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CCOP PINK SHEETS GO OUT, DETAILS STARTING TO EMERGE ON NUMBER OF AWARDS, PAYLINE, POSSIBLE EXCEPTIONS

Most of the Community Clinical Oncology Program summary statements (pink sheets) have been sent by NCI to the applicants, and NCI's recommendations on which should be funded will go to the National Cancer Advisory Board May 17. Meanwhile, details are beginning to emerge on what is probably the most complicated and largest—in terms of numbers of people involved—set of competitive awards ever made by an NIH institute. *(Continued to page 2)*

In Brief

NCAB TO HEAR REPORTS ON OUTSTANDING INVESTIGATOR AWARDS, DEFINING QRA, P01 GUIDELINES, GALLOW WORK

NATIONAL CANCER Advisory Board will hear reports on a number of key issues at the May 16-18 meeting. Harold Amos will present recommendations of the President's Cancer Panel on the proposed new Outstanding Investigator Awards; Sheldon Samuels will offer the recommendations of his Environmental Carcinogenesis Committee on defining quantitative risk analysis; Maureen Henderson will report on her ad hoc committee's consideration of new guidelines for program project grants; Robert Gallo will discuss his landmark studies of human T cell lymphoma; William Powers once again will bring the Organ Systems Program controversies to the Board; Lily Engstrom of the NIH Office of Extramural Research and Training will discuss the Small Business Innovative Research Program; William DeWys will report on diet, nutrition, and cancer chemoprevention plans; and LaSalle Leffall will present the Planning & Budget Committee's report which will include the 1985 fiscal year bypass budget. Also, Barbara Bynum will try again to get the Board's concurrence on Board committee structure and membership policies. . . . **LECTURES, ADDRESSES** at the American Society of Clinical Oncology and the American Assn. for Cancer Research meetings this month in San Diego are: David A. Karnofsky Memorial Lecture, E. Donnell Thomas, "Marrow Transplantation for Malignant Diseases;" Richard and Hinda Rosenthal Foundation Award Lecture, Robert Gallo, "The Genesis of Some Human Leukemias and Lymphomas;" G.H.A. Clowes Memorial Award Lecture, Peter Magee, "Nitrosamine Carcinogenesis and DNA Methylation: Some Facts and Speculations;" the ASCO Presidential Address by Saul Rosenberg; and the AACR Presidential Address by Gerald Mueller, "Cancer Research—An Interface to Advances in Cell Science." . . . **MICHAEL POTTER**, chief of the Laboratory of Genetics in NCI's Div. of Cancer Biology & Diagnosis, has received the 1983 Paul Ehrlich-Ludwig-Darmstaedter prize for his research on mouse plasma cell tumors. Potter's development of those tumors has made possible a wide range of activities in immunology, including production of monoclonal antibodies.

SOME CCOP AWARDS WILL BE MADE ON BASIS OF GEOGRAPHIC SPREAD

(Continued from page 1)

• NCI staff was scheduled to meet this week with representatives of the research bases (centers, cooperative groups) which have aligned themselves with one or more of the CCOPs likely to be funded. The key issue—the amount of money which will be required by the research bases for their participation—should be cleared up at that meeting. Best guess now is that, at most, the total cost will approximate that of the usual cost of data collection and analysis, about one dollar for every three spent on other aspects of clinical trials. That would require about $2.5 million of the $10 million set aside for the program, leaving $7.5 million to go directly to the CCOPs.

• How many CCOPs would that support? If they average $100,000 each, available funds would support 75. However, considering that a number of the proposals likely to fall within the funding range were the larger consortia, the average cost probably will be higher than $100,000. Best guess now: At least 40, probably 50, possibly as high as 60 CCOPs will be funded.

• The key question remains: What will be the payline? The final priority score cutoff has not yet been determined, and won't be until the research base cost has been pinned down. Best guess: Any score under 220 probably will be funded.

