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COOPERATIVE GROUPS MEET WITH NCI TO DISCUSS PLANS TO USE ROSENBERG'S REGIMEN AT MEMBER INSTITUTIONS

NCI staff members and representatives of the cooperative groups met this week to develop plans for clinical trials of Steven Rosenberg's adoptive immunotherapy with interleukin-2, as clinical investigators around the country, stimulated by last week's "New England Journal" publication and intense public interest from the subsequent media blitz, started gearing up for their own studies with the process.

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In Brief

JEROME GREEN TO HEAD NIH DIV. OF RESEARCH GRANTS; M.D. ANDERSON'S EVAN HERSH TO JOIN UNIV. OF ARIZONA

JEROME GREEN, director of the National Heart, Lung & BLood Institute's Div. of Extramural Affairs, has been named the new director of NIH's Div. of Research Grants. The position has been vacant since former DRG Director Carl Douglass retired in May ... **ROBERT WHITNEY** has been appointed director of NIH's Div. of Research Services. Whitney has served as acting director of the division since November 1984, and has been chief of the division's Veterinary Resources Branch since 1972.... **EVAN HERSH** has been appointed chief of the Section of Hematology & Oncology and professor of internal medicine in the Dept. of Internal Medicine at the Arizona Cancer Center, Univ. of Arizona College of Medicine. He will move to the new position by June, 1986. Hersh is currently professor and chairman of the Dept. of Clinical Immunology & Biological Therapy at M.D. Anderson Hospital.... **WILLIAM RICE**, formerly with CDP Associates and before that an administrative staff member of the Lombardi Cancer Center, has opened W.W. Rice & Associates Inc., health care consultants firm. Rice is emphasizing services to institutions considering the development of free standing cancer centers... **JAMES COX**, chairman of the Dept. of Radiation Oncology at Columbia-Presbyterian Medical Center, is the new president of the American Society for Therapeutic Radiology & Oncology. Other newly elected officers are Robert Edland, president elect; Theodore Phillips, chairman of the board of directors; Morris Wizenberg, secretary; and Robert Goodman, treasurer.... **GLORIA HEPPNER** has been promoted to senior VP-programs and VP for laboratory research at the Michigan Cancer Foundation. Marie Swanson is the foundation's new VP for epidemiology and cancer control research.... **JOHN LYNCH**, assistant professor of surgery at Georgetown Univ. School of Medicine, has been appointed chief of the urologic oncology service at Vincent Lombardi Cancer Center.

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UNIV. OF WISCONSIN TO BEGIN USING ROSENBERG'S REGIMEN IN JANUARY

(Continued from page 1)

Michael Friedman, chief of the Clinical Investigations Branch in the Div. of Cancer Treatment's Cancer Therapy Evaluation Program, said the meeting this week (scheduled for Dec. 11) with cooperative group representatives was called to discuss administrative problems involved in establishing the trials and to make preliminary plans for carrying them out. He said it probably would be from six to 12 months before the new studies would be started. "We want to try to get certain selected centers involved, and we are going to try to plan them carefully."

Cetus Corp., the California firm which has been supplying NCI recombinant IL-2 at no charge for Rosenberg's studies, told **The Cancer Letter** that it would give the material to other qualified institutions which initiate clinical trials with the NCI protocol. In fact, Cetus already supplies IL-2 for 35 other human trials around the country (studies using IL-2 in other regimens). "Our objective is to accumulate data as fast as we can to get new drug approval from FDA," a Cetus spokesperson said.

The Rosenberg regimen requires a lot of IL-2—five million units per kilogram per day for three days. Cetus refused to disclose any cost information on IL-2.

The cost of IL-2 is only part of the overall cost of the treatment, which involves intensive monitoring by trained nurses and, during much of the time, the full attention of physicians.

The Univ. of Wisconsin announced last week that it would start clinical trials with the Rosenberg regimen in January. Paul Sondel, associate professor of pediatrics, human oncology and genetics, and Peter Kohler, instructor of human oncology, have been supervising administration of IL-2 to cancer patients at the UW Hospital & Clinics since last June, and have been using in vitro activated cells for cancer therapy since 1983. They had not used the two agents in combination while awaiting more information on possible side effects.

