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SURGEONS FEEL COOPERATIVE GROUPS DISCRIMINATE AGAINST THEM, ASK FOR BETTER DEAL FROM CCIRC

"The point I'm trying to make is a financial one. A pattern has emerged that is discriminatory to surgeons. The money for surgeons in the Cooperative Groups is not nearly enough. If we're trying to get more surgeons involved in Cooperative Group studies, that won't do it."

Theodore Grage, associate professor of surgery at the Univ. of Minnesota, was a member of the Central Oncology Group, the group made up primarily of surgeons which was phased out because, in the opinion of reviewers, it was not performing well enough to compete for funds with the other groups.

(Continued to page 2)

In Brief

FDA COOL TO COMMITTEE REVIEW OF INDs; NEW COMMISSIONER IS DONALD KENNEDY, OF STANFORD

FDA PROBABLY will not agree to permit an advisory committee to review IND applications, as suggested by the Assn. of American Cancer Institutes as one way out of the conflict between cancer investigators and the agency. FDA executives feel that the law places responsibility on them to determine issues of safety and to hold back or release drugs for investigation. FDA does use advisory committees to make recommendations on whether or not to approve NDAs, although being careful to note that committee decisions are advisory and that the final decision is up to FDA staff. NCI does not feel that committee review of INDs is necessary to working out a mutually agreeable system with FDA which will eliminate abrupt, capricious and unjustified withholding of INDs. What is needed more than anything is the determination of FDA Bureau of Drugs Director Richard Crout to reach an agreement, and NCI is convinced Crout is so inclined. . . . **FDA HAS** its new commissioner—Donald Kennedy, professor of human biology at Stanford. Kennedy, 45, is the first non-MD to hold that job since 1965. His specialty is neurophysiology. . . . **NEW PUBLICATIONS:** "Chemotherapy And You," by Susan Golden, Cheryl Horwich and Jacob Lokich, Sidney Farber Cancer Center; and "Feeding the Sick Child," by Mikie Sherman. Both are available free, single copies or in bulk, from NCI's Office of Cancer Communications, Bethesda, Md. 20014. . . . **FOURTH UICC** training course in cancer research is scheduled for Sept. 4-17 in Budapest. The course is designed for junior post graduate students in biology and medicine under the age of 30 who wish to specialize in cancer research. Write for details to Laszlo Holczinger, Research Institute of Oncopathology, 1122 Budapest, Rath Gy. str. 7, Hungary. . . . **ANNUAL SEMINAR** of the National Capital Area Branch of the American Assn. for Lab Animal Science will be Sept. 7-8 in Cockeysville, Md. The theme will be "Current Concepts in Good Lab Animal Practices." Contact Gene New, NCI, Bldg 37-6B17, Bethesda, 20014.

MEDICAL ONCOLOGISTS DOMINATE GROUPS, SHUT OUT SURGEONS, GRAGE CONTENDS

(Continued from page 1)

Grage, a member of the Cancer Clinical Investigation Review Committee which does the reviewing of Cooperative Group grant applications, laid out his grievances for the CCIRC last week. In summary, Grage contended that:

- Surgeons who were members of COG and who were assured that they would be welcomed by other Cooperative Groups have found that the welcome sometimes has been less than enthusiastic.
- NCI's much ballyhooed decision to encourage Cooperative Groups to expand into and emphasize multimodal, multidisciplinary studies, supposedly to be implemented with a $2 million supplemental grant award, has not done much to bring in surgeons because very little of that money reached surgeons.
- Nearly all the principal investigators in the Cooperative Groups now are medical oncologists who are displaying little understanding of surgeons' problems and little inclination to bring surgeons into their groups as equal partners.

Grage claimed that only 5% of Cooperative Group patients are in adjuvant studies. "I don't think the program is going fast enough in the direction we want it to go. We're still on square one. . . . We need surgeons for their particular expertise. We need their good will, although that is worn mighty thin. We need them to educate their colleagues. We need surgeons to persuade large numbers of other surgeons to come into the groups. We have to combat the view by many surgeons that when one participates in adjuvant studies he is no longer a surgeon but is busy running around giving drugs and immunotherapy.

"This program needs more than anything else demonstrable success of adjuvant therapy."

