THE CANCER LETTER

Vol. 7 No. 37

Sept. 11, 1981

Subscription $125.00 per year

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ACCC UNIT REACHES CONSENSUS ON OUTLINE OF HOP; EACH MEMBER WOULD RELATE TO CENTER OR COOPERATIVE GROUP

The Assn. of Community Cancer Centers Clinical Research Committee has reached a consensus on most major issues involved in the recommendations it is developing for presentation to NCI regarding the ambitious new Hospital Oncology Program. However, there are several differences which remain to be resolved between ACCC's concept of what the new

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In Brief

HENNEY NAMED ACTING DIRECTOR OF DRCCA; HOUSE BILL WOULD SLASH DEEPLY INTO RESEARCH USING ANIMALS

JANE HENNEY, special assistant for clinical affairs in the Div. of Cancer Treatment, has been named acting director of the Div. of Resources, Centers & Community Activities by NCI Director Vincent DeVita. Henney will hold down the job until DRCCA Director-Designate Peter Greenwald is approved by HHS. In a memo to NCI staff announcing the appointment, DeVita thanked former DRCCA Acting Director William Terry "for his excellent performance and willingness to take on a variety of difficult and demanding tasks for the Institute over the last three years. We are all most grateful for his major contributions in resolving the complex and difficult issues with which he has dealt so effectively." Terry is on vacation, will resume his old job as director of the intramural immunology program when he returns. . . . **HOUSE BILL** (H.R. 556) introduced by Congressman Robert Roe (D.-N.J.) threatens to cut substantially into NIH research funds if it becomes law in its present form. The bill would require all federal agencies which conduct research using live animals to set aside from 30 to 50 percent of funds used in such research to develop alternate methods which do not use animals. The bill has more than 80 cosponsors, most of whom normally demonstrate better judgment, and has been promised a hearing by Henry Waxman, chairman of the Health Subcommittee. The bill ignores the fact that a fair amount of research already is being done on in vitro testing methods; whether a huge infusion of money would speed that up is debatable. The legislation would play havoc with a wide range of basic research funded by NIH, with NCI's Drug Development Program, and with the National Toxicology Program. . . . **NOMINATIONS** are being accepted for the fifth annual Bristol-Myers Award for distinguished achievement in cancer research. Winner will be selected by a nine member panel headed by Saul Rosenberg of Stanford. Nominations will be accepted from medical schools, free standing hospitals and cancer research centers until Dec. 15, with only one nomination from each institution. For forms and further information, contact Secretary, Awards Committee, Bristol-Myers Co., 345 Park Ave. Rm. 43-55, New York 10154.

ACCC AGREES MINIMUM HOP REQUIREMENT 50 PATIENTS A YEAR IN CLINICAL TRIALS

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program should be and that of NCI's leadership. Differences also exist with the Community Clinical Research Committee of the Div. of Resources, Centers & Community Activities Board of Scientific Counselors.

HOP (not to be confused with the earlier Clinical Oncology Program and the just starting Community Hospital Oncology Program supported by DRCCA) is the outgrowth of a suggestion by NCI Director Vincent DeVita that CHOP be followed up with a program which would stimulate participation of community physicians in clinical trials. DeVita asked ACCC to help formulate the program.

ACCC immediately envisioned a broader role for HOP, especially since DeVita proposed funding it with DRCCA—cancer control—money. "If control money is going to pay for it, then it has to include some control elements," is a refrain repeated many times. The division's Board and its incoming director, Peter Greenwald, apparently share that view.

The ACCC committee and other members of the organization hammered out its consensus in a three day meeting in Chicago last month.

After listening to presentations on community relationships with centers, national cooperative groups, regional cooperative groups; on various approaches to clinical research in the community; and on the respective roles of nurses, surgeons, radiotherapists and pathologists, the group agreed on the following essentials of a community cancer center, as reported by committee Chairman Edward Moorhead in his summary of the meeting:

ESSENTIALS OF A COMMUNITY CANCER CENTER

The Clinical Research Committee approved the detailed essentials of a community cancer center and a detailed description of the clinical research, and treatment control activities that such a center would be expected to undertake. The cost of such a program, while not specifically defined, was estimated in the range of $1,000 per patient (for the clinical research aspects; see below for estimates of other costs). Among the specifics approved were:

A. Encouragement of hospital consortiums in defined geographical areas.

B. Minimum requirement of 50 evaluable patients on NCI approved protocols each year. This would include patients referred to centers or elsewhere, as well as those treated in the community.

