THE CANCER LETTER

Vol. 7 No. 3

Jan. 16, 1981

© Copyright 1981
The Cancer Letter Inc.

Subscription $125.00 per year

P.O. Box 2370 Reston, Virginia 22090 Telephone 703-620-4646

ETHICS COMMISSION BACKS LIMITED PILOT PROGRAM FOR COMPENSATION OF INJURED RESEARCH SUBJECTS

The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research tentatively agreed to recommend initiation of a small pilot program to test the feasibility of providing compensation for persons injured as the result of participation in research. The pilot program probably would be limited to research conducted by federal government investigators and would not include that supported by the government and performed by non-government scientists. It also might be limited to nontherapeutic research.

The Commission's action came after a two-day meeting last week during which a proposal to recommend against any further consideration of the compensation issue was narrowly defeated in a vote Chairman Morris Abram called "to test the water."

Commission members and staff seemed stunned by the testimony of

(Continued to page 2)

In Brief

CANCER CONTROL FUNDS FOR CLINICAL TRIALS INTENDED TO UPGRADE QUALITY OF CARE: TERRY

COMMENT BY William Terry, acting director of NCI's Div. of Resources, Centers & Community Activities, that cancer control money "will be directed through Cooperative Groups, regional groups and centers to assist in increasing the flow of cancer patients to research," reported in ***The Cancer Letter*** Jan. 2, did not completely express the point he was making. Justification for using cancer control funds to support extension of clinical trials into community hospitals is to upgrade the quality of care in communities. Cooperative Group members and other investigators hope that increasing involvement of community physicians in clinical trials will help increase the number of patients entering clinical research, but that is not the primary purpose of cancer control support of that effort. . . . **GAR KAGANOWICH,** who has been a minority staff member of the Senate Appropriations Committee but is now on the majority side, is the new staff director of the Labor-HHS Appropriations Subcommittee, replacing Terry Lierman. . . . **LONG ISLAND** residents are optimistic about their ability to do something about cancer, the Long Island Cancer Council reported from a survey it conducted on health beliefs, attitudes and practices in its area. Eighty-three percent of the respondents agreed that the federal government should have the power to control suspected carcinogens; the seven cancer warning signals were identified with a 90 percent accuracy rate; and 33 percent of the women and 20 percent of the men predicted they eventually would get cancer.

ETHICS COMMISSION ALMOST DROPS COMPENSATION AS "NOT NEEDED"

(Continued from page 1)

the consultant hired to develop a prototype compensation system who said that any plan to compensate injured research subjects would be impractical, unworkable, extremely costly, and is not needed.

George Bernstein, a Washington attorney specializing in insurance matters, previously had worked under a contract with the commission to identify existing options offered by private insurance carriers and what additional coverages they might be willing to make available. After submitting his report last year, he was retained to draw up a prototype system for compensation funded by the federal government.

On the meeting agenda to present preliminary alternatives, Bernstein told the Commission:

"I would guess my conclusion is that it is unmanageable. I have rejected your contract. I urge very strongly against any but a very limited program, if you must have one, although none would be best."

Bernstein asked, "Where is the need? What is the demand? The only initiative has been from the government. There is no one out there demanding a program of reimbursement." He said that existing government controls and institutional review boards may be operating adequately to protect research subjects.

One of the problems involved in developing any compensation plan, Bernstein said, would be estimating how much it would cost. "No one has any idea of the numbers. If I was an insurer or a member of a congressional appropriations committee, I would be concerned that no one has any idea of the magnitude."

Bernstein pointed out that insurance coverage now applies to injuries generally and that "there is no exclusion for research. Private health insurance is picking up the coverage." In addition, he said, remedies are available through the courts. "There is no evidence that trial lawyers are bashful about bringing suit for negligence."

Bernstein said that when HHS Secretary Patricia Harris referred the issue to the commission, she "glossed over the issue of need." Massive costs could result from the program, largely through "induced new costs. All remedies invite poeple to use them, and it can cost a hell of a lot of money."

