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CCOP CONTROVERSY GOES ON: DCT BOARD OBJECTS, SAYS IT WAS LEFT OUT; MOORHEAD, DEVITA CLARIFY POSITIONS

The soap opera-like saga over development of guidelines for the Community Clinical Oncology Program continued last week. Here are some scenes, as the world turned from Bethesda to Grand Rapids to Houston to Washington to Williamsburg:

(Continued to page 2)

In Brief

NCI TERMINATES STRAUS' GRANT FOLLOWING SITE VISIT REPORT CHARGING "LACK OF SATISFACTORY PROGRESS"

NCI IS TERMINATING the program project grant it awarded two years ago to Marc Straus at New York Medical College. The action has nothing to do with the charges made against Straus while he was conducting clinical studies at Boston Univ., an NIH spokesman said. NCI Director Vincent DeVita notified NYMC President John Connally that, following a site visit the clinical portion of Straus' grant was suspended immediately because the reviewers found there had been "failure to obtain prior approval from the institutional review board for research involving human subjects." DeVita also wrote that the remaining portion of the grant would not be renewed after the second year expires next month because the site visit team reported "unsatisfactory progress" on the preclinical and clinical cytogenetic studies. The three year grant, with a total direct cost of $910,415, became an issue at a Senate hearing last year when DeVita was criticized for not informing the National Cancer Advisory Board of the then unpublicized Boston allegations when the Board was acting on Straus' application. The NIH investigation of the Boston charges is still going on. A spokesman for NYMC told ***The Cancer Letter*** that a statement is being prepared and would be released later this week. . . . HISTORICAL CORRECTION (again): Donald Fernbach, professor of pediatrics at Baylor, wrote regarding the Jan. 29 reporting of the history of pediatric cooperative groups, "Your correction needs correcting. It was the Pediatric Div. of CALGB that was disapproved by the CCIRC, not the Pediatric Div. of SWOG. The Pediatric Div. of SWOG seceded from SWOG to join with the former members of CALGB to form the new POG. I was a founding member of the original Southwest Cancer Chemotherapy Study Group that was a pediatric organization in 1958. The internists came on board later and then outnumbered the pediatricians leading to the formation of SWOG". . . . SEARCH COMMITTEE headed by NCI Deputy Director Jane Henney is seeking candidates for the job of permanent director of the Div. of Cancer Treatment. Deadline is March 31. Saul Schepartz, DCT deputy director, heads the search committee for a new Cancer Therapy Evaluation Program head, to replace John MacDonald. That deadline is Feb. 28. Send nominations to them at NCI.

ACCC ADDS FULL SESSION ON CCOP, NCAB SUBCOMMITTEE MEETS MARCH 4

(Continued from page 1)

• National Cancer Advisory Board member Rose Kushner, rebuffed when she tried to get issuance of the CCOP RFA delayed until after the Board's May meeting, obtained independent, private legal advice on the issue of whether reviewing an RFA before it is published would disqualify a Board member from competing for one of the awards. That possibility was offered as the primary reason why Board members could not see the final draft of the CCOP RFA; some members said they would vote for a delay only if they could review the draft, and failing that, saw no reason for delaying.

Kushner told *The Cancer Letter* that the Washington law firm she had retained at her own expense had advised that federal procurement regulations do not bar NIH advisory group members from seeing RFPs and RFAs in advance of publication, provided sufficient time is allowed after publication to permit others to respond. She said she was going to ask Board Chairman Henry Pitot to call a special meeting of the Board to review the RFA before its scheduled release in early April.

• The Div. of Cancer Treatment Board of Scientific Counselors, meeting in Houston, objected to being left out of the decision making process in developing CCOP guidelines despite the fact it will have a major impact on DCT programs and DCT-funded cooperative groups. NCI executives agreed to supply details on CCOP to members by mail and take into account recommendations they may wish to submit before the final RFA draft is written.

• NCI senior staff—director, his associate directors and the division directors—convened in Williamsburg for one of their periodic (closed door) "retreats" where they make the "corporate" decision on how the budget will be apportioned. This time, they split up the 1983 fiscal year budget, and CCOP came out of the retreat as one of Director Vincent DeVita's highest priorities.

