THE CANCER NEWSLETTER

Vol. 1 No. 17

May 31, 1974

Subscription $100 per year

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COOPERATIVE GROUPS SHOULD BE TRIMMED, BROUGHT UNDER CONTROL OF DCT, SURGICAL PANEL SUGGESTS

Cutting the number of clinical cooperative groups from more than 20 to a maximum of 10 and placing them under the control of NCI's Div. of Cancer Treatment which would exercise "a much stronger coordinating influence on clinical trials" was recommended by a panel of the Surgical Oncology Research Planning Conference.

The panel included Charles McKhann, Univ. of Minnesota; Robert Johnson, Univ. of Wisconsin; Peter Wiernik, Baltimore Cancer Research Center; and Richard Wilson, Peter Bent Brigham Hospital.

McKhann wrote to Benno Schmidt, chairman of the President's Cancer Panel, outlining his group's recommendations and presenting his argument for them. He told Schmidt that there has been "a proliferation

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In Brief

STIPENDS OUT FOR TRAINEES IN NEW CLINICAL PROGRAM, BUT THEY CAN BE PAID IF ANY MONEY IS AVAILABLE

CANCER CLINICAL education program which NCI is reviving *(The Cancer Newsletter,* April 26) won HEW approval only when stipends for trainees were removed. The Nixon Administration philosophy has been that the future clinicians will earn big salaries and thus should finance their own education. However, NCI grants division chief Palmer Saunders pointed out to the Cancer Panel that in the old program, nearly all trainees performed some kind of service, and the new scheme permits payment of salaries to students for services rendered. It still won't be like the good old days: the new program will be funded at $4 million a year, $3.5 million less than the old one. The $3.5 million was the amount paid to trainees, so there will be either fewer participating institutions, or little money for students. . . .**CIGARETTE BAN** which the Consumer Product Safety Commission thought it might have power to enforce (ban of high tar and nicotine brands, that is) won't happen. The commission voted 3-2 to reject a petition submitted by the American Public Health Assn., acknowledging that the legislation creating the body specifically exempted tobacco products from its jurisdiction. . . . **ANTICANCER AGENTS** developed by Mainland China are reported in a booklet compiled by C.P. Li for the NIH Fogarty International Center. It includes reports on scores of natural and synthetic compounds, with some clinical data. Li says we should not write off all aspects of traditional Chinese medicine: some MDs have demonstrated antitumor activity for seaweed and clams together with other ingredients. The publication *(HEW 74-441)* is available from GPO, Washington, D.C. 20402 for $2. . . .

ADVISORY GROUP TO REVIEW PROTOCOLS ASKED TO COORDINATE CLINICAL TRIALS

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of clinical evaluation programs to the point where there are now more than 20 large cooperative groups. This proliferation has been accompanied by serious and frequently detrimental competition at a variety of levels, including different extramural cooperative groups, intramural programs, grants vs. contracts, and therapeutic trials in special cancer areas and some cancer centers.

"There is a serious lack of coordination between ideas generated extramurally by cooperative groups and those developed by intramural programs or as contracts," McKhann wrote. "This proliferation and competition between many elements involved in clinical trials has led to two serious problems, a) overlap and duplication of effort, and b) development of new and novel protocols not well thought out.

"The entire clinical evaluation program is in serious need of strong, centralized coordination and guidance."

The cooperative groups are funded by grants administered by the Div. of Research Resources & Centers. They have received considerable acclaim for contributing to advances in cancer therapy, particularly in clinical trials of new drugs and drug combinations.

By definition, grant programs operate with a minimum of coordination (which is a less despised word than "direction") from NCI. The Div. of RR&C has given investigators great latitude to operate, without worrying too much about coordination.

The Div. of Cancer Treatment, on the other hand, is heavily involved in contract programs. Division director Gordon Zubrod and his associate director for cancer therapy evaluation, Stephen Carter, have been outspoken in their criticism of overlapping projects, lack of coordination, and diffusion of some programs throughout NCI.

"This whole thing is an attempt to bring the cooperative groups under the control of the treatment division," one NCI executive told *The Cancer Newsletter.*

That was openly the intent of the surgical panel, but Zubrod was the first to point out to Schmidt the impracticality of the suggestion.

"It is true that a large part of research in treatment is diffused throughout NCI," Zubrod said. "Two-thirds of it is not within the Div. of Cancer Treatment. But much of the decison making (in the treatment grant programs) is exercised by study sections. The division is not in a position to say to those funded by study sections how they should operate.

"How do you maintain the decision making process in the study sections, yet direct (grantees) to targeted goals?" Zubrod asked.

Palmer Saunders, DRR&C director, took issue with McKhann. "I don't know what he bases the contention on that there are too many cooperative groups," Saunders said.

"He sees the country divided into six to eight areas, not necessarily geographically," Schmidt said. "He would really get this thing organized."

