THE CANCER RESEARCH EDUCATION CONTROL LETTER

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DCT BOARD RELUCTANTLY OKAYS RESOURCES CONTRACTS RECOMPETITION, $6 OF $10 MILLION COMPETITIVELY

Nearly $6 million on resources contracts awarded by NCI's Div. of Cancer Treatment were reluctantly approved for recompetition by the DCT Board of Scientific Counselors and another $4.7 million approved for noncompetitive procurement.

Board members objected to "inadequate information" on which to base any decisions on whether or not to approve DCT's recommendations. The staff had prepared a booklet listing each contract, current levels and brief descriptions of the work performed.

"These statements are not adequate," BSC member Harris Busch

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In Brief

THREE, PERHAPS FOUR MAY BE RECOMMENDED TO CARTER; HUGH CREECH TO RETIRE JULY 1

HERE ARE three, and possibly four, names that may be the ones submitted to the President by the NCI Director Search Committee: Arnold Brown, the candidate of the President's Cancer Panel; William Shingleton, director of the Duke Univ. Comprehensive Cancer Center; and Baruj Benacerraf, Harvard molecular immunologist. The three represent three distinct areas of emphasis in the Cancer Program—Brown, an experimental pathologist at Mayo Clinic, as a leader in environmental carcinogenesis; Shingleton, as an outstanding clinician; and Benacerraf, as a leading basic scientist. The fourth possibility is Vincent DeVita, director of NCI's Div. of Cancer Treatment, who would be the leading candidate if the appointment goes to an NCI staff member. DeVita also would satisfy those who feel the job should be in the hands of a top clinician. DeVita took himself out of the running several months ago, but a phone call from the Oval Office might be hard to resist. The search committee had scheduled a final meeting for April 7, but it may submit its recommendations before that date. . . . **HEW SECRETARY** Joseph Califano's troubles with Congress, mostly delays on confirming his appointees, reportedly started when he gave one of his top jobs to someone other than the Senate Finance Committee staff member who wanted it. That committee handles health legislation related to Social Security and has joint responsibility with the Human Resources Committee for hearings on some appointees requiring Senate confirmation, such as the assistant secretary for health. The committee staff member is trying to tell Califano he made a big mistake. . . . **HUGH CREECH,** who has been secretary-treasurer of the American Assn. for Cancer Research for 25 years, will retire following the annual meeting in Denver May 18-21. Fred Philips, head of the Dept. of Pharmacology at Memorial Sloan-Kettering, was elected to the job. Creech's retirement is effective July 1; he'll continue as a member of the board of directors until 1979.

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RESOURCES CONTRACTS TO BE RENEWED, RECOMPETED APPROVED BY DCT BOARD

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said. "There's a sense of discomfort on the Board, as to the purpose we're serving."

DCT Director Vincent DeVita said he was asking only that the Board approve or reject the "concept" involved in the procurements. Detailed review of the contract proposals would be performed by the appropriate technical review committees.

Board member Charles Heidelberger asked if the results of the technical reviews could be provided. "There's no way I could make intelligent decisions on anything in this book," he said.

"We didn't expect you to make decisions on individual contracts, but only to raise red flags," DeVita said. "There is a time constraint. This Board meets only twice a year. We will proceed to recompete these unless you have a question about a specific one."

When Board Chairman John Ultmann asked what would happen if the Board refused to approve the recompetition, DeVita said, "We'll have to come back with more information and attempt to persuade you to let us recompete."

That will not be necessary. The Board went along with the staff's recommendations, although Heidelberger asked that the meeting record show he did not vote on the motion to proceed.

Contracts approved for recompetition will be developed into RFPs between Oct. 1, 1977, and March 31, 1978. They are:

- Support services for extramural clinical trials. Georgetown Univ. is the present contractor, and received $175,000 in fiscal 1976.