• The Assn. of Community Cancer Centers revamped the schedule for its 8th national meeting, in Washington March 4-7, adding March 3 to permit a full scale discussion on CCOP. That session will start at 3:30 p.m. March 3, with time reserved until 7 p.m., in the Hyatt Regency Hotel on Capitol Hill. Gale Katterhagen will convene his NCAB Subcommittee on Cancer Control the following evening, March 4, for what was intended to be the Board's final look at CCOP provisions before the RFA goes out. The subcommittee is charged with reviewing the guidelines and notifying Board members of any deficiencies or unresolved disputes it finds.

• Edward Moorhead, chairman of ACCC's Clinical Research Committee which played a major role in developing CCOP guidelines, wrote to DeVita expressing the association's position on provisions contained in the draft RFA published in ***The Cancer Letter*** Jan. 22. DeVita responded with a statement of his position on each of Moorhead's points and on his conception of how the program will work. Moorhead's statement and DeVita's response spell out the respective positions of ACCC and NCI at this point. They follow, starting with Moorhead:

The CCOP proposal, as reported in *The Cancer Letter,* contains many of the suggestions first made by the ACCC Clinical Research Committee and later recommended by the NCI sponsored Committee on Community Oncology & Technology Transfer, chaired by Dr. Charles Moertel of the Mayo Clinic.

As chairman of the ACCC committee and as a member of the Moertel committee, I am deeply concerned that several of the changes made in the latest draft of the CCOP proposal could doom it to failure—becoming another one of those "cancer control programs that just didn't work." I believe this would be a great tragedy to patients in the community, to community oncology, and to the National Cancer Program.

I believe that some of the past failures in the area of cancer control in the community may well have been due to an understandable lack of sensitivity on the part of program designers to the sensitivities, nuances, organizational problems, and latent paranoia in the community.

It was my hope that the CCOP program, developed after massive input from community oncologists, and prolonged consideration by a broadly representative "Moertel Committee," could avoid these crippling and potentially fatal pitfalls in program design.

My hope has become alarm.

Whereas much of the community input to this program's design indicated difficulty with the less than democratic processes (regarding the community) inherent in many cooperative group and cancer center programs, we now find a proposal that continues the martial law atmosphere for community participants, with NCI staff as the new dictators of behaviour. I do not believe that the NCI staff intends the CCOP program to operate in this manner, but this is how it reads in *The Cancer Letter.* Perhaps the problem is semantics, perhaps the problem is the reporting.

In an effort to clarify the issues, I shall present a point-by-point brief discussion of the major concerns of the ACCC Board of Directors regarding the proposed CCOP programs as reported in *The Cancer Letter.*

I. Inadequate Budget

We believe that the proposed $3 million budget for FY 1983 is totally inadequate to fund what we believe will be 50 or so high quality programs and their research bases.

It is most likely that the initial applicants will be high quality community programs with more than 50 patients per year.

We also believe that it is totally unrealistic to expect community programs entering 50 cases per year to be able to spend $15,000 to fund their research bases. We estimated that it would cost the community $1,000 per case for the clinical research structure for its first 50 cases and recommended that research bases be given $300 per case for their obligations in addition to the $1,000 given to the community program. As communities entered more cases, the cost per case would lessen, but the research base cost would be stable.

We are also disappointed that the proposed budget does not include even a small fraction of money for the non treatment cancer control projects and research that ACCC recommended as an option for CCOP programs.

II. Absence of Planning Grants

While perhaps 50 communities might qualify for immediate operational funding as CCOPs, we recommended that less organized communities be eligible to apply for "planning money" to enable them to qualify as second-generation CCOPs. These awards could be ($20-30,000), but important, to ensuring the success of the program.

III. Mandatory Regionalization

Both the Moertel and ACCC reports expressed strong preference for regionalization, but stopped short of making regionalization mandatory. This was done in recognition of the fact that unique circumstances may and do exist in a few communities that may justify "out of region" research base affiliation. It was recommended that the burden of justifying such an out-of-region affiliation be placed on the CCOP. The mandatory language of the proposed CCOP, we feel, eliminates such potentially justifiable exceptions.

IV.

"There must be clear commitment by the CCOP to enter patients on *all* protocols designated in the CCOP research base agreement and recognized as high priority by NCI."

"Programs will be monitored annually with the expectation that at least 12 percent of eligible patients will be entered for each cancer for which a protocol exists."

During our discussion at the Moertel Committee, there was a consensus that varying situations in different communities make it impossible for a specific community group to guarantee across-the-board commitment of patients.