Grage cited his own personal experience since leaving COG as an example of what is happening to surgeons who join Cooperative Groups. The Eastern Cooperative Oncology Group and the Cancer and Leukemia Group B both had studies under way at the Univ. of Minnesota. Grage elected to go with CALGB, and said he obtained assurances from B.J. Kennedy, CALGB principal investigator at the university, that "my participation would be that of a full and equal partner with full support to develop a strong partnership between medical oncology, surgery and radiation therapy."

Grage said that at that time CALGB "had only one adjuvant study, few solid tumor studies and very weak surgical representation. With my experience in the Cooperative Groups I believed I could accomplish more and do more good for the overall cancer effort in CALGB than joining ECOG, which has a far greater number of protocols in the solid tumors and had advanced substantially further in the field of adjuvant chemotherapy."

Grage said he provided Kennedy with a copy of "my grant with full particulars of my previous participation in COG activities, the resources of the Dept. of Surgery, my past experience as chairman of the Scientific Design Committee in COG, chairmanship of the Gastrointestinal Committee, study chairman of four major groupwide protocols, including a large scale adjuvant study in colorectal cancer and a preoperative radiation study for rectal carcinoma, a joint protocol with RTOG. The grant also clearly indicated that I submitted approximately 60 patients annually to group studies. Since I have enjoyed the fullest support by our chairman, Dr. John Najarian, I see almost every patient with carcinoma of the head and neck, esophagus, breast, pancreas, colon, rectum and lung, potentially available for adjuvant trials in group studies. My bibliography contains 24 publications related to COG studies. The due date for the grant was June 1, and my decision to join CALGB was indicated to Dr. Kennedy on May 4. Not a lot of time but surely enough time to xerox a few additional pages to be inserted in the grant."

After the grant was reviewed by CCIRC (with Grage absent, of course), Kennedy informed him that the Dept. of Surgery did not receive much support from NCI—$6,000. "To my great dismay," Grage said, "I discovered that in the grant application, consisting of 56 pages put together by B.J. Kennedy, my activities have been reduced to a short paragraph indicating that I will join the so-called Minnesota group in their CALGB activities. The bibliography had been reduced to a few irrelevant papers. The entire previous activities in group activities was completely eliminated.

"I do not blame the CCIRC for this. Money is increasingly tight and the reviewers must make their decisions based on the quality of grant applications, including the previous activities of the participating individuals. If no such information is on the grant they cannot, and will not provide the necessary financial support."

Grage said that Kennedy had, without his knowledge, reduced the surgery budget and had intermingled the surgical budget with those of radiation therapy and medical oncology, rather than prepare separate budget pages for each.

The result was that Grage has resigned from CALGB and will join ECOG.

Kennedy, contacted by ***The Cancer Letter,*** declined to respond to Grage's charges.

Grage made these recommendations to CCIRC to advance the implementation of multidisciplinary studies by Cooperative Groups:

—"Develop a logical program for the major tumor categories with phase I, phase II and phase III trials designed for the primary purpose of developing effective adjuvant studies.

—"Create educational opportunities for surgeons, medical oncologists, pathologists, basic scientists and

radiation therapists, to interact, possibly in the form of workshops to assess the state of the art, examine existing opportunities and to educate each other in our respective expertise.

—"Adjuvant trials should avoid the use of historical controls, have statistical input while the study is being developed, with a realistic estimate of case accrual and a design to validate even small but significant differences in treatment arms.

—"All future grant requests from participating institutions should contain a separate budget page for each therapeutic modality, medical oncology, surgery, and radiation therapy. The responsible scientist should be listed as either principal investigator or co-principal investigator. Controls of such funds should be by the respective individuals.

—"The Executive Committee should look into the issue of providing guidelines for funding of surgeons not co-principal investigators to enlarge the total number of surgeons participating in group activities to many times their present numbers.

