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NEW CHEMOPREVENTION PROGRAM WILL GET "WHATEVER MONEY IT NEEDS;" CLINICAL TRIALS IN NEW DIVISION

A new chemoprevention program with large scale clinical trials will get "whatever money it needs," Vincent DeVita said in elaborating on the statement he made last week following his appointment as NCI director. DeVita told a press conference that expanded effort in chemoprevention would be one of his first major initiatives.

"We need a formal program, something like the Drug Development

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In Brief

HOLLAND RECOVERING FROM CORONARY BYPASS; HENRY KAPLAN RECEIVES ANNUAL PRENTIS AWARD

JAMES HOLLAND, recovering from coronary bypass surgery, expects to return after Labor Day to his duties as professor and chairman of the department of neoplastic diseases at Mt. Sinai School of Medicine and chairman of Cancer & Leukemia Group B. . . . **HENRY KAPLAN** has received the third annual Meyer and Anna Prentis Award for outstanding contribution to cancer research. Kaplan, director of the Stanford Univ. Louis B. Mayer Cancer Biology Research Laboratory, received the award at the recent biological carcinogenesis workshop sponsored by the Michigan Cancer Foundation and NCI. . . . **MASONIC CANCER** Center is now the official name of the component of the Univ. of Minnesota Health Sciences Center previously known as the Masonic Memorial Hospital. The Masonic fund has donated $4.8 million over the past 22 years to support construction of cancer facilities, cancer teaching and research. . . . **JUDITH STEIN** has been named director of communications for the Florida Comprehensive Cancer Center by Gordon Zubrod, director of the center. . . . "**RECENT ADVANCES** in the Diagnosis and Treatment of Lung Cancer" will be the program for the third annual Charles A. Sammons Cancer Center Symposium Sept. 24-25 in Dallas. The center is a unit of the Baylor Univ. Medical Center. Contact the Roberts Center for Continuing Education, 3500 Gaston Ave., Dallas 75246. . . . **ANOTHER CONSENSUS** Conference: This one will be on the issue, "CEA: Its Role as a Marker in the Management of Cancer." It is scheduled for Sept. 29-Oct. 1 at the NIH Clinical Center, Masur Auditorium. Specific issues to be discussed include: Should CEA be used in cancer screening? Is CEA helpful in diagnosis and treatment? What does CEA tell us about the extent and outcome of cancer? Can the CEA assay be improved? Can CEA be used in combination with other markers? Robert McIntire, chief of the Diagnosis Branch in NCI's Div. of Cancer Biology & Diagnosis, may be contacted for further details at Bldg 31 Rm 3A10, Bethesda 20205, phone 301-496-1591.

DEVITA SEARCHING FOR TOP PEOPLE, ESPECIALLY WOMEN AND MINORITIES

(Continued from page 1)

Program," DeVita told *The Cancer Letter*. It probably will not be necessary to duplicate the Drug Development Program in its entirety, he indicated. In fact, that apparatus in the Div. of Cancer Treatment probably will be used to find new chemoprevention agents and bring them to the clinical testing stage. Responsibility for basic research on the process will remain with the Div. of Cancer Cause & Prevention.

DeVita said that the clinical trials should be handled by the new Div. of Resources, Centers & Community Activities, although that could depend on the staff situation. "I think the primary responsibility for the clinical trials should be in the new division, although you could make a case for DCCP. But if the new division is to have primary responsibility for applied prevention, then that's where the clinical trials should be."

The new program "may require a lot of millions of dollars," DeVita said. The Drug Development Program's experience is that it costs about $500,000 to bring an agent to the point where it is ready to go into clinical trials "and I don't see that this would cost any less." The clinical trial of a single agent can cost as much as $2 million.

A chemoprevention clinical study will differ considerably from that for a cancer treatment drug. It could require thousands of individuals determined to be at high risk, "something like the heart institute's aspirin study to prevent myocardial infarction," DeVita said.

The new director's top priority at the moment is filling out his staff and replacing key executives who are leaving. Foremost among these is finding a new executive officer when Calvin Baldwin's appointment to a similar job at NIH comes through. "I rely heavily on my administrative officer," DeVita said.

He also has to find three division directors. William Terry has been acting director of the now defunct Div. of Cancer Control & Rehabilitation for more than a year, and is acting director of the new DRCCA. Terry also has been acting director of the Centers Program, which is included in the new division.

Thomas King, director of the Div. of Extramural Activities, will leave next week to become director of the Kennedy Institute of Ethics at Georgetown Univ. DEA includes all NCI review committees and handles the administrative management of grants.