Rosenberg's NEJ article described the toxicities seen: transient chills and fever immediately following injection of lymphokine activated killer cells; and significant weight increase after IL-2 administration. Fever, chills and general discomfort were eliminated by acetaminophen and indomethicin. Fluid retention is a serious problem. Sixteen of the 25 patients gained more than 10 per cent of their starting weight. As IL-2 administration continued, fluid retention often progressed to fluid in the lungs, causing mild breathing difficulties in 20 patients. In all patients, adverse side effects disappeared when IL-2 administration ceased.

Rosenberg said later, Dec. 8 on the television program, "Face the Nation," that one patient (not one among the 25 in the NEJ report) had died, apparently from treatment related causes.

The procedure developed by Rosenberg and his colleagues involves extraction of lymphocytes from the patient's blood which are then treated with IL-2, a lymphokine. That converts the lymphocytes into "lymphokine activated killer (LAK) cells" which destroy cancer cells but not normal cells. The LAK cells are then infused into the patient, along with the large doses of IL-2.

Rosenberg's work with LAK cells and IL-2 had its genesis in Robert Gallo's Laboratory of Tumor Cell Biology, in DCT. Gallo's discovery of what he called "T-cell growth factor" led to his isolation, for the first time by anyone, of human cancer viruses and later the AIDS virus. Rosenberg saw the therapeutic potential in T-cell growth factor, now called interleukin-2.

Rosenberg told the NCAB that future efforts involving the procedure would include development of allogeneic LAK cells; direct arterial infusion of LAK cells into the tumor site; and treatment of minimal disease and use as adjuvant therapy. These will include stage 2 melanoma, Dukes C colon cancer, and stage 2 breast cancer, he said. An NCI committee will meet Dec. 16 to develop a protocol for stage 2 melanoma.

"There's still a lot of work to be done," Rosenberg said. That includes development of methods to abrogate the toxicity of IL-2; using LAK-IL-2 in combination with chemotherapy and radiotherapy; and using it as intraperitoneal therapy for ovarian and colorectal cancer.

Rosenberg commented that NCI had "provided a lot of resources" for his efforts, including an additional 1,000 feet of laboratory space and the additional people the work requires. "NCI is a remarkable place to work, and I think the only place where this work could be done."

IL-2's potential could not be realized until large quantities of the genetically engineered substance were available. Cetus Corp., located in Emeryville, Calif. (near Oakland), started producing recombinant IL-2 last year. Last week, Cetus stock, traded over the counter, went up almost 50 per cent in the wake of the NEJ publication.

More than a few eyebrows were raised, in fact, by the prospect that some "insider" trading had occurred. The widespread dissemination of the impending publication and Cetus' role made that unlikely, however.

"Fortune" magazine, in its Nov. 25 issue which was on the street Nov. 20, had a major article on the Rosenberg regimen and it mentioned Cetus prominently. The stock at that time was selling for $18 a share. It opened the week of Dec. 1 at 20 7/8 and on Monday, Dec. 2, jumped 2 1/8, to 23, despite a drop in the Dow Jones of 14 points. Does that indicate that some people who might have known about the upcoming NEJ article did some anticipatory buying?

That knowledge was not limited to Cetus executives, nor NCI staff, nor editors of the "New England Journal." NCI distributed a news release announcing the article's publication, which reached news offices on Friday, Nov. 29. It was "embargoed" for release on Wednesday, Dec. 4, at 6:30 p.m. So add scores of journalists to those who knew about the publication several days ahead of time, including **The Cancer Letter** staff, who could have profited had they been alert enough (they weren't) to the potential.

The stock went up another point on Tuesday, Dec. 3, so the members of the National Cancer Advisory Board and others who heard Rosenberg's presentation that day—and he mentioned Cetus, although the NCI news release did not—could have profited from advance information not available to the public at large.

After the news hit the national TV networks and press, the stock climbed to 29 5/8 when it closed at the end of the week.

The potential for abuse of advance knowledge of the publication and for stimulation of suspicions of such abuse was aggravated by NCI's insistence on observing the embargo, despite the fact that Rosenberg's presentation to the NCAB was made in an open meeting of a public body when, by law, everything said and presented is public information. Several times during Rosenberg's presentation, NCI staff interrupted to warn the press that nothing could be published until after the embargo time.