This contract provides administrative support services for clinical trials conducted under approximately 40 contracts in 20 institutions, including three groups —Gastrointestinal Tumor Study Group, Ovarian Cancer Group, Lung Cancer Adjuvant Trials Group, and a planned Head & Neck Cancer Adjuvant Study Group—and unaffiliated institutional contracts for phase II/III studies, breast cancer studies (phase II), phase II gastrointestinal studies, and melanoma studies. The services will provide the following functions: a) preparation, supply and storage of study forms and protocols; b) distribution and acquisition of forms, protocols, and informational materials to and from the contractors and other institutions carrying out similar trials; c) administrative and office support for chairmen of groups and principal investigators of unaffiliated contract-supported institutions; d) preparation and distribution of reports, including incorporation of statistical analyses into quarterly, annual, and special reports. The central support facility provides needed coordination and communication between contractors and among chairmen, principal investigators, and NCI project officers. The services will facilitate efforts toward standardization of forms, protocols, and reporting, and for assuring more rapid publication of final results of studies.

- Preclinical canine bone marrow transplantation and immunotherapy studies. Hazleton Laboratories is the present contractor and received $408,000 in FY 1976.

Board member James Holland said, "That's a bargain at 400 grand." The contract served the Experimental Hematology Section of DCT's Pediatric Oncology Branch which has established a program to improve methods for the cryopreservation of human marrow which would permit reconstitution of patients with their own marrow following ablative chemotherapy. Hazleton Laboratories will use dog models to establish the dose of stem cells, as quantitated by colony forming unit assays in vitro, that is necessary for autologous reconstruction in animals. This information will be used to assess the quantitative adequancy of cryopreserved samples of marrow of patients who are to undergo autologous marrow rescue following ablative chemotherapy. Furthermore, the contract will explore minimum effective doses of granulocytes for predictive compatability in platelet transfusions in patients. A dog model will be used to set minimum dose of granulocytes per meter squared necessary to establish a clinical response in granulocytopenic animals with gram negative sepsis for supportive hematology.

- Preparation of bulk chemicals and drugs. Parke-Davis is one contractor, with $389,500 in FY 1976; Aldrich Chemical Co. is the other, with $191,800.

These contracts provide for the resynthesis of a variety of compounds required for clinical or preclinical evaluation. The compounds prepared are not readily available on the open market or from the original supplier in the amounts required. About 50% of the Parke-Davis and 30% of the Aldrich effort is devoted to the preparation of large quantities of materials, in the multikilogram range, requiring pilot plant facilities. All materials prepared are fully characterized and of high purity.

- Acquisition of chemicals and drugs for evaluation in cancer chemotherapy. Present contractor is Starks Associates, at $373,200.

This contract supports the Drug Synthesis & Chemistry Branch's efforts in the acquisition of chemicals and drugs for evaluation in the primary screen. The contractor is required to: (1) provide liaison services to develop new sources of material and to encourage potential suppliers to participate in the program through voluntary contribution of samples; (2) collect samples; (3) provide support services in the processing of compounds; (4) aid in the management of computer-generated reports relating to compound acquisitions; and (5) assist in the development of methods for selecting materials for the screen.

- Beagle production. Three contractors presently

supply beagles needed for the Developmental Therapeutics Program toxicology effort--Hazleton Labs, $40,500; Laboratory Research Enterprises, $39,750; and Marshall Research Animals, $42,000. The animals are shipped to subcontractors working under the prime contractor.

• Rodent production. Five contractors are presently involved--Laboratory Supply, $129,731; Southern Animal Farms, $134,660; ARS/Sprague-Dawley, $227,675; Simonsen Laboratories, $220,175; and Charles River Breeding Labs, $205,234.

These contractors receive breeding animals directly from the Primary Genetic Center. This breeding stock, from pedigreed brother x sister expansion colonies, are outbred once at the Rodent Production Center. It is at this level that large volumes of pure inbred strains are produced. These offspring are then used by the hybrid breeders for producing the appropriate hybrid as well as supplying pure inbred strains to the screening laboratories.

• Operation of animal disease diagnostic lab. Litton Bionetics is the present contractor, at $71,172. This is a diagnostic contract which checks animals routinely throughout the animal program for salmonella and pseudomonas. In addition, this contract is used to confirm the flora status of the defined flora isolator animal at regularly scheduled intervals. It is planned that a new contract will be awarded to continue this work, effective Feb. 15, 1978.

