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New Breast Cancer Trials To Include Pre Vs. Post Operative Chemotherapy, CSF Pilot Studies

Cooperative groups and NCI's Cancer Therapy Evaluation Program, developing strategy for the next round of breast cancer clinical trials, have concluded that a major new study will be undertaken comparing preoperative vs. postoperative chemotherapy for both node negative and positive patients and that pilot studies should be initiated to determine the

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In Brief

Warren Ross Named Director Of Louisville's Brown Cancer Center; NCI Landow Offices Moved

WARREN ROSS, associate professor of pharmacology and medicine at the Univ. of Florida College of Medicine, has been named director of the James Graham Brown Cancer Center in Louisville. Ross is principal investigator for one of NCI's new drug discovery groups, studying the enzyme topoisomerase as a new chemotherapy target. The group headquarters will move with Ross from Florida to Louisville. Daniel Sullivan, a member of the group, will also move, along with two post doctorate fellows and a staff person. Ross was a clinical associate in pediatrics and medical oncology at NCI from 1975-1978. He takes over from acting center director, Thomas Woodcock, who is chief of the Div. of Hematology/Oncology. The cancer center is part of the Univ. of Louisville School of Medicine. It does not now have an NCI center core grant but will compete for one. . . . **ALL NCI** offices which have located in the Landow Building in downtown Bethesda have been moved to the Executive Plaza Building in Rockville. Phone numbers remain the same. NCI offices in the Blair Building, in Silver Spring, will be moved in September and October. All those phone numbers will be changed. The Grants Administration and Extramural Financial Data Branches, in the Westwood Building located in western Bethesda, will be moved to Executive Plaza in October. The Div. of Extramural Activities offices in Westwood will not move to Executive Plaza until sometime next spring. . . . **MICHAEL BISSELL**, assistant professor of pathology at the Univ. of Chicago Pritzker School of Medicine and director of general clinical chemistry at the Univ. of Chicago Hospitals, has been named director of clinical pathology at the City of Hope in Duarte, CA. . . . **VAY LIANG GO**, professor of medicine and consultant in gastroenterology at Mayo Clinic, has been named chairman of the Dept. of Medicine at UCLA.

NSABP To Do Pre Vs. Postoperative Therapy, New Node Negative Trials

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feasibility of using colony stimulating factor with intensive dose chemotherapy regimens in adjuvant therapy.

The National Surgical Adjuvant Breast & Bowel Project will undertake the pre vs. post-operative chemotherapy trial, designated NSABP B-18.

NSABP also will replace two node negative trials which were, in effect, closed when the groups and CTEP decided it was no longer ethical to enroll breast cancer patients with negative nodes in no treatment arms. Those were NSABP B-13, in which node negative, estrogen receptor negative women were randomized to sequenced methotrexate and 5-FU or to no treatment following surgery; and NSABP B-14, in which node negative, ER positive women were randomized to tamoxifen or no further treatment.

NSABP is still accepting patients in B-13 and B-14 but randomization to observation alone has stopped.

Intergroup study 0011 was closed. That trial, by the Eastern Cooperative Oncology Group, Southwest Oncology Group and Cancer & Leukemia Group B compared the combination of cytoxan, methotrexate, 5-FU and prednisone to no adjuvant therapy in patients with resected node negative breast cancer.

NSABP's new generation of node negative trials have not yet been finally determined. Tentatively, they will consist of B-19, for ER negative women, and B-20, for ER positive patients. They will build on the group's experience in B-13 and B-14, and most likely will include tamoxifen at least in the ER positive protocol.

ECOG and SWOG have been talking about initiating a new intergroup study, but no agreement has been reached on what that would be. Other groups might be invited to participate.

CTEP and the groups have been discussing a new high priority breast cancer study, with no decision yet. One and possibly more of the trials currently under negotiation could be selected.