NCI's concern, of course, was due to the policy of the "New England Journal" which decrees that it will not publish any article the substance of which has been published elsewhere. Most members of the press at the NCAB meeting agreed that the embargo accompanying the news release was appropriate, considering the NEJ policy and the fact that NCI had to go along with it as a condition of publication of Rosenberg's article. But they were outraged by the demand that reports on Rosenberg's presentation to the Board could not be presented over the air or in print for more than 24 hours.

The NEJ policy in this case did not fit the requirements of the federal open meeting laws, nor, for that matter, the First Amendment. But none of the press was outraged enough to ignore the embargo (**The Cancer Letter** would have, had that been our publication day).

PB-8512-018989

ABSTRACTS DEADLINE FOR CANCER CONGRESS EXTENDED TO DEC. 31

The registration deadline for submission of abstracts for the 14th International Cancer Congress in Budapest has been extended to Dec. 31 from the previously announced deadline of Nov. 30.

Abstract forms and additional information may be obtained fromn Dr. Edwin Mirand, Roswell Park Memorial Institute, 666 Elm St., Buffalo, N.Y. 14263, phone 716-845-2300.

A travel award program is being conducted by Roswell Park and can provide some support for invited speakers and young scientists under age 35. To be eligible, applicants must submit an abstract for the Congress. Applications for those funds are available from Mirand.

A post Congress tour to the Soviet Union has been organized which includes visits to cancer centers in Moscow and Leningrad. Arrangements are being handled by Crimson Travel Service, 39 John F Kennedy St., Cambridge, MA. 02138, phone 617-868-2611.

The Congress will be held Aug. 21-17. Information on registration, transportation and accomodations may be obtained from Mirand or Crimson Travel.

PB-8512-018990

CANCER LETTER FINAL ISSUE OF 1985; NEXT WILL BE PUBLISHED JAN. 3

This issue of **The Cancer Letter**, Vol. 11 No. 48, is the final issue of 1985. The next issue, Vo. 12 No. 1, will be published Jan. 3, 1986.

The Cancer Letter office will be open most of the time during the holidays, with some closing when the staff is participating in festivities or recovering from them. The tape machine will be on duty when we're not, and messages will be answered when we return. The schedule calls for return to normalcy Monday, Jan. 6.

Season's greetings and all the best for the New Year.

PB-8512-018991

BURTON'S "IMMUNE THERAPY" REPORTED TO CONTINUE ALTHOUGH CLINIC CLOSED

The Immune Augmentive Therapy Patients Assn., a group composed of patients who have received "immune augmentive therapy" at Lawrence Burton's Immunology Researching Center in Freeport, Bahamas, is reportedly accusing NCI's Steven Rosenberg of stealing Burton's idea for the treatment.

The news comes in the midst of reports of continuing activity by Burton and his associates on the island. The clinic was closed in late July by the Bahamian Ministry of Health after reports of HTLV-3 and hepatitis contamination of

serum produced at the facility were published in **The Cancer Letter** and the "Miami Herald" (**The Cancer Letter**, July 26). An unidentified woman answering the phone at the clinic last week said the facility is still closed. She declined to comment on any plans to reopen the clinic, or initiate screening of the serum used in the procedure. "It never was contaminated," she said. "This whole thing is ridiculous. I have no idea as to what's going to happen."

Although the clinic appears to be closed, persons traveling to the Bahamas have reported that cancer patients seeking treatment with Burton's unproven and highly controversial therapy have learned to circumvent the closure. Cancer patients awaiting treatment go to an apartment complex across the street from the clinic. A person said to be associated with Burton's clinic withdraws blood from the patient in the morning, and returns in the afternoon with the serum for the therapy.

As many as 40 to 50 patients are said to be receiving treatment at this time.

Although the Freeport newspaper reported that the clinic would be visited by inspectors who would make recommendations for screening for AIDS and hepatitis contamination, no government memo of understanding was submitted, nor has the government indicated what steps would be required for Burton to reopen the facility.