• Exceptions: One fourth to one third of the awards may be funding exceptions, with awards made beyond the payline. Those exceptions will be based on a variety of factors, one of which will be geography.

NCI will submit a funding plan to the NCAB, explaining the division of money between the CCOPs and research bases and justifying the exceptions.

The rather stuffy NIH system of treating priority scores as state secrets, to be released only after advisory council (NCAB) action, was foiled by CCOP applicants.

The pink sheets were made up by the Div. of Extramural Activities staff, with copies sent to NCAB members which included the priority scores. Copies also were sent to Div. of Resources, Centers & Community Activities staff for distribution upon request to individual applicants, with the priority scores "whited out."

No group of applicants in the history of NIH awaited the results of review more eagerly than the CCOP organizers. On some of the pink sheets, they were able to discern the priority score through the white out by holding it up to the light. Others merely ran them through their x-ray machines.

So now many of the applicants destined not to be funded are aware of that, either by learning their scores or by the fact that they were informed their proposals were disapproved. Is there a place for them in the program somewhere down the road?

It is too early to speculate on any definite prospects, although perhaps not for some. All through the two year process of developing and implementing CCOP, some persons involved felt that $10 million would not be enough to achieve either the broad geographic distribution needed to adequately cover the country or to provide the number of patients which cooperative groups and centers need for their clinical studies. NCI Director Vincent DeVita originally had hoped that that amount would support as many as 200 CCOPs. When it became apparent that the money would not stretch that far, there was talk some groups might go to Congress and ask for additional money to be put into NCI's budget earmarked for support of additional CCOPs.

That might still be an option, especially if a substantial number of CCOPs close to the payline remain unfunded. A case might be made for those filling geographical gaps, even if their scores are not all that good.

The NCAB conditioned its approval of the program on starting it as a demonstration. Presumably, any new request for applications, to solicit proposals for additional CCOPs, will have to await evidence which would satisfy the NCAB that the demonstration proved successful. That could take up to two or three years, or longer.

If it turns out that the first competition was dominated by hospitals with existing clinical research programs and affiliations, or by those with previous experience in the Community Hospital Oncology Program or Clinical Oncology Program, NCI may decide that a new round of CCOPs should include a planning phase.

Those institutions still interested in participating in clinical research even after failing to get a CCOP award should consider developing their own funding. An example is the Community Wide Hospital Oncology Program of Flint, Mich. (***The Cancer Letter***, Jan. 21).

Another source of NCI support could open up, on a limited basis. Some of the CCOP awards will go to hospitals which are participating in the Cooperative Group Cancer Control Program. They will have to give up their membership in that program, along with the more limited funding, and this will free up funds for the participating groups to make available to new affiliates.

ADMINISTRATION PLANS TO STOP PAYING ADVISORS; NIH, HHS TO MAKE PROTEST

President Reagan is now asking for volunteers to perform peer review for NIH.

The Administration last week published regulations directing federal agencies to limit payment for

service on government advisory committees to those instances where it is absolutely necessary.

The regulation was issued following a survey by the General Services Administration, published April 28 in the *Federal Register.* The publication stated, "GSA believes that a sufficient number of citizens of all backgrounds and qualifications can be found to provide advice and recommendations to the federal government." The new policy requires agencies to "make a good faith effort to solicit members on a noncompensated, volunteer basis."

The regulation says members may be paid "in the exceptional case where an agency head is unable to meet the need for technical expertise or the requirement for balanced membership."

Nearly all of NIH's advisors, including the Div. of Research Grants and NCI study sections, are paid $100 a day for attendance at review meetings, plus $75 a day for hotel and meal expenses, plus travel expenses. Members of NCI's divisional boards of scientific counselors also are paid at those rates.

Members of the President's Cancer Panel and National Cancer Advisory Board have their pay established by the National Cancer Act. That currently is $245 a day, plus the same amounts as above for hotel, meals and travel.

Those who stay in Washington area hotels, including Bethesda, usually find that $75 barely covers the hotel cost. They have to dip into their daily honoraria to pay for meals. Take away their daily pay and you're taking away their daily bread.