But the key issue, Bernstein said, is that there is "no reasonable chance to identify the injury with the event." He criticized the "on balance" method of making such an identification as "an ingenious way to get around the problem."

The "on balance" method was included in the recommendations of the HEW Secretary's Task Force on the Compensation of Injured Research Subjects made in 1977. The recommendation was:

"Human subjects who suffer physical, psychological, or social injury in the course of research conducted or supported by the Public Health Service should be compensated if (1) the injury is proximately caused by such research and (2) the injury on balance exceeds that reasonably associated with such illness from which the subject may be suffering, as well as with treatment usually associated with such illness at the time the subject began participation in the research."

Bernstein continued, "The preliminary data before this Commission is not sufficient to justify a compensation system." His recommendation to the Commission is that it attempt to determine the scope of the need and to collect information along that line. "If the Commission determines we must have an insurance program, think small. Limit it to payment only for medical care and not for residual needs (such as lost wages, nonmedical assistance, transportation, etc.). It should be supplementary to private health insurance."

Bernstein apolozed "for not being able to give what was asked of me. . . . But my recommendation is to do very little, if anything."

Earlier in the meeting, Mary Harvey of Yale discussed results of a survey of 2,200 clinical investigators which attempted to determine the approximate number of research injuries occurring in their studies. Excluded from the survey were studies involving noninvasive procedures and those not presenting more than minimal risk to patients.

The result of the survey: "Data are inadequate to allow calculation of reliable estimates of numbers injured," Harvey said. A wide range of morbidity was reported, from zero to 65 percent. Variables difficult if not impossible to allow for included condition of the patients and skill of investigators. "It is impossible to extrapolate to maximum extent of risk," Harvey said.

Robert Levine of Yale added, "The data are totally useless for actuarial purposes in setting up an insurance system for compensation."

The Assn. of American Cancer Institutes and the American Society of Clinical Oncology are two organizations which have been concerned about the impact compensation would have on clinical cancer research.

Jerry Lewis, Univ. of California (Davis) and vice chairman of the Northern California Cancer Program board of trustees, represented AACI President Alvin Mauer at the meeting.

"It is our contention that therapeutic research in oncology, when placed in its proper perspective and occurring in a setting of vigorous local peer review, institutional human rights review, and frequent review at the national level, represents optimal care often more efficacious than standard textbook

management, and, as such, compensation for injured parties is totally inappropriate," Lewis said.

"A compensation program for injury of patients engaged in therapeutic studies of their cancer will impede our attack on the cancer problem and when applied specifically to patients with cancer in well organized clinical trials will slow our progress in managing this disease. In the face of the threat of compensation, clinical trials will not be encouraged but will be discouraged, and community and university physicians who join in many of these trials will likely refuse to place themselves in financial jeopardy. . . .

"Man is the only natural resource of the clinical investigator, and it is only through studies of human disease that disease in man will be conquered. This necessitates carefully designed studies carried out under the protection of the human subjects review system. Our current protection through such human subjects review boards provides assurance that the benefit of the therapeutic treatment outweighs the risk and that no more appropriate treatment for that particular patient exists. Nothing more can be asked by the patient, his physician, or by society as a whole. The patient cannot anticipate compensation for failure in any regimen any more than we can anticipate reimbursement for not living out our full life expectancy or failing to achieve our life goals.

"Compensation of subjects injured in oncologic research cannot be fairly weighed," Lewis continued. "The injury itself will be exceedingly difficult, if not impossible, to quantitate and to separate from the ravages of malignancy. It should be recalled that if left unattended, the course of malignancy is progressive and clear, through disability to death. Only medical intervention offers an opportunity to alter this course. Unfortunately, medicine is not so far advanced that cures at this point can be promised. Improvement can only be achieved in the face of some toxicity, at times severe toxicity. Our therapeutic modalities are not capable of selectively destroying only the neoplastic cell without touching the healthy nonmalignant cell. This is true for all of our therapeutic approaches, including surgery, radiation therapy, and chemotherapy, whether the patient is treated in the community with a published protocol or in a research institute on a protocol deemed to be potentially superior.

