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NCAB GROUP ASKS DRG ADJUSTMENTS FOR INSTITUTIONS WITH PEER REVIEWED COMPONENTS, 25 PROTOCOL PATIENTS

The National Cancer Advisory Board Committee on Cancer Control & the Community agreed Monday to recommend to the full Board that it ask the Administration to make adjustments in Diagnosis Related Group reimbursement for institutions involved in clinical research.

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In Brief

CLARK, HUTCHINSON GAIN NEW HONORS; NOMINATIONS OPEN FOR BRISTOL-MYERS AWARD; NIH APPOINTMENTS

LEE CLARK, who directed M.D. Anderson Hospital & Tumor Institute for 32 years, now has a building named for him. The R. Lee Clark Clinic Building was so designated by the Univ. of Texas System Board of Regents on the recommendation of Charles LeMaistre, who succeeded Clark as president of the cancer center. The regents waived traditional rules requiring that UT buildings not be named for living persons. Clark, 76, retired in 1978. . . . **WILLIAM HUTCHINSON**, president and founding director of the Fred Hutchinson Cancer Research Center, has received the Alumnus Summa Laude Dignatus Award from the Univ. of Washington, the highest honor bestowed by the university's Alumni Assn. The award noted Hutchinson's "more than 40 years of service to mankind as a surgeon and a leader in the field of cancer research and treatment." Hutchinson is a 1931 graduate of the university. . . . **ALBERT OWENS**, chairman of the Seventh Annual Bristol-Myers Award Selection Committee, has announced that nominations are now being accepted. The $50,000 award is made for outstanding contributions to cancer research. Nominations will be accepted from medical schools, free standing hospitals and cancer research centers until Dec. 1—one nomination per institution. For forms and further information, contact Secretary, Awards Committee, Bristol-Myers, 345 Park Ave., Rm. 43-38, New York 10154. Owens is director of the Johns Hopkins Oncology Center. . . . **JAMES WYNGAARDEN**, NIH director, announced two new major staff positions and the appointments to fill them. Joseph Rall, who has been deputy director for science, is the new deputy director for intramural research. William Raub, associate director for extramural research and training, was elevated to deputy director with the same responsibilities. Thomas Malone will continue as overall NIH deputy director. . . . **NTP BOARD** of Scientific Counselors Subgroup on Data Requirements from Prechronic Studies (subgroup of the Panel on Chemical Carcinogenesis Testing & Evaluation) meeting July 15 will hear presentations on chemical disposition, metabolism, maximum tolerated dose, short term testing, and dose vehicles. The meeting will be held at NIH, Bldg 31 Rm 9, 9 a.m.

CENTERS, CCOPS, COOPERATIVE GROUP MEMBERS DRG EXCEPTIONS MAY BE ASKED

(Continued from page 1)

The committee emphasized that it would ask for exceptions or adjustments only for those institutions with an NCI peer reviewed component and which place a minimum of 25 patients a year on NCI approved protocols.

Committee members (Chairman Gale Katterhagen, Rose Kushner and William Powers–the other members did not attend) agreed on the general outline of a recommendation which will be mailed to all Board members with a request that they respond by mail with their reaction. The next meeting of the full Board is Oct. 3-5, after the scheduled Oct. 1 date for implementation of the DRG reimbursement system. The Health Care Finance Administration intends to publish its proposed DRG regulations by Sept. 1.

After the meeting, Katterhagen drew up the statement to be sent to Board members:

"The committee recommends that the policy of the National Cancer Advisory Board be as follows:

"–The Diagnosis Related Group system of reimbursement is not appropriate for total reimbursement of patients on clinical trials.

"–Without additional reimbursement, NCI's clinical research program will falter, ending a decade of significant progress against this dread disease.

"–Clinical research conducted under the auspices of an NCI peer reviewed institution (e.g. comprehensive center, specialized center, member institution of a cooperative group, or a Community Clinical Oncology Program), contributing data on at least 25 protocol patients per year, require an adjustment in their reimbursement mechanism.

"–Comprehensive and specialized centers are involved in unique research that will require institution specific rates.

"–Cooperative group member institutions and CCOP institutions will require at least double the average reimbursement rate.