The character of the DEA director's job has changed considerably from that of running the predecessor Div. of Cancer Research Resources & Centers. When King took over that division, it had program responsibility for most NCI grants, requiring a director with top scientific credentials as well as administrative ability. DeVita believes the DEA director still should be a scientist, although agreeing that a first rate manager nonscientist probably could handle it. "He has his face to the scientific world," DeVita said. Scientists supported by NCI or seeking such support "look to him as their advocate."

However, "good people are good people." Like professional sports teams who draft the best athletes available rather than trying to find those with specific talents, "we'll take the best people we can get and find places for them."

A job that is crucial to DeVita's successful operation of his office as he has organized it, retaining the position of clinical director and himself remaining active in research, is his deputy director. The demands on an NCI director are incredible, for appearances at meetings and conferences around the world, before congressional committees, responses to phone calls, etc. A strong deputy who can help meet those demands is essential. He also must be able to handle a variety of special assignments.

DeVita is leaning toward selection of a deputy with a background different than his own, probably someone strong in epidemiology or other aspects of prevention. This was the model he established at DCT, with Saul Schepartz as his deputy—DeVita the clinician, Schepartz (who had headed the Drug Development Program) the technician.

That worked well, but it meant that when DeVita moved upstairs and Schepartz became acting DCT director, DeVita has to spend about an hour a day helping out with his old division on clinical matters. Finding a new DCT director is high on his list.

Another important new appointment will be for a newly created position—heading the Biological Response Modifiers Program. It will be a highly visible job, with a growing budget. DeVita has already interviewed candidates and may be near a selection.

DeVita's use of the pronoun "he" in relation to filling top staff positions was strictly rhetorical. He is working hard at trying to hire women and minority group members, but has encountered the problem which frequently frustrates other government and business recruiters: Outstanding women and minority scientists and executives are in great demand everywhere. They command top salaries and highly responsible positions. Most would have to take severe pay cuts to work for the government.

DeVita and Terry have solved one of their recruiting problems, not for staff but for a crucial advisory position.

Stephen Carter, director of the Northern California Cancer Program, has agreed to serve as chairman of DRCCA's new Board of Scientific Counselors.

That board will have a wide range of responsibilities—the centers, organ site, training, and construction programs as well as all of the existing Cancer

Control Program. It will have to work in the division's mandate for applied prevention.

"It will be an interesting experience, dealing with such a variety of programs," Carter said. "I'm looking forward to it very much."

Could it be too much for one Board to handle? DeVita doesn't think so. "There are just as many varied subjects in DCT," he said. "No one DCT Board member is expert on everything in the division. It bends those with vested interests."

The new Board will look at the entire division, weigh the merits of each program, help NCI determine priorities. For the first time, the Centers Program will have an outside advisory group other than the National Cancer Advisory Board and, DeVita hopes, will be able to go into more detail with that program than the NCAB could do. Its first task in that regard will be looking at the proposed new guidelines for center core grants. That sort of help "has been missing from the program," DeVita said.

"I'm a great believer that the process works. When push comes to shove, our advisors make the right decisions."

Thanks to the National Cancer Act of 1971, DeVita has a weapon denied other institute directors at NIH: NCI's bypass budget.

Sometime in September, he will submit directly to the White House NCI's own estimate of how much money it can usefully spend in the 1982 fiscal year, without any alteration by intervening bureaucrats in NIH or HHS. Every dollar in the bypass budget will be fully explained and justified; the budget is public information and available to members of Congress and their staffs.

It is a powerful weapon, and for 1982 will request $1.192 billion—$192 million more than NCI is getting in 1980 and $184 million more than originally requested in the President's budget for 1981.

The 1982 bypass budget includes a 12.5 percent across the board increase for inflation, plus another 5 percent for program growth. Not every program would get those increases if Congress went along with the entire amount. Some would be increased only 8-10 percent, less than anticipated inflation, with the extra amounts there going to areas of higher priority or need. Other phaseouts and terminations would free up additional funds for new or expanded programs.

Other items touched on by DeVita:

* Cancer centers funding. The original 1981 Presidential budget request of about $66 million not only would force NCI to hold competing renewal core grants to a modest cost of living increase (probably the 7 percent solution) but also would eliminate entirely funding of four to six grants. An unusually large number of core grants are up for renewal in 1981, straining mightily the flat budget.

"I don't think that will happen," DeVita said, referring to the prospect that some may not be funded. "I can't rule it out, but I think we will find the money somewhere."

* Organ site programs. Remarks earlier this year by DeVita, to the effect that some cuts might be made in the programs, had caused some concern among those involved.

"We have to look at them like any other program," DeVita said. "If the reason for creating them is still there and they are doing excellent work, then we should leave them alone. I think they are doing pretty well, but what if it comes to a choice between the organ site programs and centers?