Intergroup 0011 was one of six high priority trials, designated as such under CTEP's new policy of attempting to speed up accrual to those studies which could have a major impact on mortality. Trials are selected for high priority status by CTEP and the group chairmen, with approval of the DCT Board of Scientific Counselors.

Ongoing breast cancer clinical trials conducted by the cooperative groups are cited in the overview of breast cancer research starting on page 3.

Meanwhile, NCI has issued a press advisory which emphasizes several points that arose from the "clinical alert" on treatment of node negative breast cancer, sent out last May.

The clinical alert, widely distributed to the nation's physicians, advised them that adjuvant chemotherapy or hormonal therapy should be considered for node negative breast cancer patients.

NCI has taken considerable criticism for sending out the alert, which was based on results of three studies before they were published, and on three foreign studies. NCI Director Vincent DeVita justified the alert on the basis that it was approved by the National Cancer Advisory Board, the PDQ editorial board and the NCI Executive Committee; that 30 percent of node negative patients recur, and that cooperative group chairmen and the Div. of Cancer Treatment's Cancer Therapy Evaluation Program had decided to stop accruing patients to untreated control arms of their node negative studies. He insisted that node negative patients and their physicians had a right to that information immediately to help them make their treatment decisions.

DeVita also advised "New England Journal" Editor Arnold Relman of the decision to issue the alert prior to publication of the studies. Relman assured him the alert would not jeopardize publication in "NEJ."

The new press advisory deals with questions patients and some physicians have been asking since the alert was issued. It emphasizes that not all node negative patients are in the 30 percent recurrence category, and that several important questions remain to be answered.

"The American studies did not include women with preinvasive or in situ breast cancer (confined to the site of origin, without invasion of neighboring tissues)," the statement says. "Adjuvant therapy is not considered necessary for these noninvasive cancers.

"The studies included very few breast cancers that are very small (under 1 centimeter) but that are invasive. There are no data yet to indicate whether or not adjuvant therapy is clearly beneficial for these cases. Women and their physicians should discuss the treatment options."

The advisory added these statements and questions:

"It should be noted that the available data from these clinical trials leave unanswered several important questions regarding the best treatment for node negative breast cancer. These include:

*What is the extent of benefit from adjuvant therapy for women with very small invasive tumors?

*What is the best treatment policy for women whose diagnosis and initial surgical therapy took place more than six to eight weeks before consideration of adjuvant treatment? Is any treatment effective under these circumstances?

*Which treatment is the preferred one for patients with node negative breast cancer--tamoxifen or combination chemotherapy?

"Decisions on these points are a matter of clinical judgment and should be made on a case by case basis by the physician and patient."

Status of Breast Cancer Research Updated In Overview Compiled By NCI

The overview of breast cancer research compiled recently by the Organ Systems Section of NCI's Div. of Cancer Prevention & Control included reports on the status of all areas of the disease. In the last two issues of **The Cancer Letter**, the overview's sections on epidemiology, prevention, carcinogenesis and biology were published; following are the reports on detection, diagnosis and treatment, which completes publication of the overview.

Copies of the overview may be obtained from either Andrew Chiardo, OSP section chief, or Elizabeth Anderson, breast cancer program director, NCI, DCPC, Blair Bldg Rm 717, Bethesda, MD 20892, phone 301/427-8818.

Detection and Diagnosis

Research shows that aggressive screening programs for women over 50 can reduce breast cancer mortality by 30 percent. NCI's current screening guidelines state that all women should be encouraged to do monthly breast self exams; physicians should be encouraged to do a breast examination during a woman's routine checkups; and beginning at age 40, all women should be encouraged to have a mammogram every one to two years until age 50, after which it should become annual.

The new "Working Guidelines for Early Cancer Detection, Rationale and Supporting Evidence to Decreast Mortality" has been developed to address the needs of patients in the offices of physicians. The guidelines also encourage increased physician use of clinical examination and increased women's use of breast self examination.

Meanwhile, research is in progress to find ways to increase the use of mammography and breast self examination. For example, a program is under way in Florida to encourage the teaching of breast self examination in high schools and is studying how the NCI Cancer Information Service can be used to increase the utilization of mammography.