"It is our belief that this emergency situation requires the immediate attention of the full National Cancer Advisory Board. Without our complete backing, the National Cancer Program's research efforts will come to an abrupt halt. The President, Secretary (of Health & Human Services), and Health Care Finance Administration need to heed the direction of Congress, that institutions "involved extensively in treatment for and research on cancer" require this type of exception. Anything less will defeat the congressional intent to preserve our nation's clinical research efforts against cancer."

Katterhagen had sent committee members a draft of a statement summarizing the DRG problem, including his suggestions for correcting it:

Over the past several years, the federal government and Congress have considered a variety of mechanisms for containment of health care costs and expenditures. In October 1982, Congress passed the Tax Equity & Fiscal Responsibility Act of 1982 (TEFRA) which legislates a two-step transition from our current system of reimbursement to Diagnosis Related Groups (DRG). This system establishes fixed prices for specific types of admissions and, over a period of four years, phases in the use of these prices. Congress made provisions for the development of equitable DRGs based upon regional costs, hospital case mix, and cases with unusually long lengths of stay.

Congress made further provisions for adjustment to these average DRG rates in the Social Security Amendments of 1983. In this law, Congress prescribed an adjustment in the rates for medical schools and gave the Secretary the authority to "provide by regulation for such other exceptions and adjustments to such payment amounts under this subsection as the Secretary deems appropriate (including exceptions and adjustments that may be appropriate with respect to hospitals involved extensively in treatment for and research on cancer."

It is our understanding that the Secretary is not considering the implementation of this provision or is considering its implementation in only a handful of the U.S. institutions involved in clinical cancer research.

It is our judgment that a lack of an exception or adjustment will cripple and soon cause widespread halt to the National Cancer Program's clinical research initiatives, thereby ending a decade of significant progress against this most dread of all diseases. Indeed, it will set the National Cancer Program back 30 years.

We urge the President, Congress and the Secretary of HHS to assure that this important program does not end. For with its end, it is an end to the hopes of millions of Americans who look forward to our continuing and winning the battle against cancer.

The crux of the problem was carefully set forth by Congress. There are a number of hospitals in the U.S. which are conducting clinical research on new methods of attacking the myriad forms and stages of cancer. Together these institutions account for less than 5 percent of U.S. hospitals, yet they provide almost all of the progress in improving cancer diagnosis, treatment and continuing care.

These institutions have two or three important characteristics. First, they are involved in direct, formal clinical research programs with the National Cancer Institute, one of the cooperative research groups or are one of the large designated cancer research centers.

Second, in order to qualify for this role, these institutions have been reviewed and found to have the cancer specialists, personnel and facilities necessary to support the more sophisticated care and treatment required by clinical research. These "environments for research and treatment" include dedicated oncology beds, specialized (more intensive) nursing care, pharmacy, dietary, social service and data management facilities that are all extraordinary.

Not only do patients on clinical trials benefit from these environments, but every cancer patient referred to these institutions also benefits directly from these "environments of excellence." It is fair to say that these institutions represent the most advanced state of the art cancer care, although it is clear that other institutions also provide the best available care for many kinds of cancer. In all, we are speaking of approximately 80 cancer centers and medical schools and, perhaps 150 to 200 community hospitals which enter a minimum of 25 patients on clinical protocols each year.

Clearly, the costs of this clinical research effort are significantly different from the mainstream of cancer care costs. These institutions are continuously involved in new experiments that will put their patient costs well outside the average

costs developed for DRGs. Rigorous research requires extra testing and procedures to assess the impact of new research protocols. It requires environments where patients can be managed using potentially toxic regimens and other advanced therapeutic modalities. To lump these institutions and patients with the 95 percent which give more standard treatments is a major error. Hospital administrators will quickly tell researchers to cease research activities and disband specialized cancer care resources, since these endeavors will literally generate major monetary losses for hospitals. Cancer centers caught at the same rates as average hospitals will quickly fold. Their levels of intensity are far above normal rates.

More importantly, it is a major error for our society to limit cancer research initiatives to a given amount. What this says is that an advance in cancer care cannot even be attempted unless it is as cheap as the average cost of a technique in current use. One of the distinctions of cancer treatment is we have no final answers. We may have dramatically improved our percentages, but many of the final cures lie ahead.

In outlining this position, we do not mean to attack the DRG system as a whole. However, we are concerned about the rapid dissemination of new technologies to cancer patients wherever they are tested. In this paper, the focus of our concern is the potential loss of the total national cancer research program.