"The Breast Cancer Task Force has been very successful. It has really done a job, stimulated the field, done an enormous amount of work, with the result there has been a lot of progress. I think there is very, very little chance that if the Breast Cancer Task Force were to be stopped, work on breast cancer would stop. We are spending $5 million very well, but if it were stopped and that money put into the grants pool, what it would fund might be even better."

* The GAO report on cancer control. "We don't agree with it. They were rediscovering the wheel. We know cancer control was in difficulty. We always had trouble with the concept. It was not easy, but it is not as bad as they pictured. There have been a lot of changes. Our contracting apparatus is far better than others at NIH. Part of the problem often has been due to misinterpretation. The audit review by the Inspector General contained erroneous information on what a research contract is."

CONSENSUS: ADJUVANT CHEMOTHERAPY PROVEN FOR PREMENOPAUSAL PATIENTS

Adjuvant chemotherapy with established combination regimens "now appears indicated" for premenopausal breast cancer patients with one or more positive lymph nodes, an NIH consensus development conference panel concluded last week.

Panel members further concluded that:

—"Survival benefits in premenopausal patients with histologic evidence of lymph node metastases appear to outweigh the disadvantages of early toxicity."

—"For the present, it appears that no hormonal manipulation has been established with enough confidence to make hormonal alterations, either alone or with chemotherapy, a standard form of adjuvant chemotherapy. . . . Estrogen receptor activity should be quantified routinely in all patients with breast cancer."

—"No conclusive data from clinical research exist to support the routine use of adjuvant chemotherapy" for stage 1 patients (those with histopathologically negative axillary nodes)."

—Although "recent analyses of some ongoing

studies seem to show early benefit in disease free survival in subsets of postmenopausal patients, the preliminary nature of this information precludes a definitive statement as to the role of such treatment (for postmenopausal patients). . . . Postmenopausal women with estrogen receptor positive tumors may benefit from the adjuvant administration of relatively nontoxic hormonal treatment."

The consensus conference panel on adjuvant chemotherapy of breast cancer thus came in with considerably softer recommendations than last year's panel on alternatives to radical mastectomy for local control of the disease.

The recommendations seemed too conservative for some, particularly that for postmenopausal patients. "Much too conservative," commented Stephen Jones, Univ. of Arizona. "Nine clinical trials clearly show a benefit for postmenopausal patients."

The panel recommended that clinical investigations should "continue to explore the role of adjuvant therapy in postmenopausal women with positive axillary nodes" and that "broad acceptance of the results of such trials would require an untreated concurrent control group."

"Trials in which half the patients receive no treatment (following mastectomy) would be a step backward," Jones insisted. He referred to five studies, in addition to those presented at the conference, which demonstrate improved survival for postmenopausal patients receiving adjuvant chemotherapy. "I wonder if the panel would consider making a stronger statement?" Jones asked.

Conference Chairman Stephen Carter said the panel "spent more time on that issue than any other. We did get the complete Southwest Oncology Group report on five drugs (CMFVP) vs. L-PAM, and took it into consideration. . . . There were only two trials before us which randomized patients to surgery only, with no benefit shown for postmenopausal patients.

"We recognized there was the dose response problem," Carter continued. He was referring to the presentation by Gianni Bonadonna, repeating the data he presented at the ASCO meeting in which he reported that postmenopausal patients in his study who received 85 percent or more of the protocol doses of CMF had survival increases over untreated controls comparable to premenopausal patients.

Jones suggested that since there are four major studies in progress which include untreated control groups of postmenopausal patients, no further such studies be initiated.

The panel's recommendation included the statement, "It appears logical that hormonal treatment with or without chemotherapy should be explored in ER-positive women."

A comment was made from the floor that "physicians may just use this as an excuse to use tamoxifen and nothing else. Tamoxifen only is easier."

A practicing physician attending the conference commented, "It would be helpful if a national panel would say that a treatment is good, or is not warranted. It might help us with malpractice problems."

"The one way we can help keep you out of malpractice problems," answered panel member Walter Lawrence, "is to not say too much about a treatment which is not clearly established by the data."

The panel's statement emphasized the value of continuing clinical investigations, even for the one group (premenopausal patients with positive nodes) which clearly benefits from adjuvant treatment. "Since the optimal adjuvant therapy for the premenopausal patient with lymph nodal metastases has not yet been achieved, continued clinical investigations are indicated."

The consensus statement made it clear that combinations of drugs were preferable to single agents. "Adjuvant combination chemotherapy, consisting of agents shown to be active in the treatment of advanced breast cancer, has been shown to be more effective than a single agent. The current information suggests that these drugs should be given at full dosage since lesser amounts of chemotherapy have shown inferior results."