C. A written working agreement with an NCI approved center or cooperative group. The status of the community center within the (larger) center and/or group was addressed in various reports. It includes specific recommendations that the community oncologist play a meaningful role in such organizations.

D. The opportunity for a community cancer center to develop its own satellites.

E. Direct funding of the community program (as opposed to funds going from NCI to the major centers or cooperative groups, to be dispensed to the community centers). The affiliated center or group, chosen mutually prior to the application, will also be funded directly for its support activities.

F. A broad based cancer control effort in addition to the treatment control aspect of the program.

"The exact details of the broaded based cancer control effort would vary considerably from community to community," Moorhead wrote. "Many communities (present COP and CHOP contractors, participants in comprehensive cancer center outreach projects, community based cancer control program participants, etc.) already have rather sophisticated control projects in operation. Others have minimal or no activities. The committee was directed to expand its recommendations in this area to encompass this wide diversity presently found in communities that could qualify for the treatment control portion of the program. These recommendations will be developed at the committee's next meeting, Sept. 24, in Indianapolis."

AFFILIATED COMMUNITY PROGRAMS

Moorhead's summary continued: Recognizing the important contributions of hundreds of community hospitals and oncology groups throughout the nation who are only able to enter a small number of patients in clinical studies each year, the committee approved several options open to such hospitals and groups.

1. A satellite relationship with an NCI approved group or center.

2. Development of a satellite (by subcontract) relationship with one of the HOP community centers.

3. Application to become a HOP community cancer center despite inability to register 50 patients annually and to enter into a consortium that can meet that requirement. The proposal recognizes that certain circumstances (rural population, distance from other cities, etc.) should permit exceptions to the 50 patient guideline.

THE COMPREHENSIVE CANCER CENTER AND THE COMMUNITY

1. Several structural variations of center-community cooperation are existent and can serve as models for communities and centers that choose this option. Flexibility should be preserved.

2. A functioning center-community link in research (treatment control) can and should serve as the nidus for a broad based program in cancer control.

3. Both the center and the community should be individually funded for their contributions to the joint effort.

4. Community physicians must be given a meaningful role in the cancer center organization including all aspects of operation–representation on the governing board and executive committee, the cancer control and/or outreach committee, positions of responsibility for research efforts involving the community, including site and modality committees. A community physician should have input into the design and operation of cancer control and outreach efforts.

COOPERATIVE GROUPS AND THE COMMUNITY

Only one affiliation between a community center and broad based cooperative group should be encouraged. Exceptions would include the single disease site, or modality oriented groups, such as Gynecologic Oncology Group, Radiation Therapy Oncology Group, National Surgical Adjuvant Breast & Bowel Project, etc. The contract, however, would require entry of 50 patients into one group.

2. Cooperative groups wishing to participate in this program should revise their structures to permit:

A. "Control" membership status for an approved community cancer center. The control member will be permitted to develop satellites.

B. A voting voice for all control members including election of at least some members to the group's cancer control committee.

C. The appointment of representative cancer control members to each site and modality committee.

D. The cancer control committee to be given budgetary responsibility for some cancer control funds.

E. The cancer control committee would be allowed to elect one member to serve on the executive committee of the group.

F. All proposed protocols to be circulated through the cancer control committee for review and comment.

G. Community physicians wishing to participate in the program will meet certain standards and guidelines.

H. Community centers would reach agreement with a cooperative group before submitting a joint application. Each would be funded directly.

REGIONALIZATION

1. All other things being equal, regionalization will be encouraged.

2. A community program that wishes to affiliate with a group outside its region would be expected to accept the burden of explaining why that was desirable.

3. Cancer control programs are amenable to the regional approach.

4. Regional groups have many real and potential advantages. The major potential disadvantage is isolation. The proposed National Committee on Intergroup Protocols and other mechanisms should be designed to overcome this.

"It's clear that no matter what the linkage–to national or regional cooperative groups, or centers–the community oncologist wants and deserves to be treated as an equal partner. It has not always been that way."