We cannot have all of the details yet, since the HCFA has not yet released its DRG rates. However, we have several key pieces of information which provide us with important information.

The first is the New Jersey experiment. In New Jersey, a form of the DRGs has been in effect in hospitals for one to three years. Case study data shows, for example, significant losses of $160,000 in one cancer hospital program in one year.

Data from cancer centers are even more varied. A bone marrow transplantation for ALL at a comprehensive cancer center costs from $70,000 to $210,000. The DRG reimbursement is $4,000 for an ALL admission in New Jersey.

Discontinuation of these experimental programs would be a significant blow to American research in general, and cancer research in particular.

It is our belief that research which is already reviewed and approved by peers for its scientific validity, should not be stopped or radically altered for marginal cost savings. We believe that "environments for research and treatment" require our support without a specific lid.

Thus, while we can make estimates of today's costs and today's average additional costs for research in these designated hospitals, it is scientifically and ethically foolhardy to use today's average as a lid against which tomorrow's innovations must be measured before they are implemented in experimental trials.

While the cost of health care must be constrained, the loss of the National Cancer Program is too high a price to pay.

Some HCFA officials have suggested that if research costs are extra, these should be paid from the NCI budget. Patient trial costs have never been included in NIH funding. And, it is hard to believe that anything less than a multibillion dollar transfer from one account to another could cover the costs. This is not now the purview of the NIH. Moreover, the "environment for research and treatment" is difficult to apportion between patients on trial.

If some rates must be established, then we recommend they be institution-specific for comprehensive and specialized cancer centers and approximately double the DRG rate for other medical school and community cancer centers. Anything less will defeat the congressional intent to preserve our nation's clinical research efforts against cancer.

Powers went along with the requirement for 25 patients on protocols but insisted that eligibility also be limited to institutions with peer reviewed cancer center core grants, the designated comprehensive cancer centers, specialized clinical cancer centers with core grants, those with clinical program project grants, CCOPs, and full members of cooperative groups.

Powers objected to including satellite cooperative group members (those affiliated with groups through the NCI supported outreach program). "Those aren't really reviewed," Powers said.

Jerome Yates, associate director in the Div. of Resources, Centers & Community Activities, said, "That's changing. The groups are scrutinizing them much more than in the past."

Lee Mortenson, executive director of the Assn. of Community Cancer Centers, said that there are only about 15 or 20 cooperative group satellite hospitals which otherwise would qualify by placing 25 patients on protocols each year. They would still be excluded by the committee's recommendation, unless they could qualify for and obtain full group membership.

Yates and DRCCA Director Peter Greenwald had some reservations about the recommendations.

"The last thing we want is to be a licensing agency for reimbursement from another part of the government," Yates said.

"The only excuse for having a DRG exclusion is that you're contributing to the National Cancer Program," Powers argued.

"Some institutions would be excluded because they chose to not compete for a CCOP because of a variety of reasons, but they are making solid contributions, some through the cooperative group outreach program, some otherwise. Let the existing research mechanisms be part of the definition. . . . I would be very concerned about pressures from hospital administrators to get groups to participate in clinical research for marginal reasons. . . . We should support research and not get into who should be getting DRG exceptions and who shouldn't."

Powers said that if the only criterion is 25 patients a year on protocols, "three hospitals in Detroit would be on my neck" to get patients onto Radiation Oncology Group protocols. "It would be a mad race. If there is a mad race to get peer reviewed approval to participate, then I'm for it."

"The underlying philosophy is the question, 'Is it appropriate to use a research program as a basis for determining reimbursement?' " Yates said.

"The threat is that if something is not done, the clinical research program will go down the tubes," Powers answered.

Mortenson asked if the qualifying peer review could be that done by centers or cooperative groups. "No," Kushner said. "I don't trust centers or the cooperative groups."

Robert Frelick, CCOP project officer in DRCCA, said he would like to have the definition of qualifying peer review include local institutional review boards. Also, "I hate to see the American Cancer Society excluded."

Mary Sears, executive secretary of the DRCCA Board of Scientific Counselors, noted that there is some clinical research which is not funded by NCI, including "some very good work by pharmaceutical houses."

Greenwald said he thought the "general thrust" of the recommendations "is reasonable. It may need some fine tuning." However, Greenwald later told ***The Cancer Letter*** that since it is such an important issue, more information should be obtained from institutions doing clinical research, along with opinions of economists.