The statement was negative on adjuvant radiotherapy. "In the context of adjuvant chemotherapy of stage 2 disease, adjuvant radiotherapy has not provided significant increases in survival although it has reduced chest wall and regional lymph node recurrence in some studies."

A new report on a CALGB study strongly supports adjuvant chemotherapy for patients with four or more positive nodes without regard to menopausal status.

The multi-institutional, grant supported study was conducted by Cancer & Leukemia Group B primarily in the U.S. but also at institutions elsewhere in North America, Europe and Africa. James Holland is chairman of CALGB, and Douglass Tormey, at the Univ. of Wisconsin, was the principal study chairman. Raymond Weiss, chief of NCI's Clinical Investigations Branch, was cochairman and presented the report at the European Organization for Research in the Treatment of Cancer in Paris.

The study compared the five drug regimen CMFVP to CMF. Another arm added the immunotherapy agent MER to CMF but was discontinued when a preliminary analysis demonstrated a lack of survival benefit plus a large percent of intolerable side effects.

Weiss reported that at 36 months, analyzing only those patients with more than three positive axillary nodes, 75 percent of the women treated with CMFVP were disease free compared to 61 percent treated with CMF.

"There is a significant advantage with CMFVP therapy for premenopausal women with more than

three nodes, P=.05. A similar trend is seen in postmenopausal women, but the P value is .11."

Weiss' report concluded:

"This CALGB study has shown that in patients with breast cancer at higher risk, those with more than three involved nodes, CMFVP given as an intensive induction followed by maintenance courses is significantly superior in terms of disease free interval to CMF given by an identical schedule. The activity is demonstrable in premenopausal women and indicated in postmenopausal women and independent of tumor size. At this time, these data are applicable only to patients with mroe than three positive nodes."

Holland added as his own conclusion, a copy of which he provided *The Cancer Letter* (part of which follows:

"The toxicity of CMFVP is tolerable and aside from specific side effects related to vincristine and prednisone, nearly identical to CMF. For women with breast cancer with four or more metastatic axillary nodes, the CALGB has shown that CMFVP is superior to CMF.

"I recommend its use for patients who are not or cannot be participants in further study programs to achieve more effective therapy."

Holland emphasized "the need for continued research since we surely are not at the final solution, and participation in research is advantageous for patients, and for patients as yet unafflicted who are still, predictably, to come."

GAO REPORT ON FIVE CONTRACTS AWARDED BY NCI'S CANCER CONTROL PROGRAM

The General Accounting Office report on its investigation of five NCI Cancer Control Program contracts, the publication of which started in last week's issue of *The Cancer Letter,* continues:

Advisors Have Mixed Opinions On The Cancer Control Program and Its Future

We discussed the accomplishments of the cancer control program and its outlook for the future with the former chairmen of the President's Cancer Panel, and the Cancer Control Control & Rehabilitation Advisory Committee, and the current chairmen of the National Cancer Advisory Board, CCRAC, and the Cancer Control Merit Review Committee. These groups provide advice to the Cancer Control Program. They had mixed opinions on the program's accomplishments.

Four of the five said that the Cancer Control Program was worthwhile and should be continued. The former chairman of the CCRAC said the areas that showed the program's accomplishments were cervical cancer screening, breast cancer demonstration projects, the Cancer Information Service, the asbestos education program, and the community based cancer programs. The current chairman of the committee said the accomplishments were the community based programs and the Cancer Information Service. With the exception of the Cancer Information Service, the current chairman of the National Cancer Advisory Board cited the same accomplishments as the former CCRAC chairman. In addition, he cited hospices, pain management for cancer patients, studies on effects of exposure to diethylstilbesterol, radiotherapy practices, and psychosocial impact of cancer, state of the art consensus conferences, cancer rehabilitation programs, and funding for training of oncology nurses.

The chairman of the merit review committee said the program had accomplished little that the medical community would not have done anyway and had not increased the body of knowledge needed to control cancer. He believed that the only part of the control program worth continuing was the community based programs, but these programs needed better NCI management. NCI officials discussed the program's accomplishments with the chairman after our meeting with him. NCI officials told us that the chairman intended to convey that the program focused on procedures that were already being performed, and that the program helped disseminate them more rapidly, but that for some of them, dissemination would have happened sooner or later.

The former chairman of the President's Cancer Panel offered no specific program accomplishments. He said that the accomplishments were in generating activity in proper cancer control areas and in getting known techniques put into use.

In terms of future funding levels and areas of emphasis for the control program, the chairmen's views were also mixed. However, none said the program suffered from a lack of funds. The chairmen's views concerning future direction of the program could be summarized as follows:

–Only fund community based programs and put remaining funds into basic cancer research.

–Continue funding the program at the current fiscal year 1979 level.