At the more basic level, research programs are exploring techniques for improving breast cancer diagnosis and for improving predictions of clinical outcome. Steroid receptor assays already are being used to identify patients whose disease may respond to hormone therapy. Patients whose tumor cells are receptor negative have a much poorer prognosis. However, there is a proportion of patients who are resistant to anti-estrogen therapy even though receptors are present in their tumors. Since some patients' tumors are heterogenous, the assessment of receptor activity has required the development of sophisticated new techniques that quantitate receptors on a cell by cell basis. If there is a subpopulation of cells which does not have receptors, these cells may continue to grow even in the presence of anti-estrogen therapy. It is also possible that some receptor containing cells do not respond because of other factors affecting growth regulation. Presently, focus is on the high level of production and secretion of certain growth factors by these unresponsive cells that seem to modulate the ability of estrogen receptor positive cells to respond to the steroid. This suggests that these cells may produce their own autocrine mechanisms to facilitate resistance to therapy.

Another important area is the search for molecular markers of tumor cells which may be useful in monitoring therapy, indicating recurrence and in developing new patient therapies. An important cellular antigen recently described, the human milk fat globule membrane protein, seems especially useful in this regard. Antibodies now available against this protein crossreact with tumor antigens and may be useful to target against the tumor cell. Women with breast cancer, but not normal women, also have components of the globule membrane in their boood and the antibody is being tested for its usefulness in diagnosis or

monitoring treatment. After surgery, this marker disappears and a later reappearance may indicate recurrence of disease.

Amplification (multiple copies) of the HER-2/neu oncogene correlates directly with poor prognosis and predicts recurrence of disease. Probes are being used to measure gene amplification as part of diagnosis.

A radiolabeled monoclonal antibody (MaB b72.3) is being developed as a useful marker for detecting and localizing metastatic breast lesions. B72.3 labeled with higher doses of radioactivity is now undergoing clinical trials to determine its therapeutic value in suppressing tumor growth.

Treatment

The major goals of the breast cancer treatment research program are threefold. Firstly, the extramural program sponsors drug development trials in order to identify new and more effective agents in the treatment of breast cancer. Both cytotoxics and biologic response modifiers are being studied. Radiolabeled antibodies are evaluated for their potential imaging and cytotoxic targeting capabilities. Studies to identify breast cancer antigens that might be used for screening or staging are ongoing. Secondly, the program supports novel approaches for the treatment of breast cancer, such as bone marrow transplantation, chemotherapy dose intensification incorporating colony stimulating factors and hormonal synchronization of tumor followed by cytotoxic therapy. These studies are carried out in individual institutions, cancer centers and in the clinical cooperative groups supported by NCI.

The third role of the program is to test the highest priority hypothesis for improving the treatment of patients with metastatic breast cancer or for improving their adjuvant therapy by coordinating randomized clinical trials, conducted in the clinical cooperative groups (NSABP, SWOG, CALGB, ECOG and NCCTG).

Current activities include:

*CALGB 8642 and NCCTG 87-32-52--These studies are comparing standard chemotherapy (CAF or CSP) to new cytotoxics in patients with metastatic disease. The purpose of these studies is to test new agents in patients without prior therapy for metastatic breast cancer while comparing survival to insure that the initial therapy with new agents does not negatively impact on the overall disease outcome.

*SWOG 7827--In premenopausal estrogen receptor positive women, CMFVP is being compared to CMFVP plus oophorectomy. In postmenopausal estrogen receptor positive women, tamoxifen is compared to CMFVP with or without tamoxifen. ECOG is participating in this study with SWOG.

*CALGB 8541--This trial randomizes patients to intensive CAF for four cycles vs. standard dose CAF vs. low dose CAF for six cycles.

*NSABP 15--This is a three arm clinical trial comparing short intensive adriacyclophosphamide (ACD) chemotherapy with and without reinduction chemotherapy (CMF) vs. conventional CMF in node positive premenopausal patients.