Edward Brandt, HHS assistant secretary for health, has told his agencies they will have his full support in fighting against the regulation. Agencies have 90 days to comment. The HHS responses will go through Secretary Margaret Heckler's office, and she has not indicated where she will stand on the issue.

The *Federal Register* notice said that the new regulation would apply only to advisors appointed after May 15. Betty Beveridge, NIH committee management officer, said that department lawyers have not determined yet if that means that those serving long term appointments will continue to be paid throughout those terms. NCAB members are appointed to six year terms. No new NCAB or Panel appointments will be made until next year, barring unexpected vacancies. However, several vacancies are coming up on the boards of scientific counselors. Most study sections are presently filled into next year.

The GSA survey found that all members of advisory committees at four agencies were compensated, regardless of need. Those agencies were HHS, with 3,992 advisory committee members; National Endowment for the Humanities, with 998 members; National Science Foundation, 741 members; and Dept. of Education, 277 members. In contrast, the Dept. of Interior, with the second largest number of advisory committees after HHS, pays only two percent of its advisors. Throughout government, more than 50 percent of advisory committee members serve without pay, GSA said.

HHS in the past has always defended its policy of paying its advisors. Peer review demands individuals of the highest quality, training, and experience. It involves more time than is actually paid for, and reviewers perform work which, if the government had to do it with full time employees, would wind up costing the taxpayers far more than it does now.

However, NIH never has conducted a survey to determine if members would serve without pay. Undoubtedly some would, and in fact a few never bother to collect their pay. Many continue to be paid by their institutions and must turn their government pay over to their employers.

This is one of those issues which might end up in Congress, if the Administration persists.

TALBOT, SCHEIN ASK WEICKER COMMITTEE FOR $1.3 BILLION FOR NCI IN FY 1984

Timothy Talbot, speaking as chairman of the board of the Assn. of American Cancer Institutes, and Philip Schein, president elect of the American Society of Clinical Oncology, both asked the Senate Labor-HHS-Education Appropriations Subcommittee for $1.3 billion as NCI's appropriation in the 1984 fiscal year.

Talbot's request actually was for $1 billion, 320 million, the full amount authorized in the house bill renewing the National Cancer Act.

"The American Society of Clinical Oncology believes that this is a time of great opportunity in the short history of the National Cancer Program, and that we are in imminent danger of losing important gains," Schein told Sen. Lowell Weicker (R.-Conn.), chairman of the subcommittee. "We have noted with great concern that the budget of the National Cancer Institute has remained relatively fixed since 1977, but in current dollars has been declining as a consequence of inflationary pressures. In 1981, for example, the inflation rate was 9.5 percent while cancer appropriations increased only 0.2 percent. The programs and cancer centers that have been built up with such enthusiasm and expectation during the past decade are now very much endangered, and some are threatened with being rapidly dismantled over the next two to three year period.

"We note with considerable alarm that the newly proposed Administration budget would result in the the loss of funding for 16 of 20 cancer centers up for renewal in fiscal year 1984," Schein continued. "This would affect all cancer centers in future years if this policy is accepted by Congress. This comes at a time when we are in a position to begin to exploit the achievements of our past efforts. The restricted funding of individual research grant applications, which are approved and recommended highly for

funding, has already led to significant cutbacks in cancer programs, in personnel and in capabilities throughout the country. We are losing, through attrition, some of our best cancer scientists and physicians; only one-quarter to one-third of approved grant applications are ever awarded any funds, and often in amounts reduced below the level recommended and required for the conduct of the program of investigation."

Talbot made a plea for "stable funding of cancer centers and the biomedical research system of this nation, of which these centers are such an important part," arguing against the Administration's plans to eliminate core grants for 16 of 20 centers which will be up for renewal in 1984.

"Cancer center core grants provide central support services and highly specialized laboratory services that are uniquely suited to the common interests of several investigators working in close proximity within a cancer center," Talbot said.