Stephen Carter, chairman of the DRCCA Board, offered that statement as one of his observations from the meeting.

Some of the "hard decisions" still to be made, Carter said, include the question of whether the community center would have to have an established link with a group or center before it could compete for HOP funding. The general view of the meeting was that the link should be established prior to funding. "Will NCI put forth a list of acceptable linkages? That is one of the sticky issues that still need to be resolved," Carter said.

Another is the cancer control question. "With DRCCA funding using cancer control money, it is important that cancer control activities be built in. Clinical research by itself is not enough. Participation in clinical research is a potent cancer control activity, but unless there is a framework with further relevance, the justification is not there. I would guess that would be the approach of the Board of Scientific Counselors," Carter said.

A third aspect still to be decided, "one we were least able to discuss because of the lack of representation from established clinical research mechanisms and NCI," is the issue of reciprocal funding for the mechanisms handling community participation, Carter said.

Those at the meeting agreed that participation in clinical research would cost $1,000 a patient. That would be the cost to the community organization, paid out of its NCI funding. That would not include any money for cancer control activities. And it would not include any funds for the cooperative group or center allied with the community, for its increased overhead, such as quality control and statistical analysis.

Carter said he felt it might require an additional $1,000 per patient for the groups or centers, although that figure could be reduced as the number of patients increases.

DeVita had estimated that as much as $10 million might be available for HOP. At $1,000 per patient, that would fund the 10,000 patients he would like to add to clinical trials. However, if Carter's estimate of $1,000 per patient for the mechanism holds up, that would require another $10 million. And add $5 million for cancer control, if the estimate (mentioned by several at the meeting) of $500 per patient prevails.

The grand total cost would be $25 million, probably beyond NCI's capability in the 1982 fiscal year, which means that a more modest start of 3,000

to 5,000 patients is a more likely number.

Once HOP is under way, demonstrates that it is working at 30, 40, or 50 community centers, the pressures inevitably will build for funding others. Even with 10,000 patients, if the average number from each is 100, that would mean 100 funded community centers. NCI and ACCC have suggested that as many as 200 HOPs might be required to assure complete coverage of the U.S. population. The total annual cost of the program then could reach $50 million.

"When the number of communities capable of running good programs exceeds NCI's funding limits, we'll go to Congress and ask for more money," ACCC Executive Director Lee Mortenson said.

Moorhead agreed. "ACCC has not been bashful in asking Congress to support community cancer activities," he said. But he suggested that many communities might be able to help foot part of the bill with their own fundraising efforts.

Carter saw another problem that might come up. "What if an existing group refused to accept communities as full fledged members? The community people could be in the majority and take over control of a group. This needs more discussion by the Moertel committee." Charles Moertel, member of the DRCCA Board, heads its Clinical Research Committee.

It does not seem likely that a HOP proposal suitable for concept review can be put together in time for the DRCCA Board's Oct. 22-23 meeting.

Without approval of the concept, at that time or at least by the Board's January meeting, funding of any HOPs in FY 1982 probably will not be possible. A complicating factor is that the existing Cooperative Group Cancer Control Program, in which six existing groups are funded to support extension of their protocols into community hospitals, will come before the Board in October for concept approval.

Continuation of that program or modification of it undoubtedly depends on what happens with HOP. Since that probably will not be determined by then, it will be difficult for the Board to know what to do about the existing program. "There is no question that each satellite member (in the existing program) would prefer to be funded as a HOP," Carter said. He suggested that the Board may consider extending the existing program for a minimum time while the development of HOP continues, phasing it into HOP eventually.

In his remarks opening the meeting, Moorhead said, "There are many reasons making it urgently necessary to improve the present efforts at community cancer control. Chief among these are:

"• The increasingly complex and rapidly developing new technology for optimal cancer care. While most large community hospitals are today equipped to treat most cancer patients who seek their care in the community, today's research promises in hyperthermia, immunology, in vitro laboratory tumor cultures, newer radiological diagnostic and therapeutic equipment indicate that the community hosital will need to be closely attuned to clinical applications of such advances if they are not to fall behind. For a period of time, significant new advances will only be available at a limited number of major centers. Cancer patients from the community will thus, for a period, flood certain major centers. Rapid dissemination of proven technology will be needed to prevent an inhumane traffic glut.