"The clinic is still closed," Ministry of Health Chief Medical Officer V.T. Allen told **The Cancer Letter.** "I am not aware of any activity" on the behalf of Burton or his associates from the clinic. Allen refused to make any further comment on the subject, including whether the government plans to investigate reports of activity by clinic staff.

In a recent letter to Div. of Cancer Treatment Deputy Director Gregory Curt, however, Allen said the department will investigate the reports. "We will look to see if the information is correct."

The Bahamas government is well aware of the stakes, both for Burton, who reportedly was grossing as much as $30 million a year before he was closed down, and for the small nation, which is expected to take in $880 million this year from its tourist industry. That industry would be in real jeopardy if the word gets around that the government is permitting an operation to continue which may be exporting the AIDS virus.

Of 2.325 million tourists who visit the Bahamas, the vast majority are from the United States.

Apparently, the U.S. government does not intend to take any action if Burton's clinic is permitted to continue operating.

TOXIC WASTE AND CANCER LINKED; NCI'S URBAN DATA QUESTIONED IN BAY STUDY

Industrial wastes flowing into the Chesapeake Bay may be contributing to an 8% boost in the white male cancer mortality rate in the bay region, a study by the Council on Economic Priorities suggests. The study linking toxic wastes and cancer deaths analyzed data from NCI, the Environmental Protection Agency and the Census Bureau in two dozen counties that border the bay and its main tributaries.

The bay region as a whole didn't report above average levels of toxic waste generation. CEP, however, singled out 30 small localities with the highest per capita levels of toxic waste generation and abandoned waste sites for special study. Calculated cancer mortality rates for the localities, mainly in the Baltimore and Norfolk areas, ran several times higher than the national rate.

The worst single location is Zip Code 21226 in Baltimore, with a per capita level of toxic waste generation 46 times greater than the national average and a cancer mortality rate several times greater than the national average.

The study also questions the link between cancer mortality and urban life reported in a joint EPA-NCI study, Cancer Mortality Trends 1950-1979.

"While analysts had attributed this finding to the belief that certain stresses associated with urban life such as cigarette smoking and alcohol consumption were major contributors to cancer, CEP analysis reveals that this 'urban connection' has been overstated due to serious flaws in the way death certificates are recorded," CEP Director of Environmental Research Jay Gould said.

CEP found that death certificates often show the urban hospital location as the site of residence rather than the true residence of cancer victims. "This bias can be reduced when data from an entire metropolitan region (as opposed to just the central city) is analyzed on the theory that the residents of suburban and exurban counties surrounding a central city are most likely to go there for terminal cancer care," the study suggests.

Based on a technique to estimate cancer mortality rates by zip codes," CEP can now pinpoint those locations where the per capita generation of toxic wastes and the number of abandoned waste sites is very high and anlayze this data in relation to cancer mortality rates," Alice Tepper Marlin, CEP executive director, said. "Because of the urban bias in the NCI data on cancer deaths, we need accurate information on the true residence of every cancer victim to verify our findings. It should be possible for local health officials to look at such data and take action when warranted."

PB-8512-018993

HHS ASKS MSKCC TO REPAY $638,371 TO NIH FOR SALARY COST TRANSFERS

Negotiations are currently underway between HHS and Memorial Sloan Kettering Cancer Center officials over the repayment of more than $600,000 in funds the government says MSKCC transferred inappropriately to NIH grants. An audit recently completed by HHS' Office of Inspector General maintains that "at least $638,371 of costs were claimed by the grantee on the basis of journal entry transfers which were inadequately documented and which we believe were not justified."

The audit, and the negotiations surrounding a final adjustment figure, are not uncommon for institutions receiving NIH and NCI funds, a department spokesman said. The MSKCC case involves the transfer of funds to NIH grants, mostly NCI grants.

The report recommends that MSKCC refund the $638,371 to NIH. An initial audit completed by the department in February recommended that the center repay NIH $724,952 of labor costs relating to 83 salary transfers. That review identified 42 labor cost transfers at Sloan Kettering Institute and 30 at Memorial Hospital that HHS did "not believe were proper."

The center and its affiliated organizations had combined revenues totaling $274 million in the calendar year 1983. HHS grant and contract activities represented $28.6 million and $8.6 million respectively of those revenues, HHS says.

In responding to the draft report in late March, MSKCC officials denied the charges and insisted that the transfers were appropriate.