—"To provide an environment conducive to scientific endeavors to recognize the contributions made by clinical scientists from several disciplines and to share the rewards and responsibilities of these endeavors, Groups should clearly state that they recognize the principle of 'prince among equals.' "

Grage expressed further his complaints in a letter to Div. of Cancer Treatment Director Vincent DeVita, written prior to last week's meeting:

"At the last meeting of the CCIRC after review of the first dozen grant applications by members of the Primary Breast Cancer Therapy Group, two out of three applications were turned down and it was only after I raised a howl that we started all over again and finally ended up funding at least some of the members. But, as you rightly pointed out, the net effect of the actions of the committee resulted in a substantial under-funding of a group which by any standard has been more successful addressing itself to the treatment of early solid tumors in an adjuvant setting than all of the other 'multimodal, multidisciplinary' groups combined.

"Also at that meeting each one of the surgeons, formerly a COG member, applying for support to participate in the surgical activities of SWOG, Eastern and Southeastern Groups, faced an unusually difficult uphill battle, necessitating a strong intervention on my part to see that these people got funded at all and at levels commensurate with their participation.

"When we finally got to the application of Dr. William Fletcher of Oregon, the committee members realized that he would be the single surgical principal investigator in these four multidisciplinary groups, the efforts of various committee members to disallow this grant application reached such a pitch that I finally blew my cool and pointed out that the committee was giving plenty of ammunition to those critics who have maintained that there is a strong anti-surgical bias on the CCIRC. Dr. Fletcher's grant application finally went through. In part because of this incident, Dr. D'Angio (CCIRC chairman) asked me to prepare for the CCIRC at its next meeting, a presentation addressing itself to the function, responsibility, and the role of surgeons in these four major cooperative groups.

"Since the Potomac Conference a fundamental shift in direction and emphasis has taken place toward clinical research in early, potentially curable solid tumors, based on the probably correct assumption that advances in cellular kinetics, chemotherapy, and radiation therapy had indeed paved the way for substantial improvements in cure rates in some of the major solid tumors. This challenge was enthusiastically accepted by all of the group chairmen, who promptly proceeded to effect the appropriate turnaround in their groups, with development of appropriate committees, protocols and supplemental fund applications to realize this goal.

"As a member of the CCIRC I have observed the subsequent changes with growing apprehension. Not only are all of the chairmen of these multidisciplinary groups medical oncologists/hematologists, but of the over 100 principal investigators in these four groups, with one exception, all are medical oncologists/hematologists. Of the six surgeons on the CCIRC during the past few years only one has made a substantial commitment toward cooperative group effort. By and large, academic surgeons have chosen to ignore the Cooperative Groups, and if I were to make a list of some 25 academic surgeons in this country most closely identified with cancer, almost none is participating in cooperative group efforts. Almost every medical oncologist/hematologist of some academic standing is in one way or another involved with the working of the Cooperative Groups, whereas the surgical community, which controls over 90% of the tumors that this effort is directed at, has chosen to remain at the sidelines. The morale of those surgeons who have chosen to work in the cooperative groups is at an all time low. At the time of the Potomac Conference Dr. Guy Newell stated: "I wish I were a surgeon, those guys really have it made." I don't know of any single statement made at that meeting that could be further from reality.

"I may be the only one pointing out that 'The Emperor Has No Clothes,' but I am firmly convinced that the way the program is organized right now it has every potential built into it for significant failure."

CCIRC member William DeWys asked Grage, "How can you and your surgeon colleagues address the problem of quality control? Some may have stature as surgical oncologists but have little feeling on what cooperative groups are all about."

"It's no different than with medical oncologists," Grage said. "Surgeons have to provide the guidelines."

"But you always have a problem getting two surgeons to agree," DeWys commented.

"It's an enormous education problem, getting surgeons to understand," Grage said. "I spend a significant amount of my time on that."

CCIRC Chairman Giulio D'Angio said, "You've outlined the problems, both personal and conceptual. What can the committee do about it?" He suggested that each Cooperative Group could bring together surgeons to discuss and identify problems. "We need positive, concrete recommendations to make surgeons full partners."

Grage referred to his suggestion for workshops, "so that surgeons can educate each other."

CCIRC member Edward Beattie said, "There are two problems from a surgeon's point of view. One is the surgical approach–lesser versus greater operations. The surgeon is not interested in controlled studies. Another is the inability to convince surgeons that cancer is a specialty. We need a subspecialty in surgical oncology but we can't get it. We're told that it's ahead of its time."

CCIRC member Teresa Vietti said, "It's a good idea to have surgeons sign each budget page of grant applications. And we should be aware of which budgets we are turning down."