"• The development of large numbers of competent, well trained cancer specialists who have established themselves in community practice. It falls to the community oncologist to apply newly discovered optimum care programs in the community, where more than 80 percent of cancer patients obtain their care. The oncology specialties have and will need a continuing oncological education program that will dwarf those of other specialties, so that practicing oncologists become capable in the new technologies.

"• The need of the National Cancer Program and its research effort to obtain large numbers of patients to study both the natural history of the disease and the effect of various forms of therapeutic intervention upon the natural history. As cancer becomes more complex, it requires more and more patients to answer questions posed by increasing numbers of subsets of patients. Larger numbers of patients participating in such protocols will shorten the time necessary to answer many of the important questions asked in the protocol.

"• Promising new technologies in cancer prevention and cancer detection that will require large numbers of community based patients to demonstrate their effectiveness.

"• The need for rapid, effective, and continual communication between the cancer research effort and those physicians who are caring for large numbers of cancer patients is obvious:

"1. The informed community oncologist informs his patients of such new research approaches and offers the patient the opportunity to choose the research path or the standard therapy route.

"2. The oncologist also provides cancer researchers with the experiences of the practicing community oncologists. Such experiences might include observation of an unusual response or occurrence in an individual or small group of patients; and determination of major problems in oncology as viewed from the 'front-line trenches' of patient care.

"• Failure of previous cancer control efforts to put into effect a 'national' system of access to excellence in cancer diagnosis and treatment.

Carter in his remarks at the meeting, said, "One of the major developments in oncology has been the

training of large numbers of young oncologists from all disciplines, especially medical and radiation oncology, who have gone into community practice. These individuals have been taught how to optimally treat cancer and what supportive resources are required. Many have developed extremely busy and thriving practices and see large numbers of patients with cancer. What is not known is how well they can actually translate the techniques they learned in their research oriented training to their everyday community practices. These data which would need to come out of patterns of care studies, combined with end results analysis, would tell us what gaps, if any, need to be filled.

"Many cooperative clinical trials groups and cancer centers are developing, or have developed, community participation in protocol studies. The major attractions of this approach are:

"1. The potential increase of patients for clinical research studies.

"2. The increased availability of patients with newly diagnosed early stages of disease.

"3. The psychosocial and socioeconomic gains of having patients treated in their community setting.

"4. Diminishing the cost of clinical research.

"The major concerns about community participation involve:

"1. Dilution of the quality of data.

"2. Compromise of the scientific quality of the protocol questions asked to accommodate what will be acceptable in a community setting.

"3. Possible higher costs in terms of physical morbidity and expense due to a higher degree of complications when newer treatments are attempted in less sophisticated surroundings.

"What will determine the outcome balance between the potential attractions and concerns are individual physician quality, existence of a multidisciplinary team, the quality of available treatment facilities, the quality and availability of ancillary and supportive care resources, and the adequacy of the required continued dialogue between the community and the research center.

"What we need are detailed analysis of these factors in ongoing demonstrations of community participation in clinical trials and a careful scrutiny of the end results achieved.

"Ideally, one could hope that all patients in the United States would participate in clinical research to some degree. This idealization is currently not feasible because the requisite physical and physician resources do not exist, and because the requisite costs of developing these resources are unrealistic in the current political climate. Despite the increase in trained oncologists, a significant number of patients is probably currently being treated by physicians who are not adequately trained in oncology and who both would not and could not participate in clinical research. These priorities must concern diseases, stages and modalities to be emphasized, as well as the balance between efforts in research centers and in community settings. This latter prioritization is not a pleasant one to contemplate and is rarely if ever debated in an open forum, but it is ongoing all the time, nonetheless.

"What is often not emphasized enough in community outreach programs is the need to bring minimal standards of care to all cancer patients. The patients destined to die of their cancer still can be given significant palliation in many instances. Therapies improperly or inappropriately administered can cause significant physical, psychosocial and economic morbidity. This aspect of cancer control is not glamorous and is difficult, if not impossible, to evaluate in terms of end results. The proper application of patient management guidelines may not change ultimate end results, but may have a significant impact in terms of process alteration, with resultant patient benefit in physical, psychosocial and economic terms.