The only institutions with hard data on how DRG impacts reimbursement for cancer patients are those in New Jersey.

Rodger Winn, director of oncology at St. Barnabas Hospital, presented some data from his experience with the state's DRG experiment.

St. Barnabas has 1,100 new cancer patients each year, a 25 bed oncology unit, "excellent pathology" headed by Robert Hutter, and "excellent radiotherapy and Ob-Gyn."

Winn reported, "The major sources of loss for the cancer program were in three or four areas related to providing state of the art cancer research and therapy —acute care, laboratory, radiology, and other support services, including dietary, supportive care, and pharmacy. The additional costs of acute care were not from length of stay." In a majority of cases, cancer patients averaged below the state average.

Total loss for the year on cancer patients was $160,000, Winn said.

In analyzing the extra costs, Winn cited three levels where those costs occurred:

• Level one—The cancer program environment, which benefits all patients is more intensive—more nursing, more supportive care, more dietary and pharmacy requirements. Non-protocol patients tend to have state of the art management as well.

• Level two—The protocols require extra tests. Winn pointed out that the five protocols at St. Barnabas probably require fewer tests than most cooperative group protocols, and far fewer than phase I studies at cancer centers. His studies included:

—Phase II lung—required extra Muga scans because of cardiotoxicity, more CAT scans of the lungs to follow tumor size.

—Phase II breast—Muga scans and CAT scans of the liver were extra.

—Phase III colon—Mostly done with outpatients.

—Adjuvant colon—Regalin required for nausea, but mostly done with outpatients.

—Phase II melanoma—Extra Muga scans and CAT scans were required.

—Most of the patients had a complete workup prior to surgery done as outpatients, and were not reflected in the bills. Also, the drugs were provided free by Memorial Sloan-Kettering, St. Barnabas' research base for those studies.

The bottom line: The lung study, involving five patients, lost $838 per patient after DRG reimbursement; phase III colon study, four patients, resulted in a profit of $774 per patient after reimbursement; the breast study, five patients, lost $2,366 per patient; the melanoma study, two patients, lost $3,178 per patient; and the adjuvant colon study lost $586 per patient.

• Level three—This includes the resources St. Barnabas committed to CCOP, including unreimbursable local support for program administration, research nurses and other costs for which neither NCI nor DRG will pay. That totals $108,000 a year in St. Barnabas' case.

Winn said the reaction of the St. Barnabas administration to those losses was: "You have one year and then we stop CCOP."

ACCC sees the problem in a broader context than that of institutions engaged in clinical research.

The organization is preparing to go to bat in Congress and elsewhere for all hospitals which attempt to provide up to date, state of the art care for cancer patients.

Mortenson said ACCC will go along with the Katterhagen committee recommendation for double reimbursement for hospitals which place 25 or more patients a year into clinical trials. ACCC will not ask that this be limited to peer reviewed institutions, but will recommend that only those with oncology units be included.

For all those hospitals which do not meet the 25 patients on protocol requirement but which do try to provide top quality care, the solution lies in the fairness and efficiency which will be obtained in updating the DRG averages. ACCC is planning to do everything possible in supplying data continually to the Office of Technology Assessment for updating the average costs.

GAO FINDS LITTLE WRONG, BUT OFFERS SUGGESTIONS ANYWAY TO FDA, NCI

The General Accounting Office, reporting on its review of the clinical testing of anticancer drugs and the regulation of that testing by FDA, found no blockbuster deficiencies nor even anything to warrant the smallest of headlines in the lay press. GAO did find some relatively minor problems, as related last week in a hearing before Sen. Paula Hawkins, who had ordered the investigation in 1981.

William Densmore, deputy director of GAO's

Human Resources Div., said in his report to Hawkins that "FDA and NCI have made or are making a number of improvements in the way they carry out their responsibilities of assuring that patients involved in the clinical testing of anticancer drugs are protected. . . . The informed consent process was generally carried out in accordance with FDA regulations, and clinical investigators were generally complying with protocol requirements."

Of 171 patients files at seven institutions checked by GAO, only one file was missing the informed consent form. Four forms had not been updated about the risk of cardiotoxicity. A few lab tests were not performed.

Densmore said investigators found FDA does not always follow up to see whether IND sponsors have complied with its recommendations. Also, sponsors do not always submit IND amendments to FDA for review, or sometimes when submitted, FDA sometimes does not review them. One instance was cited in which human testing was undertaken on protocols before NCI or FDA could review them.