Preliminary results of a review undertaken by the center "has enabled us to satisfy ourselves that the auditors' conclusions are substantially incorrect," MSKCC said in March 27 comments in response to the draft audit report. The center noted that it "does not preclude the possibility that its completed review will reveal some errors or poor documentation on its part. In an institution this size, processing the numbers of awards that we have is a significant managerial and clerical activity. It is conceivable that a large enough sample of transactions, particularly if selected on a biased basis, will reveal statistically a deviation from perfection. MSKCC contends, however, that such errors are bound to occur, and do not truly reflect our policies and practices."

The center reviewed 56 of the 83 transfers and concluded that all 56 were correct and adequately documented.

A subsequent review by HHS utilizing additional documentation available from the MSKCC review resulted in the department's reduction of the amount of costs initially recommended for adjustment by $86,581. The eliminated costs related to 11 of the transfers originally recommended for adjustment.

HHS, however, was "not convinced that the [remaining] transfers were correct."

The final report stated that in each of the 72 cases, "the after-the-fact employee effort report, which was prepared at the time the services were rendered and certified as correct by both the employee and supervisor, did not support or agree with the transfer." In addition, written explanations were not provided as to why the original ceritifications were wrong, how the error was found, or how it was determined which project was the correct one to charge. Transfers were also not made within a reasonable period of time after the original charges were made and there were no written explanations available as to why the transfer was late.

The department's audit included all journal entries in excess of $1,000 that transferred direct labor costs to a federal project. A total of 78 such transfers related to grant or contract agreements sponsored by NIH were identified at SKI and 43 at MH.

Of the 78 transfers examined at SKI, HHS was satisfied that 36 were appropriate. The transfers were generally made to correct posting errors in the original recordations, to post stipend payments to training grants, and to record salary adjustments necessitated by late submissions of employee after-the-fact effort reports.

In the remaining 42 transfers, however, "the only justification provided for the transfer was that the employee's original after-the-fact effort report was 'not properly reviewed against actual effort.'" No additional documentation was available for any of the 42 transfers to explain how both the employee and the supervisor erroneously certified to the accuracy of the original report. Similarly, although almost all of the transfers were not made within a reasonable period after the recordation of the original charge, there was no documentation available to explain why the transfers were late.

Examples of transfers HHS did "not believe were appropriate" are:

In June, 1984, SKI transfered $3,362 of an employee's salary costs originally booked to a privately funded award to a National Institute of General Medical Sciences grant. The $3,362 represented 100% of the employee's salary payments for the period Jan. 1 to April 10, 1982. HHS says the only explanation made available to the

department for the transfer was "ERD (i.e., Effort Report Document) not properly reviewed against actual effort.)" The employee's after-the-fact effort reports did not show that he worked on the NIH grant in the period, but rather on the privately funded award. No further explanation was available to explain why the original certification was incorrect or why it took more than two years to discover the error.

HHS did note, however, "that the NIH award had an unexpended balance of exactly $3,362 as at May 31, 1984, and that the privately funded award showed an over expenditure of $5,996 at that date. It is our opinion that this transfer was not justifiifed and that it was made principally for funding purposes."

Another example cited in the report is SKI's transfer of $6,334 of an employee's salary costs from one NCI grant to another NCI grant. The only explanation made available was that the "turnaround document (i.e., employee after-the- fact effort report)" was not properly reviewed against actual effort. HHS review of the employee's effort records indicated that he and his supervisor certified that his efforts were on the grant originally charged rather than on the grant to which his salary charges were transferred. The review also found that the grant to which the employee's salary was originally charged was over expended by $11,059 as of March 31, 1984, while the grant to which the salary transfer was made had an under expended balance of $24,806 as of March 31, 1984. The report asserts that "we believe this transfer was not justified and that it was made primarily to transfer the deficit balance from the grant originally charged."

In a case involving another NCI grant, SKI transferred $12,730 of salary costs for two employees to the NCI grant. The explanation for the transfer of the salary costs, which were originally charged to two MH operating accounts in calendar year 1982, stated, "ERD not properly reviewed against actual effort." SKI could not identify the specific payroll periods it was adjusting for the two employees in calendar year 1982. Neither employees' effort reports showed they worked on the NIH grant in all of 1982, the project director did not approve the transfer as correct, and the NCI grant had an unexpended fund balance of $18,603 as of Feb. 28, 1984.