"Within the National Cancer Program, cancer control and clinical research are in two separate divisions of the National Cancer Institute. Many clinical investigators have become concerned about what they perceive as an artificial separation between cancer control and clinical research. For some, extension of clinical research into the community would accomplish most of the goals of the Cancer Control Program. Clearly, there is no finite line that can be drawn between research and control, but there is a finite amount of available funding and a finite number of programmatic thrusts which can be attempted. If clinical researchers and those involved in cancer control work closely together, a maximal amount can be achieved with existing resources and funding. We need more data, and less unsupported strong opinion, as we debate our future course of action."

A paper by Moertel, written after his committee had met earlier in the summer to discuss the issues, was circulated at the Chicago meeting. Although ACCC members challenged some of Moertel's points, it appears that his outline of the characteristics of community centers qualified to participate in the program is compatible with theirs.

Moertel represents the view that good clinical research is cancer control and that justifies funding with cancer control money. In particular, they questioned this statement:

"The technology transfer accomplished through such clinical research activity plus the accompanying quality control will not only benefit the protocol patients directly but will indirectly benefit all other nonprotocol patients managed at community cancer centers."

Some members also disagreed with Moertel's con-

tention that, "It is not the purpose of this program to subsidize non-research 'protocols' for best standard clinical practice since again knowledge of best clinical practice should be regarded as the responsibility of any private physician who undertakes to treat a cancer patient."

Those who did not agree felt that the task of determining just what "best standard" treatment consists of, and assuring that those who treat cancer patients are aware of it, is a major task of cancer control and thus might well qualify for funding under the cancer control element of HOP.

Few argued with Moertel's statement, "It certainly may be anticipated that participation of community centers in well designed and conducted clinical research protocols will enhance the overall quality of care rendered by the community center." But some were uncomfortable with:

"It is specifically not the purpose of this program to reach out to every private physician who treats cancer patients regardless of his research motivation or capabilities. This is a research program that will be organized with the primary purpose of providing the highest quality research performed at the lowest possible cost."

"I think our members feel that if that is the case, the program should be funded by the Div. of Cancer Treatment," Mortenson said.

For the most part, Moertel's views coincided with ACCC's.

"It is projected," Moertel wrote, "that this program will involve a total of approximately 200 community cancer centers demongraphically and geographically located so that they can conveniently serve the entire population of the United States. These community cancer centers will work in cooperation with approximately 20 support units provided by major cancer centers, national cooperative groups, or regional cooperative groups."

Following are the characteristics of an eligible community cancer center as described by Moertel:

A. A community cancer center may be defined as a single clinic, a single hospital, or a consortium of clinics or hospitals. In the latter instance cohesion must be demonstrated and there must be a unifying administrative structure.

B. Each funded community cancer center must have a designated and committed multidisciplinary professional team including Board certified or eligible surgeons, radiation oncologists, medical oncologists, and pathologists. Appropriate other disciplines may be added, e.g. gynecologic oncologists, pediatric oncologists. One of this group will serve as principal investigator and a representative of each of the remaining subspecialties will serve as coinvestigators.

C. Each community center must have a well defined area for administrative activities which will serve as a focus for data management, quality control, and communication. Usually this would be in a hospital or clinic. It is anticipated that this area will be in close proximity to clinical activities so that prompt data transmission can be accomplished as well as on scene eligibility checks and quality control.

D. Each community center must have an established working relationship with a nationally recognized clinical cancer research base, e.g., major cancer center, national or regional cooperative group. Multiple affiliations are discouraged unless they are clearly not conflicting, e.g., ECOG for adult tumors, CCSG for childhood tumors.

E. Each community cancer center must identify the population it serves. Empahsis will be placed on demographic and geographic distribution of community centers. It is anticipated that a minimum population of 100,000 should be identified to justify establishment of a community center although exceptions could be made for sparsely populated regions. Multiple community centers competing for the same patient population will be discouraged. A primary objective of this program will be to meet the Congressional mandate that high quality cancer care will be available to every United States citizen without the necessity of an overnight stay for travel purposes.