Zubrod pointed out that the suggestion involve "a lot of delicate and touchy issues. There are so many useful and valuable things to do, so great are the opportunities, that there are more things to do than there are patients and investigators to do them. We need to develop some kind of priorities."

The recommendations by McKhann's panel, which are intended for inclusion with the updated surgical therapy component of the National Cancer Program Plan, follow:

—(A) The number of cooperative groups should be greatly reduced to a maximum of 6-10. Each group should include all appropriate disciplines and should be much less specialized than they currently are. Institutions participating in cooperative groups should be obliged to adhere to chosen protocols and not to skip around until sufficient data on each protocol has been obtained. Larger cancer centers should be encouraged to join cooperative groups or submit all major clinical studies to the same review procedures as the cooperative groups, as outlined below. Rare tumors may require the use of identical protocols by two or more cooperative groups in order to have sufficient input of patients.

—(B) The Div. of Cancer Treatment must exert a much stronger coordinating influence on clinical trials. The division has at its disposal important instruments for control and coordination of clinical studies, including financial support and new drugs. It should be the responsibility of this division to avoid wasteful overlap, determine the appropriateness of studies, insure adequate statistical analysis of data, obtain objective and authoritative review of all protocols (through its advisory committee), provide publicity to physicians and to the public concerning the protocol studies available and assure that the studies are large enough to obtain meaningful answers in a maximum of two or three years. It should be a primary responsibility of the division to coordinate all areas of clinical investigation in cancer including intramural contracts, in-house studies, grants, comprehensive centers and cooperative groups. This latter is essential if needless duplication is to be avoided.

It should also be a responsibility of the Div. of Cancer Treatment to review all protocols submitted from any source and to any division of the NCI and to advise cooperative groups, etc., about potential

overlap. To assist in this effort the NCI should develop extramural advisory committee to review all protocols and to provide input into the general development of adjuvant therapy. It should be the responsibility of this committee to review all protocols, sending their recommendations to the Div. of Cancer Treatment. In addition, this committee should evaluate the progress of the entire clinical research program annually and report its findings to the National Cancer Advisory Board. A much higher level of central coordination and protocol review is required if this objective of the cancer plan is to be achieved at all.

–(C) Development of protocols. Each cooperative group or institution (i.e., comprehensive centers) should file a letter of intent with the NCI before the development of a major new protocol. This letter of intent should outline briefly the general area to be covered. In return for this letter the group proposing the new protocol should receive from NCI a complete list of all protocol studies, including details of the actual protocols and copies of other letters of intent for all studies that are even remotely related to the new study being proposed.

The new protocol being developed should then account for any similarities or overlap with other protocols, acknowledging acquaintance with the overlapping protocol, and justifying clearly why such overlap or duplication should be permissible. The completed protocol should be submitted to NCI and from there to the Advisory Committee on Clinical Studies for evaluation. The advisory committee should make its recommendations to NCI and NCI in turn should pass its recommendation on to the cooperative group.

LASKER PUSHES NCI TO GET RESEARCH RESULTS QUICKER, INTO PRACTICE SOONER

Are results of research in chemotherapy and combination modalities being moved as quickly as they should into clinical practice?

Mary Lasker, who through the devotion of a great deal of time and money has been a prime mover in the National Cancer Program, does not think so.

Moreover, when new treatment regimens are recognized as more effective than accepted procedures, there seems to be no system whereby this knowledge is available to the public or all but a few physicians in the big cancer centers, Mrs. Lasker believes.

Benno Schmidt, chairman of the President's Cancer Panel, brought Mrs. Lasker's views and some suggestions to the panel's meeting last week. He said she had "left a briefcase full of material with me" supporting her charges and outlining her suggestions.

An example, Schmidt said, was when Sen. Edward Kennedy's son was diagnosed as having osteosarcoma, he was placed in the hands of investigators who had been developing adjuvant therapy regimens and had achieved some remarkable progress combining surgery with chemotherapy–"people who have been making the greatest contribution in that particular field," Schmidt said.

"But how about John Doe in Throckmorton, Texas?" Schmidt asked. "He's in a situation where he isn't getting that kind of attention. How does he know where to go to make inquiries?"

NCI's answer to this question, which has been asked many times, is that its information office responds to about 18,000 inquiries a year. Also, it has arranged with the National Library of Medicine, a component of NIH, to include cancer references in its MEDLINE system, a computer-based phone system in which MDs receive the latest data found in the literature relating to specific inquiries.

It isn't just the delays in getting information to the clinicians that bothers Mrs. Lasker, however. She cited (through Schmidt) examples which seem ripe for clinical trials but where in fact none are in progress: chemotherapy for prostatic and ovarian cancer, the potential for antibiotics against any form of cancer, the use of drugs in clinical studies designed especially for stomach cancer were among those mentioned.