–Emphasize prevention activities and let other projects expire and reduce the funding level.

In addition to the areas mentioned above, the NCAB chairman recommended that NCI evaluate the impact of existing methodologies on cancer morbidity and mortality.

NCI officials believed that the Cancer Control Program had many significant accomplishments. They listed 57 items, such as:

–Techniques for measuring, monitoring, and lowering mammographic radiation.

–Task forces on asbestos exposed workers and diethylstilbesterol exposed offspring.

–Prototype clinical oncology programs for community hospitals to improve cancer management.

–Development of rehabilitation and outreach programs.

–Education programs for health safety of workers exposed to carcinogens.

We did not assess the effect that cited accomplishments had on controlling cancer.

NCI Comments and Our Evaluation

In the draft report provided to NCI for comment, we included a recommendation that the Congress, possibly through oversight hearings, decide what the objectives of the Cancer Control Program should be and what level of effort is needed to accomplish these objectives. NCI disagreed with our recommendation.

In February 1980, we discussed our draft report with staff of the Subcommittee on Health & Scientific Research, Senate Committee on Labor & Human Resources, and the Subcommittee on Health & the Environment, House Committee on Interstate & Foreign Commerce. Both subcommittees were working on amendments to the Public Health Service Act (S. 988 and H.R. 6522, respectively), which include language on the Cancer Control Program. The [Senate Subcommittee] was in the process of marking up the bill. The [House Subcommittee] held hearings on Feb. 25, 1980, and raised several questions regarding the Cancer Control Program.

Since the congressional committees have recently held hearings on the program, and we provided the information

from our review to the appropriate legislative committee for their use in considering the bills, we have deleted sections from the report that pertained to our proposed recommendation.

NCI's Administration of Five Cancer Control Contracts Has Been Weak

NCI's administration of the five cancer control contracts we reviewed was weak in both awarding of contracts and post-award management. In our opinion, the inadequate contract administration is attributable to heavy caseloads for some project officers, lack of cooperation between project officers and contract officers, and failure to use prudent management practices. As a result, the benefits from three completed contracts were substantially less than expected. Although our review of five contracts is not a sufficient basis on which to characterize programwide contract administration, we noted that other reviews made of contracting in NCI—some of which included the Cancer Control Program—have indicated contract administration problems. Also, the chairman of the Cancer Control Merit Review Committee told us that he believes problems similar to the ones we found exist in about 50 percent of NCI's cancer control contracts.

In response to a May 1978 HEW Inspector General's audit report, an action plan to correct NCI contracting deficiencies was prepared. This plan was approved on May 24, 1978, by the HEW assistant secretary for management and budget. The Inspector General's staff is now reviewing how well the plan is being implemented and whether it is overcoming deficiencies, such as the ones described in our report.

Of the $301 million allocated by NCI for the Cancer Control Program in the last five fiscal years, about $216 million (72 percent) was obligated for contracts. The five contracts we reviewed amounted to about $10.3 million.

NCI Used Questionable Practices in Awarding Some Cancer Control Contracts

NCI's contracting procedures, (referred to as the Orange Book), require that, before a contract is awarded, a project plan must be prepared. The procedures state that major project changes require amendments to the project plan. NCI did not adhere to this requirement before awarding some cancer control contracts. As a result, NCI awarded contracts for amounts greatly exceeding that approved in project plans. Further, NCI has failed to correct some deficiencies found by preaward review groups.

Revised project plans

The Orange Book states that, when the final negotiated cost of a contract is to be significantly different from the original project plan, the project plan must be revised. Further, any contract modification that increases funding by $50,000 or more, or by 25 percent or more above the funding levels for the project plan period, requires an amendment to the project plan. Our review indicated that NCI did not adhere to these requirements for two of the five contracts we examined.

In the contract awarded to the Univ. of Louisville to develop a model program for the early detection and prevention of liver cancer caused by worker exposure to vinyl/polyvinyl chloride, the estimated amount of the project as noted in the project plan was $880,000. However, the negotiated amount of the contract was about $2.8 million—more than three times the original estimate.

NCI contends that the project plan was revised and the increase in costs was properly approved. NCI advised us that the responsible officials—with the exception of the former director, DCCR—attended a meeting during which the project plan revision was prepared. The officials who attended this meeting and later signed the revision document were provided a proposal containing the increased cost estimates. Because the former director, DCCR, was out of the country at the time of the meeting, she did not know of the increased project cost. When she signed the plan revision document as the approving official the portion of the document that was to show the revised cost estimate was blank. She told us she did not know that she had approved a contract award for $2.8 million until she later read about it in a news release. NCI does not agree that it failed to follow procedures for revising the project plan. It characterizes the situation as a clerical error. We believe that, when an approving official signs a document which authorizes the expenditure of $2.8 million of federal funds without knowing how much of an expenditure is being approved, it is more than a clerical error.