Of 43 transfers at MH, HHS was satisfied that only 13 were appropriate. Examples of the remaining 30 transfers HHS does not believe are justified are:

The Dec. 31, 1983 transfer of $11,009 of an employee's salary cost to an NCI grant. The transferred salary costs represented 100% of the employee's salary for the period July 1, 1982 to Dec. 26, 1982, which were originally charged to a private foundation research award. The only explanation made available was "ERD not properly reviewed against actual effort." The employee after-the-fact effort reports did not show that he worked on the NCI grant, but rather on the privately funded award.

Another case involved the transfer of $7,640 of an employee's salary costs to an NCI grant. The transferred salary, which represented 100% of the employee's salary payments for the period Jan. 1 to April 30, 1983, was originally charged to two (50% to each) private foundation research awards. The only explanation was that the turnaround document was not properly reviewed against actual effort. "We examined this employee's after-the-fact effort reports for the nine separate bi-weekly payroll periods involved in this transfer and the hospital's explanation does not appear valid," HHS says. "For five of the payroll periods, we found that the employee's salary costs had been initially charged to entirely different accounts. And, at the time the effort reports were prepared, the employee and her supervisor both indicated that the initial salary allocations should be corrected to the two private foundation accounts which MH was again adjusting in this entry."

MSKCC, however, notes in its comments that of more than 2,500 quarterly and over 800 current and prior year retroactive salary cost transfers that were made during the period under review, HHS selected only 83 that it felt were not adequately justified, or, "in other words, about 2.5% of all the salary transfers completed during this period did not meet their initial specifications."

The center also contends that by looking solely at transfers made into government projects, and not any federal projects credited with nonfederal monies, "the auditors appear to have made a biased test selection and drawn equally biased conclusions. The auditors contend that transfers have been made to liquidate unexpended fund balances. By their looking only at those journal entries which transfer costs to federal projects, it is apparent that they only chose transfers that would support their hypothesis. Had they looked at transfers which backed expenses out of federally funded projects and into other sources of support, it would be obvious that MSKCC's use of cost transfers is not to liquidate available balances, but rather to correctly allocate time and effort."

HHS responds that "we generally limit our audits only to those costs which are claimed under federal projects." The department also contends that the cost transfers selected for review were not chosen on a statistical basis, but by examination of all the journal entry transfers that met its established criteria.

MSKCC says the correlation between the amount of a transfer and the balance remaining in a grant is "not surprising." The center "could not transfer a greater salary figure to the grant because a deficit would result. Residual salary costs would have to be transferred to another source—in many cases to institutional funds. This fuller picture was not revealed due to the sampling pattern of the auditors."

HHS, however, says a number of memos found among correspondence contained in the grant and contract files "clearly indicated, in our opinion, that transfers were being made to avoid cost overruns and to use up unexpended funds."

For example, a memorandum attached to the report discusses the transfer of funds from one related NCI grant to another. "The reasons for this request are that we appear to have a considerable overexpenditure in the related MH grant...Because there is some overlap between the two [program] grants... it may be possible to eliminate the overexpenditure in [one grant] by applying available funds from [the second grant] to the extent that such expenditures are appropriate," it says. "If, for any reason, these funds cannot be used to offset the overexpenditure in [the first grant], I will be able to supply documentation from other SKI sources to fully obligate the balance."

HHS contends that "as can be seen from the attached memorandum, the primary purpose of the transfer was to use up the unexpended fund balance. This was to be accomplished by a transfer of overexpended funds from a hospital grant."

HHS also challenged MSKCC's contention that many of the problems, particularly "the lack of timeliness of many of the questioned cost transfers" cited in the audit were due to problems with its time and effort system. The facility converted the system from a biweekly to a quarterly system in January 1983. "MSKCC's introductory comments on its systems and start-up problems are factual, but not relevant to the finding contained in our audit report," it says. "In particular, we believed that the problem centered on the fact that direct labor costs were intitially charged out to grants and contracts on the basis of budgeted effort. And, that budgeted costs were not being adjusted to actual costs because MSKCC's computerized accounting system and available support staff were not capable of handling the volume of adjustments necessitated by the differences between the budgeted efforts and the actual efforts as reported by the employees on their after-the-fact biweekly or monthly effort reports. Therefore, we believed that the data reported by employees on their effort reports were reliable and accurate and our recommended adjustments were based upon that premise."