"If it is decided to reduce or obliterate core grants, and if as a result more R01s and P01s are thus made competitively available to the entire biomedical research, then in some fashion that amount of money will need to be found to replace what was removed from the the centers—it is also true that this "replacement" will, to the extent possible, be found from R01 or P01 grants. But total "replacement" of the core grants would be functionally impossible. Thus, the only places that would be victims of 'taking from' would be the centers."

NEUTRON ANSWERS NEEDED SOON, REQUIRE CLOSE COORDINATION, KLIGERMAN SAYS

"It is 10 years since the neutron program was begun in the United States, some 2,500 patients have been treated and National Cancer Institute support has been approximately between $125 million and $150 million, yet the value of neutron therapy remains elusive. . . . The size of the past and continuing expenditures makes this program highly visible to those whose programs compete for support from NCI. Unless some hard answers are available soon, this project will be terminated, and if terminated without decision, the entire radiation therapy program of the National Institutes of Health will be endangered."

Morton Kligerman, Univ. of Pennsylvania, one of the country's leaders in high LET radiation therapy research, offered that warning to his colleagues in his presidential address, "High LET Radiation Therapy, Past and Future," at the 65th annual meeting of the American Radium Society.

NCI is supporting development of four clinically dedicated neutron therapy facilities, at Univ. of Pennsylvania, Univ. of Washington, UCLA, and M.D. Anderson, and has supported through grants high LET research at other institutions.

While not criticizing past neutron clinical research, Kligerman related some of the history involved and suggested changes in approaches he said must be undertaken if new trials are to provide any answers.

"Early in the investigation of high LET radiation it was appropriate to explore treatment in all body sites," Kligerman said. "Normal tissue tolerance had to be determined, and preliminary results could lead to the development of protocols for tumors which appeared to be responsive. However, the time is past for the treatment of a wide variety of tumors, especially when some sites develop tumors whose natural history precludes adequate observation of local control, let alone regional control. Furthermore, the characteristics of patients accessed to this program must be suitable for approved protocols. Incredibly, as few as 20 percent of patients treated by particle beam in some high LET centers are assigned to any protocol.

"At this time I believe that very circumscribed parameters must be accepted by the investigators and their institutions. . . . I believe that the vehicle by which the high LET programs are funded should be changed to that of a modified grant mechanism which permits the intellectual flexibility of the grant for the investigator and the regulation of effort through monetary control for NCI. To be certain that adequate evaluable case material is available to each program, the principal investigator's institution should make a commitment to NCI, that no less than every second patient who qualifies for phase 3 trials of high LET radiation be made available first to high LET trials and only secondly available to programs competing for such cases. By making available every second case, no existing competing program in an institution would be eliminated. The case accession to competing programs would be curtailed, without NCI censure, only for the effective period of the high LET protocol.

"However, the neutron program must severely limit the number of test sites being examined at any one time. Preferably, this would be one site, but no more than two randomized trials should be underway during any one period. This would create the shortest time that restrictions would be placed on site assignment by the institutions involved and at the same time provide enough clinical material to obtain sequentially the specific answer to the question of superiority or lack of superiority of neutron therapy for specific tumors. It would mean the use of a single staging system, a single dose fractionation schedule and treatment plans common to all institutions for the control arms.

"To promote uniformity of staging and assessment of normal tissue reactions and tumor responses, principal investigators and their project lieutenants should visit the other programs on a regular basis to

observe new patient accessions, and on-treatment and followup evaluation of patients. Technical procedures also would be observed.

"The report of Catterall of her results in the treatment of salivary gland tumors is impressive. However, such tumors comprise less than one percent of all malignancies. The clinical investigation of neutron and other high LET beams is supported in an attempt to solve a public health problem, which is the local-regional cure of tumors with high incidence rates which are now not controlled by existing techniques or combination therapies. Tumor site, stage and histology should have a reasonable survival so that there is time to make observations on local control and late effects. As an example, esophageal carcinoma with its short median survival is a poor test site."