In a contract awarded to the New York State Dept. of Health and Health Research, Inc., to conduct a cervical cancer screening demonstration program, the estimated amount of the contract as stated in the project plan was $750,000. However, the negotiated amount of the contract was about $2.5 million. NCI failed to prepare a revised project plan which specifically mentioned the large increase in the New York contract. NCI did prepare a revised project plan that covered the entire cervical cytology screening program involving many contracts. However, the revision showed a decrease in the estimated costs for the initial year of the total program, and makes no mention that the annual cost of the New York contract was being more than tripled from the costs approved in the original project plan for the New York project.

NCI has failed to correct deficiencies found by preaward review groups

As stated previously, NCI has a system whereby both NCI staff and advisory groups review proposed cancer control projects before contract award. For the Louisville and New York contractors, our review showed that these groups identified many problems in the proposed contracts and made nine recommendations to correct them. However, we found no evidence that DCCR took any action to implement the recommendations before awarding the contracts. The following paragraph discusses the problems found and recommendations made in the preaward review of the Louisville contract.

In May 1975 the Cancer Control Intervention Programs Review Committee found three deficiencies that it said should be corrected before the contract was awarded. These deficiencies pertained to the (1) absence of an individual to conduct the health education program for plant workers and their families on the hazards of vinyl/polyvinyl chloride and the lack of a strong participatory role for the educator, (2) lack of coordination and cooperation among various parties in the program, and (3) lack of a system for locating about 1,500 former plant employees. We found no evidence that DCCR required the applicant to correct these problems before award of the contract. While the coordination problem was later resolved, we found no evidence that the problem in locating former employees was ever corrected, as the problem continued to be reported by advisory groups that reviewed the contract while the project was ongoing. The contract did take action to hire a health educator for the program in September 1975; however, that person was not able to fulfill the role needed for the program and was replaced. A new health educator was not hired until November 1976—15 months after the contract was awarded. In commenting on our draft report, NCI agreed that no action was taken on these deficiencies before the award of the Louisville contract. However, NCI said these deficiencies represented contracting practices that occurred in 1974 and 1975, which have been corrected.

NCI is unaware of the extent that demonstration projects are continued

In fiscal year 1977 Senate appropriations hearings, NCI stated that cancer control funds are used as "seed money" for prototype studies and not for general health care delivery. Also, NCI said that projects are expected to ensure a means of self-support after the grant or contract period. In this regard,

many of DCCR's grants and contracts are classified as demonstration projects. According to the acting director of DCCR, their purpose is to demonstrate, in a field setting, a new research finding or technique, and after federal funding of the demonstration project ends, the local community is to decide whether to continue the project.

The five contracts we reviewed were classified as demonstration projects. According to the acting and former directors of DCCR, the division does not normally attempt to require contracts to inquire into efforts being made to continue projects after federal funding has ended. These officials said that DCCR has never done a study to determine how many demonstration projects have continued. Consequently, DCCR does not know the extent to which demonstration projects are continued by localities after federal funding ends.

NCI Has Not Effectively Managed Cancer Control Contracts

NCI did not effectively manage four of the five contracts we examined. It failed to (1) correct problems found by advisors that reviewed the contracts and (2) require contracts to complete required tasks. In our opinion, this contributed to three of the contracts not fully achieving their intended objectives. The project officers' caseloads may have contributed to the inadequate management of these contracts. However, we believe a more significant reason was the failure of the principal parties responsible for managing contracts–project and contracting officers–to cooperate in guiding projects toward successful completion.

NCI has not implemented recommendations of postaward review groups

In addition to preaward reviews, DCCR established in 1975 a system in which each cancer control contract is reviewed midway through the life of a contract by a merit review committee. In 1978, NCI established a separate committee–the Cancer Control Merit Review Committee–to perform this function. When the merit review is completed, the executive secretary of the committee prepares a summary that assesses the strengths and weaknesses of the contract and makes recommendations to the DCCR director and chief of NCI's Control and Rehabilitation Contracts Section on future actions. Also, some DCCR project officers and specialists make site visits to contractor facilities to monitor contractors' performance.

In addition, DCCR stated that the project officer has the major responsibility for managing the contracts' technical merits. In 1971, HEW published a guide, "The Negotiated Contracting Process," for project officers to follow in performing this function. In 1978, NIH published a similar document called "A Guide for Project Officers." In July 1978 the director of NCI established a policy that required each project officer to prepare a semiannual report for submission to his/her supervisor indicating the technical progress of each contract. A copy of the report was to be submitted to the cognizant contracting officer for appropriate action. The director stated that, in preparing the reports, project officers were to stress the issues discussed in "The Negotiatied Contracting Process," covering such areas as management, level of performance, need for approvals to change contract terms, and the need for site visits.