• Study of effects of anticancer agents on reproduction. Dow Chemical Co. is the present contractor, at $156,000.

Dow performs standard reproduction studies in accordance with the "FDA Guidelines for Reproduction: Studies for Safety Evaluation of Drugs for Human Use," dated January 1966, in three different phases: Phase 1, general reproductive performance and fertility, employs rats or mice of both sexes; Phase 2, the teratology phase, employs mice and/or rats and rabbits; and in Phase 3, the perinatal-postnatal phase, mice and/or rats are used. The FDA guidelines are revised and/or supplemented by the project officer whenever the acquisition of new data indicates it to be advisable. Upon completion of each study, a complete report is prepared in a format suitable for direct publication in a well-recognized scientific journal. The data also becomes an integral part of the new drug application submitted to the FDA.

• Procurement of embryonic cell lines with variable growth rates. Litton Bionetics is the present contractor, at $281,000.

Busch said he was reluctant to approve the contract at that level; DeVita said the new contract probably would be at a "slightly" reduced level. The main objective of this contract is the preparation, growth and characterization of defined tissue culture cell lines and of fresh human leukemic blood cells for use by project officers. Cell cloning, cell genetics, cytochemistry, defining immunological cell markers and labeling cells with radioisotopic precursors for the isolation of metabolic products are also performed.

• Prime contractor for protocol toxicology studies. Battelle Memorial Institute, at $2.9 million. Most of that amount goes out in subcontracts.

Battelle supervises all contracts carrying out the toxicologic evaluation of potential oncolytic agents under the aegis of the Laboratory of Toxicology. Through the prime contract mechanism, eight contracts formerly carrying out these studies have been consolidated under a single management-type contract. The workscope is comprised of four tasks as follows: Full protocol studies; high priority toxicity studies; specific organ testing, and automation of toxicity data.

The sole source contracts which will be renewed on a noncompetitive basis include $4.3 million for one program with seven contractors:

• Primary and detailed in vivo screening for anticancer activity. Contractors are Hazleton Labs, $568,000; Battelle-Columbus, $764,000; WARF Institute, $673,000; A.D. Little, $559,000; IITRI, $836,000; Mason Research Institute, $663,000, and Institut Jules Bordet, $288,000.

These contracts are for the in vivo screening of new synthetic and natural product materials and the followup testing of active materials. The level of effort is based on the effort required to do a six mouse L1210 assay. These contracts range in level of effort from 25,000 to 50,000 L1210 equivalents.

NCI justified the noncompetitive procurement by stating that "no other sources could implement the program without a delay of six months to a year just to become competent with the established systems. . . . The methodology work currently being carried out could not be readily moved to another source since it is a process of inquiry and change built on knowledge and experience."

• In vitro testing for cytotoxicity of chemical agents. A.D. Little is the contractor, at $210,000.

This contract was awarded competitively to Little, and expires Dec. 31, 1977. In vitro contracts with other labs expire in Dec. 1978 and Feb. 1979. NCI wants to extend Little's contract through Dec. 1978 and then competitively bid all of them in a single package.

• Operation of cancer chemotherapy research collaborative offices. Institut Jules Bordet maintains a liaison office in Brussels, at $62,000 a year, and the Japanese Foundation for Cancer Research maintains a similar office in Tokyo, at $47,000 a year.

DeVita said that the FY 1976 figures did not necessarily represent the amounts that would be awarded in the new contracts. NCI does not like to reveal the money budgeted for projects in upcoming contracts. "When we let them know what we expect to spend on a contract, that's the figure they come in with," DeVita said.

FISHER GROUP SUGGESTS CANCER PROGRAM CHANGES TO ENHANCE SURGICAL ONCOLOGY

An ad hoc committee of surgeons headed by Bernard Fisher has submitted recommendations to NCI aimed at "bringing surgeons into the mainstream" of the National Cancer Program by providing for more representation of surgeons on NCI advisory groups and by funding more surgical oncology research.

The committee also asked for reorganization within the Div. of Cancer Treatment as a "major positive step toward enhancing the posture and contributions of surgical oncology." Another suggestion was that surgical oncology departments be established in cancer centers and medical schools.