In some communities, patients with certain types of tumors may not be referred to the oncology team, and in a few cases, the oncology team might decide that a specific protocol is not in their patient's best interest.

The use of 12 percent of eligible patients as a requirement is another item to which the members of the Moertel Committee were opposed. You indicated at that time that 10 percent or so should be cited as a general guideline or goal. The committee expressed the fear that such guidelines or goals, in the hands of the bureaucracy become hard and fast requirements. The fears were justified.

We recommended that community physicians be given a significant voice in the operations of the research base and in the determination of which protocols were to be labeled high priority. At the Moertel Committee, we discussed methods of encouraging entry into high priority protocols (graduated credit) recognizing that coercion not only builds reactive resistance, but also can be accused of pressuring the practicing physician to choose a specific protocol that he might not feel is in his patient's best interest. I know you agree that this program is aimed at improving cancer care in the community and does not wish to be accused of sacrificing quality care for research objectives.

I do not think that the CCOP programs should have any such specific quota requirements that are not a requirement of University Hospitals and others that are participating in present NCI sponsored research programs.

Obviously a CCOP program that found all or many high priority protocols objectionable should not be a CCOP. We feel it is of the utmost importance that the CCOP proposal specifically state that community physicians (preferable chosen by the community) will play a meaningful role in the determination of which protocols are high priority.

One of the objections to past community research efforts has been the fact that protocols are rained down on the community by the research bases like lightning bolts from Mount Olympus. The proposed CCOP outline substitutes "NCI" for "research base" at the top of the mountain. As recommended in our report, we suggest all three groups be represented on a committee to determine high priority protocols.

V. Cancer Control (other than treatment control)

The ACCC Board and I were deeply concerned with:

a) The less than lip service given to non treatment cancer control programs in the CCOPs.

b) The dictatorial flavor directing the community to "required" participation in "NCI initiated cancer control activities."

There is obvious disappointment that the Div. of Cancer Treatment is not recorded as contributing money for the research aspects of the program (i.e., funding of the research bases). Both the ACCC and Moertel Committees recommended that both DRCCA and DCT contribute to funding without spelling out percentages. We felt this preserved your options. We did not expect you to exercise your options so one-sidedly.

The ACCC committee recommended that a percentage (20-30 percent) of the proposed CCOP budget could be designated for non treatment cancer control, for those communities who wished to apply for such funds. It was our feeling that this was necessary to preserve funding for these important non treatment areas of cancer control which could be obliterated if the CCOP program is as successful as it could be, and if DCT continues to contribute zip to the effort.

We believe that the CCOP members should work with and not for NCI to carry out well thought out cancer control projects. Again, as in the designation of high priority protocols, there is no guarantee that community physicians will have input, let alone decision making power as to what cancer control projects the CCOP group will undertake. This is far from acceptable or advisable.

We also feel strongly that those CCOPs who have the ability and potential to carry out locally initiated cancer control research projects of merit should be able, under the CCOP program, to apply for limited funds to help finance them. ACCC also recommended that the community make significant financial contributions to this part of the CCOP effort.

We strongly recommend:

a) The inclusion of non treatment cancer control as an option for communities that become CCOPs. A fixed (i.e., 15-20 percent) percentage of the CCOP budget, taken from DRCCA, should be allocated to these non treatment control activities.

b) That a mechanism be developed and specified for community physician participation in decisions as to what are NCI initiated (i.e., approved) cancer control activities. The same mechanism should be able to and should review community initiated cancer control activities for general implementation by CCOPs.

c) That community support of cancer control activities be strongly encouraged to supplement, but not replace, NCI funding.

VI. Relationship of CCOPs and Research Bases

We believe that reports and rumors about the proposed CCOP program have led to a false impression that the community programs are pitted against the comprehensive cancer centers and cooperative groups in a war over power and funding. The harmony on the Moertel Committee belies this impression. There is general agreement on our goals and remarkable agreement on ways to get to those goals.

The proposed details in *The Cancer Letter* regarding CCOP/Research Base relationships need more discussion than can be included in this letter. I suggest an immediate meeting of the Moertel Committee to discuss these items.

I do believe that ACCC has been misrepresented as favoring that money for research bases be funneled through CCOPs. Some members of ACCC might welcome this approach, but I call attention to the fact that the official ACCC recommendation was that both the CCOPs and research bases be funded directly as outlined in the Moertel Committee report.

The ACCC committee also felt that the proposed $50,000 per program for 50 evaluable cases does not include funds for non treatment control projects, and does not include money for research bases.