HHS repeats that it "did not believe the cost transfers we recommended for adjustment were proper or warranted because, in each case, the after-the-fact employee report, which was prepared at the time the services were rendered and certified as correct by both the employee and a supervisor, did not support or agree with the transfer."

In addition to recommending that the center repay the $638,371, the report recommends that MSKCC "strengthen its management controls to ensure that all cost transfers are sufficiently documented. The supporting documentation should include, at a minimum, a clear statement of the reason for the transfer, reference to or attachment of supporting data and approval of responsible personnel."

"Much of that has already been done," MSKCC asserts in its response to HHS. "Our conversion to quarterly time and effort reporting has signficantly reduced the need for retroactive salary cost transfers... More than 99% of all salary transfers are now handled (within 90 days) on the quarterly effort reporting documents."

The late receipt of awards was also cited as justification for many of the 1983 and 1984 cost transfers by MSKCC. "For example, a series of 1983 adjustments questioned by the auditors were unavoidably due to the late receipt of awards," it said. "It is MSKCC's policy not to establish funding for any individual until an award is officially received, administratively executed and activated by the accounting department...As some awards are not executed until well after the project period has begun, the need for an eventual cost transfer is predetermined. Expenses are captured in 'holding' accounts until the receipt of the award, and salary transfers subsequently made in order to correctly apply salary expenses to the appropriate fund."

Work supported by closely related projects may also require salary cost transfers, MSKCC said. "Since only subtle distinctions sometime differentiate these projects, it is not until after a significant phase of work has been completed and assessed, and after the certification of time and effort has been completed, that the employee and/or administrator recognizes the need to transfer salary costs."

HHS, however, countered that no employees on any of the transfers in question had indicated on the after-the-effort reports that they were working on a project on which the award documents had not yet been received. "All the costs were transferred from other research projects," and none from a holding account. It also notes that no explanations regarding costs incurred on closely related projects

were provided on any of the transfers.

HHS also wants a centralized log of all cost transfers affecting federal projects, but MSKCC said that would be duplicative and unnecessary.

Suzanne Rauffenbart, MSKCC vice president for public affairs, told **The Cancer Letter** that the center would not make any further comments on the HHS report while discussions with NIH continue.

PB-8512-01899

NCI ADVISORY GROUP, OTHER CANCER MEETINGS FOR JANUARY, FEBRUARY

Developmental Therapeutics Contract Review Committee--Jan. 6-7, NIH Bldg 31 Rm 10, open Jan. 6 8-8:30 a.m.

Cancer Biology & Immunology Contract Review Committee--Jan. 8-10, NIH Bldg 31 Rm 8, open Jan. 8 and 10 9-9:30 a.m.

Health Implications of Smokeless Tobacco Use--Jan. 13-15, NIH Clinical Center, Masur Auditorium, 9 a.m. NIH consensus conference.

Current Therapy of Gastrointestinal Malignancies--Jan. 18, Cleveland. Contact Barbara Guy, Lowman 211, University Hospitals of Cleveland, 2074 Abington Rd., Cleveland 44106, phone 216-844-7856.

Div. of Cancer Prevention & Control Board of Scientific Counselors--Jan. 23-24, NIH Bldg 1 Wilson Hall, 8:30 a.m.

Gastroenterology Update: 1986--Jan. 25-Feb. 1, Vail, Colorado. Johns Hopkins Univ. School of Medicine and Presbyterian Hospital of Oklahoma City. Contact Jeanne Ryan, Program Coordinator, Office of Continuing Education, Johns Hopkins Univ. School of Medicine, 720 Rutland Ave. Turner 22, Baltimore 21205, phone 301-955-6046.

Developmental Therapeutics Contract Review Committee--Jan. 27-28, Linden Hill Hotel, Bethesda, open 8-8:30 a.m. both days.

