THE CANCER LETTER

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XIIITH INTERNATIONAL CANCER CONGRESS IN SEATTLE DRAWING RECORD NUMBERS FOR TOP SCIENTIFIC PROGRAM

The quadrennial gathering of the world's leading cancer scientists, held this year as the XIIIth International Cancer Congress Sept. 8-15 in Seattle, probably will draw a record number of participants—more than

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In Brief

NCAB LACKED COURAGE ON SOME SPECIAL ACTIONS, AMOS SAYS; PICK REVIEWERS ON ABILITY ONLY, SCIENTIST ASKS

HAROLD AMOS, member of the President's Cancer Panel who until his term expired this year had served on the National Cancer Advisory Board since it was established in 1972: "As a 10 year member of the Board, I think that the Board has not exercised its real role in decisions about the uniqueness and relevance of grants. Dr. DeVita and staff have in fact brought grants to us as special actions, and I think the Board has not had the courage to act on some of those." Amos' comment was made at the Panel's meeting in Los Angeles. Other comments included: **ROBERT PARKER, UCLA**—"We should improve and not dismantle the system which is the best ever devised by man for allotting government funds to support biomedical research. We could increase the interval between reviews for excellent programs and good investigators. We should shorten the interval between conception of an idea and work on it in the laboratory. Time for research might be increased by selectively shortening the grant application and making progress reports less onerous. Study section members must be selected on a single basis, and that is scientific ability, not geography, not six, not other things. And they should be senior investigators. There should be more than two reviewers for each grant. The balloting of study section members should be known to all present at the time." **FREDERICK EILBER, UCLA**—"Investigators should have more voice in selection of people who are going to review their grants. There should be some appeals mechanism after the site visit has taken place, when the investigator can physically go before the study section and rebut any misconceptions or misinterpretations that occurred at the site visit." **STEPHEN STOWE, American Assn. for Cancer Education**—"We are particularly concerned with the Clinical Cancer Education Program. (NCI) has decided that it would now fund only those education programs for people already committed to careers in oncology. The Association feels that this is an unwise new direction to take." NCI Director **VINCENT DEVITA, responding**—"The Clinical Education Program has in fact paid a big price over the last two years. We did reduce the budget in half. The group that considered this felt the climate at medical schools has changed to such an extent that the level of support for modifying curriculum training of students is not as much as it was in the past."

REAGAN DECLINES SEATTLE INVITATION IN FAVOR OF "CAMPAIGNING FOR PARTY"

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10,000. They will hear what Congress President William Hutchinson, Secretary General Edwin Mirand, and National Program Committee Chairman Enrico Mihich say will be the most outstanding group of scientific presentations in the history of the event.

"Advances in oncology achieved in recent years will be reviewed and discussed within a balanced program which includes consideration of highlights in basic preclinical and clinical research, in community application, in the modern interdisciplinary approaches to the care of the cancer patient, and in a variety of other areas related to the epidemiological and public health considerations of the cancer problem," Mirand said. "The format of the various sessions will vary from classical symposia to seminars, postgraduate courses providing updating in different areas, informal round table discussions, regular profferred papers and posters, and panels. In each case there will be ample opportunities for discussions from the floor. The geographical distribution of the participants in the program will add further opportunities for interactions among interested oncologists with diversified expertise and professional background."

Eleven plenary lectures will be given:

—Gerald Murphy, USA, secretary general of the sponsoring Union Internationale Contre le Cancer, "The Role of National Efforts in Developing Coordinated Programs on International Oncology," Friday, Sept. 10, 11:15 a.m.—12:15 p.m.

—Francis Wilcox, USA, "The Role of Volunteer Agencies," Sept. 10, 12:45—1:45 p.m.

—Nikolai Blokhin, USSR, "Advances in Surgical Oncology," Sept. 10, 1:45—2:45 p.m.

—Vincent DeVita, USA, "Advances in Cancer Therapeutics," Sept. 11, 11:15 a.m.—12:15 p.m.

—Calum Muir, France, "Epidemiology," Sept. 13, 11:15 a.m.—12:15 p.m.

—E. Donnall Thomas, USA, "The Role of Intensive Chemoradiotherapy and Marrow Transplantation in the Therapy of Disseminated Malignant Disease," Sept. 13, 1:45—2:45 p.m.

—Elwood Jensen, USA, "The Development and Clinical Application of Hormone Receptor Concepts," Sept. 14, 11:14 a.m.—12:15 p.m.

—Leo Sachs, Israel, "Growth, Differentation and Malignancy," Sept. 14, 1:45—2:45 p.m.

—George Klein, Sweden, "Tumor Immunology Revisited," Sept. 15, 11:15 a.m.—12:15 p.m.

—Takashi Sugimura, Japan, "Environmental Mutagens, Carcinogens and Tumor Promoters," Sept. 15, 1:45—2:45 p.m.