GAO noted that therapeutic intent does indeed exist with phase I studies (a question Hawkins had asked), but that only a small percentage of patients benefit. The report noted that NCI has claimed 9.5 percent of patients in phase I trials respond to the drugs, but found only 5 percent responded in the GAO review, and when limited to 1979-82 studies, less than 3 percent responded.

(Bruce Chabner, director of the Div. of Cancer Treatment, later told Hawkins that NCI disagreed with GAO on those figures. GAO did not include tumor regression of 50 percent or less as a response. "In fact, it is, and that accounts for the difference," Chabner said.)

GAO said FDA lacks sufficient administrative staff to process IND documents promptly. And, "while adverse drug reaction reporting has improved since the 1981 congressional hearings, problems still exist in this area. The lack of specific time frames for reporting adverse reactions and the lack of a clear, generally agreed upon definition of a reportable adverse reaction may be contributing to the untimely reporting, or the nonreporting, of such reactions."

Finally, "although various aspects of NCI and FDA clinical drug study monitoring appear to be adequate, both agencies could make improvements. NCI's computerized data base, which is maintained by a contractor to provide reports on the status of the clinical studies, is not as complete or current as it could be because not all drug investigators are submitting timely or complete data. The data base, therefore, cannot be relied upon to present an accurate picture of drug study progress."

GAO recommended that FDA:

—Establish a formal followup system so that FDA can know whether IND sponsors respond to its recommendations to improve patient safety.

—Revise its regulations to require sponsors to approve and submit all clinical protocols for FDA review before clinical testing begins.

—Develop a system for identifying major IND amendments and more promptly distributing them to reviewers.

—Give sponsors more precise guidance as to what types of adverse reactions should be reported and when they should be reported, particularly in cases in which the reaction's relationship to the drug is uncertain.

—Urge sponsors, if they have not already done so, to establish definite time frames for clinical investigator reporting of reactions which will allow the sponsors time to meet FDA's reporting requirements.

—Instruct sponsors to label or otherwise highlight adverse reaction forms or mailing envelopes so that adverse drug reactions will be recognized and can be dealt with immediately upon their arrival at FDA.

—Issue final sponsor-monitoring regulations.

—Establish specific requirements for information to be included in progress reports submitted by sponsors of drug studies.

GAO recommended that NCI:

—Advise FDA in a timely manner of actions taken or to be taken on FDA's concerns.

—Review the need for and usefulness of its drug study data base. If needed, NCI should require clinical investigators to submit data in a more timely and complete manner; if not needed, NCI should terminate the effort.

—Ensure that NCI's site visit monitoring includes all NCI investigators; devise a procedure to verify investigators' drug disbursements to their satellite locations or require that drug shipments be made directly to these locations by NCI; and if possible within allocated resources, increase the frequency of site visits to monitor investigators' performance.

Edward Brandt, assistant secretary for health, said in presenting his statement to Hawkins, "It is important to emphasize that neither (the GAO or the HHS Task Force review also requested in 1981 by Hawkins) has uncovered any systematic mismanagement." Brandt said that NCI and FDA "have been operating and cooperating appropriately for several years. . . . NCI has implemented 26 of the 31 task force recommendations, and only those which by nature require more time have not been implemented. . . . The task force, although making a number of suggestions regarding the drug development program, found a well functioning system that is serving our country well."

Brandt said he was pleased with the "generally favorable tone" of the GAO report. "However, we do have several concerns. Of greatest concern is the Department's belief that the report implies cancer patients have been or are being exposed to 'unnecessary

risk.' GAO contends that, due largely to inadequate recordkeeping, FDA cannot be assured that patients have not been exposed to unnecessary risks. We believe that such procedural deficiencies which 'could' or 'might' imply risk do not establish risk. This distinction is not made in the report. It also is true that in studying new drugs in patients who have life threatening diseases such as cancer, patient deaths are more frequently caused by the patient's disease than by the investigational drug; reports of deaths, before full information is obtained, should not reflect adversely on the sponsor, the drug, or the regulatory agency.