F. Each community center must have a demonstrated potential and stated commitment to contribute at least 50 patients per year on the nationally approved clinical research protocols active in the center or group with which the community center is affiliated.

G. Each community cancer center must have established or well planned procedures for regular communication with the practicing physicians of their region, e.g., education programs, workshops, grand rounds, tumor boards, etc.

H. Each community cancer center must have established or well planned programs to meet the human needs of cancer patients in their community, e.g., patient education, cancer rehabilitation, "hospice" programs, etc.

I. Each community cancer center must have, either individually or in cooperation with a major center or national group, a plan for evaluating the impact of its community programs.

J. Funding for a community center will be based on established ability to contribute patients to national clinical research protocols with additional funds available for cancer control type activities or for evaluation activities if such funding can be justified before peer review. Anticipated total yearly budget for a center contributing the minimum of 50 patients and without major cancer control activities would be $30,000 (ACCC's figure is higher). The budget would be increased proportionately for centers capable of greater case contributions. Allowable items in the budget would be for personnel engaged

in data handling and study assistants, supplies and services directly related to study activities (e.g., processing and sending material for pathology review, processing and sending port films for radiation therapy quality control), travel to meetings directly related to study activities, and support for cancer control activities. Staff salaries, not to exceed five percent of an FTE would be allowable only for time spent away from clinical practice, e.g., as principal investigator of a protocol or in nonclinical cancer control activities. Funding would be allowed for five years.

Developmental grants over a two year period could be allowed for community cancer centers with a clearly established potential for case contribution that had not been documented by past performance. These grants could be extended for an additional three years by NCI staff review without site visit if adequate case contributions could be documented during the initial two years.

Moertel's paper also described the functions of support units provided through comprehensive cancer centers, other university cancer centers, national or regional cooperative groups. Those functions would include stimulating, facilitating, coordinating and evaluating the research and control activities of affiliated community centers. A single support unit would be expected to be affiliated with at least five community cancer centers contributing at least 300 research protocol entries a year.

Specific functions of the support units would include the following:

1. To assess the capabilities of affiliated community centers for participation in clinical research and cancer control activities.
2. To assist the community centers in any necessary upgrading of personnel and facilities and to provide training when indicated for supporting personnel, e.g., data handlers, study assistants, oncology nurses, etc.
3. To join with the community centers in developing and/or making available appropriate clinical research protocols.
4. To develop appropriate quality control procedures for data recording, protocol compliance, and reporting of adverse reactions.
5. To join with radiation therapists of the community centers by assisting with treatment planning and in providing quality control both with regard to standardization of equipment and to dose and field.
6. To join with surgeons in the community centers to standardize operative reporting and, when feasible, operative procedures.
7. To join with pathologists in the community centers to standardize pathology reporting, to standardize pathology procedure, and in providing mechanisms for pathology review for appropriate protocols.
8. To establish an operations office which will provide regular and timely pertinent communication with affiliated community centers and establish logistics for data transmission.
9. To establish a statistical center fof data management and to provide statistical assistance in the protocol design, protocol monitoring, data analysis, and manuscript preparation.
10. To monitor new drug procurement, to transmit new drug orders, and to monitor new drug use by affiliated community clinic members.
11. To organize regular meetings with its community affiliates for review of ongoing research activities, planning of future activities, and related professional education.
12. To join with its community clinic affiliates in the planning and conduct of cancer control activities.
13. To assist community centers in evaluating the impact of their research and control activities.
14. To evaluate the quality of performance of its affiliated community centers.
15. To prepare at least once annually a comprehensive report of the overall activity of the community center program.

It is anticipated that a minimum support unit would be funded at a total cost of $100,000 per annum. Proportionately greater funding would be allowed for a larger number of protocol entries. Additional funds could be added for appropriate and approved cancer control activities.

Allowable budget items for a support unit would include professional (physician, statistician, nurse) staff salaries for administrative and advisory activities; paraprofessional salaries for administrators, data clerks, statistical assistants, secretaries; supplies, services, and equipment directly related to support services; computer charges; editorial, graphic, and photographic services; travel.

Awards would be made for five years for established support units. Developmental awards of two years could be made for units with demonstrable potential but without established productivity. These latter awards could be extended for an additional three years by NCI staff review if productivity is established during the initial two years.