HEW's "The Negotiated Contracting Process" emphasizes the need for project and contracting officers to cooperate in managing the contractors' performance. It states that, if performance is not proceeding satisfactorily or if problems are anticipated, the project officer should notify the contracting officer of the causes and the recommended course of action from a technical standpoint. Also, it stresses the need for immediate notification to assure that the contracting officer takes appropriate action to protect the government's rights under the contract.

"The Negotiated Contracting Process" also states that no one can direct, or should request, the contractor to do anything that is not expressed as a term, condition, or provision of the contract. The HEW guidelines further state that the agent for action is the contracting officer and that the project officer is to monitor a contractor's performance closely and identify potential problems that threaten performance so that remedial measures may be taken.

NIH's "A Guide for Project Officers" emphasizes the importance of written communication between the project officer, contracting officer, and contractor. It states "unwritten understandings can result in serious contract and legal problems".

We reviewed the reports filed by the various merit review committees and the site visit teams for the five contracts we examined to determine DCCR's actions to correct problems and implement reviewers' recommendations. For the Louisville, Tyler, and Illinois Cancer Council contracts, we determined that the review groups identified 52 problems and made 43 recommendations to DCCR applicable to the contracts. These problems and recommendations dealt with such issues as contract tasks not being done, data collection problems, low levels of patient participation, technical deficiencies in project design and performance, poor coordination among various parties, and failure to emphasize key tasks.

DCCR told us that it took action to implement all 43 recommendations made by the various review groups and site visit teams and provided us with memorandums, which DCCR considered to be evidence of its actions. Our review showed that DCCR's actions consisted of verbally informing the contractors of the review groups' recommendations and sending copies of the review groups' reports to the contractors. We found no evidence that DCCR ever directed the contractors in writing to implement the review groups' recommendations, nor was there any evidence to show why the recommendations should not be implemented. Thus, NCI left it up to the contractors to decide what recommendations to implement.

NCI advised us that sufficient followup was taken to determine that the contractors were taking steps to correct deficiencies. Again, we found no documentation to indicate contractor action. NCI believes this is more a failure of documentation rather than a failure to obtain action and represented past, rather than current, practices. However, we found nothing in NCI's procedures or practices to indicate that review groups' recommendations are handled differently from the manner we found in the contracts we reviewed.

We discussed this with the chairman of the merit review committee. He said that his committee also found that DCCR apparently does little to implement the recommendations made by the committee. In his opinion, DCCR's failure to act on the reviewers' recommendations made merit review a waste of time. When NCI asked the chairman of the committee about this statement, he said, according to NCI, that his committee never received information concerning implementation of its recommendations and, therefore, had little basis to evaluate the matter. He also said this lack of information was a source of frustration.

According to the chief of NCI's Control & Rehabilitation Contracts Section, one reason for contracting officers' failure to direct contractors to implement the recommendations of advisory groups is that DCCR project officers fail to notify the contracting officers of contractors' poor performance and to develop, with the contracting officers, a course of action to improve contractor performance. For example, in the Tyler contract, the project officer was informed by site visitors of problems in the contractor's performance as early as three months into the contract period. However, the contracting officer at that time was not informed of the problems. The subsequent contracting officer only learned of problems when

the merit review was performed—33 months after the contract began.

We discussed the management of cancer control contracts with the chief of the contracts section. He cited a lack of cooperation between the DCCR project officers and the NCI contracting officers. He could recall few instances where the project officers brought problems to the attention of the contracting officers for resolution. In his opinion, this situation has improved recently.

NCI now has a system that requires each project officer to prepare a semiannual report on the technical progress of each contract. We examined 108 of these reports prepared from January to August 1979. We found that the reports provided mainly a summary of the progress of each contract, with 20 of the 108 reports (18 percent) discussing problems in performing the contracts. The chief of the section said that in the past he could recall only a few instances in which the reports identified any problems. The acting director of DCCR said that recently he had established a format for project officer reports, which he believes will identify weaknesses in contractor performance.

In a memorandum, the former director of DCCR stated that the mechanisms for the interaction between the contracting and project officers did exist. In response to our inquiry, she advised us that the mechanisms were established by the start of fiscal year 1975. She said these mechanisms consisted of the chief of the contracts section attending meetings of the DCCR Executive Committee. Also, the staff of the contracts section attended preaward and merit review committee meetings, planning sessions, and project plan reviews. She added that the NCI contracting officers were encouraged to attend review sessions, advisory committee meetings, and meetings with contractors and to make site visits with project officers. Finally, she said that she had almost daily communication with the chief of the contracts section to discuss technical and contracting issues.