All of the plenary lectures will be given in the Seattle Center Arena.

Although the opening ceremony will be held Thursday, Sept. 9, with the sceintific sessions starting Sept. 8, various UICC committees will meet Sept. 6 and 7. A joint meeting of the Assn. of American Cancer Institutes and UICC's Committee on International Collaborative Activities is scheduled for the afternoon of Sept. 7. A number of other international and U.S. organizations will meet at various times during the Congress.

The opening ceremony Sept. 9, from 6-7:30 p.m., will include welcoming addresses from Seattle Mayor Charles Royer, Washington Governor John Spellman, UICC President Umberto Veronesi, Mirand, and Hutchinson.

The $100,000 Mucio Athayde Foundation Award to an outstanding oncologist will be presented during the opening ceremony by Antonio Jungevira. The Mucio Athayde Foundation is a Brazilian organization.

A wine and cheese reception for all Congress registrants will follow.

Notably absent from the opening ceremony schedule, at least so far, is any top level representation of the United States government.

When the Congress has been held in other countries, the chief of state and the minister of health have always been on hand to greet the assembled scientists. When the event was last held in this country, in Houston in 1970, Vice President Spiro Agnew opened the meeting.

Congress officials this year were informed, when they extended an invitation to President Reagan, that "the President will be too busy campaigning for his party to attend," with the November election less than two months away.

Not only were Congress officials offended by the rebuff, but they were astounded. If campaigning was what the President has on his mind, no better forum than the Seattle meeting would be available for a major speech. World scientists are tremendously impressed by the leadership being provided by the U.S. in the fight against cancer. The President quite properly could point to NCI's role in that leadership and take some credit for supporting the Cancer Program. Passing up that opportunity in favor of party politicking makes little sense.

Petty intraparty politics also may have been a factor. Reagan has been at odds with Republican Gov. Spellman over a pipeline controversy, and there is speculation in the state that the President did not want to appear on the same platform with him.

There may be another political factor. Washington Democratic Sen. Henry (Scoop) Jackson is running for reelection. He is an almost certain winner, and Reagan needs his support, especially on national defense issues. If the President were to appear in the state, he would find it very difficult to avoid making some gesture of support for Jackson's Republican

opponent and risk offending Jackson.

There seems to be no good reason why Vice President George Busch cannot attend. And it is incredible that HHS Secretary Richard Schweiker can't somehow fit the Cancer Congress into his schedule.

Three satellite symposia sponsored by pharmaceutical companies will be held concurrently with the Congress:

• Sequential Methotrexate and 5-FU in the Management of Neoplastic Disease. Sept. 10, 6:30–9:30 p.m., Grand Ballroom, Westin Hotel. Sponsored by Lederle Laboratories.

Joseph Bertino, Yale Univ., is chairman, and will introduce the program and discuss the basic concept. Martin Tattersall, Univ. of Sydney, Australia, will discuss current studies of MTX/5-FU and their interaction in human tumor cells. Susan Pitman, Yale, will talk on MTX/5-FU in head and neck cancer, as will Ulrich Ringborg, Karolinska Hospital, Stockholm. Joseph Allegra, Univ. of Louisville, will discuss MTX/5-FU following tamoxifen and premarin in advanced breast cancer. Howard Bruckner, Mount Sinai School of Medicine, will talk on MTX/5-FU in gastrointestinal cancer.

A buffet reception will precede the symposium, starting at 5 p.m.

• Breast Cancer–World Wide Experience with Aminoglutethimide. Sept 12, Four Seasons Olympic Hotel, 11:30 a.m. (brunch). Sponsored by CIBA.

Topics will include the London Experience; Treatment of Advanced Breast Breast with Aminoglutethimide: a 14-year Experience; Aminoglutethimide in Tamoxifen Resistant Patients; the Melbourne Experience; Aminoglutethimide in Advanced Breast Cancer: the Sydney Experience; and a Crossover Comparison of Tamoxifen and Aminoglutethimide in Advanced Breast Cancer.

Harold Harvey and Allan Lipton are cochairmen. Other speakers will be R.C. Coombes, Kenneth Gale, Adrian Harris, S.B. Kaye, William McGuire, Robin Murray, Trever Powles, Richard Santen, Ian Smith, and Samuel Wells.

• Progress and Controversies in Leukemia and Lymphoma. Sept. 12, Grand Ballroom, Westin Hotel, 11:30 a.m. (buffet brunch). Sponsored by Parke-Davis.