*NSABP 16--This is a three arm clinical trial comparing tamoxifen alone with melphalan, adriamycin, 5-FU and tamoxifen (PAFT) or with short intensive adriamycin, cyclophosphamide and tamoxifen (ACT) in node positive postmenopausal patients.

*SWOG 8313--In this study, postmenopausal node positive women are randomized either on short intensive adriamycin containing regimen (5-FU), adriamycin, cyclophosphamide and methotrexate) or to one year of standard chemotherapy (CMFVP).

[Intergroup 0011 and NSABP 13 and 14 were included in the overview, which was initially compiled while they were active and carrying out their protocols as planned. See previous article].

All of these adjuvant trials are near completion and will be replaced within the coming year.

Additional studies include the investigation of normal breast, benign breast diseases, breast carcinomas of different histologies, and metastatic breast tumors in various sites in an attempt to identify important markers of the development and progression of malignancy, prognostic factors of malignancy, and areas of treatment potential. A tissue bank with available clinical data has been organized which will be used to screen various benign and malignant breast tumor for oncogenes, growth factors, hormone receptors, drug resistance and kinetic alterations. Along with this information and clinical information a clearer picture of the progression of breast cancer will be obtained along with the development of new treatment strategies.

The clinical goals are to take information obtained in the laboratory and apply it to the treatment of breast cancer. This includes identifying targets for growth factor blockade, developing antibodies to breast cancer

antigens, changing breast cancer kinetics in vivo, increasing binding of drugs to certain enzymes important for tumor cell growth, blocking hormone receptors in tumor cells, and developing a drug sensitivity assay to determine the best drugs to use.

In addition, a study of early breast cancer is ongoing. This study includes assessing patients for local control, survival, psychological response to the diagnosis and treatment of breast cancer including psychosexual problems, rehabilitation during and after local therapy with determinants of cosmetic and functional outcome, and for the effect of breast reconstruction on patients psychological outlook.

The current NCI protocols at the NIH Clinical Center include:

--A multimodality regimen of a dose intensive combination chemotherapy with hormonal synchronization in stage 3 and 4 patients (CAMFTP).

--A salvage regimen of 5-FU, high dose leucovorin and carboplatin.

--A combined endocrine regimen of tamoxifen, aminoglutethimide, and leuprolide.

--Infusional vinblastine in patients who have had a skin biopsy of a recurrence to determine if a drug sensitivity assay is predictive of response.

--An adjuvant trial in male breast cancer.

--A randomized study in patients with metastatic breast cancer and one site of recurrence to local treatment alone vs. combination chemotherapy.

--A study in early breast cancer randomizing patients to lumpectomy and radiation therapy vs. modified radical mastectomy.

The overview pointed out that NCI supports research on all aspects of breast cancer, its cause and prevention, early detection and diagnosis, treatment and control. "Increasing emphasis is being placed on prevention and control of the disease. Recent advances in molecular biology and immunology are accelerating applications to clinical research and to prevention and control research. Large scale communications programs are under way to alert women and their physicians to the importance of early detection and up to date treatments. In FY 1987, total NCI expenditures on breast cancer research was $60.894 million."

Correction: Rose Kushner, in justifying her new BreastPac political action committee, was incorrectly quoted on NCI spending (The **Cancer Letter**, July 8). It is $451 per new case, not $50.

Cancer Letter Accepts "Substantial" Settlement In New Copyright Claim

The Cancer Letter Inc. has accepted a substantial cash settlement from an organization which the newsletter company had discovered was photocopying entire issues of **The Cancer Letter.**

Amount of the settlement and identity of the organization were not revealed, under terms of the agreement. "It is a significant amount, which reflects the seriousness with which we view violations of our copyright," Cancer Letter Editor Jerry Boyd said.