"Another concern we have raised with regard to the draft report is that it does not accurately reflect the system as it is currently administered by the Department. A number of procedures for clinical trials research at NCI have evolved over the last several years, and these changes are not reflected in the draft report. For example, of the 10 experimental drugs examined by the GAO, five of them entered clinical testing prior to 1981. We believe that if the GAO's review had been limited to drugs which entered clinical trials after 1981, the changes we have effected in policy and procedures might more readily be seen. We note also, that this report does not discuss NCI's peer review process, a vital component of NCI's ongoing monitoring practices."

Hawkins, although far milder than she was two years ago, managed to find something to criticize. In the 1981 hearings, she had jumped on the alleged finding of 25 cases of congestive heart failure supposedly caused by the drug DHAD. She was particularly critical of the fact that, while one investigator had found evidence of cardiotoxicity in tests of the drug with rabbits, NCI had not included that information in its clinical brochure accompanying the drug.

Hawkins recounted that history and then added a statement describing continued lack of awareness by physicians of the drug's cardiotoxic effects. "This case is reflective of the fact that the monitoring system for protection of patient safety is still not adequate in all respects."

Chabner responded that of 1,400 patients treated with DHAD since 1979, there has been only one instance of congestive heart failure in which the patient had not had a pre-existing heart problem. Most patients who get DHAD have previously received adriamycin, and "we feel that most reports of congestive heart failure are due to adriamycin." Nevertheless, NCI still advises physicians of the drug's possible cardiotoxicity, Chabner said.

NCI CONTRACT AWARDS

Title: Characterization of HLA antigens on donor's lymphocytes

Contractor: The Blood Center of Southeastern Wisconsin, Inc., Milwaukee, $499,834.

NCAB COMMITTEE APPROVES CONCEPTS FOR CIDAC RECOMPETITION, TWO OTHERS

The National Cancer Advisory Board's Committee for Review of Contracts & Budget of the Office of the Director has given concept approval for recompetition of the contract for the carcinogenesis and cancer biology CIDAC.

That CIDAC (Cancer Information Dissemination & Analysis Center) contract currently is held by Franklin Research Institute. Another CIDAC contract, for clinical cancer research, is held by M.D. Anderson Hospital; it is not up for recompetition at this time.

The carcinogenesis and cancer biology CIDAC work has been performed by Franklin under two contracts, which will be consolidated into one in the recompetition. Estimated total cost for four years is almost $3 million.

Staff narrative describing the program:

The International Cancer Research Data Bank Program is responsible for the collection, analysis, storage, and dissemination of information to cancer research scientists and clinicians. The purposes of a CIDAC are to provide scientific analysis and peer review necessary to produce high quality information products and services for cancer researchers, to provide information for the NCI/NCP concerning the status and trends in cancer research, and to identify innovative means of information transfer among cancer researchers. This proposed contract will process information covering all aspects of carcinogenesis and cancer biology, including the epidemiology, etiology, virology, immunology and biochemistry of cancer, and represents a combination of two existing CIDACs.

Principal activities of this combined CIDAC are the regular production of over 40 monthly CANCERGRAMS (current awareness bulletins containing abstracts of recently published literature) and 10 Oncology Overviews (retrospective bibliographies with abstracts concerning high interest topics in cancer research) per year. Material for these publications is derived from the ICRDB Program's CANCERLIT database, and peer reviewed by a network of consultants to the CIDAC who are active researchers. These consultants select and organize the information for presentation in the most focused and useful manner. The CIDAC also performs custom searches of the CANCERLINE databases in response to requests for information, submits monthly Highlight Reports pinpointing significant new developments in cancer research, and assists in database quality control.

The CIDAC, with its biomedically trained search personnel, consultant network and advisory board consisting of distinguished researchers, is a valuable resource for NCI and the worldwide cancer research community. The CANCERGRAMS collectively provide comprehensive coverage of the entire spectrum of cancer research, quickly alerting researchers to new findings with minimal expenditure of effort, and thereby allowing them more time for productive research. Oncology Overviews enable researchers rapidly to update their knowledge in emerging areas of research concentration.

The committee approved recompetition of the contract now held by JRB Associates for budget formulation and presentation support system, at an estimated cost of $1.3 million for five years. The narrative:

The BFPSS provides computer support for the three major budget submissions completed each year by the Financial Management Branch—the preliminary budget, the OMB sub-

mission and the Congressional justification as well as development of five year budget projections for use by the NCAB in planning future program directions.