"It must be recognized that under such conditions the patient is aware of the side effects, as is his physician, and in properly designed clinical studies, both have reached for the hope of improvement even in the face of these toxicities. This hope—the concerted effort to survive—is a force intricately entwined in the nature of life itself. When failure occurs, as often it may, it seems inappropriate to compensate the individual for his disease which has failed to respond to a treatment regimen which in other settings has been demonstrated as being successful.

"I must point out that medicine is no more an exacting science than is man a well oiled robot with a finite series of options that are programmable in a readable format. Thus, it is simply not possible to predict the exact time of death and the complications of the disease per se which may develop. Therefore, it is not usually possible to determine that the exact time of death has occurred earlier or later because of participation in a clinical trial or that a particular complication occurring during treatment was related totally to the therapy or perhaps in part to complications of the disease per se. . . .

"It is difficult, if not impossible, in most cases to know in a given patient whether or not life has been shortened or lengthened, whether or not the toxicities which the patient experienced were associated with any beneficial effects in tumor response. That is one of the reasons why our clinical trials are not done with one patient but are done with a number of patients and then are confirmed by repetition and finally are repeated by others, often with a different outcome. We believe it is simply not possible to determine in any individual case with a fair degree of certainty whether or not injury has occurred, and if it has occurred, it would be impossible to place a monetary value on this occurrence," Lewis concluded.

Philip Schein, Georgetown Univ. Lombardi Cancer Research Center, presented ASCO's position.

"We feel that such a system (of compensation), as it might relate to cancer care and research, is impractical and would have a serious negative impact on current and important research through the diversion of limited research funds for the administration and payment of such compensation, as well as discouraging investigators and institutions from participating in the ongoing and necessary clinical studies," Schein said.

"The practice of medical oncology is a relatively new subspecialty. Effective drugs for human cancer were first introduced in the 1940s. There has been substantial progress made for the control of some tumors during the succeeding short period of treatment development, notably the lymphomas and pediatric malignancies. This has come about through the process of clinical investigation at a time when no alternative effective treatment was available. The patients who participated in these clinical trials benefitted, in the length and quality of their lives. At the present time we can list 12 tumors where some patients can be provided a normal life expectancy with chemotherapy. Unfortunately, these tumors represent only a very small fraction of all malignant disease that is diagnosed in the United States. The more common adult solid tumors such as lung cancer, gastrointestinal cancer and breast cancer remain relative-

ly resistant to treatment. Only a small proportion are diagnosed prior to dissemination and where prompt surgery may be curative. Over 50 percent of these patients will die of their malignancy and for some tumors, such as cancer of the pancreas, there are many good medical centers that have yet to record their first five-year survivor.

"Surgery and radiation therapy, despite the application of new techniques and methodologies, have become recognized as having many important limitations and it is unrealistic to expect major changes in survival statistics with these modalities used alone. By the time a tumor is diagnosed it contains over one billion cancer cells and there is a high probability that viable cancer cells will have already spread prior to diagnosis of the primary tumor and its removal. Therefore the majority of cancer patients will require some form of systemic treatment, chemotherapy, either as a preventive measure to eradicate residual microscopic disease after surgery, or for the treatment of overt metastatic disease. This assumes that standard forms of chemotherapy of proven efficacy for these conditions are already available. Unfortunately this is not the case. For the most common malignancies such as epidermoid carcinoma of the lung and colorectal cancer there is no standard, and all forms of chemotherapeutic management remain investigational. This emphasizes the urgency to proceed expeditiously with the investigation of new treatment in the hope that the current cancer survival rates might someday be improved."