This was the second copyright infringement claim pursued by The Cancer Letter Inc. within the past 12 months. The first, involving a New York public relations firm, was settled last November and reported then in **The Cancer Letter.**

"We were disappointed that these violations continued despite the warning the previous case should have conveyed," Boyd said.

"We always give permission for copying single articles from our newsletters as long as appropriate credit is given," Boyd continued. "But we absolutely refuse to permit copying or reproducing by any means entire issues of our newsletters. Most of our subscribers understand our reasons for this policy and comply with it and the law. The few who do not are not fair to the rest. Our subscription price is modest compared with the industry average for a weekly newsletter. Any dilution of our subscription base eventually will be reflected in a higher price.

"We understand that organizations we serve frequently have several persons who read the newsletter. If that need cannot be met by passing each issue around, additional subscriptions are not much more costly than photocopying when staff time is considered, they are legal, and they certainly are cheaper than defending against copyright infringement."

Violators of copyrights are not only subject to payment of statutory damages of up to $50,000 for each work violated, plus legal costs, but also to criminal penalties under certain circumstances. The copyright prohibits reproduction as well as storage in a retrieval system, recording, and transmission by any means, including electronic, without prior permission of the publisher.

NCAB Decision On Comprehensive Center Issues May Be Made In Sept.

The National Cancer Advisory Board Centers Committee will meet on the evening of the first day of the Board's Sept. 26-28 meeting, with the possibility that it will reach a consensus on recommendations for a revived and enhanced comprehensive cancer centers program.

Recommendations made by the committee, chaired by John Durant, will be presented to the full Board at the Sept. 28 session. NCI could proceed with drawing up details for implementation, possibly with further consideration by the committee and Board at the December or February meetings.

Durant and other committee members will have the rest of the summer to study and analyze the transcript of the July workshop, in which directors and other center representatives discussed and debated the NCI staff proposal for a revamped comprehensive center program.

Durant said that he felt the workshop participants supported a strong program, including most of the proposed "descriptors" (or characteristics) which comprehensive centers would be required to possess; that they were not enthusiastic about tying comprehensive recognition to the proposed P60 grant but did favor rigorous, periodic peer review; and that the proposed program, carrying with it additional demands on comprehensive centers, depended on a substantial increase in NCI's cancer centers budget (**The Cancer Letter**, July 29).

Durant indicated that comments by the workshop participants, as well as written opinions offered in response to the questionnaire sent out by NCI, would be considered in developing the committee's recommendations. Many of the written responses appeared in the May 6 issue of **The Cancer Letter**, along with the response of the Assn. of American Cancer Institutes. Many of the comments made at the workshop follow.

Walter Lawrence, past director of the Masssey Cancer Center at Medical College of Virginia, on the proposed requirement for participation in high priority clinical trials:

"Despite the fact that we have effective cooperative clinical trial groups, oncology clinical trials are not answering current cancer research questions fast enough. The major defect producing this problem is slow patient accrual in phase 3 trials. We need more physician and patient participation in these trials, particularly those that deal with the common cancers.

"Can NCI designated centers play a role in solutions? How? What are the specific organizational structures for producing coordinated efforts without interfering with the uniqueness or self determination of centers? How is it determined which clinical trials will be designated as high priority? How would cancer centers actually recruit more physicians not now participating, and their patients, into these studies? Through reimbursement? That may well be. Or simplify protocols?

"Would patients cared for and studied by cancer center oncologists be entered into national phase 3 trials? Or would they participate instead in feasibility studies for the next generation protocols?"

Lawrence offered those questions as items for consideration by the workshop.

Sydney Salmon, director of the Arizona Cancer Center in Tucson, was responsible for reviving interest in comprehensive centers when he asked NCI Director Vincent DeVita to consider his center for recognition as comprehensive. It was the first such request since 1979, when Columbia Univ. became the last to be so recognized. DeVita decided that it was time to review the entire issue of comprehensive centers--whether they were still needed, whether the requirements should be updated, how the review should be done.