This project has become an integral part of the budgeting and planning process, having developed into a data management tool which generates reports showing summary and detailed data for the programs, thrusts, mechanisms and divisions. The development of dollar levels and initial data input are managed by NCI staff. Following input of data, the BFPSS allocates management costs to the appropriate programs using algorithms developed by NCI and approved by the General Accounting Office. Then, building from the division data files, the BFPSS provides approximately 30 tabular displays of the budget which allow the FMB to provide detailed analyses of the budget, throughout the budget cycle as requests for information arise from the Department, Congress, the NCAB, and the public. The BFPSS also allows automatic input of actual obligations from the accounting tapes.

Because of this capability to quickly generate internally consistent sets of reports, it is feasible to produce options fully supported by detailed tables. By relieving the FMB of some of the complex but mechanical burden of producing tabular support for each budget submission, the BFPSS allows the FMB to manage a stratified budget and program planning at more detailed levels than would be possible with a less complex structure.

The committee approved the concept of a new contract supported project, for evaluation of NCI's communications programs. It was approved for three years, at an estimated cost of $200,000 a year. The narrative:

In response to the NCI mandate for the dissemination of information to the public and health professionals, the Office of Cancer Communications operates a variety of communications programs. While some of these have been evaluated, no current contract provides sufficient support for full scale evaluation. Further, as pressures increase to do more with less, particularly in an area where outside forces create demands upon limited resources, an increased evaluation effort is required for sound management.

Due to the wide variety of program activities, the scope of work will include a range of tasks to be performed over the life of the contract, which is expected to be of the work order type. Thus, the contract would support evaluation and quality control efforts for the Cancer Information Services, the Cancer Information Clearinghouse, response to public inquiries, public education programs, and individual publications and audio-visuals. It also would support media tracking and evaluation studies, such as measuring the amount of TV public service advertising time allocated to NCI spots, content analyses of broadcast and print media coverage of cancer, and limited survey research related to mass media programming sponsored by NCI. Further, some formative evaluation, such as title testing, focus group interviews, and broadcast message testing would be included. This contract would also permit easy access to evaluation experts, allow for limited data processing, and include preparation of OMB clearance packages as required.

The committee approved the concept of renewing noncompetitively three existing contract support projects:

—International Scientist to Scientist Information Exchange Program, with the International Union Against Cancer, five years, estimated cost $100,000 a year.

—Latin American Cancer Research Information Project, Pan American Health Organization, three years, estimated total cost, $551,690.

—Clearinghouse for Ongoing Research in Cancer Epidemiology, International Agency for Research on Cancer, four years, estimated total cost, $637,899.

A quorum of the committee, chaired by Robert Hickey, was not available for the scheduled meeting in May, so the concepts were presented to members by mail.

CONCEPT REVIEW FIGURES ARE ESTIMATES ONLY; RFPs, RFAs NOT YET AVAILABLE

The dollar estimates with each concept review brought before the various boards of scientific counselors are not intended to represent maximum or exact amounts which will be spent on those projects. They are intended only as guides for board members to help in determining the value of the projects in relation to resources available to the entire program or division. Responses should be based on the workscope and description of goals and methods included in the RFPs (contracts) and RFAs (grants and cooperative agreements). Availability of RFPs and RFAs will be announced when the Institute is ready to release them.

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. NCI listings will show the phone number of the Contracting Officer or Contract Specialist who will respond to questions. Address requests for NCI RFPs to the individual named, the Blair building room number shown, National Cancer Institute, 8300 Colesville Rd., Silver Spring, Md. 20910. RFP announcements from other agencies reported here will include the complete mailing address at the end of each.

RFP N01-CM-37615

Title: *Biochemical and biological characterization of antitumor drugs*

Deadline: *Approximately Aug. 30*

NCI's Div. of Cancer Treatment, Developmental Therapeutics Program, is seeking organizations having the necessary experience, scientific and technical personnel, and physical facilities to evaluate antitumor agents being considered for development to clinical trial by DCT in a series of estanlished biological/biochemical tests appropriate to the individual agent.

Experiments will be conducted to determine whether antitumor agents with novel structures have biological/biochemical activities similar to those of clinically evaluated chemotherapeutic agents, and whether structural analogs of clinical drugs have different biological/biochemical properties. Intent of the studies is to provide clear leads as to how a de-

velopmental drug exerts its effects, and not to elucidate definitively the mechanism of action of the drug.