As the Moertel Committee recommended, we suggested $300 per case for the research base, directly funded by NCI.

Regarding the issue of university hospitals, it was our recommendation that hospitals owned and operated by universities be excluded from the CCOP program. This is a complex issue in which further discussion is needed.

DeVita's letter in response:

Dear Ed:

Thank you for your letter in reference to the CCOP programs. I'm distressed at the amount of misinformation around. I believe this was due to a staff leak of an old version of the description of the CCOP.

Much of the information you wish us to detail in the RFA is really unknown. Some of the greatest failures of previous programs have been related to inaccurate initial projections. This is, by the way, the reason that we are having workshops with community physicians. At the workshop in Los Angeles many of the points you raised were identified and our own incomplete information emphasized. Why guess when we can work out the details in negotiations?

I am concerned about the tone of your position paper, which is clearly one that will raise deep alarm and anxiety, and yet I believe the development of the CCOP is working harmoniously. Let me address some of the issues you raise specifically.

I. Inadequate budget. A comment made by a staff member at a board meeting, in reference to the budget, was inappropriate. At the DRCCA Board, I clearly stated that we have committed to funding *up to* $10 million worth of high quality CCOP programs, if such exist. I don't really know the exact amount required for an individual CCOP; I don't believe anybody does. Therefore, it seems inappropriate to argue over $15,000 to fund research for the research bases, $1,000 per case versus $300 per case etc. Some centers have indicated their willingness to collaborate with CCOPs without any transfer of funds. Others have indicated they may require some but they aren't sure what the amount will be. My point is, (and always has been) that we will provide enough.

II. Planning grants. We don't, again, know the number of institutions that will qualify for CCOPs. Therefore, we don't know the need yet for planning grants! We have a strong feeling that many CHOP programs will probably apply and apply successfully to become CCOPs. If this is so, and if we have less than the desired number of CCOPs, we may need to send out additional announcements for CHOPs to be followed by additional announcements for CCOPs. I've been told by some prominent individuals, who know community medicine very well, that there will be hundreds of hospitals applying all of which have qualifications to become CCOPs. If so, we may have many more than we can possibly even fund with the $10 million. Therefore, simultaneous issuance of planning grants would be inappropriate, and if we issue an RFA for more CHOPs, these are not planning grants.

III. Mandatory regionalization. It seems clearly inappropriate for a physician in the city of Los Angeles to be working in a clinical protocol with a cancer center located in Chicago. Therefore, we have attempted to enforce some regionalization in order to be able to defend the regional nature of many of our programs. The "mandatory nature" of this is negotiable if there is a good reason. Obviously, there will be several centers in regions that are within the geographic location of a CCOP. Choices won't necessarily have to be made vis-a-vis the exact closest center as long as it is not 3,000 miles away.

IV. There was a trend, it seems to me, on the Moertel Committee to make CCOPs just an addition to the Cooperative Group Program. Clearly, CCOPs will use protocols they agree to use jointly with the research bases. Not all protocols will be appropriate for some CCOPs and some CCOPs may choose to work out an arrangement whereby they will contribute to all protocols of a research base. Again, both are allowable and we do not have any idea yet as to how many CCOPs will elect to work with cooperative groups versus cancer centers, which will dictate different arrangements. I sincerely hope many will work with centers.

The misrepresentation of the tithe, which is the cornerstone of the CCOP concept, is legion. It is meant to be both a ceiling and a floor; or in another sense, a governor. What this means is that you cannot be forced to put more patients on protocol than the small fraction specified. In other words, a CCOP cannot be penalized by withdrawal of funds for not having contributed more. It also means if patients with diseases of specific interest and priority are available at a CCOP, and a protocol is available at the research base, some contribution to the research base can be required in the negotiation. At the recent L.A. workshop, we indicated in response to several questions that if a CCOP sees enough patients with breast cancer to satisfy its minimal numerical requirement with breast cancer patients alone, and *this is mutually agreed upon by the research base and the CCOP,* this is a sufficient way of meeting the goal.

We certainly agree that community physicians should be given a significant voice in determination of high priority protocols.

The second cornerstone of the CCOPs is the administration of funds directly to the community hospital so that they have some room to negotiate. It is surprising to me that this has been misunderstood. Having the funds directly in the hands of the community hospitals, coupled with an obligation on the part of the community hospitals to participate to a certain level (the tithe) was meant to encourage a new level of negotiation amongst centers, groups and community hospitals, as equal partners, that has not existed before.