Salmon described the attributes of his center which he feels makes it comprehensive--it has a broad array of basic research projects, it is deeply involved in clinical trials, particularly as a member of the Southwest Oncology Group, it has a very active prevention and control program headed by Frank Meyskens including some statewide screening efforts (melanoma, colorectal and mammography), and it has an active outreach program through satellite offices around the state.

The center took the lead in pushing through the Arizona legislature a bill requiring insurance carriers which reimburse for mastectomies to pay for mammography screening. "Our dean said it was a model of the way a university can become involved in a major health issue."

Ross McIntyre, director of the Norris Cotton Cancer Center at Dartmouth-Hitchcock Medical Center, agreed that cooperative groups have made major contributions and "have tremendous potential. On the other hand, the

cooperative group mechanism has undergone major attrition. Some of it has been useful pruning, but some recent cuts have affected the trunk. How can we increase group participation when the budget is restricted?"

McIntrye said that the New Hampshire legislature, in a state which has no income tax or sales tax, "has given new meaning to the state's motto, 'Live free or die.' State participation in cancer programs is mediocre, with only a small appropriation to the state health department for cancer prevention."

John Glick, director of the Univ. of Pennsylvania Cancer Center, responding to the concerns expressed on how cooperative group studies are initiated and how selections will be made for high priority trials:

"During the last year, with CTEP (NCI's Cancer Therapy Evaluation Program) support, cooperative group leaders get together to plan the next generation of studies. I have a lot of confidence in this. As for the next generation of ideas for high priority studies, where will they come from? NCI intramural? I hope so. The centers? I hope so. Sometimes it takes two to three years for a well designed trial in a center to be ready for high priority."

Paul Carbone, director of the Univ. of Wisconsin Clinical Cancer Center and chairman of the Eastern Cooperative Oncology Group, pointed out that one third of ECOG's patients are entered from community hospitals. That has helped increase accrual to treatment protocols. However, "where we don't have a good mechanism is in prevention trials. I don't think community hospitals can offer the kind of people (needed for prevention trials) that centers can. We know we can decrease mortality by one third in breast cancer (with screening and early detection), but centers are doing very little."

Helene Brown, director of community applications at UCLA's Jonsson Comprehensive Cancer Center, asked Salmon, "What do you see that comprehensive recognition will bring to your center that you don't already have?"

"Some additional money, with expanded overall funding of the center. The ability to better coordinate outreach activities that are not permitted in the P30 grant (the existing center core grant)," Salmon replied.

Jerome Yates, associate director for clinical affairs at Roswell Park Memorial Institute and former director of the Centers & Community Oncology Program at NCI, on examples of intercenter collaboration, one of the proposed "descriptors" of comprehensive centers:

"The MRI story started out well (when AACI members joined to win an NCI contract to compare MRI with other modalities in various tumor sites), but Gramm-Rudman got in the way (the contract was terminated because of a budget reduction). Another was the flow cytometry cell sorter."

Yates suggested as a possible collaborative project a study in states where mammography legislation has been passed to collect and pool data on how to get women into screening. "There are some important developments in new technology where centers could pool information, and maybe move a little faster than we did with the cat scanner."

John Ultmann, director of the Univ. of Chicago Cancer Research Center, noted that the proposed new characteristics do not seem to include consortia centers. Chicago is part of the Illinois Cancer Council, a statewide consortium of universities, hospitals and cancer centers which is one of the 20 presently recognized comprehensive centers.

"The bottom line is that none of the universities could do what the consortium does, for NCI and for themselves. We have a broad based cancer prevention and control program. None of the institutions could do that alone without being accused of trying to grab patients."

Ultmann deplored the fact that "every President has ignored NCI's bypass budget. That budget (NCI's initial request which goes directly to the White House) is put together by knowledgeable people. It has a scientific basis, and describes how we can reduce cancer mortality by the Year 2000. There is nothing wrong with the Cancer Centers Program that couldn't be fixed by realignment of priorities in the office of the President of the United States and in Congress.