Fisher, as chairman of the National Surgical Adjuvant Breast Project, represents the most successful attempt yet in combining the efforts of surgeons with other disciplines in an NCI-supported clinical research program. He is a member of the DCT Board of Scientific Counselors, and was asked by DCT Director Vincent DeVita to organize a committee of surgeons to develop recommendations for the division relating to the needs of surgeons to develop recommendations for the division relating to the needs of surgical oncology.

Excerpts from the report follow:

"In recent years, a concerted effort has been directed toward developing and strengthening medical and radiation oncology in this country. Funds and programs have been made available and implemented for that purpose. The entire Clinical Cooperative Group Program, almost entirely oriented toward medical oncology, has influenced and strengthened that specialty. Training programs at all levels (pre- and postdoctorate) have, within a few years, developed an entire generation of clinical and research specialists in those disciplines.

"As a natural consequence, clinical and research leadership positions in oncology as well as policy making and peer review committees have been heavily dominated by members of those specialties. Equally important is the fact that NIH study sections which review oncologic research proposals are more often than not composed almost entirely of individuals from a variety of disciplines, e.g., immunology, cell biology, experimental pathology, etc. that have received expansive support from a variety of sources which have permitted their (the specialties) growth and development.

"In contrast, despite the dominant role of surgery in the management of patients with solid tumors, there has been almost total neglect in making available the necessary resources and intellectual commitment which would have permitted the development of surgical oncology in a fashion commensurate with that of the other disciplines. Whether this event may be ascribed to the fact that there may not have been progressive, unified surgical leadership as has existed with the other specialties or because it was the constricted view of those in policy making positions that surgeons could make no further contribution to the advancement of oncology is irrelevant. The fact is that this has occurred and requires correction.

"Due to this omission, only a handful of individuals and a miniscule number of training programs represent the leading edge of surgery in oncology. One impediment relates to their inability to obtain peer review for their research grants and project proposals in study sections and at site visits. It is emphasized that this statement is not intended to convey the thought that there is intentional bias or prejudice against such proposals—although it has not infrequently been indicated that scientific competence somehow relates to one's discipline. Nor is it the belief that their proposals should be given preferential consideration. They must compete on an equal basis relative to scientific merit with those from all disciplines.

"There is, however, all too frequently a difference in orientation by reviewers who fail to appreciate the true significance of a proposal because of their lack of familiarity with the discipline. As a result, when priorities for funding are established, those with surgical biological significance are apt to be at a disadvantage.

"The tragic and most important consequence of this situation is that the potential contributions in clinical and basic research from more than a generation of talented young surgeons has been underdeveloped. The biologic and physiologic, as well as conceptual contributions which surgeons have made since World War II and which were a major factor responsible for progress in cardiovascular, transplantation, and gastrointestinal fields, for the most part, have not been realized in oncology.

"The following recommendations are considered imperative in order to update the contributions and involvement of surgeons in basic and clinical oncologic research and to ensure that they provide more than token representation with the sole function of 'providing patients and patient material' so necessary for the investigations of others.

"1. There should be established within the National Cancer Institute a study section for surgical oncology.

"2. Each NCI clinical review group, task force or advisory committee have representation by surgical oncologists.

"3. Surgical oncologists have specific involvement in the preparation of RFPs for clinical and basic research where applicable.

"4. Contracts or research grants be made available for research which has a surgical oncologic orientation.

"Since only through training will it be possible to upgrade the specialty and make available the number of surgical oncologists required to enhance the con-

tribution of that specialty, it is recommended that:

"1. Surgical oncology departments or centers be established in cancer centers and medical schools.

"2. NCI training awards in surgery be given.

"3. Programs in post-residency surgical training be established.

"4. Specific programs for the teaching of medical students, residents and fellows in oncology be implemented.

"5. Funds be made available to attract young investigators at the junior faculty level into the specialty of surgical oncology.

"It is reiterated that the above presents an overview of a problem and recommendation toward its solution, which goes beyond the purview of the Div. of Cancer Treatment. DCT is, however, in a position to take a major positive step toward enhancing the posture and contributions of surgical oncology. The following are specific recommendations deemed necessary for this accomplishment.