You complain that you should have the same requirements as university hospitals and centers. Yet, requirements for CCOPs are different from those of research grants from university hospitals because universities are required to go through a review mechanism that assesses "track records" (prior scientific output) as opposed to proposed participation in clinical protocols. If CCOPs are forced to do this they could be in the old Catch 22 position of yesteryear. Many of the concerns about relationships to centers and cooperative groups vis-a-vis protocols, selection, priorities, etc., will be further clarified at the time of negotiation after the instrument (RFA) is issued.

V. Cancer control. We recognize there is more to cancer control than CCOPs. On the other hand, Rome wasn't built in a day either. I have always lived by the Churchill statement that "the maxim nothing avails but perfection may be spelled paralysis." We are anxious to develop a mechanism that takes advantage of the community oncology expertise. The choice is wait and do it all together later or do it a piece at a time starting now. Dr. Greenwald has developed other instruments to cover the waterfront in cancer control. The CCOPs themselves through their "diffusion effect" we hope will be a control effort as well. We will have to assess the impact of having a CCOP on the management of patients in the hospital, if, in fact, these research ventures in cancer control are to continue.

In reference to financial contributions by the Div. of Cancer Treatment, let me assure you that there is only one budget for the National Cancer Institute. One should not view the Institute in such narrow compartments. The highest priority programs will get sufficient funding and CCOPs, as we have said publicly, have a high priority. Therefore, whatever is

required to fund them will be made available, if we have any flexibility left at all. To the extent that this money goes to DRCCA and not to DCT, DCT and the other divisions are contributing to the success of the CCOPs.

We also believe that CCOP members should work with, and not for, NCI and that has been our intention all along. Never in the history of the Cancer Control Program has there been so much involvement by the community in the development of a program before the instrument is on the streets. It began over a year ago when I announced the CCOP program at the ACCC and your Clinical Research Committee was developed in response. It has continued with repeated public discussions, and deliberations of a very well organized subcommittee of NCI, and will continue with more of the same at the upcoming [Feb. 1-3] National Cancer Advisory Board meeting. All of this precedes the issuance of the instrument, to assure the maximum amount of input from the community we serve. At the same time we are letting the community know the areas of uncertainty facing the Institute, most of which I have mentioned above.

VI. Your comments on reports, rumors and cooperation.

I'm sorry about reports and rumors, but these kinds of things always happen when one deals with controversial programs. Often, the only option is not to start controversial programs. I prefer to debate them publicly, and take my chances. At the end of each workshop we attend the concern seems much less than at the beginning. This indicates to me that there is, indeed, a good deal of misinformation around.

Some community hospitals work very well with centers and cooperative groups—others do not. That is a fact of life, not a rumor. The fact that I have said I believe the community organization should have funds of their own in order to deal on an equal basis with the research bases, should not be interpreted to mean there is no harmony. Facts are facts. Resources often dictate the level of cooperation.

Again, I do not believe that the issue of research bases receiving money from CCOPs is settled at this point in time—an issue discussed above. If it is unnecessary, that's fine. If it's necessary, then it's an option that CCOPs and research bases can choose.

Finally, on the issue of university hospitals as candidates for CCOPs we meant only not to exclude any hospital that operates as a community hospital. This is not meant to divert the funds away from the majority of CCOPs. Also, if any hospital is already funded for this kind of work and applies for a CCOP, they will have to relinquish other funding.

I hope these words allay some of your anxiety. I am sure these points will be discussed again (and again) in more detail at the National Cancer Advisory Board and elsewhere.

Editor's note: DeVita referred, in his letter to Moorhead and later at the NCAB meeting, to *The Cancer Letter's* publication of the draft RFA as the result of a "leak" by a staff member. The term "leak" is inaccurate and inappropriate.

That draft was the centerpiece of a long discussion at an open meeting of the Div. of Resources, Centers & Community Activities Board of Scientific Counselors. The Freedom of Information Act spells out that documents brought to public meetings of government bodies and used as a basis for public discussions are in fact public records. When *The Cancer Letter* requested a copy of the draft RFA, the staff member had no choice but to comply. The draft was not a leak; the Moorhead/DeVita exchange was.