Schein described phase 1 trials and pointed out that for many classes of drugs, such as analgesics and hypnotics, phase 1 studies are carried out in normal volunteers. Because of the toxicities produced by anticancer agents, he noted, they are never tested in normal subjects "but in cancer patients for whom the new drug may ultimately be found to have an important indication. Because the study population always has active and lethal cancer, it can be argued that all drug trials of antineoplastic agents, phase 1 or otherwise, have therapeutic intent. . . . While future cancer victims will benefit from the patient's participation in the trial, the research subject himself also stands some probability of achieving a reduction in the mass of the tumor, improvement of symptoms and prolongation of life.

"This issue becomes clearer when one considers phase 2 and phase 3 investigation trials, which have as their principal goal the direct control of the cancer. It is through this orderly system of drug and treatment development that the present advances in cancer management have been achieved, and by which future progress will be made. This system must be preserved and left without additional impediments if the public and congressional mandate for improved cancer care in our country is to be fulfilled.

"This is not to say that the patient should be unprotected. Our profession recognizes that the evaluation of a new anticancer therapy in human subjects is a clinical exercise that requires the highest standard of medical ethics. Care is taken to insure that patients do not relinquish their rights to established and effective therapy, assuming such treatment exists. Safeguards are set so that patients who are severely debilitated or terminally ill are not subjected to needless toxicity. The study design must provide for careful and continuous monitoring for acute and cumulative toxic reactions, and provide for corrective measures and dose-reductions when indicated. These provisions for patient safety are standard features of our current system of protocol development, which includes review and approval by the institutional human research committees, and federal funding agnecies such as the National Cancer Institute. All studies require informed consent by the patient. This is one of the major checks that the public and the regulating agencies have already placed on the investigator. Underscoring this process is the freedom to choose. . . .

"Assuming that your Commission mandates a system of compensation for injury, can it be expected to be effectively implemented? I have already briefly described some of the adverse reactions that are an expected commitant of effective anticancer treatment. Given the marked biologic variability between patients in regard to their tolerance to cytotoxic therapy, who will set the criteria to say how much toxicity is acceptable and how much exceeds some arbitrary limit? Recognizing how cancer can ravage any organ of the body, how will a committee separate, with any certainty, the morbid effects of the tumor from that of its treatment?

"It must also be recognized that patients with symptomatic cancer frequently require the concomitant use of analgesics, hypnotics, antibiotics, diuretics etc. Can one adequately distinguish adverse effects of these supportive measures from those of the investigational program? It was suggested that the survival of the patient can be used as an endpoint; and as an example, that we have the capability of determining that a patient's death from lung cancer four months earlier than might have been expected if the disease ran its usual course. What is the usual course of lung cancer? The median survival of the major forms of lung cancer untreated, as demonstrated by the Veterans Administration studies, is only three-four months, and essentially all patients are dead within one year. This disease and all others have such variable biology that it is impossible to set absolute standards and expect them to either work or be accepted. In essence, the problem of determining whether excessive injury has been sustained from cancer treatment may be insolvable when one is dealing with oncologic cases."

ASCO President Emil Freireich, in a letter to

Abram, asked that cancer patients and cancer treatment research be excluded from any compensation program.

"The physician in clinical science and in clinical practice is always faced with the problem of weighing the potential for benefit against the potential risk of any treatment recommendations," Freireich wrote. "In the case of malignant disease the threat to the individual's life is so great that treatments which would otherwise not be considered are regularly taken.

"It seems clear to me that in consideration of compensation one must consider the motivation for the subject participating in clinical research. In those instances where the motivation for participation is personal gain, that is where a patient is motivated to participate in research in order to benefit his own health and survival, it seems that compensation would not be indicated. In contrast when society finds it necessary to ask people to participate in clinical research where the individual himself has no potential for benefit, but where the community as a whole does have a potential for benefit, this is an area where participation in clinical research should be accompanied by some mechanism for compensation should injury result from such investigation. If this is considered, then treatment of patients with a malignant diagnosis would be generally excluded from any compensation considerations and this would eliminate the concern of those in the field of clinical oncology about considerations of this subject."