"1. There must be a proper administrative structure within the DCT to implement the recommended surgical program.

"a) This requires the establishment of a separate and new program which in the table of organization of the division is of the same posture as the Cancer Therapy Evaluation Program, the Experimental Therapeutics Program, the Drug Research & Development Program, etc. This program will be known as the 'Surgical Therapy Evaluation Program (STEP)'.

"b) STEP will be directed by an associate director of DCT with appropriate supporting staff. He will be full-time in this position. It was unanimously held that the individual appointed to this position be a current member of the Surgery Branch of DCT. A major commitment of this individual will be to develop visibility of the surgical program and to promote involvement of the surgical community in the program.

"c) There will be a strong extramural advisory group consisting of surgeons and representatives of other disciplines such as medical oncology, radiation therapy, immunology, pathology, etc. The advisory group will convey to the program director the direction and scope of the program which the surgical community deems appropriate. The group will also play a major role in the preparation, review, selection and subsequent evaluation of RFPs and other projects which come under their purview.

"d) The STEP will be composed of two branches—the Surgical Studies Investigations Branch, and the Surgical Adjuvant Therapy Branch.

"2. The Surgical Studies Investigations Branch will be directed by a branch chief. Because of the emergence of new modalities that appear to be effective against solid tumors, the role of surgery in the treatment of solid malignancies needs to be reassessed. This will be a principal goal of the branch. It will be chiefly concerned with the generation and conduct of RFPs in those scientific areas which have special surgical orientation. The following are examples of areas which might be considered worthy of investigation:

"a) Hyperthermia. Questions needing answered concern the use of such hyperthermia systemically or localized; whether the hyperthermia should be pre-, intra-, or postoperatively; the possibility of its use in esophageal or stomach cancer or other advanced tumors; and whether hyperthermia might make nonresectable cancers resectable.

"b) Immune effects of surgery. It is imperative that more information be available concerning this subject. There is relatively little known about the immunosuppressive effects of anesthesia in surgery and whether or not immunopotentiators are of significance in that regard.

"c) Sequential relationship of other therapeutic modalities to surgery, i.e., radiation therapy, chemotherapy, immunotherapy and hormonal therapy. Are such agents more effective when given preoperatively, postoperatively, intralesionally before surgical resection, and so forth?

"d) Effects of cyto-reductive surgery, both for primary or secondary disease. Is there any merit to the surgical treatment of metastatic disease?

"e) Cryotherapy and fulgeration vs. surgery with adjuvant therapy.

"f) Effect of surgery on blood coagulation.

"g) Nutrition and relation to immune competence.

"h) Routes of administration of adjuvant therapy and the temporal relation to surgery.

"Each of the above are considered to encompass a large area which would answer many questions related to surgery and the science of surgery. Such issues as to whether: Radical surgery vs. restrictive surgery has any effect on immune parameters; the administration of BCG, C. parvum, or levamisole prior to surgery influences the immunologic effects of surgery; cyto-reductive surgery has a place in the management of ovarian or renal tumors or soft tissue sarcomas, and the role surgery plays in the control of cancer relative to other modalities require consideration.

"3. The Surgical Adjuvant Therapy Branch. This branch will have several key objectives. It will have as a primary mission the upgrading of surgical input into all protocols involving surgery. Second, it will attempt to insure that there is adequate peer review for surgical proposals. In that regard, the associate director of STEP should serve as a representative to the CCIRC. Third, and most important, the Surgical Adjuvant Therapy Branch will be concerned with the issuing of RFPs for the programs directed toward clinical trials of therapy involving specific organ sites, such as liver, lung, colon and rectum, pancreas and breast. These studies will require the 'intense' participation of surgeons. Examples of such studies are the segmental mastectomy protocol for breast cancer, the value of

removing regional lymph nodes in operations for melanoma, and the use of conservative surgery for sarcomas.

"4. General considerations.

"a) STEP would provide a mechanism whereby the organized surgical community such as the American College of Surgeons (ACS), the Society of Surgical Oncology and the Head & Neck Surgical Society would have access to the DCT relative to cancer programs. The ACS Commission on Cancer has recently acknowledged surgical oncology as a specialty and the Society of Surgical Oncology is developing criteria regarding training programs in surgical oncology.