James Holland, Mount Sinai, is chairman and will open the program. E. Donnall Thomas, Univ. of Washington, will discuss marrow transplantation for AML. Peter Wiernik will talk on advances in chemotherapy for AML. Arnold Freeman, Roswell Park, will present on changing approaches to CNS leukemia. Emil Frei, Harvard, will discuss progress against lymphoma. Emil Freireich will talk about new drugs in leukemia and lymphoma. Zalem Arlin, Sloan-Kettering, will discuss the clinical role of AMSA in treatment of previously untreated and refractory acute leukemia.

Scientific and plenary sessions of the Congress will be held in the Seattle Center. Shuttle bus and monorail transportation will be provided between the center and hotels, motels, and Seattle downtown area.

A wide variety of entertainment will be available throughout the week, and a schedule of events and information on purchasing tickets is provided with registration information. Those who have not yet registered may receive registration forms by contacting XIIIth International Cancer Congress, Operations Office, Fourth & Blanchard Bldg., Suite 1800, Seattle 98121.

Following are summaries from a small sampling of the more than 4,000 abstracts which were submitted to the Congress:

Walking the Leukemic Cell Surface with Monoclonal Antibodies: Making Diagnostic Virtue Out of Biologic Complexity. Tucker LeBien, Robert Ash, Ulus Atasoy, Daniel Boue, Garrett Bradley, Anne Goldman, Esmail Zanjani, and John Kersey, Univ. of Minnesota and VA Medical Center, Minneapolis.

Our laboratory has produced a panel of three monoclonal antibodies designed BA-1, BA-2, and BA-3. All three monoclonal antibodies were produced by immunizing mice with the human leukemic cell line NALM-6. The antibodies all recognized different leukemic cell surface molecules although none are "leukemia-specific," i.e., they do react with some non-leukemic (normal) cells.

The three antibodies react with leukemic cells obtained from approximately 70 percent of children diagnosed with acute lymphoblastic leukemia. In this regard, we have recently demonstrated the usefulness of BA-1, BA-2, and BA-3 in the diagnosis and immunologic classification of childhood acute lymphoblastic leukemia. We have shown that dramatic differences exist relative to the usefulness of each antibody in predicting prognosis. This information suggests that the "immunologic phenotyping" (characterizing) of leukemic cells with BA-1, BA-2, and BA-3 can assist in identifying high risk groups among the common forms of childhood acute lymphoblastic leukemia.

The implications of our data are two-fold. 1) The usefulness of our monoclonal antibody panel (BA-1, BA-2, and BA-3) in phenotyping leukemic cells, and the ability of the panel to assist in the identification of high risk groups, suggests that such data may provide a basis for future decision making relative to therapy. 2) The fact that BA-1, BA-2 and BA-3 react with most cases of childhood acute lymphoblastic leukemia indicates that they may be useful for therapy in circumstances where patients have failed conventional chemotherapy. In this regard, a study is currently underway at the Univ. of Minnesota to use BA-1, BA-2, and BA-3 for the ex vivo elimination of leukemic cells in autologous bone marrow transplantation.

Prognosis of Acute Lymphoblastic Leukemia Related to Initial Findings and Treatment. Gunter Henze, Fritz Lampert, J.J. Langerman, Gunter Schellong, and H. Riehm, West Germany.

The results of three cooperative clinical trials involving more than 700 children in the Federal Republic of Germany over the last 10 years readily demonstrate the impact of therapy intensification and stratification on long term survival. The Main difference in these three studies was the mode of treatment during the first half year after diagnosis.

The therapy of the nationwide DAL-study 71/74 (495 pa-

tients) closely followed the Memphis protocol VII, i.e. weak prednisone-vincristine induction, followed by CNS-irradiation.

In the BFM-study 70/76 (119 patients), the induction therapy was prolonged (eight weeks), intensified (8 drugs: 4 in the first 4 weeks, 4 in the next 4 weeks) and included CNS-prophylaxis. In the BFM-study 76/79 (158 patients), a six-week intensive reinduction therapy course during the first six months after diagnosis was added to the former therapy in a defined high risk group after stratification.

The results can be expressed in numbers or life table curves using the probability of continuous complete remission (p-CCR) as the major criterion for cure. In these three therapeutic trials, the proportion of p-CCR related to all patients (including early and late, disease or therapy related mortality) increased from 0.33 to 0.55 to 0.69 respectively. This improvement was mainly due to the reduced incidence of isolated bone marrow relapses which decreased from 45 percent in the DAL-study to 26 and 9 percent in the BFM studies.

The effects of more aggressive therapy on various high risk prognostic parameters were as follows:

1. High initial white blood count (WBC): In patients with WBC over 25.000, the proportion of p-CCR increased from 0.21 in the DAL-study to 0.40 and 0.68 in the BFM-studies. The introduction of intensified re-induction therapy minimized the importance of high initial WBC as an adverse prognostic factor.