Review Procedures

A. It is anticipated that individual support units and affiliated community cancer centers would be evaluated at a single site visit.

B. Awards would be based on approval and priority scores of the gorup as a whole (support unit plus affiliated community centers). Each community center would also be individually judged for approval and priority.

C. A single award could be made for the entire group with funds managed by group administration through consortium agreement. This would seem most suitable for developing groups. For well estab-

lished groups, support unit and community centers could be funded individually.

D. Supplemental awards could be sought by each group for addition of new community centers or based on increased productivity of the group as a whole. NCI staff would decide whether site visit was required for approval of such supplements.

E. If an institution providing a support unit will also be entering patients into protocols of the group it supports, or if some protocol patients will be jointly managed by the supporting institution and the community centers, this supporting institution may also request additional funding for its protocol patient contributions. These funds will be awarded at a rate not to exceed that awarded to the community clinic participants unless special services are offered to protocol patients for which additional funds can be justified, e.g., special laboratory procedures.

Other ACCC recommendations and presentations at the meeting will appear next week in ***The Cancer Letter.***

RACKER SAYS DATA "A MESS," WITHDRAWS SOME CLAIMS IN JULY *SCIENCE* ARTICLE

Efraim Racker, perhapse the world's foremost biochemist, and graduate student Mark Spector authored an article which appeared in the July 17, 1981 issue of *Science* which created a sensation in the fields of biochemistry and molecular biology.

The article, "Warburg Effect Revisited: Merger of Biochemistry and Molecular Biology," reports on Racker's studies at Cornell (with Spector and four others). Those studies, the article contended, found that transformation of normal cells to tumor cells is related to a deficiency in an enzyme pump, a deficiency caused by phosphorylation catalized by a protein kinase. It seemed to be a solid hypothesis on how transforming viruses did their work.

A few weeks later, the article and its exciting conclusions were very much in doubt. Racker has sent a letter to *Science* withdrawing some of the claims.

It seems that other investigators in Racker's lab were unable to verify his and Spector's findings. Presented with that challenge, Racker undertook the job of duplicating the study himself.

"I personally have verified some of it," Racker told ***The Cancer Letter.*** "But I am now very suspicious of all the virology involved. I would not be surprised if the basic concept still turns out to be correct. But there is no question, that the data are a mess. Right now, we don't know what is right and what is wrong."

Racker is supported by an R01 grant from NCI's Div. of Cancer Biology & Diagnosis. "I'm sorry this exciting study has been called into question," one NCI executive said. "But this shows that the system is self regulating. No one can get away with anything. Anything this important would have to be confirmed in labs all around the world."

ETHICS COMMISSION TO MEET IN L.A.

The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research once again will take up the issue of compensation for research injuries at its meeting Sept. 11-12 in Los Angeles.

The meeting will be in the Hilton Hotel, from 9 a.m. to 5 p.m. both days. Compensation is scheduled for the first day's agenda.

Also scheduled are discussions on the role of institutional review boards in implementing federal regulations, and in decisions to forego life sustaining therapy.

The controversial proposals to establish some form of compensation for patients injured while participating in clinical research has split the commission almost down the middle. The only consensus achieved so far is that, if a plan is to be recommended at all, it should start on a small scale. Some members feel that while there may be a moral obligation to provide compensation (in addition to legal and other remedies already in existence), implementation would be impractical, or could lead to a program of unmanageable size. Others have argued that the moral question should override all other concerns.

Cancer investigators and representatives of the Assn. of American Cancer Institutes and American Society of Clinical Oncology have objected to compensation, fearing that it would inevitably hamper clinical research and that any plan proposed so far is unworkable.

NCI CONTRACT AWARDS

Title: Manufacture of clinical formulations in soft gelatin capsules

Contractor: Banner Gelatin Products Corp., Chatsworth, Calif., $162,900.

Title: Cancer Control Program for clinical cooperative groups–Radiation Therapy Oncology Group, 10 month renewal

Contractor: American College of Radiology, $603,300.

The Cancer Letter _Editor Jerry D. Boyd

Published fifty times a year by The Cancer Letter, Inc., P.O. Box 2370, Reston, Virginia 22090. Also publisher of The Clinical Cancer Letter.