"b) STEP will provide a mechanism for ensuring that protocols generated by Cooperative Groups and others which involve surgery will have adequate peer review.

"c) Since it is realized that the viability of surgical oncology in this country may well relate to the policies in divisions of the NCI other than DCT, STEP through its associate director could provide interlinks with other divisions which could lead to correction of the deficiencies enumerated which are outside of the DCT. An alternative consideration is that, in the future, there will be another branch of STEP which will concern itself with cancer biology having surgical implication.

"d) STEP should provide an additional mechanism whereby the goals of DCT may be accomplished; particularly that which relates to improving the end results of patients with cancer. It should enhance through the intra- and extramural interplay envisioned in a better cooperation and participation of the surgical community in clinical trials. This will enhance the quality and quantity of clinical investigation with commensurately less cost."

Members of the committee were Alan Baker, Paul Chretien, Elwin Fraley, Yes-Tsu Lee, LaSalle Leffall, Donald L. Morton, Steven A. Rosenberg, Edward F. Scanlon, Frank Sparks, and Richard Wilson.

Fisher told the DCT Board that he "abhored the concept of discipline chauvinism. I sincerely believe that progress will be in cooperation of the disciplines. But over the years there have been indications that the surgical community has not been in the same vantage point as other disciplines."

Board member Donald Morton observed that "most departments of surgery do not recognize surgical oncology as a specialty. . . . Surgery is in need of the same developmental support that medical oncologists and radiotherapists received some time ago."

Chretien said that "progress may depend on chemotherapy before surgery. We have to convince the surgeons not to immediately remove the tumor, but to use his knowledge of the patient's tolerance and capability, to manipulate the use of chemotherapy and radiotherapy before surgery."

"Where does the medical oncologist fit into this reorganization (recommended by Fisher's committee)?" Board member James Holland asked. "The medical oncologist fears he may have no access to patients."

"The surgeon, who sees the patient first, has got to be brought into the mainstream, as an equal partner, and not sprinkled around as we tried to do in the Cooperative Groups," Fisher said.

"The problem I've encountered," said Board member Samuel Hellman, "is that most surgeons are not knowledgeable enough about medical interventions to talk to other surgeons about it."

DeVita had some reservations about the recommendations. He pointed out that DCT has a Cancer Therapy EValuation Program that definitely was not limited to chemotherapy. Also, the issues of training grants and special study sections belonged in the Div. of Cancer Research Resources & Centers. "I share the view on the need for a special study section, or at least to expand existing ones. All clinical research fares poorly with the present study sections, other than the Cooperative Groups."

OBEY CARRIES ON CARCINOGENESIS TACK, RAISES NEW ISSUE ON SHUBIK CONTRACT

Congressman David Obey (D.-Wisc.) has been engaged in a crusade of sorts for the past year in which he has (a) forced NCI to beef up its Carcinogenesis Program, particularly the phase of the program which tests chemicals for their carcinogenicity, and (b) has raised issues aimed at questioning NCI's dealings with the Eppley Institute and its director, Philippe Shubik.

Obey pursued that crusade again during the hearing on NCI's 1978 budget before the House HEW Appropriations Subcommittee, of which Obey is a member.

Shubik has been a member of the National Cancer Advisory Board since it was created by the National Cancer Act of 1971, and before that was a member of the National Cancer Advisory Council. He is chairman of NCAB's Subcommittee on Environmental Carcinogenesis.

Eppley Institute, at the Univ. of Nebraska, has had a contract with NCI's Div. of Cancer Cause & Prevention for many years, performing carcinogenesis research. At the budget hearing last year, Obey raised the issue of work Shubik and Eppley had done for industrial firms, implying a conflict of interest.

This year, Obey's line of questioning implied that the renewal of the Eppley–NCI contract in 1973 was not properly and perhaps not legally reviewed, and that NCI staff may be more lenient in scrutinizing Shubik's work out of deference to his position on the NCAB and the subcommittee.