While the mechanisms for cooperation between the project and contracting officers may have existed in DCCR, they apparently did not work. The large caseload of both grants and contracts assigned to some project officers may have contributed to the lack of cooperation and coordination. For fiscal years 1975-79 the number of active grants and contracts was as follows:

Fiscal year	Total grants	Total contracts	Total grants and contracts
1975	28	240	268
1976	59	251	310
1977	77	248	325
1978	83	198	281
1979	100	176	276

The project officers' caseloads vary significantly. Twelve of the professional staff have project officer responsibilities for grants and contracts. Caseloads vary from three to 44 projects, according to an October 1979 program list. In addition to being the project officer for 30 projects, one staff member also had to carry out the responsibilities of a branch chief. NCI commented that lumping grants and contracts together is misleading because grants require less monitoring. Also, NCI said that managing many contracts on the same project required less work than managing an equal number of contracts with different work scopes.

Publication of portions of the report will continue next week.

NCI ADVISORY GROUP, OTHER CANCER MEETINGS FOR AUGUST, SEPTEMBER

UICC Biennial Meeting—Aug. 3-5, Oslo.
Symposium on Trends in Cancer Incidence—Aug. 6-7, Oslo.
Special Session on Highlights in Cancer Epidemiology—Aug. 11-12, Helsinki.
Annual Florida Registry Workshop for Physicians, Registrars, and Others Working or Interested in Registries—Aug. 13-15, Daytona Beach Holiday Inn Surfside. Contact Herbert Kerman, Halifax District Hospital, Daytona Beach 32014.
Biometry & Epidemiology Contract Review Committee—Aug. 14-15, NIH Bldg 31 Rm 7, open Aug. 14 9:30–10:30 a.m.
6th International Congress on Histochemistry & Cytochemistry—Aug. 17-22, Brighton, UK.
Subcellular Methodology Forum on Cancer Cell Organelles—Aug. 27-30, Univ. of Surrey, UK.
National Cancer Advisory Board Working Group on Board Activities & Agenda—Aug. 28, NIH Bldg 31 Rm 11A10, noon, open.
2nd International Congress on Cell Biology—Aug. 31-Sept. 5, Berlin.
2nd International Conference on Cancer Nursing—Sept. 1-5, London.
Large Bowel Cancer Review Committee—Sept. 3-5, Houston Prudential Bldg., open Sept. 3, 7:30–8 p.m.
National Capital Area Branch American Assn. for Laboratory Animal Science—Sept. 3-4, annual meeting, Marriott Hotel, Hunt Valley, Md.
2nd Annual Preventive Oncology: Nutrition & Cancer—Sept. 6-7, San Francisco Sheraton Palace. Univ. of California continuing education in health sciences.
European Symposium on Lung Cancer—Sept. 7-13, Porto Carras, Greece.
Bladder Cancer Review Committee—Sept. 8-9, Boston Ramada Inn, open Sept. 8, 1–1:30 p.m.
Head & Neck Oncology Multidisciplinary Conference—Sept. 8-10, Key Bridge Marriott, Rosslyn, Va.
Interbalkan Congress of Oncology-Radiology—Sept. 8-14, Bucharest.
Cancer 1980: Achievements, Challenges, Prospects—Sept. 13-18, Grand Hyatt Hotel, New York. Sponsored by Memorial Sloan-Kettering Cancer Center, with the American Cancer Society and NCI.
Advances in Rehabilitation of the Cancer Patient—Sept. 18, Roswell Park continuing education in oncology.
Research Frontiers in Aging & Cancer—Sept. 21-26, Washington D.C. Shoreham Hotel.
Biological Bases & Clinical Implications of Tumor Radioresistance—Sept. 21-24, Rome.
International Symposium on Gastric Cancer—Sept. 22-23, Univ. of Birmingham, UK.
Recent Advances in Diagnosis & Treatment of Lung Cancer—3rd Annual Charles A. Sammons Cancer Center Symposium—Sept. 24-25, Dallas.
Cancer Research Manpower Review Committee—Sept. 25-26, NIH Bldg 31 Rm 4, open Sept. 25, 9–10 a.m.
Nature, Prevention & Treatment of Clinical Toxicity of Anticancer Agents—Sept. 25-27, Institut Jules Bordet, Brussels.
Progress in Cancer Control—Sept. 29-30, Roswell Park Memorial Institute.
CEA: Its Role As a Marker in the Management of Cancer—Sept. 29-Oct. 1 NIH consensus conference, Masur Auditorium.

The Cancer Letter _Editor Jerry D. Boyd

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