. 24). Committee members asked that the RFP be delayed six months to give them time to accomplish that task.

That meeting was adjourned without any discussion on the RFP workscope, and with no firm statement by NCI staff on what the committee's role would be.

Since then, NCI determined that the RFP could not be delayed, and it has gone out. A preproposal conference has been scheduled for Nov. 30 and Dec. 1 at Frederick for prospective bidders, and completed proposals are due Jan. 10. Indications are that several organizations intend to submit proposals which will present strong competition to Litton Bionetics' bid to keep the contract another five years.

So the committee missed its chance to exert any influence over the RFP. Just what will it do now?

Richard Tjalma, NCI assistant director, spelled it out:

1. The committee will review the basic science program at Frederick, operated by Litton Bionetics and directed by Michael Hanna.

2. Review any new proposals for that program which may be submitted by the proposers.

3. Take a second look at the various scientific proposals which make up the bulk of work performed at FCRC as components of other NCI programs, after they are reviewed by the appropriate regular technical review committees.

The basic science program review will be the temporary committee's primary job. It has not had any review since it was established, at the direction of the National Cancer Advisory Board, two years ago.

Proposers are required to submit a base proposal for operation of the entire facility. If they choose to do so, they may also submit alternate proposals for changes in the basic science effort. "The scope of such proposed changes may be without limitation," contracting officer Ronald Defelice said in his letter to recipients of the RFP. "Such alternative proposal must be in full detail, and shall include a complete cost estimate."

Defelice said that Litton Bionetics is among those invited to submit a proposal. "However, the incumbent will not be accorded any special consideration by virtue of being the present operating contractor."

Committee member Bernard Weinstein said he was "concerned about projects beamed to Frederick that might go elsewhere . . . that the quality of surveillance (by review committees) may not be as good."

"We feel the quality is equal to any other," Tjalma said.

The RFP suggests that proposers consider developing their proposals retaining all those employees of Litton Bionetics at Frederick who would wish to stay. There are about 800 employed there now. Committee chairman James Liverman said he thought perhaps only 10 or 12 would want to remain with Litton, "or maybe it would be one or two."

James Graalman, chief of NCI's Research Contracts Branch, pointed out that although NCI has established a limit of $25 million that will annually go into all FCRC operations, the RFP notes that the government will consider an inflation factor in the negotiations. "That is subject to the budget. If the budget does not allow for inflation, then we'll have to reduce some of the activities," Graalman said.

Work is performed at Frederick for programs under direction of three NCI divisions—Cause & Prevention, Treatment, and Biology & Diagnosis. Some of it is arranged through sole source procurement when it can be justified, some on competitive awards in which the contractor competes with any other organization responding to the RFPs.

CENTER DIRECTORS, NCI STAFF PONDER VARIETY OF ISSUES CONFRONTING THEM

Financial support of cancer centers, the reliability of NCI's commitment to provide its share of that support, and the nearly impossible situation in which federal government demands on centers are not matched by the funds required to meet those demands were the problems which were continually discussed—and argued— at the meeting of cancer center directors with key NCI staff in Florida recently (*The Cancer Letter*, Nov. 5).

Other problems, such as quality of site review teams, relationships of oncology departments to cancer centers and institutions, and various technical questions involving center operations and their involvement with NCI were on the agenda.

William Walter, director of the Cancer Centers Program, said the meeting resulted in making NCI staff more aware of the concerns of center directors and perhaps opened the way for better dealing with those concerns.

"The question of NCI's commitment to centers is one that ought to be spoken to firmly by NCI," Walter said. Issues he felt were sharply developed included:

—Differences between free standing cancer centers and those affiliated with universities. "NCI needs to be aware of those differences, and we need to be flexible to take into account those differences."

—The opinion among center directors that there is an over-emphasis on organizational structure of centers.

—NCI's ability to sustain support of construction.

—Fragmentation of support for centers from NCI's other divisions.

"The center directors want to be part of the entire Cancer Program," Walter said. "The Centers Program can act as a coordinating point, a clearinghouse, for problems they may have with other NCI divisions."

Questions and comments by center directors and their staff members, and responses from NCI staff, reveal the extent of the problems and offer some clues on what NCI proposes to do about them:

Hilary Koprowski, Wistar Institute: "We've been told that centers will have to seek support elsewhere (in addition to NCI). Has the NCI intrainstitute committee on centers considered where we should go to seek it?"