Obey also questioned NCI Acting Director Guy Newell and DCCP Director James Peters closely on the disposition of the 77 new positions which he had written into last year's appropriations bill, earmarked for the Carcinogenesis Program. After receiving assur-

ances those positions would be filled, Obey indicated that he might legislate even more slots for that program this year.

Here's how the questioning went on Shubik:

Obey: Last year Dr. Rauscher said one of his key advisors was Dr. Shubik. Is that still true now as far as you are concerned?

Newell: Dr. Shubik is a member of the National Cancer Advisory Board appointed by the President.

Obey: That Board is rather unique, isn't it? It is appointed directly by the White House. In fact, some people have argued that the Board and the Panel are considerably more broad than just advisory. Wouldn't you say that is true?

Newell: They give a lot of advice, if that is what you mean.

Obey: Shubik is a member of the Board, and he is chairman of the Subcommittee on Environmental Carcinogenesis, isn't he?

Newell: Yes sir.

Obey: So Dr. Shubik is the man who is in charge of looking over the shoulder of the Div. of Cancer Cause & Prevention, so to speak. Would that be an accurate description?

Newell: Well, I think the role of the advisory committees has been a bit broader than that. I don't think they delve very much into the operational aspects of any division.

Obey: I understand it is broader. But one of the functions for them is to sort of oversee in a general way, isn't it?

Newell: Yes.

Peters: Historically, if you go back about three or four years, to the time when that subcommittee of the Board was established, you will find that it was established by the chairman of the Board for a specific purpose. To the best of my knowledge, there were only two specific charges to that subcommittee, both of which have been completed. I do not believe that the degree of their overseeing the direct operation of the Carcinogenesis Program is that great.

Obey: Well, nevertheless, it would be helpful for you or anyone else working in that area if you had good relations and good communication with Dr. Shubik, would it not?

Peters: With all members of the committee.

Obey: Isn't it extremely important that any dealings that take place between the institute and the DCCP and Shubik and the research organization over which he presides be handled in the most open, regular and rigorous possible review?

Peters: Yes sir.

Obey: The Eppley Institute is one of the largest recipients of NCI money of any organization in the country, isn't it? What did it receive last year?

Peters: About $3 million.

Obey: Over the last eight years?

Earl Browning, NCI budget officer: About $20-$25 million.

Obey: Let's take one year in those eight. Take 1973. What kind of review took place both internally and externally? Let's take internally first. You say there would have been no internal review of the Eppley contract?

Peters: I cannot be sure for any specific year, including 1973, but to the best of my knowledge there has always been an internal review.

Obey: Okay. Was there an in house review of the Eppley contract in 1973?

Peters: I would assume so. I see no reason for there not to have been. I would have to go back and check the record. That is four years ago.

Obey: Could you provide for the record what scientists in your shop participated in that review?

(***The Cancer Letter*** was told later by NCI that the in house review was performed by a committee headed by Saffiotti, and including Richard Bates, Andrew Peacock, Herman Kraybill, John Berg, Elizabeth Weisburger, Thaddeus Domanski, John Cooper, Herbert Rapp, Michael Sporn, Gori, and Allen Heim.)

Obey: What kind of outside review of that contract did you have?

Peters: For several years that contract was reviewed by special ad hoc review groups, as were other contracts of a large multidisciplinary nature. This was because the activities within these contracts were such that we felt that no one individual review group could adequately provide a review.

Obey: Did any standing advisory committee in your operation review that? The answer would be no.

Peters: That is correct.

Obey: So a special committee was appointed to review. Is that correct?

Peters: That is right.

Obey: Who was responsible for collecting the names of people served on that special advisory committee?

Peters: This was done in conjunction with the project officer and the senior investigator in the program area. I'm sure Dr. Saffiotti, as program director, had input.

Obey: Any idea who else?

Peters: Dr. Gori was the project officer.

Obey: Would you have any responsibility in that area?

Peters: I would have had approval responsibility for the selection.

Obey: Could you tell us who served on that committee and give us the dates they met to discuss the contract?

Peters: I can provide that.