DeVita and other NCI staff members have said that the draft published by *The Cancer Letter* was an "outdated" version of their thinking regarding CCOP guidelines. At the time it was obtained by the editor, it was the latest draft in existence, although the DRCCA Board discussion obviously would lead to changes and such were noted in the accompanying story reporting that discussion.

Finally, a review of the draft fails to find many provisions which were disavowed by DeVita in his response to Moorhead. The most significant perhaps is that he does not want to be tied to the $1,000 per patient cost, and that probably will not be in the RFA. He is insisting on direct funding to CCOPs and on the patient tithe, although attempting to be as flexible as possible in how the tithe is to be determined. He has not backed away from the regional requirement, although agreeing this could be waived for good cause.

The Cancer Letter will continue to publish material, leaked and otherwise, which shows NCI policy in the making. Updates will be published as they become available.

DCT BOARD INSISTS ON GETTING ITS OPINION INTO DEVELOPMENT OF CCOP

Members of the Board of Scientific Counselors of NCI's Div. of Cancer Treatment were not pelased that most of the decisions on the Community Clinical Oncology Program were made without their opinions being heard.

"It should have been discussed by this Board," Theodore Phillips said. "The program has great implications for our grantees, and the cooperative groups. They will bear the brunt."

"They also will bear the fruit of the program," NCI Deputy Director Jane Henney said. "I think it is appropriate for this Board to discuss CCOP, although the DRCCA Board has given concept approval, and the NCAB has approved it."

"But it is more important to this division than to DRCCA," Phillips insisted.

"For the treatment portion, perhaps," Henney said. "But it is broader than that. Eventually, CCOP will get into control and prevention activities."

CCOP's first goal is to increase the flow of patients into clinical trials from community hospitals, to reverse what has seemed to be a trend of diminishing numbers of patients available for clinical research. Phillips challenged the concept that "our biggest problem in clinical trials is the lack of patients. Our biggest problem really is a lack of ideas. The whole idea of taking in this new group of people and placing the scientific load on our grantees needs some study."

"The concept is attractive," said Board Member Paul Marks, who is director of Memorial Sloan-Kettering Cancer Center. "We have relations with 23 community groups and it works very well." He em-

phasized the need to "build in the regional concept. Geography is important because patients are involved."

"I agree with the concept. It is a laudable effort," said Board member Carmack Holmes. "One big area is quality control. As we begin to use patients in stage 1 or earlier, it is extremely important to have quality controls. That is precisely the area which is the most difficult to convince community physicians to adhere to. This will be your most difficult area."

Henney said the RFA will require that patients be treated according to protocols.

William DeWys, chief of DCT's Clinical Investigations Branch, said all participating institutions will be expected to undergo exact quality control requirements.

Board member Sydney Salmon said he agreed that developing relations between communities and the cooperative groups is important, "but I object to the way this has been carried out. This is an Institute-wide program but it was not brought formally to the DCT Board for concept review. I have little doubt it will have a major impact on DCT and our funding."

"I had a number of considerations on my mind about the impact of CCOP on clinical trials," DCT Acting Director Bruce Chabner said. "The program will tie in with many of the research bases we operate, it will have an impact on drug distribution, monitoring of clinical trials, evaluation of protocols, and the dollar amount it will cost our division is not clear. I sought assurances from Dr. DeVita that we will not have to take money out of clinical trials for CCOP. He assured me the Institute will provide the money. It probably won't be as expensive (to DCT) as it sounds. We're already reviewing most protocols. It will not result in clinical trials cutbacks. We have that as a firm commitment."

"The real problem is how community groups will become involved," Phillips said. "Many communities are affiliated now. The difference now is that a prospective member has to show a track record. It's evaluated, they compete, are on probation before accepted as members. Half of them drop out. With CCOP, the community group will step up and get money up front."

"They can be thrown out if they don't produce," DeWys said.

Board Chairman Samuel Hellman said, "There will not be a discussion on whether there should be a CCOP. That decision has already been made. This Board is asking only for input on how it will impact clinical trials."

Henney agreed to send background information to Board members by mail and that return correspondence with suggestions will be taken into consideration in writing the final RFA.

NCAB SUBCOMMITTEE SEEKS NEW TASK FORCE TO GENERATE NUTRITION RESEARCH

The National Cancer Advisory Board's Ad Hoc Subcommittee on Nutrition & Cancer has recommended that NCI establish a Nutrition Task Force to define areas of research needs, solicit and review grant applications as the key feature of a major increase in emphasis on diet, nutrition and cancer research.