Thomas King, director of the Div. of Cancer Research Resources & Centers: "No. The position is that it is NCI's responsibility to help develop emerging centers. . . . After 10 to 15 years, centers should be able to sustain themselves without NCI support."

Charles Moertel, Mayo Clinic: "How permanent can we consider the commitment to space and activities?" (If core grants are phased out after 10 years.)

King: "It may be that 10 years is not enough, but it seems to me that that is sufficient time."

Lawrence Piette, Cancer Center of Hawaii, questioned the coordination of cancer control, education and other activities supported by NCI at centers.

King: "NCI will promote coordination. We need a greater degree of internal coordination within NCI. We are achieving it, and we must have it."

Harold Rusch, Wisconsin Clinical Cancer Center: "The glue that holds a center together is the discretionary funds the directors have to pay for space and key salaries."

King: "I agree. The trouble with discretionary funds is that they can be used most indiscreetly. They need to be monitored carefully. We won't have to stay on people's back. We have to put trust in people. Those that don't use discretionary funds wisely won't survive."

Gordon Zubrod, Florida Cancer Center: Commenting on the NCI committee report which suggested definitions for cancer centers, and their responsibilities, "That is a good model for a center in a university setting. . . . A university is in a particularly good position to serve as a regional center. But the criteria for a free standing center would not work very well at a university. . . . Funding can be destructive toward a center's objective. NCI's objectives may be very different from those of a center. To qualify for funds, a center may hurt its own objectives. The director could lose control over his program. This is especially true in clinical research. His investigators may go after the objectives of a cooperative group, or an organ site program to get the money."

King: "It is true that university based centers are quite different from the free standing ones. . . . University deans look askance at the requirements for departmental status (for a cancer program) that is traditionally organized by discipline. They find it difficult to comprehend what we mean by regional responsibility. They don't know what their region should be. In New York City, is it from 40th and Broadway north, or west of the Harlem River? In Albuquerque, is it all of New Mexico? The region depends on you. How much you can get people to accept you. It is not always logical. Who would have predicted a major center in Rochester, Minn. in 1890? It was leadership that did it."

John Potter, Lombardi Cancer Center: "Centers have key needs. Ours is space. Construction funds have been cut by $10 million. Can anything be done about it?"

King: "Approval for reprogramming the construction money has not yet been obtained from Congress."

Gregory O'Conor, NCI associate director for international affairs: "NCI recognizes the need for stable funding for centers. The practical side, however, has the budget constraints. There never will be enough money for all core support. You will have to be competitive. There has been too much emphasis today on phasing out rather than on the intent to continue support, on a competitive basis. We do need to encourage centers to solicit non federal support where possible and appropriate."

Timothy Talbot, Fox Chase Cancer Center: "Our mandate sometimes is a little fuzzy, sometimes clear. The intent of the National Cancer Act is, through geographical distribution of centers, to bring the benefits of the Cancer Program to the largest fraction of the American people as possible. The ideas was left with Congress that we were ready to go to the people with a massive program. . . . The reality is that it takes 20 to 40 years to build most centers. Time is required. . . . The whole idea of a center is made to appear to be cancer control, when in fact the whole idea of a center is fundamental, multidisciplinary research. To think that we could set up a center where that spirit isn't there bothers me. I'm concerned that we're thinking of setting up clinical centers without the research component. . . . We need to give cognizance to the fact that a university can't always properly divert funds to a cancer center. . . . The budget is what talks. That says what your priorities

are. . . . Without wishing to denigrate the inhouse progra (at NCI), and there are some excellent programs there, I wonder if the NCI budget is set by those with inhouse responsibilities. I don't want to hurt them, but they shouldn't be setting the priorities. . . . The issues are—Stability. The core grant should do that. The regional concept distorts the program. We should not be considered responsible for all cancer activities in our regions. Clearly, there should not be any more comprehensive centers, or at least not many, until we can reconnoitre and regroup."

O'Conor: "The term 'clinical center' is causing some confusion. Clinical center implies research, all types of clinical research, not routine patient care. Would you recommend increasing the core budget at the expense of regular research support?"

Talbot: "Let's cut out the waste and nonsense. That's up to the (NCI) director. NCI staff had a frightening job, when they had all this money dropped onto their laps. A lot of nonsense got funded. You or I wouldn't have done any better. They're reconnoitering and regrouping now, but let's keep an eye on it. No one in this room wants to see fundamental research cut, at this stage of our ignorance. But lots of programs that looked good in a PR sense, or satisfied an immediate need, were favored over those with long term benefits. We can solve a lot by underplaying the regional problem."