Kligerman listed his recommendations, in some detail:

After a dozen years of the second trial of neutron therapy during which time extensive radiobiology and radiation physics has been available, the experiment to test neutron therapy against conventional radiation therapy is still to be done. For the United States program where four "ideal" neutron radiation sources will be available a strict discipline among the investigators could provide appropriate answers.

I am aware that considerable thought and discussion has occurred about the neutron program during construction of these new units. Drs. Pistenma, Mahoney, Smith and Sheline have held coordinating meetings. Therefore, some of what is expressed below might be planned. Fundamentally, I believe the four units and any others supported by NCI should act in consort.

1. Common protocols must be developed, reviewed (see Panel below) and prioritized.

2. Site selection should be from those tumors which have a high incidence in the United States with relatively late metastases beyond the loco-regional site. The tumors should be moderately advanced if the site has a high photon cure rate in lower stages, or, lower stage if local control rate is poor. High priority should be given to those tumors where direct observation of tumor response and normal tissue reaction can be made. Survival must be long enough to observe late complications. This has been stressed by Duncan.

3. Preferably only one protocol—at most two—would be active at one time so that a conclusion can be reached in the shortest elapsed time.

4. Since the known major biologic advantage of neutrons is to be effective against hypoxic tumors one would want tumors known to have microscopic hypoxic regions. However, Dr. Thomlinson assures me that all tumors have hypoxic regions so this is not a problem in selection.

5. Strict stratification by stage and histology is necessary. Wambersie questions the comparison of results of treatment of salivary tumors at Hammersmith and Amsterdam because of a different histologic mix. At the same time Catterall and Duncan take opposing sides in the elimination of other than squamous cell tumors in reporting results of treating head and neck tumors. I must side with stratification in histology in this instance. Not only does this maintain purity of protocol but could help in giving further clinical testing to Batterman's proposal that a criteria for selection of neutron treatment might be tumors with doubling times greater than 100 days, usually found in well differentiated tumors.

6. The protocol should carefully spell out the anatomic location of portal margin, portal position and angle. The treatment plan and portal films should be express mailed to control as soon as developed so that any deviations or oversights, especially dangerous hot spots can be changed as treatment begins. Gardner suggests the use of telephone transmission equipment. This would permit instant communication between all institutions and with control. Such a system was used between Albuquerque and Los Alamos and it was invaluable. The expense is not a factor when the entire cost of each project is considered.

7. The program should start by comparing pure neutron beam with photons, except for the continuation or modification of protocols using neutron boost at the end of photon therapy believed to be of interest through the analysis of RTOG protocols by Griffin.

8. In combinations of mixed beams the actual doses and treatment factors given by each generator should be entered. If a particular institution wants also to use equivalent doses or compare TDFs or other techniques of reporting that is satisfactory as long as the raw information is available for evaluation and comparison.

9. Two eight-hour shifts should be required of each institution. This not only would increase information accrual and improve statistical validity, but it would reduce unit treatment cost. Again, this is an entirely feasible requirement. Good experience resulted operating under such a schedule at Los Alamos.

10. Catterall's dose-time schedule for neutrons-only must be tested. It is my understanding that it is planned by two of the new units namely at the univertisies of Pennsylvania and Washington.

11. Treatment plans for photon controls should follow RTOG best treatment regimes for the particular site, rather than the usual and customary plan of the individual institutions.

12. Fifteen percent of each unit's time should be reserved for pilot studies to permit program development. This would amount to 2½ hours a day during two treatment shifts.

"A trial using neutrons at the beginning of therapy when a greater number of regions of the tumor is

likely to be hypoxic and anoxic should be tried. One plan might be to start with a short course of neutron therapy followed by a two-week interval to maximize reoxygenation, and then complete treatment with photons. Seven to 10 days before photon therapy is to finish, evaluation of the patient could take place and if a persistent mass is found the last treatments should be conedown neutrons.