The presentations by the cancer scientists along with Bernstein's bombshell convinced at least some of the Commission members.

Ann Scitovsky, chief of the Health Economics Div. at Palo Alto Medical Research Foundation, asked, "Why have a task force and a government commission spent so much time on this problem? On economic grounds, it is not a big problem. I have seen no evidence of demand. I can see that in the future there may be a large number of health ethical issues infinitely more important than this. I suggest that we wind it up, that for the time being at least, recommend no program other than collection of data."

Albert Jonsen, professor of ethics in medicine at the Univ. of California (San Francisco), agreed that he could see no need, no demand, and that those who are injured are already covered. "I'm left with zero. . . . However, as long as we have a sense that there is an ethical obligation, we'll be bedeviled by this."

Most of the public outrage which has developed over injured research subjects involves tests conducted by the CIA, the Army, and the Tuskeegee fiascos where informed consent was not obtained, Jonsen noted.

Mathilde Krim, Sloan-Kettering Institute for Cancer Research, said she felt that there should be some compensation for injuries, "but we heard no practical solutions. This is part of a broader problem. I would find it difficult to help one group of disadvantaged people and neglect others. What we need in this country is a comprehensive health insurance system that would pay for all medical care."

Commission members seemed impressed by a summary of the problem presented by Daniel Wikler, a member of the Commision staff on leave from the Univ. of Wisconsin where he is an associate professor of medical ethics. He suggested that the issue was whether there is an ethical obligation to compensate injured subjects. "This is a moral question, not a legal or economic one," he said. A narrow interpretation would be, "Is this a right, such as a right to a fair trial or to vote? If so, cost should not be a factor. A wider interpretation would be the question, is it morally advisable? The Commission can answer two ways. There are honorable positions on both sides. My personal feeling is that there is no strict obligation to compensate. Persons are apprised of the risks and agree to assume them. They are making a gift to society. On the other side, in a broader sense, it may be morally advisable to compensate. Not all subjects are ideally informed volunteers. We may be overlooking the realities of consent.

Staff member Alan Weisbard, an attorney, suggested that the strongest moral obligation for compensation would be for subjects injured in nontherapeutic research. He acknowledged this probably is a small problem, the numbers are not great and the cost would not be great. He advised the Commission either to proceed with a limited program "or say the problem is too small and drop it."

"There is in a certain sense and to a certain degree an obligation to compensate under certain conditions," Jonsen said. "Our problem is to ascertain those conditions."

Abram called for a vote on a proposal to drop further consideration of a compensation program but to proceed with collection of data on the extent of the problem. Krim, Scitovsky, Mario Garcia-Palmieri and Charles Walker of the nine members present (two missed the meeting) voted for that proposal.

Abram then asked for a vote on a recommendation to develop a small pilot program limited to subjects participating in research conducted by the Public Health Service (the federal Dept. of Health & Human Services, including NIH).

Voting for that proposal were Jonsen, Garcia-Palmieri, Walker, Donald Medearis, Renee Fox, and Carolyn Williams.

Staff was directed to develop a proposal, including various alternatives such as inclusion of therapeutic vs. nontherapeutic research, for presentation at the Commission's next meeting.

AGREEMENT NEARS ON NEW CORE GRANT GUIDELINES; AACI HAS ONE RESERVATION

The Working Group on Guidelines of the Board of Scientific Counselors for NCI's Div. of Resources, Centers & Community Activities moved closer to approval of new guidelines for cancer center core grants last week.

Meeting in Chicago with three representatives of the Assn. of American Cancer Institutes, the Working Group agreed on recommendations it will make to the BSC for limiting the size of core grant applications and the amount of support for staff investigator salaries. Further modifications may be made on details before the recommendation goes to the BSC at its Jan. 29-30 meeting, with Working Group members considering any proposed changes through a conference phone call.