"The thrust of the recommendation is that it would be a one shot effort, over two to four years, to generate a block of new research on nutrition, after which the grantees would have to seek support elsewhere," Subcommittee Chairman Maureen Henderson said.

The subcommittee's report asks NCI to earmark more money for nutrition, but Henderson said there was no intention of asking Congress for a line item of additional money.

"The committee believes that an expanded effort in this field of research is necessary to increase the knowledge and understanding of such basic mechanisms as tumor promotion and anticarcinogenesis," the report said. "The subcommittee came easily to the firm conclusion that the current NCI research emphasis in diet, nutrition and cancer is not sufficient. It felt that an appropriately constituted and charged scientific review group should look at the quality of research work being supported. . . . Research in nutrition and cancer is at an evolutionary stage in its development. It needs to bring new sciences and scientists into the field and persuade them to apply their technologies to cancer research. It has to conceive and implement multidisciplinary research approaches and to prepare the way for community based trials of cancer prevention."

Other conclusions reached by the subcommittee:

- Presence and absence of anticarcinogens in the diet and the mechanisms by which diet acts as a promoting agent are important areas of research.
- Dietary and nutritional balance is as important a subject of research as the specific effect of dietary carcinogens and anticarcinogens.
- Chemoprevention trials are an important but limited component of nutrition research directed at cancer prevention.
- Biochemical epidemiology will be an important research resource.
- Attention must be given to the development of animal models in all aspects of nutrition research.
- The body of information assembled from clinical studies in appropriately selected patients is inadequate to answer some questions that are fundamental to further research.
- There is need for research in nutrition and cancer which takes a much more comprehensive view of toxicity.

• There is need for a definite program with its outline and goals known to the scientific community so that individual research projects and additional research needs can be designed and identified in relation to the goals of the program.

• There must be input from all NCI divisions into the goals, design and specification of the overall program.

• There must be continued, and probably increased, coordination between intramural and extramural research activities, at least until the nutrition and cancer research effort is adequate in amount, quality and focus.

The report said that the earmarked additional funds should be provided for a limited time "to implement and stabilize an NCI wide research thrust.... This allocation should be in addition to, and not instead of, funds now spent on nutrition and cancer research within intra- and extramural divisional programs."

The task force should be administered within NCI and should be interdivisional, the report said. It would include at least the following elements:

—Members from various disciplines judged to be essential to the nutrition-cancer area.

—A representative from each of the four boards of scientific counselors to provide liaison with the divisional programs.

—A representative from the National Academy of Sciences group which is now preparing the NCI-sponsored nutrition-cancer report. Since the final report is not due until 1983, it would be important for each group to know of the other's activities and plans.

—NCI staff would consist of an executive secretary from the Div. of Extramural Affairs, and a liaison person such as the coordinator of the Diet, Nutrition & Cancer Program.

—The task force would be divided into various subcommittees as needed to focus on more specialized areas such as training, research areas, and clinical problems.

Functions of the task force would include:

1) Planning—It should produce comprehensive documentation and set priorities for a national agenda on nutrition and cancer. The agenda should specify the major goals and problems in the nutrition-cancer area, and critically define the research and manpower needs. The task force should also address how it plans to target, recruit, and utilize the following potential populations of scientists: those currently active and funded for nutrition and cancer research; those in the nutrition area but not working on cancer problems, and the converse group: scientists who have not yet specialized and scientists seeking a mid-career change.

The task force should identify critical research areas that need to be urgently explored and then formally solicit grant applications targeted at these research problems.

The task force should consider whether it wants to exercise a screening function prior to review to determine if an application is appropriately addressing the identified targeted goals of the program or is an obvious deviation of already supported nutrition-cancer research. This screening function could have several advantages: the review process and use of funds would be more efficient; a more rapid feedback could be provided for desirable applications which need to be strengthened; and the task force could monitor the effectiveness of its methods and quickly identify needed modifications.

2) Review—The task force would review new applications using the same criteria as regular study sections with the added element of program relevance and need. NCAB concurrence would be obtained as usual.

Successful applications would be managed and administered by the appropriate program officials from the operating NCI divisions.

Limitations recommended by the report include:

—The task force would have a limited lifespan of two to four years (to be determined in advance). Up to one year would be devoted to planning, with subsequent years devoted to review.

—Task force members would not submit applications in direct response to this committee's solicitations. They could continue to seek support through the previously available NIH mechanisms.