Zubrod: "Tim (Talbot) made many of my points. One—Clearly, innovative research is the key to curing patients who can't be cured now. Many could be cured if we use what we already have. Centers cannot be involved with everything in their regions. They can be heavily involved in education. Don't let medical students go without (some education in cancer). They can be involved with education of physicians in the community. Centers can't be heavily involved with patient care. Regional responsibility should be in education rather than patient care or setting up large regional demonstration programs."

Moertel: "I am pro regionalization. There is no question that in pushing the National Cancer Act, a persuasive argument was presented to Congress that it would be a benefit to cancer patients. The premise was that we would deliver this care. By assuming this responsibility, we were able to garner additional funds for basic research. In many areas, patient care is neglected. In our region, there is not a single member of a cooperative group, not a single center (other than Mayo). These poeple rightly feel they are being deprived of the benefits of the Cancer Program."

R. Lee Clark, Univ. of Texas System Cancer Center: "The most difficult thing (for a center) to achieve is central authority for center activities. If you are associated with a university and have autonomy, you can round out your activities. A center needs association with an academic environment. In a region, your influence can be extended by competition, to stimulate physicians to seek whatever new knowledge you may have. They don't want to lose their paying patients. They feel they need to keep up to compete with you."

Palmer Saunders, Univ. of Texas Medical Branch (Galveston): "The quality of a center comes across to the cancer patient as the quality of care he receives. He's not interested in the fine points we've been discussing. We certainly should educate the clinical staff in the best treatment techniques. . . . We're going to be judged by people who get the benefit of centers, not by Congress, not by NCI."

Talbot: "That's the most important thing that's been said today."

Center representatives were critical of the "Cancer Center Profile" questionnaire which was developed to provide NCI with a complete picture of each center's capabilities (*The Cancer Letter*, Sept. 17).

Mahlon Hoagland, Worcester Foundation: "The profile is thorough, but not as thorough as the information in core grant applications. That would be a better source for the information you want."

Bernard Keele, NCI Centers Program taff: "Core grants include information we may not be able to interpret. I would be subjective."

Richard Steckel, UCLA Cancer Center: "The core grant application includes all the information you are seeking."

Paul Marks, Columbia Univ. Cancer Research Center: "I understand why you want this information. But we are overwhelmed by questionnaires. Is this activity worth it in cost effectiveness? We've been site visited. You already have most of this information. I don't have confidence you're moving ahead with this questionnaire. You may be misled. You'll be under the gun to use the information you get. Some questions are not answerable. Some cancer centers are not keeping the records required to provide much of the information you want."

John Yarbro, Missour Cancer Programs: "As a former bureaucrat (director of the Centers Program at NCI), I don't have quite the same anaphylactic reaction to the questionnaire as others here. I went through it and about half the answers fell out easily. I agree, NCI has to have the information the questionnaire seeks. But some of the questions can't be answered."

Keele: "We need your comments on what is useful, what is not. This (the questionnaire) was a strawman draft."

Walter: "Obviously we have to go back to the drawing board on the profile. We need your help."

The matter of quality of review was brought up.

Koprowski: "I have been extremely perturbed by the level of review committees. DCRRC needs to exercise more influence on selection of people for those committees."

King: "Our requests for changes on study sections sometimes are honored, but not always. We do recommend and appoint members of initial review groups. You're talking about project site review teams."

David Joftes, chief of NCI's review and referral branch: "One major problem we have is that we're dealing with a limited amount of talent. We're calling on the same people all the time."

King: "We need to get new blood into the review system."

Joftes: "We've tried to get accomplished, experienced people. It is not fair to say the site visit teams are not scientifically competent. If so, we're failing."

Koprowski: "Perhaps some committees could be consolidated, or individuals permitted to serve on more than one committee."

King: "Consolidation would be better."

Jack White, Howard Univ. Cancer Center: "I don't have any problems or concerns with NCI staff or reviewers. I do have problems with site visitors and with grant guidelines. Site visit teams sometimes include people to review epidemiology who don't know anything about epidemiology. And please don't shift the guidelines after I write my grant application. Give me guidelines and say, 'These are the guidelines we'll use. They won't change.' And send me site visitors who know the guidelines as well as NCI staff and my staff know them."

Joftes: "It would be foolish for me to insist that the quality of reviewers is equal. We try our damnedest to do our best. You will have to consider the possibility that sometimes when you get a low priority ranking, or when your application is disapproved, perhaps the proposal was bad."