Mrs. Lasker suggested that NCI establish a computer data bank which would compile information by organ sites: which investigators were working on each type of cancer, what therapy modality were they using, what are the latest comparative results.

"Is it feasible or desirable to have someone pull all that information together?" Schmidt asked. "That information is available somewhere. . .There's absolutely no question that grantees and contractors can be directed to provide that information."

Gordon Zubrod disagreed. "We're not in a position to tell grantees how and in what form to bring information to NCI," the Cancer Treatment Division chief said.

"The scientific community is very careful about the rights of grantees," Zubrod continued. Intramural research and contract programs frequently involve certain aspects of research being conducted by grantees. "There is a question of propriety in using our authority (to demand progress reports) considering our inhouse and contractual operation," Zubrod said.

The kind of information that could be used effectively in a computer data bank would necessarily be that of a proprietary nature, and would constitute release prior to publication, Zubrod contended.

Schmidt answered that he "couldn't believe" any investigator would not want to make available potentially life-saving information as soon as he has it.

"We feel this keenly," Zubrod said. "And we do get that kind of information, much of it verbally, at

meetings. People with clinical information get together and discuss what they have found. The best current knowledge does reach the progessionals. But to try to document this and get it together in a computer is something else."

Panel member Ray Owen said "I had the impression the answers Mrs. Lasker is looking for don't require complete, documented information. Your friend, Mr. Doe in Texas, doesn't need all that backup data. He just needs to know who to ask about a particular treatment."

Nathaniel Berlin, director of the Div. of Biology & Diagnosis, pointed out that NCI does have in a computer all current protocols supported by NCI involving therapy and diagnosis. It is of limited use to general practitioners, however, since most of it is coded. "The question is, at what point does this coded data become useful," Berlin said. "Sometimes early dissemination can be dangerous."

ZINDER REPORT IMPLEMENTATION, SURGICAL CONFERENCE, ON NCAB MEETING JUNE 17-18

A report on implementation of the Zinder report recommendations dealing with the Special Virus Cancer Program is on the agenda for the National Cancer Advisory Board meeting June 17-18.

Board member Harold Amos of Harvard is chairman of the subcommittee charged with overseeing the Zinder recommendations. NCI had already moved in the direction of implementing those recommendations before the board officially accepted them. Essentially, the report suggested steps aimed at giving outside advisors more control over SVCP's contract program and removing conflicts of interest involving NCI segment chairmen and program managers.

Reports on the conference on surgical oncology, large bowel organ-site program, the controversial and long-delayed smoking resolution, environmental carcinogenesis, status of Frederick Cancer Research Center and recruitment of a basic science director for it, and on the status of AHH as predictor of lung cancer risk due to smoking are on the agenda.

CONTRACT AWARDS

Title: Technical writing services in support of cancer related written inquiries from the general public
Contractor: Biospherics Inc., Rockville, Md., $172,175

Title: Analysis of chemicals and pharmaceutical formulations
Contractor: Midwest Research Institute, Kansas City, Mo., $852,075

Title: In-house tissue culture assays to guide antibiotic development
Contractor: Michigan Dept. of Public Health, $54,166

Title: Maintenance of a virus diagnostic laboratory
Contractor: College of Medicine & Dentistry of New Jersey, $328,421

Title: Operation and maintenance of a rodent production center in a modified conventional environment
Contractor: Harland Industries, Cumberland, Indiana, $135,077

SOLE SOURCE

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

Title: Radiation therapy research
Contractor: Mary Hitchcock Memorial Hospital, Hanover, N.H.

Title: Breast cancer detection demonstration project
Contractor: Rhode Island Hospital

Title: Operation and maintenance of a drug research and development biological data processing system
Contractor: Value Engineering Co., Alexandria, Va.

Title: Research study, population-based cancer registry for surveillance, epidemiology and end results (SEER)
Contractor: Commonwealth of Puerto Rico

MEETINGS

NCI advisory group meetings frequently are closed, usually for review of contract and grant applications. Times scheduled as open will be shown with each listing, but these sometimes are changed.

Fourth International Convocation on Immunology, Buffalo, June 3-6.

Workshop on the Serologic Protection of Leukemia Associated Antigens, Duke Univ., June 3-11.

Committe on Cancer Immunotherapy, NIH Bldg. 10, room 4B17, open 12-12:30 p.m.

Southwest Oncology Group, Kansas City, Kan., June 5-7.

Western Cancer Study Group, San Francisco, June 6-8.

Eighth Miles International Symposium—The Role of Immunological Factors in Infectious, Allergic & Autoimmune Processes, Johns Hopkins Univ., June 6-7.

American Public Health Assn. Conference on Public Health Hazards of Viruses in Water, Mexico City, June 9-12.

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Published weekly by National Information Service Inc., 11800 Sunrise Valley Drive, Reston, Va. 22091.