—The task force would not review any Type 2 renewal applications. All such applications would go through the regular NIH review mechanisms.

The report said that the subcommittee "came to the strong conclusion that the state of the art of research in nutrition and cancer had to be given serious consideration. Specific nutrition and cancer grants (R01) from the extramural grants program have been reviewed twice within the past two years by the NCAB Subcommittee on Special Actions as part of its systematic review of summary sheets and program objectives with the staff of each NCI program. The findings of the Special Actions and Ad Hoc Nutrition subcommittees were in agreement about the difference between the state of the art of research in nutrition and cancer and that of cancer research in other disciplines. . . . The overall focus of current research was hard to evaluate by the process chosen by the subcommittee, although it was perfectly clear that there is little or no overall direction in the intramural or extramural programs, with the exception of epidemiology and chemoprevention. . . . The intramural program as such is a paper program comprised of whatever could be considered nutrition research already under way in laboratories of NCI. . . . There are good reasons to reconsider the intramural program with a view to bringing diet and nutrition

into focus with two or three distinguished young investigators."

NCAB members agreed to placing the report on the agenda of the May meeting for a full discussion of the recommendations.

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-25609-68

Title: *Preparation and supply of fresh and cultured mammalian cells*

Deadline: *March 29*

The Developmental Therapeutics Program, Div. of Cancer Treatment, NCI, is seeking an organization qualified to provide large quantities of well characterized normal, virus infected, and transformed cells grown in culture. It is anticipated that 100 grams of fibroblastic cells grown as monolayer and 100 grams of suspension cultured cells will be required each year. The contractor should also be able to process up to 125 samples of human leukemic blood and supply the leukocytes to the government.

The contractor is also required to provide storage facilities for up to 1,500 sera samples per year, and up to 3,000 grams of leukocytes per year in addition to 20,000 grams of existing frozen leukocyte samples, and 14,000-15,000 ml of sera. Total storage capacity for leukocytes will not exceed 30,000 grams.

All aspects require strict quality control and maintenance of complete records.

These services will include daily courier services for pickup and delivery of specimens. The organization must be located within a 35 mile radius of the NIH, Bethesda, Md. location so as to be able to provide fresh specimens within one hour of processing to enable the government to carry out biochemical, biological and immunological studies.

It is expected that one award will be made for a three year period, September 1982 through September 1985.

Contract Specialist: Karlene Wakefield
RCB, Blair Bldg. Rm. 212A
301-427-8737

RFP N01-CM-25610-73

Title: *Production and isolation of Type I and/or Type II (immune) mouse interferon*

Deadline: *April 26*

The Biological Response Modifiers Program, Div. of Cancer Treatment, NCI, intends to acquire a large supply of type I and/or type II (immune) mouse interferon for testing in a variety of in vivo and in vitro systems. The knowledge gained from understanding the biological properties of interferon in the model system will provide a rational basis for refining the therapeutic potential of human interferons.

The BRMP seeks a contractor who can produce and isolate, in the most efficient and cost effective manner possible, 5 billion units yearly of type I and/or type II (immune mouse interferon at a minimum specific activity of 5×10^6 units per mg of protein. Because the BRMP wishes to obtain a large quantity of highly pure interferon stressing the cost effectiveness of the procedure employed, proposals in response to this solicitation are anticipated from individuals qualified to produce type I and/or type II mouse cell interferon by established animal cell culture technology or procedures relying upon recent advances in recombinant DNA cloning techniques.

It is anticipated that master agreements and at least one task order will be awarded as a result of this solicitation. As requirements arise, RFPs will be issued to all MA recipients eligible for the particular effort. The ensuing awards will be designated as task orders. Only those organizations who have received master agreements will be eligible to compete for task order awards.

Contract Specialist: Rodolfo Reyes
RCB, Blair Bldg. Rm. 212A
301-427-8737

RFP NCI-CP-FS-11030-63

Title: *Support services for a study of cancer following 131-I therapy for hyperthyroidism*

AMENDMENT:

The due date for receipt of proposals has been extended to close of business, 5 p.m. on Thursday, March 25.

NCI CONTRACT AWARDS

Title: Cancer Communications Network (CCN)
Contractors: Univ. of Texas System Cancer Center, $835,563, and Duke Univ., $677,430.

Title: Conference and logistical support services
Contractor: Social & Scientific Systems, Bethesda, Md. $458,579.

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