David Yohn, Ohio State Univ. Cancer Center: "One of the elements in the glue for cancer centers is program project grants. I see a considerable potential for that approach, and I am concerned that support for program projects is ebbing."

King: "We are in the throes of putting together guidelines for them. Applications need to be more tightly written. You need to relate dollars requested to the effort, so that it can be reviewed. Some applications are asking two to four times the previous level of support. There is a direct fiscal confrontation with areas, regular grants especially. The suggestion has been made that we eliminate program projects and put all our efforts into RO1s (traditional research grants). I would not like to see total elimination of program projects."

Stephen Carter, Northern California Cancer Program: "If there is a ceiling on the amount of money available for core grant support, what is the philosophy for new centers?"

King: "There will always be a need for new activities, research or core. I would not want to see any mechanism cut off and new people coming onto the scene in new institutions not have support available. We haven't resolved the questions on level of funding for any program, such as program projects. But they must compete. If the review is fair and objective and competent, you can live with funds approved. But we can't accept a further cut of 20%."

Walter said NCI is planning another meeting with center directors for next year, probably during October in the Washington, D.C. area.

NCI ADVISORY GROUP, OTHER CANCER MEETINGS FOR DECEMBER, JANUARY

National Bladder Cancer Project Working Cadre—Dec. 1-2, Deauville Hotel, Miami Beach, open Dec. 1, 1:30–5:30 p.m.

Diagnostic Research Advisory Group—Dec. 1, NIH Bldg 31 Room 6, open 8:30 a.m.–11 a.m.

National Large Bowel Cancer Project Working Cadre—Dec. 2-3, Anderson Mayfair Hotel, Houston, open Dec. 2, 7:30 p.m.-8:30 p.m.

Drug Development Committee—Dec. 2-3, NIH Bldg 31 Room 9, open Dec. 2, 9:30 a.m.–5 p.m.

Clinical Cancer Program Project Review Committee—Dec. 6-8, NIH Bldg 31 Room 8, open Dec. 6, 8:30 a.m.–12:30 p.m.

Carcinogenesis Program Scientific Review Committee A—Dec. 6, Landow Bldg Room C418, open 9–9:30 a.m.

President's Cancer Panel—Dec. 7, NIH Bldg 31 Room 7, 9:30 a.m., open.

Workshop on DNA Repair & Carcinogenesis—Dec. 8-10, Old Town Holiday Inn, Alexandria, Va., all sessions open–8 p.m.–9 p.m. Dec. 8, 9 a.m.–5 p.m. Dec. 9, 9 a.m.–noon Dec. 10. Contact Thaddeus Domanski, Biomedical Research Programs Branch, NCI, Westwood Bldg Room 850, Bethesda, Md. 20014.

Diagnostic Radiology Committee—Dec. 8, NIH Bldg 31 Room 9, open 8:30–11 a.m.

Chromosomes in Clinical Practice—Dec. 9, Roswell Park continuing education in oncology, registration required.

Clinical Trials Committee—Dec. 9-10, NIH Bldg 31 Room 8, open Dec. 9, 8:30–9 a.m.

Carcinogenesis Program Scientific Review Committee B—Dec. 10, NIH Bldg 31 Room 9, open 9–9:30 a.m.

American Assn. for Cancer Education—Dec. 10-11, Charleston, S.C.

Clinical Cooperative Group Chairmen—Dec. 14, NIH Bldg 31 Room 8, 9 a.m., open.

Diet, Nutrition & Cancer Program Advisory Committee—Dec. 14-15, NIH Bldg 31 Room 10, 9 a.m. both days, all open.

Committee on Cancer Immunobiology—Dec. 14, NIH Bldg 10 Room 4B14, open 2–2:30 p.m.

Committee on Cancer Immunotherapy—Dec. 16, NIH Bldg 10 Room 4B14, open 1–1:30 p.m.

Developmental Therapeutics Committee—Dec. 16-17, Blair Bldg, open Dec. 16, 8:30–11 a.m.

Breast Cancer Task Force—Jan. 12, Bethesda Holiday Inn, open 8:30 a.m.–adjournment.

Course in Hematology-Oncology—Jan. 13-16, Miami. Contact Sam Gunn, Univ. of Miami Medical School, PO Box 520875, Miami 33152.

Some Basic Approaches to the Early Diagnosis & Treatment of Gynecologic Cancer—Jan. 13, Roswell Park. Contact Joseph Barlow.