The Working Group agreed, at least in principle, to these limits:

- Applications for renewal of core grants would be held to a maximum request not to exceed the current year total plus 50 percent.
- No more than 40 percent of the total grant could be used to support staff investigator salaries.
- No more than 10 percent of any increase in funds could be used for staff investigator salaries, in the case of centers which use less than 40 percent of their core money for such support.

The Working Group at its previous meeting had arrived at a method for limiting the overall size of grants by suggesting that renewal applications be limited to 10 percent increases over current totals, accompanied by a sliding scale of "bonuses" and "penalties" based on priority scores (***The Cancer Letter***, Nov. 14, 1980).

That brought negative reactions from centers with smaller grants which would be more severely restricted and limited in growth than those with the larger ones. The Working Group agreed that 10 percent was too small and considered other limits up to 150 percent of current totals, an unrealistic figure in light of NCI's overall no growth budget. The Group agreed that 50 percent was an acceptable compromise although still not holding out any guarantee.

In any event, peer review—by the Cancer Center Support Grant Review Committee—still will play a major role in determining final grant awards. Whether the sliding scale scheme with its bonuses and penalties is built into the guidelines was not agreed upon. The BSC and the National Cancer Advisory Board will be asked to consider those details along with the various percentage limits.

NCI staff members are adamant about imposing some limits on staff investigator salary support. As the guidelines presently stand, peer review cannot restrict that support; a few centers have taken advantage of that and have loaded up their applications with huge increases for staff investigator salaries.

A relatively few centers have always required more support for staff investigators than others. Those which now exceed the 40 percent limit would have a grace period to phase down to that (or any other percentage which might be applied). The Working Group discussed the length of the phase down period, but reached no conclusion.

The Working Group agreed on the remaining proposed guideline changes not considered at the previous meeting (***The Cancer Letter***, Nov. 21). These included:

—Interim and new investigator salary support. Center directors would be permitted to pay those salaries from the core grant for up to two years (rather than one year in the proposed guidelines), the Working Group recommended. This would include investigators who lose their peer review support, even when that support came from sources other than NCI.

—Charge back for shared resources. The Group recommended that this be left as flexible as possible, with the mechanism of charge back and determination of who should pay for use of shared resources and how much left up to center directors. Peer review would look at the quality of the overall system and how it is working, with the committee retaining authority to reduce funds for shared resources when it feels that is appropriate.

—"Control" of beds and space. The Working Group felt that "control" was not a good term and not applicable in some cases, particularly in relation to consortia centers.

—Letter of authorization. The new guideline proposal includes the requirement that centers must have a "letter of authorization" from NCI staff before they may submit grant applications. Center executives opposed that, feeling that this gave NCI staff review authority. NCI answered that preliminary staff review is necessary to screen out applicants who do not meet the eligibility criteria (previously approved by the Working Group, including a peer reviewed research base of $750,000 a year). The Working Group agreed that "certification" for administrative purposes was a more appropriate term.

AACI President Alvin Mauer of St. Jude Children's Research Hospital, President-Elect Richard Steckel of UCLA, and Timothy Talbot of Fox Chase represented the centers at the Working Group meeting. They agreed that most cancer center executives recognize the need for some overall cap on core grants. The 50 percent limit would be acceptable, they felt, especially with removal of categorical limits on the flexibility offered to center directors to use their grants as they see fit.

They objected, however, to the 40 percent limit for staff investigator salaries. "That is the one residual issue still to be decided," Mauer said.

Mauer and his colleagues feel that the 50 percent cap on grants, coupled with the 10 percent limit on use of new money for staff investigator salaries, is sufficient to prevent the abuses and to hold increases to reasonable levels. They contend that imposing the 40 percent limit is an unnecessary restriction on flexibility and would penalize those centers which require a higher degree of staff investigator salary support for a variety of valid reasons.