"In 1988, every member of the House of Representatives is up for reelection. One third of the Senate is up for reelection. And this year we are electing a President and Vice President. No prior platform of either party has ever contained a plank on biomedical research. The people that will make a difference are not Vince DeVita, or Peter Greenwald (Div. of Cancer Prevention & Control director), or Bob Young (director of the Centers & Community Oncology Program). They do their best with what they have."

Ultmann, who is chairman of the National Coalition for Cancer Research, urged the centers executives to contact their own representatives and senators, and the

presidential candidates. "Make everyone understand that biomedical research should have a high priority. Get them to pledge that it will have a high priority, or they will not get elected."

Gordon Zubrod, director emeritus of the Papanicolaou Comprehensive Cancer Center at the Univ. of Miami Medical School, said "I find myself in general agreement with using the P60 mechanism to designate a comprehensive center." The P60 grant has been used by a few institutes at NIH but not by NCI. It permits support of a broader array of activities than the P30.

Zubrod suggested that speeding up accrual to therapeutic clinical trials, while important, "will not get us to the Year 2000 goal. Prevention will do that. The requirement for clinical trials participation should include prevention trials."

The National Heart, Lung & Blood Institute does not have a mechanism comparable to NCI's cooperative groups, but it has carried out very successful prevention clinical trials, Zubrod said. "Maybe the cooperative group mechanism is not the one to get a high priority major question in prevention answered."

Brian Henderson, director of the Univ. of Southern California Cancer Center, asked "What is it that's broke?" that brought on consideration of changes in the comprehensive center guidelines. He acknowledged clinical trials deficiencies and the need for stepped up prevention efforts "that might be better addressed by centers. But that doesn't mean the criteria for designating and funding centers need to be changed."

"We don't perceive that anything is broke," Durant responded. "Just, are there ways to do it better? Things such as moving town to gown. Training. How do centers become a more meaningful part of NCI? The P60 is seen as a gimmick. We shouldn't focus on that."

"There are two separate issues," Henderson said. "The focus on the P60 grant confuses me. We can focus on better accrual, better research, better community involvement. We should keep it separate from funding. We can do this without coming up with another funding mechanism."

"What might be more valuable than money is holy water," Durant said, as he referred to NCI's "blessing" of a center by designating it comprehensive.

Gordon Cohn, director of public relations and marketing at the USC center, suggested that one of the problems in accruing patients for clinical trials has been the efforts by small hospitals to sell themselves as cancer centers. "I believe there is a large number of cancer patients not available for clinical trials because they are being bombarded with full page ads which is confusing them on where to go for treatment."

Cohn suggested that the term "NCI designated" be emphasized for comprehensive and clinical centers which qualify for that term.

Francis McKay, executive vice president of Fox Chase Cancer Center, reported that his discussion group (one of six at the workshop) had attempted to come up with a name other than "comprehensive." The growing use of that term by community hospital programs, has "diluted" its effectiveness in describing a large center with basic and clinical research, outreach and cancer control, as originally intended by NCI. McKay's group suggested alternatives might be "National Cancer Center" or "Presidential Cancer Center."

Robert Capizzi, director of the Wake Forest Univ. Cancer Center, said that a potential major impediment to patient accrual from community hospitals is the recent decision by the NIH Office for Protection from Research Risk to require every hospital, no matter how small, to have its own IRB before it can participate in clinical trials.

"Heretofore, they have relied on our IRB," Capizzi said. "Now, with the requirement for each to set up its own IRB, we have had to deny accession to some." It is completely impractical for the smaller hospitals to have their own IRBs, Capizzi said.

DeVita pointed out that Vice President George Busch has asked Chairman Armand Hammer of the President's Cancer Panel to look at the impact of regulations on cancer clinical trials. "The OPRR issue should be No. 1," DeVita said. "It is clear that we can't go forward being handcuffed like this. The Panel will form a committee, hold hearings, and make recommendations. We'll make sure the major issues are covered. OPRR is one of them."

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