Recent Advances in Diagnosis & Treatment of Lung Cancer—Jan. 13, Roswell Park continuing education in oncology, registration required.

National Cancer Advisory Board—Jan. 24-26, NIH Bldg 31 Room 6.

Assn. of Community Cancer Centers—Jan. 28-30, Key Bridge Marriott Hotel, Washington, D.C.

Additional meetings for January will be listed in *The Cancer Letter*, Dec. 10.

SCHMIDT: SURGEONS, INTRAMURAL STAFF CONCERNED ABOUT NCI REPRESENTATION

Benno Schmidt, chairman of the President's Cancer Panel, sometimes passes on to members of the National Cancer Advisory Board encounters he has had with persons interested in the Cancer Program.

At the recent NCAB meeting, he told of "several communications I have had with the Society of Surgical Oncologists. They feel they are not adequately represented in the high councils of the Cancer Program." Schmidt noted that Jonathan Rhoads, an eminent cancer surgeon, is NCAB chairman, and R. Lee Clark, another premier surgeon, is a member of the Cancer Panel. "I had thought surgeons were effectively and powerfully represented," Schmidt said. "I thought perhaps they were talking about NCI staff. I told them that Dr. (Vincent) DeVita has set up a group of surgical oncologists to work with him. But I think what they wanted was to have members of the Society appointed to the Board."

"I suspect we have a generation gap," Rhoads said.

"I'll let you tell them that," Schmidt responded.

Schmidt said that NCI intramural scientists have expressed concern about their programs in view of impending arrival of a new NCI director. "They felt their input into the program was better than ever since 1972, and they felt this was at least partially due to the fact that Dr. (Frank) Rauscher had been an intramural scientist himself. They hope the Panel, Board and new director will maintain those relationships."

After going over some of the old complaints he has heard about support of basic science, Schmidt said, "Of far more concern to me are the concerns and criticisms of those who are best informed about the program. Many are extremely worried and concerned as the result of communicating with NCI about their own support.

"Contrary to the notion that NCI is rolling in money, in the last three years in terms of constant dollars, we have been losing support, especially in 1977 fiscal year. This has meant we have had to project restrictions in support of training, research grants, construction. We have to address ourselves to those problems.

"Oddly enough, and ironically, with a budget that has gone from $221 million in 1971 to $819 million in 1977, 1977 looks like the tightest, most difficult year since I've been associated with the program. We've built up a level of administrative commitment to the program that is well in excess of our ability to fund it.

"We may have to make the case for modest increases in the cancer budget or we're going to see institutions and programs thrown into disarray."

"If Mrs. (Mary) Lasker were here, she would ask that you omit the word 'modest'," Rhoads commented.

"Whatever we request, we'll describe it as modest," Schmidt said.

Acting Director Guy Newell reported on grants supported in FY 1976. A total of 3,202 was awarded, of which 2,930 were funded through the Div. of Cancer Research Resources & Centers, which administers the regular, program projects, and center grants; 178 through the Div. of Cancer Treatment, all for the clinical cooperative groups; 55 through the Div. of Cancer Control & Rehabilitation; and 30 Cancer Research Emphasis Grants.

Seventy per cent were non competitive renewals, Newell said, 10% competing renewals, and 20% new grants. Research grants accounted for 78.7%, center grants 2.4%. Manpower grants totaled 540.

Newell pointed out that the new administration will require agencies to submit budget proposals to the White House for development of a new budget President Carter will submit to Congress. President Ford's budget, which will be released a few days before he leaves office in January, will have around $800 million for NCI. "This will give us another crack at $955 million," Newell said.

CARCINOGENESIS TESTING BACKLOG WILL BE CLEARED UP IN A YEAR, NEW CHIEF SAYS

Robert Squire, formerly head of the tumor pathology section in the Carcinogenesis Program at NCI, has been appointed director of the Carcinogenesis Bioassay Program by Div. of Cancer Cause & Prevention Director James Peters.

Squire heads one of the two major elements formed out of the Carcinogenesis Program when Umberto Saffiotti resigned as program director earlier this year. The Bioassay Program handles the testing of suspected chemical carcinogens (the other element is carcinogenesis research).

The Bioassay Program has been criticized by Congressman David Obey and others for the backlog of completed tests which has piled up awaiting analysis before reports are issued on them. Obey blamed mismanagement and failure of Peters and former Director Frank Rauscher to adequately support Saffiotti for the backlog; others even less informed than Obey have blamed it on alleged incompetence of the test contractors, a conspiracy by industry to suppress the findings, or some other evil influence of unknown origin.