AACI will discuss the issue again with DRCCA Acting Director William Terry and other NCI executives, perhaps including Director Vincent DeVita, at the association's meeting Jan. 25-27. It is on the agenda for 10 a.m. Jan. 26.

GROUP CHAIRMEN OBJECT TO VARIOUS CCIRC PEER REVIEW DEFICIENCIES

Cooperative Group chairmen expressed concerns about the peer review process at their recent meeting, objecting particularly to adverse "personal" comments in summary statements and to budget decisions by the Cancer Clinical Investigation Review Committee.

"Items are appearing in summary statements that are injurious to groups and institutions, unjustifiably so," commented Barth Hoogstraten, Southwest Oncology Group.

"It is the responsibility of the executive secretary to transmit opinions of the committee which may not always be sweetness and light," replied James Holland, Cancer & Leukemia Group B.

Edwin Jacobs, associate chief of the Clinical Investigations Branch, said that he discusses summary statements with Dorothy MacFarlane, CCIRC executive secretary, and "changes are made when appropriate."

Denman Hammond, Children's Cancer Study Group, said, "Statements such as Dr. X is not qualified in such and such are not appropriate."

"One of the responsibilities of reviewers is assessing qualifications of investigators," MacFarlane said. "We're willing to revise statements if they are not factual."

"Dr. MacFarlane and others are reporting what they heard," Holland insisted. "She didn't make the comments, the committee did. Part of the committee's function is to police such things."

"I'm talking about personal comments that are not factual," Hammond answered. "In one instance I know of, a rampant opinion was made by site visitors not qualified to make that judgment."

"Site visitors frequently are fishing," said Paul Carbone, Eastern Cooperative Oncology Group. "We felt ours went well, but when it went to the CCIRC, something changed. I think they try to decide policy, not science. Perhaps they reduced our budget because they felt there was not a lot of money around. I can't understand priority scores given to some of our people. They are inconsistent with the site visit and with accomplishments."

"We've told reviewers not to make judgments based on the NCI budget," MacFarlane said. She added that CCIRC member Hugh Davis is heading a subcommittee studying group budget applications and their review. The subcommittee will meet Feb. 13 at NIH, Bldg. 31 Room 8.

"Peer review originally was to review science," said Bernard Fisher, Primary Breast Cancer Therapy Group. "Review committees should not talk about how much money is available, or how many years an investigator has been getting money. They should go back to reviewing the science." Fisher added that the President's Cancer Panel, of which he is a member, considers the quality of peer review "a predominant issue."

Hammond said that "one of the critical assumptions of the peer review system is that those selected are experts in the areas for which their committees are responsible. The selection of committee members and site visitors is very difficult. I would like to see it more formalized. There were many advantages to having program people directing review (before NCI's reorganization separated program from review). Program people had goals in mind, and they made those goals happen. That is out of fashion now."

MacFarlane said she works with Jacobs in the selection of site visitors. "Part of the problem is that we need to have more CCIRC members on site visit teams."

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. Address requests to the Contracting Officer or Contract Specialist named, Research Contracts Branch, National Cancer Institute, Blair Building, 8300 Colesville Rd., Silver Spring, Md. 20910. Deadline date shown for each listing is the final day for receipt of the completed proposal unless otherwise indicated.

RFP NCI-CM-17396-14

Title: *Preparation of plant extracts*
Deadline: *Feb. 6*

NCI's Div. of Cancer Treatment will make available to interested contractors a request for proposal concerning a project to prepare initial extracts of plants for anticancer screening. The contractor must provide an extraction laboratory, have capacity for storage of 10,000 plant samples, and show evidence of experience in extract preparation.

All samples of dried plant materials (3 lbs. each) will be supplied by the government. It is planned that one contract will be awarded for a three year period of performance at a level budget for all three years

with the number of extracts to be prepared being 2,800 in year one, 2,500 in year two, and 2,200 in year three. All extracts will be prepared in accordance with a standard procedure supplied by the government and will be shipped to other government laboratories for anticancer testing.