DeVita said he was "sympathetic" to the problems of surgeons, but told Grage that "much of what you said is confusing. Surgical oncology is in bad shape, but surgeons have to take at least 50% of the responsibility. Surgeons are responsible for breast cancer adjuvant studies being delayed for 15 years. You ought not to confuse the chaotic state of surgery with radiotherapy. Radiotherapists are well organized."

As for COG, DeVita said he wanted to "lay to rest the myth that it was disbanded because it was a surgeons' group, and that we wanted to kill it so the surgeons could be redistributed among the other groups." COG was denied continued funding because it could not compete in peer review, DeVita emphasized.

DeVita said that "Many Cooperative Groups won't make it into multimodal groups. If they can't, they may or may not survive. I don't believe every group should have a breast program."

Responding to an earlier statement by Grage that chemotherapy has not yet been able to cure any metastatic cancer by itself, DeVita said, "That is dreadfully incorrect. We have spent 15 or 20 years proving that. The reason that adjuvant studies are going on now is because we have proven that."

DeVita continued, "We do need surgeons in multimodal studies. Part of the reason for the failure of COG is that the group did not use its surgical expertise. We need suggestions on how to get surgeons more involved . . . surgeons must bear the responsibility for their field being in disarray. They hit their heyday 25 years ago and then sat on their laurels."

"We're not far apart on COG," Grage said. "The point I was trying to make was not whether it should have been discontinued. Those involved feel the good things we did were ignored."

The issue of developing a subspecialty in surgical oncology is a difficult one, Grage said. "Surgeons feel that this would rob the surgery field. Cancer is an important part of the training program."

CCIRC member John Bennett said that Grage's statement that 4-5% of cancer patients in Cooperative Group trials are in adjuvant studies was "taken out of context. It looks bad, but it is 200% greater than a year ago."

CCIRC member Alvin Mauer said, "Over and over, this goes back to the supplements for multimodal studies. As reviewers, we are in the business of funding ideas. We have to get back to reviewing ideas, not solving socio-economic problems."

DeVita disagreed. "Clinical research is more complicated than basic research, and clinical therapeutic research grants are usually considered too expensive by study sections. Medical economics are not appreciated by study sections. We need appropriate funding, to allow surgeons to make a living and devote time to group studies. We do need to consider socio-economic problems."

"This is disturbing to me," D'Angio said. "The committee was trying to remove impediments to progress by funding other specialties, the Potomac Conference ratified that. We were to take leads obtained in studies of advanced cancer patients and apply them to earlier stages. We will get patients in earlier stages by getting surgeons to bring them to us.

"We need to work with (NCI) staff to develop an evaluation. Why aren't surgeons more involved? Surgeons must do it themselves. If a surgeon is going to compete as a chemotherapist, that's how he's going to be judged. He will not be funded just because he is a surgeon."

D'Angio asked the four surgeons on the committee –Grage, Beattie, Jerome DeCosse and Frederic Herter –to form a subcommittee to study the issues.

The total budget for Cooperative Groups in 1977 fiscal year is $26.4 million. A little more than $2 million is the amount for which groups competed separately to fund multimodal expansion.

Hugh Davis, chief of DCT's Clinical Investigations Branch, told ***The Cancer Letter*** he has asked the groups to provide information on how much of that $2 million actually went to surgeons, radiotherapists, and immunotherapists.

Davis said some groups made subcontracting arrangements with institutions for surgeons and radiotherapists. These averaged from $10-15,000, with some as low as $5,000, some as high as $30,000.

A substantial portion of the $2 million went for start up costs, to establish statistical offices, discipline committees, extra travel requirements, and other items that probably will not be recurring. Davis pointed out that indirect costs, which grown to become a substantial portion of all grant awards, were funded out of the $26.4 million.

HYPERTHERMIA OFFERS PROSPECT OF MAJOR TREATMENT ADVANCE, INVESTIGATOR SAYS

"If the biology is properly done, there is a good possibility that this will yield a major advance in treatment techniques."

George Hahn, Stanford Univ., was describing his research using hyperthermia combined with chemotherapy and radiotherapy in a presentation to the Cancer Clinical Investigation Review Committee. Hahn said that animal tests indicate that hyperthermia used with drugs shows promise of improving control of metastasis and that hyperthermia with radiation demonstrates "considerable hope of controlling local disease."