"Lastly, I would like to recommend a technique which I suggested and was implemented in 1979 by Antonio Antunez at Cleveland Clinic. There Antunez and I were able to convince the hospital administration to move a cobalt unit into the neutron therapy room. This was based on our report that the high LET radiation in the peak of the pion beam accounted for not more than 5-10 percent of the total radiation, yet the RBE for single doses was on the order of 1.3. At the same time clinical observation showed the same reaction in proximal and distal portions of the peak, in spite of a 100 percent variation in high LET energy. We believed that this could be accounted for by the interference of repair of low LET sublethal damage by a relatively small amount of high LET radiation. Yuhas and Lee demonstrated that there was a 30 minute window before or after pion irradiation which magnified the effect of low LET irradiation. The period of potentiation of low LET irradiation is sharply peaked. To be successful the two irradiations must be given within 15 minutes and preferably in a shorter time interval.

"I would suggest that for the high LET programs, the Radiation Therapy Oncology Group be asked to change its role from implementor to regulator. The present high LET committee should be supervised by a five member control panel composed of radiation therapists without direct responsibility for a particle program. Physics approval for programs would be provided by a three person physics panel selected from the Particle Task Force chaired by Dr. Alfred Smith. The control panel would give final approval to protocols and determine the order in which they would be tested. The photon control arm would be that treatment plan which has been found to be a 'best' plan in previous RTOG randomized trials. Failure to comply to case accession or approved treatment plan would be made known to NCI which would act to interrupt the institutional program under its contract authority."

David Pistenma, director of NCI's Radiation Research Program which oversees the Institute's support of extramural radiation research, told *The Cancer Letter* that Kligerman's recommendations for the most part coincide with NCI's plans.

On the funding mechanism, NCI intends to support the new clinical trials through cooperative agreements, the mechanism now favored for most clinical trials. Cooperative agreements are reviewed and awarded as grants, but permit more NCI staff involvement in planning and monitoring. The existing high LET clinical trials grants probably will be converted to cooperative agreements.

On earmarking every eligible second patient for high LET trials, Pistenma said, "We'll take every patient we can find." But whether the Div. of Cancer Treatment, which has other high priority clinical trials it supports, and the institutions involved will consent to that arrangement is "something we will have to look at."

Pistenma agreed "in principle" that the number of protocols should be limited. Whether the limit would be one or two as Kligerman suggested, or three or four, is still an open question, Pistenma said.

Standardizing the staging, dose fractionation, and treatment plans "generally are the most critical part of a trial," Pistenma said, but has not always been followed in the existing high LET trials because of variations in the machines.

DEVITA, LOSING PATIENCE, RESPONDS TO POWERS' LETTER TO ARMAND HAMMER

NCI Director Vincent DeVita, losing patience with the "current protracted debate" with National Cancer Advisory Board member William Powers over details of the Organ Systems Program, responded to Powers' letter to Cancer Panel Chairman Armand Hammer (*The Cancer Letter*, April 22) with a letter to Hammer answering points made by Powers.

"I would like to reply to the points raised under paragraphs A through F in the letter to you of April 5 from Dr. Powers. This is a separate attachment to this letter and identified as they were in Dr. Powers' letter to you.

"I would like to reiterate the concerns of the NCI Executive Committee with three issues: First, science is moving too fast to pocket the development of any program in a manner that slows the Institute's response time to advances in the laboratory. Molecular biology has moved to the bedside and nowhere is this more vividly demonstrated than in the development of monoclonal antibodies to surface targets of a variety of solid tumors, as you know so well. Most of the people doing this kind of work are not (nor would they appropriately have been) members of any specific organ site program, until they had developed their antibodies, specific for the tumor in question. The new system affords the flexibility to make these adjustments rapidly.

"Second, the directive to separate program from review has been given to us by the inspector general, the department, and NIH, and has been accepted universally in all other NCI programs. This is an important part of the changes recommended in the Organ Site Program.