The principal investigator must be a chemist trained at the BS or MS level in organic chemistry or phytochemistry and must devote a minimum of 20 percent effort to the contract.

Contract Specialist: Susan Hoffman
Cancer Treatment
301-427-8737

RFP NCI-CP-11013

Title: *Production and distribution of avian myeloblastosis virus and AMV reverse transcriptase*

Deadline: *Approximately Feb. 23*

NCI has a requirement for in vivo production, purification and processing of approximately 700 grams of AMV per year and a requirement for distribution of approximately 120 grams of virus per year. Also, the contractor shall produce in vivo, approximately 10 million units of MAV reverse transcriptase per year.

Contract Specialist: Elizabeth Osinski
Biological Carcinogenesis & Field Studies
301-427-8888

RFP NCI-CO-14347-38

Title: *Cancer Information Dissemination & Analysis Center (CIDAC) covering cancer diagnosis, treatment and rehabilitation*

Deadline: *March 16*

NCI intends to issue a request for proposal to obtain the services of an organization with demonstrated scientific and technical capabilities to assume the operation of a Cancer Information Dissemination and Analysis Center (CIDAC) for the International Cancer Research Data Bank (ICRDB) Program.

CIDACs serve as the major resources for providing to the ICRDB Program scientific guidance essential for maintaining the high quality of ICRDB publications and services designed for cancer researchers. The major activities of this CIDAC include:

1. Assuming regular production of 20-25 different "Cancergrams" (monthly current awareness bulletins containing 30-100 abstracts of recently published cancer research). For each Cancergram topic, a CIDAC staff member (subject specialist) regularly screens, sorts and categorizes abstracts retrieved from computerized searching of an ICRDB data base. The resulting package of abstracts is then reviewed by a consultant (identified by the CIDAC) who is currently involved in research pertinent to the Cancergram topic area, and who need not be an employee of the organization. In order to meet short production deadlines, it is essential that the work of the subject specialist and the consultant-researcher for each monthly Cancergram can be completed with a turnaround time of a few days.

Examples of Cancergram topics, production of which must be assumed by the contractor, are: "Breast cancer—diagnosis, treatment, preclinical biology," "Cancer detection and management—nuclear medicine," and "Rehabilitation and supportive care."

2. Producing annually 10 different "Oncology Overviews" (retrospective compilations of 100-500 selected abstracts on high interest cancer research topics). These publications are developed by the subject specialists in consultation with researchers (identified by the CIDAC) who are recognized as experts in the subject area of each Oncology Overview. Examples of previously published Oncology Overview topics (new topics of similar scope are to be developed by the contractor) are: "The role of computed axial tomography in detection, diagnosis and therapy of cancer" and "Chemotherapy of acute leukemia with anthracycline antiobiotics."

3. Responding rapidly to requests for information in specific cancer research subject areas.

4. Planning and implementing innovative projects to promote communication and exchange of technical information between cancer researchers. The organization must have previous experience in analysis and processing of cancer research information or similar biomedical information. The project director must have a PhD or MD in a biomedical subject relevant to research, and administrative experience. Subject specialists must all have at least an MS or equivalent (approximately half should have a PhD or equivalent), plus research experience in a biomedical subject area relevant to the CIDAC subject area, and collectively they must be able to cover all subject areas relevant to the CIDAC.

The consultants for Cancergrams must all have a PhD or MD and current research involvement in biomedical subject areas directly relevant to the Cancergram each will be reviewing. Collectively they must cover all Cancergram topics within the CIDAC's purview, and should be located within approximately a 25-mile radius of the CIDAC office.

Contract Specialist: Barbara Mercer
Biology & Diagnosis
301-427-8877

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. All rights reserved. None of the content of this publication may be reproduced, stored in a retrieval system, or transmitted in any form or by any means (electronic, mechanical, photocopying, recording or otherwise) without the prior written permission of the publisher. Violators risk criminal penalties and $50,000 damages.