Following is a summary of Hahn's presentation:

Raising the temperature to 43 degrees centigrade either before or after radiation has a demonstrable effect on cells in vitro. "Heat plus radiation is not just additive but is synergistic," Hahn said. Heat by itself can kill tumor cells. Tumor cells are more sensitive to heat, and normal cells are more resistant to hyperthermia.

The tests exposed cells to 43 degrees for various lengths of time, before radiation, after, and both. Combined pre- and post-heating appeared to get the best results. Longer heating periods increased the cell kill. One protocol called for 15 minutes of heating followed by radiation followed by heating for 45 to 60 minutes.

Heating in situ is accomplished either by electromagnetic waves or ultrasound systems.

In tests with mice, Hahn studied effects of heat combined with chemotherapy and heat with radiotherapy. "One problem we had was that the controls were cured so rapidly by heat alone." With one tumor type, heat alone, at 43 degrees, produced no cures, but increasing the temperature to 44 degrees produced 100% cures. But with another tumor type, no cures were obtained with heat alone. By adding drugs or radiation, "an appreciable" cure rate was obtained for that tumor, Hahn said.

In another experiment, no cures were obtained with five treatments of adriamycin. By combining heat with adriamycin, 75% of the animals were cured.

"We can design protocols in which we can get no kill of normal cells but an appreciable kill of tumor cells using heat in combination with chemotherapy and radiotherapy," Hahn said.

In one experiment, 75 animals with spontaneous tumors referred by local veterinarians were treated. All had advanced disease, frequently with lung or liver metastasis. Complete cures were obtained for 20, using heat with either drugs or radiation. There were partial responses in 40% of the animals. The remainder either were not evaluable or showed no response.

Hahn mentioned two clinical studies with human patients. One, with multiple squamous cell carcinoma with metastasis to the skull and lung, received radiation and cis-platinum. One of two nodules on the skull was heated and both were exposed to 4,000 rads. The nodule not heated has recurred, the one that was heated has not.

Another patient with thyroid cancer had been treated previously with radiation. Heat treatment was applied for one hour every other day for six weeks, with no further radiotherapy. Hahn said the tumor has shrunk appreciably and continues to shrink to the point where the patient is almost asymptomatic.

Hahn said that several manufacturers are developing equipment for application of heat. RCA has a microwave applicator which is commercially available. There is at present no ultrasound equipment available commercially, but at least two manufacturers are interested in that area, he said. Several are working on fibreoptic temperature monitors.

Whole body techniques using extra corporeal heating is another possibility, Hahn said. Whole body hyperthermia is done "almost routinely" at two places in England. NCI is starting a whole body trial using a type of "space suit" to raise the body temperature.

Hahn said that normal tissues are "remarkably able" to withstand increased temperatures. Three dogs in the experiment were killed because, having been fed prior to treatment, the temperature of the food in the body was increased past the critical point. Animals now are not fed for 24 hours prior to treatment. In whole body treatment, the temperature is critical. "Over 42 degrees, there are problems," Hahn said.

"There is a lot of work to be done on determining which tumors are more susceptible to hyperthermia," Hahn concluded.

BENNETT HEADS NCI DIRECTOR SEARCH COMMITTEE; EARLY APRIL DEADLINE

Ivan Bennett, dean of the New York Univ. School of Medicine, is the chairman of the search committee which started this week to look for a director of the National Cancer Institute.

The committee was scheduled to hold its first meeting this week. Plans call for winding up its work by the first week in April with the submission of at least two and possibly more names to President Carter. The committee was established by HEW Secty. Joseph Califano.

Other members of the committee are Bruce Ames, professor of biochemistry at the Univ. of California and a member of the National Cancer Advisory Board; Mary Ellen Avery, of Harvard; NIH Director Donald Frederickson; Robert Gallo, NCI scientist in the Div. of Cancer Treatment; Charles Moertel, director of Clinical Cancer Research at Mayo Clinic; and Benno Schmidt, chairman of the President's Cancer Panel.

Seymour Perry, special assistant to Fredrickson and former DCT deputy director, is executive secretary.