"And finally, with the Board having made a unanimous recommendation for reorganization of the

Organ Site Program in May 1982, and having repeatedly confirmed those recommendations, the current protracted debate by Dr. Powers has become detrimental to the functioning as well as the image of the Institue and the National Cancer Advisory Board. It was Dr. Powers, as chairman of the Organ Site Committee, who presented the recommendation for reorganization to the NCAB. If I had been advised as many times to continue the Organ Site Program in its original form, I would have done so long ago."

The issues raised by Powers, and DeVita's responses, were:

"A. Reduction of funds for the Organ Systems Programs: Dr. Powers is mistaken about restoration of funds to NCI over the period the Organ Site budget was reduced. Between 1979 and 1983, the Cancer Institute's Executive Committee was faced with a reduction of 1.5 percent in the overall NCI budget. These funds were never restored. Considering the impact of inflation, this meant that the NCI Executive Committee had to find a way to absorb a loss of almost $200 million in purchasing power. At my first meeting of the NCAB in 1980, I expressed the desire that they join with me in establishing priorities for the Institute since, obviously, it was quite impossible to increase support of all programs with a shrinking budget. All NCI programs were reviewed and adjusted—some up and some down. At that meeting, and at every subsequent NCAB meeting, at every subsequent meeting of the Budget Committee of the NCAB (a combined total of 12 meetings between 1980 and 1983) the Board and its committee ranked the Organ Site Program at a lower priority than most other programs. Dr. Powers' statement that "when the rescissions were restored other programs were restored, but the money was still cut from the Organ Systems Program," is not accurate and does not reflect the realities of an actual 1.5 percent decrease in the budget. Within that budget, monies were reprogrammed to those considered of high priority within the constraints of NCI's diminishing budget. Dr. Powers was a member of the Board at that time and should be aware of the process. When some monies were restored in 1983 to give the program a 4 percent increase, the Organ Systems Program was not cut further, which was consistent with the ranking given by the National Cancer Advisory Board Budget Committee.

"B. Cancellation of NCAB Committee meeting: This issue is a straw man. The NCAB committee may meet as often as it feels the necessity for doing so. The issue raised related to the fact that Dr. Powers wished the Organ Site Committee to meet at a time of another publicly announced committee meeting and at a November Board meeting, which is devoted to program review and not normally to the routine business of the Board. Since Dr. Powers and other members of the committee were concerned that some action might be taken in the interim before the next NCAB meeting, NCI agreed to withhold the announcement of the Request for Application for the new Organ Systems Coordinating Center until the committee and the Board felt they had explored the issues sufficiently. NCI did exactly that and the RFA was not issued until late March, after a day and a half meeting of the Organ Site Committee and the full NCAB meeting in February.

"C. Committee recommendations rewritten without committee participation: At the February NCAB meeting following discussion of the committee's report, there was a good feeling that we had reached an agreement all could live with. Dr. Powers' committee report was modified slightly by Dr. Hickey, a member of the NCAB, at the full meeting of the Board and the modifications were accepted by the full NCAB. The transcript substantiates this statement. The combination of Dr. Hickey's modifications and the committee report ultimately constituted the substance of the RFA issued in March. This interpretation has been confirmed by Dr. Hickey. The point of contention, if any, refers to the fact that, instead of our guaranteeing a fixed increase in the Organ System budget, we have added the words, "as available"—in reference to the budget, as all prudent formulators of budgets would do in times of budgetary uncertainty. Since our budget and programs are reviewed by the NCAB and its committee, further adjustments, as in the past, will be with their full concurrence.