(Members were Leon Goldberg, Albany Medical College; Harold Grice, Canadian Food & Drug Directorate; Paul Harris, who had retired as a scientist from Eli Lilli Co.; Martin Lipkin, Sloan-Kettering; J.A. Swenberg, Upjohn; I.B. Weinstein, Columbia; and Gerald Wogan, MIT. NCI staff members on the committee were Berg, Domanski, Kraybill, Sporn, Luigi DeLuca, Jerry Rice, James Selkirk, Carl Smith and

Frederick Wiebel.)
Obey: Do you know if in fact they ever met?
Peters: They may have conducted a mail ballot. That is frequently done.
Obey: Did they ever meet?
Peters: I don't know. For that particular year I will have to check the record.
Obey: If they had met would that have been or not have been a violation of HEW regulations? What I am trying to get at is, was this in fact a duly constituted advisory committee under HEW regulations?
Peters: As far as I know, we always have operated within the regulations. I am not aware of any operation outside the regulations.
Obey: It was not one of the nine standing committees, but you say you think that committee could have met without being in violation of HEW regulations?
Peters: No, I said I think it may have been an ad hoc committee, but I am not sure, and I said it may have conducted its business by mail ballot. I am not sure about that either, but I can provide it for the record.
Obey: Could that committee have met under HEW regulations seeing that it was an ad hoc rather than a regular committee?
Peters: I don't think so. I don't know exactly what the stipulation was or when the Committee Management Act came into being.
Obey: Once the contract was awarded, what effort was made by the institute to monitor the progress of the Eppley Institute during the year? I am talking about 1973. Do you have any idea?
Peters: I feel sure there were routine visits.
Obey: Any progress reports which are sent to you for something like that?
Peters: Yes, quarterly progress reports and an annual report.
Obey: Now, this year I understand the institute will be handling that contract a little differently.
Peters: That is correct.
Obey: They will receive the normal in house and standing advisory committee review that everybody gets.
Peters: That is correct.
Obey: How will you go about that? You will break down the contract into its constituent parts?
Peters: Yes, four areas.
Obey: Given the ability to do that this year, why wasn't it done in the past?
Peters: The reason that it was not done in prior years is that we were working closely with the people at the Eppley Institute in order to provide them an opportunity to come in for grant support, which they did.
Obey: I guess I still don't understand that response. My point is, given the position that Dr. Shubik occupies, given the relationship he has to the institute, wouldn't it have been more appropriate if you had used the same procedure which you plan to use from now on in previous years to review that contract?
Peters: It would have. I indicated a moment ago that because of the multidisciplinary nature of that contract, it and others of that type are frequently reviewed by special ad hoc groups because there is not sufficient expertise on any one committee to evaluate all facets of that type of contract.
Obey: Why is it possible to do it now?
Peters: Because we split it into four areas each of which will be reviewed by a contract review committee.
Obey: Why couldn't that have been done before, is my question?
Peters: We were in the process of attempting to do that. It took time.

RFPs AVAILABLE

Requests for proposal described here pertain to contracts planned for award by the National Cancer Institute, unless otherwise noted. Write to the Contracting Officer or Contract Specialist for copies of the RFP, citing the RFP number. Some listings will show the phone number of the Contract Specialist, who will respond to questions. Listings identify the respective sections of the Research Contracts Branch which are issuing the RFPs. Their addresses, all followed by NIH, Bethesda, Md. 20014, are:
Biology & Diagnosis Section — Landow Building
Viral Oncology & Field Studies Section — Landow Building
Control & Rehabilitation Section — Blair Building
Carcinogenesis Section — Blair Building
Treatment Section — Blair Building
Office of the Director Section — Blair Building
Deadline date shown for each listing is the final day for receipt of the completed proposal unless otherwise indicated.

RFP NO1-CO-75390-04

Title: *Systems planning support services for the National Cancer Institute, National Cancer Program*
Deadline: *Approximately early June*

NCI is seeking organizations having capabilities and facilities to provide systems planning support services for the Office of Program Planning & Analysis of NCI. The services are directed toward planning and analysis activities in support of the National Cancer Program. The services required include:

1. National Cancer Program planning documents.
2. Planning related support.
3. Conference and meeting management.
4. Documentation and presentation support.

Contracting Officer: Patricia Ann Eigler
Office of the Director

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