In Congress

SENATE FINISHES ORGANIZING WITH FINANCE/HEALTH SUBCOMMITTEE

Final committee organization in the Senate with authority in the health field was completed last week, the Health Subcommittee of the Finance Committee. This is the subcommittee which handles legislation on Medicare and Medicaid and will also have authority over national health insurance proposals.

Herman Talmadge (D.-Ga.) is chairman. Other Democrats are Abraham Ribicoff (Conn.), Gaylord Nelson (Wisc.), Lloyd Bentsen (Tex.) and Spark Matsunaga (Hawaii). Republicans are Robert Dole (Kan.), Paul Laxalt (Nev.) and John Danforth (Mo.)

The Health Subcommittee of the Human Resources Committee, chaired by Sen. Edward Kennedy, will have responsibility for most health-related bills.

The House Health Subcommittee, headed by Rep. Paul Rogers, approved and sent to the full committee last week HR 3539, Biomedical Research Extension Act, and HR 3538, Health Planning and Health Services Extension Act.

In listing members of the Senate HEW Appropriations Subcommittee, ***The Cancer Letter*** (March 4) left out the name of Sen. Birch Bayh. Bayh continues as a member of that subcommittee.

Health bills introduced last week include:

HR 4367, by David Obey (D.-Wisc.), to amend the Social Security Act to include eligible drugs, requiring a physician's prescription or certification and approved by a formulary committee, among the items and services covered under the hospital insurance program.

HR 4006, by Barber Conable (R.-N.Y.), to amend the Social Security Act to establish a program of long term care services within Medicare, to provide for the creation of community long term care centers and state long term care 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, citing the RFP number. Some listings will show the phone number of the Contract Specialist, who will respond to questions. Listings identify the respective sections of the Research Contracts Branch which are issuing the RFPs. Their addresses, all followed by NIH, Bethesda, Md. 20014, are:

Biology & Diagnosis Section – Landow Building
Viral Oncology & Field Studies Section – Landow Building
Control & Rehabilitation Section – Blair Building
Carcinogenesis Section – Blair Building
Treatment Section – Blair Building
Office of the Director Section – Blair Building
Deadline date shown for each listing is the final day for receipt of the completed proposal unless otherwise indicated.

RFP NCI-CM-87154

Title: *Adjuvant chemotherapy trial in head and neck squamous carcinomas*

Deadline: *May 20*

The goal of this project is to determine the adjuvant effects of chemotherapeutic agents which have been shown to induce relatively high incidences of remissions and increased remission durations in patients with locally incurable or metastatic squamous carcinomas, when used in conjunction with surgery with or without radiation therapy in the treatment of clinically localized, potentially curable head and neck squamous carcinomas.

Specific details of the trial include:

1. The comparison of the relative efficacy of high-dose preoperative chemotherapy and adjuvant radiation therapy in the surgical treatment of advanced head and neck squamous carcinomas.

2. The tumor sites will be limited to the floor of mouth, anterior tongue and anterior tonsillar pillar-retromolar trigone areas in the oral cavity, the supraglottic and glottic areas of the larynx, and the pyriform sinus.

3. The project is limited to the study of stage III and IV tumors as classified by the American Joint Committee TNM system and those classified histologically as squamous carcinomas.

4. The preoperative chemotherapy regimen, the radiation therapy regimen, and the surgical procedures will be standardized through joint agreement of the contractors and the project officer.

The initial preoperative drug regimen to be considered will consist of high-dose cis-platinum, bleomycin, and high-dose methotrexate. The projected patient accrual is of at least 125 patients per year each with carcinomas of the oral cavity and carcinomas of the larynx-pyriform sinus.

Additional criteria for patient selection include (a) no previous therapy for head and neck carcinoma, (b) no previous malignancy, excluding minor skin cancers, (c) minimal nutritional deficiencies only, (d) no contraindications to intense chemotherapy, (e) sufficient life expectancy for long-term followup, (f) social and geographical factors which favor adequate followup for the results of treatment.

Multiple awards are expected in order to meet the projected patient accrual. It is expected that each institution must accrue a minimum of 20 patients.

Contract Specialist: T. Hardy
Cancer Treatment
301-427-7463

The Cancer Letter—*Editor* JERRY D. BOYD

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