20th Annual Vail Midwinter Seminar--Jan. 29-31, Mark Hotel, Vail. GU and GYN cancers. Contact Chris Heminway, American Cancer Society, Colorado Div. Inc., 2255 S. Oneida, Denver 80224, phone 303-758-2030.

Administrators' Challenge: Responding to Change--Jan. 30-31, Four Seasons Hotel, Houston. Third annual administrative conference. Contact Office of Conference Services, M.D. Anderson Hospital & Tumor Institute, 6723 Bertner Ave., Houston 77030, phone 713-792-2222.

Diagnostic Cytopathology for Pathologists--February to April, Johns Hopkins Univ. Home Study Course A, 1986 postgraduate institute. Course B will be in residence in Baltimore. Contact John Frost, M.D., 604 Pathology Bldg, Johns Hopkins Hospital, Baltimore 21205.

National Cancer Advisory Board--Feb. 3-5, NIH Bldg 31 Rm 6, 8:30 a.m. each day. Closed Feb. 4.

Div. of Cancer Treatment Board of Scientific Counselors--Feb. 6-7, NIH Bldg 31 Rm 10, 8:30 a.m.

Technology Transfer Program in Cancer--Feb. 9-15, Taj Mahal Hotel, Bombay. Organized by the Tata Memorial Centre, Bombay.

Div. of Cancer Biology & Diagnosis Board of Scientific Counselors--Feb. 10-11, all closed for review of the Laboratory of Pathology.

Progress in Gynecological Cancer--Feb. 12, Moseley-Salvatori Conference Center, Los Angeles. Contact Dolores Gay, Hospital of the Good Samaritan, 616 S. Witmer St., Los Angeles 90017, phone 213-977-2352.

Univ. of California (Irvine) First International Cancer Conference--Feb. 13-15, Newport Beach Marriott Hotel & Tennis Club. Contact Assistant Director, Center for Health Education, 2801 Atlantic Ave., Long Beach 90801, phone 213-595-3823.

National Surgical Adjuvant Breast & Bowel Project--Feb. 17-19, Fairmont Hotel, San Francisco. Contact NSABP, Operations Office, Rm 914, 3550 Terrace St., Pittsburgh, Pa. 15261, phone 412-624-2671.

Div. of Cancer Etiology Board of Scientific Counselors--Feb. 20-21, NIH Bldg 31 Rm 6, 9 a.m.

Immunoproliferative and Immunodeficiency Diseases in Children--Feb. 21-22, St. Jude Children's Research Hospital, Memphis. 20th annual clinical symposium. Contact Director, St. Jude Children's Research Hospital, PO Box 318, Memphis, TN 38101.

Advances in Cancer Prevention & Treatment--Feb. 22, Toledo. Contact Teri Swimmer, M.S., Northwest Ohio Cancer Network, Medical College of Ohio Cancer Program, C.S. #10008, Toledo 43699, phone 419-381-3717.

Calories and Energy Expenditure in Carcinogenesis--Feb. 24-25, Capital Hilton, Washington D.C. Contact Wendy Gasch, ILSI-NF, 1126 16th St. NW, Suite 111, Washington 20036, phone 202-659-0074.

Treatment Planning in the Radiation Therapy of Cancer--Feb. 28-March 1, Sheraton-Palace Hotel, San Francisco. 21st annual San Francisco Cancer Symposium. Contact West Coast Cancer Foundation, 50 Francisco St., Suite 200, San Francisco 94133, phone 415-981-4590.

FUTURE MEETINGS

1986 Fundamental Tumor Registry Operations Programs--Sponsored by the American College of Surgeons Cancer Dept. March 12-15, Fort Worth, Texas, St. Joseph's Hospital. Contact Margaret Aguilar, local coordinator, phone 817-336-9371; March 17-20, Atlanta, St. Joseph's Hospital, Patty Winters, coordinator, phone 404-876-7535; May 5-8, Chardon, Ohio, Geauga Community Hospital, Susan McGowan, local coordinator, phone 216-729-1946; May 27-28, Coeur D'Alene, Idaho, Kootenai Medical Center, Jo Ann Beers, local coordinator, phone 208-667-6441.

The Cancer Letter _Editor Jerry D. Boyd Associate Editor Patricia Williams

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