Squire had a simpler explanation. The backlog was created, he told the Clearinghouse on Environmental Carcinogens, when 200 chemicals were put on test in a two-year period, 1971-73. "The number of pathologists on hand was not adequate to handle the wave of tissues and printouts" generated by that number, Squire said.

The number included in the backlog is about 250, not the 500 that has been bandied about. Squire said "a major effort" is being made to get the backlog

cleared up within a year. "That's not a promise, that's our optimistic goal," he said.

The major problem is logistics, Squire said. "There's an enormous amount of data coming out of computers. Pathologists won't sign a report unless they are confident there has been no computer error."

The backlog refers only to those chemicals on which tests have been completed, not those still in the pipeline. Seventy-three chemicals were put on test this year, "all that available resources can handle," Squire said. Another 51 have been approved for testing and are waiting to go on.

"We can handle about 50 a year, going into the pipeline, and with more manpower probably could handle 100," Squire said. Thanks to Obey, the Carcinogenesis Program will get all the manpower it needs, if it can recruit the right people. "We don't intend to get all 60 of those positions (written into the appropriations bill by Obey)," Squire said. "But we certainly can use some additional help."

The Toxic Substances Act passed this year by Congress could have a major impact on NCI's Carcinogenesis Program. The Act authorizes the Environmental Protection Agency to order tests of suspected dangerous chemicals, including potential carcinogens. This includes pre-market testing of new chemicals as well as those already in use which one way or another become suspects.

It would appear that EPA now has the authority to assume control of carcinogenesis bioassays, a move that probably would be welcomed by NCI. Research is NCI's primary mission, and the scientist-managers there would like to get out of the business of large scale testing of chemicals, concentrate on carcinogenesis research, and leave the routine testing to the regulatory agencies.

RFPs AVAILABLE

Requests for proposal described here pertain to contracts planned for award by the National Cancer Institute, unless otherwise noted. Write to the Contracting Officer or Contract Specialist for copies of the RFP. Some listings will show the phone number of the Contract Specialist, who will respond to questions about the RFP. Contract Sections for the Cause & Prevention and Biology & Diagnosis Divisions are located at: NCI, Landow Bldg., NIH, Bethesda, Md. 20014; for the Treatment and Control Divisions at NCI, Blair Bldg., 8300 Colesville Rd., Silver Spring, Md. 20910. All requests for copies of RFPs should cite the RFP number. The deadline date shown for each listing is the final day for receipt of the completed proposal unless otherwise noted.

SOURCES SOUGHT

RFP NCI-CB-74137-34

Title: *Serum collections from patients biopsied for benign and malignant breast lesions*

Deadline: *Dec. 17*

Provide sera from patients scheduled for primary biopsy of benign and malignant breast lesions. The minimum patient load considered necessary for such an effort is in the range of 500 biopsies annually. The sera will be banked for future use in evaluating potential diagnostic tests for breast cancer. The candidate institutions should be prepared to collect 30 cc of blood prior to biopsy, process, label and ship the serum to central banking facility. Clinical documentation on each patient donor and histologic diagnosis should be submitted with sera. Access to specimen slides and blocks should be made possible for review. A resume of capabilities should be in the form of a brief letter expressing an interest and stating qualifications.

This is not a request for proposals. Responses should not include cost or pricing information. Responses should be specifically directed to the points mentioned herein. Only those sources which are considered to be most highly qualified for this project will be invited to submit a proposal at the time a request for proposal is issued. Sources that are judged not to have superior qualifications will not be notified. Organizations interested should submit 15 copies of the resumes of experience and capabilities.

Contract Specialist: E.J. Abbott
Biology & Diagnosis
301-496-5565

PROPOSED NONCLINICAL LAB REGULATIONS

The Food & Drug Administration published in the Nov. 19 *Federal Register* its proposals for regulations for methods, facilities and controls for conducting nonclinical laboratory tests. The regulations grew out of FDA's reported discovery of alleged deficiencies in tests conducted by and for pharmacuetical companies on certain color additives. FDA will accept comments on the proposals until March 21.

SOLE SOURCE NEGOTIATIONS

Proposals are listed here for information purposes only. RFPs are not available.

Title: National cancer consultative programs for hospitals

Contractor: The American College of Surgeons, for an additional four month extension.

The Cancer Letter—*Editor* JERRY D. BOYD

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