Work to be undertaken will include (a) determination of the growth inhibitory and cytocidal properties of each agent and (b) determination of the agent's effects on the rate of synthesis of DNA, RNA and protein. Cultured murine P388 leukemia cells will be used for these studies although, on occasion, the use of a different tumor cell line may be required. Additional studies will be chosen based on the results of the initial studies and the agent's resemblance (if any) to other agents of which the biologically important effects are known.

Possible studies include measurement of (a) reversal of growth inhibition or inhibition of macromolecular synthesis by metabolites, (b) effects on DNA, the mitotic process or cell membranes, (c) alkylating activity, (d) inhibition of specific enzymes. Approximately six compounds will be supplied by the government for evaluation per year. As compounds of a commercially confidential nature may be evaluated, pharmaceutical and chemical firms will be excluded from the competition. Also, because radioisotopes will be used in the project, organizations responding will be required to have a Nuclear Regulatory Commission, or state equivalent, license for handling radioactive compounds.

It is anticipated that one award will be made for a three year incrementally funded contract as a result of the RFP. It is anticipated that the level of effort for each year of the contract will be three staff years.

Contract Specialist: Charles Lerner
RCB, Blair Bldg. Rm. 228
301-427-8737

NEW PUBLICATIONS

"Nutrition in Cancer Causation and Prevention," supplement to *Cancer Research.* Proceedings of a workshop conference in 1982 sponsored by the American Cancer Society. It includes reports on the possible role of diet in the etiology and inhibition of carcinogenesis. Copies of the supplement, paid for by ACS, are available from Cancer Research Editorial Office, Temple Univ., Fels Research Institute, West Bldg. Rm. 301, Philadelphia 19140.

"If You've Thought About Breast Cancer. . .", by Rose Kushner. Originally published by NCI to serve clinicians and other persons interested in education of women patients with breast disease. NCI supplies of the booklet have been exhausted, and government funds for reprints are not available. Community Radiology Associates, 10401 Old Georgetown Rd., Bethesda, Md. 20814, is sponsoring the 1983 reprint. Copies are available at $1 each, less for quantity orders.

"Adult Patient Education in Cancer," prepared by NCI's Office of Cancer Communications. Examines state of the art in cancer patient education and points out those issues that create special educational needs of cancer patients. Programs and activities for meeting those needs, as well as planning and evaluation of those activities, are discussed. Available free from NCI, Bldg. 31 Rm. 10A18, Bethesda 20205.

"Questions and Answers About Pain Control," prepared by NCI and distributed by the American Cancer Society. Deals with over the counter products, prescription medicines, and narcotics, comparing advantages and disadvantages of individual preparations. Available free from local ACS units.

"Survey of Compounds Tested for Carcinogenic Activity," PHS-149, compiled by NCI's Div. of Cancer Cause & Prevention. Volume for 1961-67, for 1968-69, and for 1970-71. Copies available to anyone interested in carcinogenesis research. Contact Office of the Scientific Coordinator for Environmental Cancer, DCCP, NCI, Landow Bldg. Rm. 3C 37, Bethesda 20205, phone 301-496-1625.

"Oncology Overviews," by NCI's International Cancer Research Data Bank Program. Selected abstracts on cancer research topics. For a list of available titles and ordering information, contact ICRDB Program, NCI, Westwood Bldg. Rm. 10A18, Bethesda 20205, phone 301-496-7403. Each requestor may obtain up to three complimentary copies. Additional copies may be purchased at prices from $4.50-$8 domestic, and $9-$16 outside North America.

"Self Learning Modules for Nurses Caring for Clients with Cancer," series of 11 volumes designed by Joyce Yasko, RN-PhD, Univ. of Pittsburgh. Provides the practicing nurse with a core curriculum in cancer nursing. For brochure and ordering information, contact Reston Publishing Co., 11480 Sunset Hills Rd., Reston, Va. 22090.

RFP NCI-CP-FS-31034-77

Title: *Support services for clinical epidemiological studies*

The due date for proposals, which was listed in the May 20 issue of ***The Cancer Letter,*** has been reset for the close of business, 5 p.m. local time on July 22.

NCI CONTRACT AWARDS

Title: Iso-antigenic typing of mouse strains
Contractor: Northwestern Univ., $61,323, one year, with four one year options to extend.

The Cancer Letter _Editor Jerry D. Boyd

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