"D. The inappropriate review of Organ Site Program grants: The report of the scientific review of the Organ Site Program, commissioned by the NCAB, expressed a major criticism of the failure to separate program direction from its merit review. They felt that this failure to separate program from review had resulted in better scores for grants in the Organ Systems Program than those reviewed under the regular peer review system within NCI and NIH, and further, that there was a compression of priority scores in the Organ Systems Program that would result in the funding of a higher percentage of organ site grants at the average payline cutoff than comparable R01 grants. Since we have been under pressure, as a result of a previous investigation by the HHS inspector general, to separate program direction from the review process in all our programs, and have completed this separation for all other NCI programs; NCI proceeded to transfer the review of organ systems grants to the regular review system, again with full NCAB approval in May 1982. If review at the NIH level proves a problem, we have agreed to set up special NCI review groups to ensure that the best organ site grants are continued, based on program relevance.

"E. Concern about the phaseout of headquarters: We have repeatedly extended the funding of headquarters grants without additional review so that they can remain stable and functional until the time

a single outside headquarters has been organized and become operational.

"F. Failure to involve all existing working groups in major new projects: When one is developing complex scientific programs, many groups are consulted for their advice. The Breast Cancer Task Force Committee (a group distinct from the Organ Site Program because it is directed inside NCI itself) was consulted at the end rather than at the beginning of the decision making process about two clinical trials of dietary modifications aimed at preventing occurrence or recurrence of breast cancer. The scientific issues themselves have, however, been widely debated at NCI and various boards and councils over the last two years. In the new system, NCI will ensure that the outside Organ Systems Program Coordinating Committee will be heard and that its recommendation compete for a share of all appropriate NCI budgets."

CELL LINES AVAILABLE FROM NCI FOR TUMOR IMMUNOLOGY RESEARCH

The Tumor Immunology Bank (known prior to September 1981 as the Cell Distribution Center with Melvin Cohn of Salk Institute as the principal investigator) is currently managed by the American Type Culture Collection in Rockville, Md. and is supported by a contract in the Immunology Program, Div. of Cancer Biology & Diagnosis, NCI.

Currently the bank has approximately 200 cell lines available for distribution. The cell lines are of following general types: transformed human and mouse T and B lymphocytes, macrophage/monocyte lines, hybridomas, fusion partners, and targets of immune function.

All cell lines have been verified for species and tested for microorganisms including mycoplasma, bacteria and fungi. Where appropriate, confirmation of Ig class is performed. Other specialized information has been supplied by the originator of the cell line. Information concerning the growth of the cells and other technical data, e.g. antibody specificity and publication references, are made available.

At this time, the cost per vial of cells (frozen or nonfrozen) is $37 to nonprofit and $59.50 to profit making organizations. In addition, there is a variable shipping charge.

For additional information call Dr. Anita Weinblatt at ATCC, 301-881-2600.

Since the source of cell lines for the bank is the scientific community, offers to donate cell lines are appeciated.

NTP CARCINOGENESIS GUIDELINES PANEL TO HOLD FIRST MEETING MAY 17 IN D.C.

The Panel on Chemical Carcinogenesis Testing & Evaluation, established by the National Toxicology Program Board of Scientific Counselors to develop new guidelines for the detection and evaluation of chemical carcinogens, will hold its first meeting May 17 in Washington D.C.

The meeting will be in the first floor auditorium of the Humphrey Building, on Independence Avenue, starting at 9 a.m. It will be open.

Comments from members of the public, industry, and academia may be submitted in advance of the meeting to NTP, PO Box 12233, Research Triangle Park, N.C. 27709.

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 NCI-CM-37616-21

Title: *Evaluation of high energy photon external beam treatment planning*

Deadline: *Approximately July 6*

The Radiation Research Program of the Div. of Cancer Treatment of NCI is seeking a contractor to be part of a collaborative effort to develop criteria, guidelines and methodology for the performance and evaluation of state of the art high energy photon external beam treatment planning.

This will be accomplished by extensive treatment planning for actual patients and by using state of the art beam delivery, computerized treatment planning, and imaging systems. The contractor shall furnish all necessary personnel, labor, material, equipment and facilities not otherwise provided by the government.

It is anticipated that a multiyear, incrementally funded, completion type contract will be awarded for a period of three years. Each increment will be for a 12 month period.

Contract Specialist: Barbara Shadrick
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301-427-8737

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