2. Presence of mediastinal mass at diagnosis: The p-CCR for patients with initial mediastinal mass increased from a meager 0.13 in the DAL 71/74 study (n = 47) to 0.47 in the BFM 70/76 study (n = 15) and to 0.79 in the BFM 76/79 study (n = 14). A highly significant difference in the outcome of children with (p-CCR = 0.13; n = 47) and without (p-CCR = 0.35; n = 448) mediastinal mass was found only in the DAL 71/74 study. Thus, the prognostic significance of a thymus tumor depended on the intensity of treatment.

3. T-cell characteristics: In the BFM 76/79 study, there was no difference in the p-CCR between children with and those without immunologically T-ALL characteristics when the former group was stratified to the more intensive treatment group in most cases because of the high concomitant WBC.

Percutaneous Drainage of the Biliary and Urinary Tract. Rolf Gunther, West Germany.

In malignant obstruction nonoperative decompression by percutaneous drainage offers an alternative or adjunct to surgery and is applied as a preoperative, postoperative or palliative procedure:

1. Preoperative drainage: Patients with tumor obstruction of the biliary or urinary tract are often in poor general condition. Preoperative decompression permits surgical intervention to be deferred until the patient has recovered and can be operated upon under more favorable circumstances. In highly jaundiced patients preoperative drainage of the biliary tract improves liver function and is presumed to reduce postoperative mortality.

2. Postoperative drainage: Postoperative complications like edema after biliary-digestive anastomosis, bile leakage or urinary fistulas can be successfully managed by temporary drainage.

3. Palliative drainage: If operative relief of obstruction is contraindicated due to high operative risk or to being technically unfeasible, percutaneous drainage may be a lifesaving procedure. Percutaneous decompression is performed under local anesthesia using ultrasound or fluoroscopic control with the aid of a catheter needle, a guide wire and a drainage catheter.

Teaching Adaptive Coping to Cancer Patients. William Worden, Massachusetts General Hospital.

To study the effectiveness of preventive intervention in lowering emotional distress and improving coping, 381 newly diagnosed cancer patients were assessed shortly after the time of initial diagnosis. Subjects predicted by a screening instrument to be at risk for high levels of emotiona distress and poor coping during the second through sixth months of their illness were randomly allocated to one or two short term intervention programs (N=59).

Specific techniques to lower distress and improve coping were given during the four weeks following diagnosis. A control group (N=58) received no intervention. All were followed at two month intervals to six months by interview and testing. There was a significant lowering of emotional distress in the intervention group as compared to the control group ($p > .05$). There was also a significant increase in the level of problem resolution in the intervention groups ($p. > .01$), although the numbers of problems experienced by both groups were no different.

Growth Control by Cell-Cell Interactions. Luis Glaser, Washington Univ. School of Medicine.

Our major conclusion with regard to the action of growth factors is that an early event that can be observed in many cells is the rapid entry of sodium following addition of epidermal growth factor to cells. Electrophysiological studies in collaboration with Paul Rothenberg and Luis Reuss have shown that this entry of sodium into the cells is electroneutral (does not change the membrane potential). A tentative mechamism for the action of epidermal growth factor can be formulated on the basis of our own, and most importantly on the basis of a large body of information currently available, notably from the laboratory of Stanley Cohen to suggest the following.

Epidermal growth factor binds its receptor and the receptor is a protein kinase which in turn stimulates entry of sodium into the cell. The entry of sodium into the cell is an electroneutral and operates by exchanging sodium ions for hydrogen ions and therefore changes the pH (acidity of the cell). This change in pH is the primary trigger for subsequent events involved in a mitogenic response.

JOHNSON, KATTERHAGEN APPLAUD CCOP RFA, BUT DISAPPOINTED ON CONTROL

Reaction of two of the principals involved in controversies surrounding development of the Community Clinical Oncology Program request for applications, issued last week generally was favorable, although both had some reservations.

Gale Katterhagen, member of the National Cancer Advisory Board who had argued eloquently for inclusion of some cancer control elements, said he felt the RFA was a "sound compromise which should form the basis for an excellent program."

Katterhagen said he was "a bit disappointed that there is not more fundable cancer control in the RFA," and noted that it "encourages CCOPs to do all sorts of things for which it does not provide money."

Katterhagen suggested, however, that the fact that NCI does not plan to pay for anything in CCOPs not directly related to clinical trials, should not preclude community hospitals from carrying on those activities. "Our experience here (Tacoma) has been that there are resources in the community to do these activities, and that money is available without federal

strings. Much of it can come through third party reimbursement if you play your cards right."

The RFA says that reviewers assessing CCOP applications "will consider the quality and effectiveness of existing cancer control efforts." Those include educational programs, tumor board conferences, patient management guideline development, formal supportive care efforts, and participation in cancer control network, outreach, and research programs. But "no one activity will be considered a requirement," and there is no money available to support those activities.

David Johnson, president of the Assn. of Community Cancer Centers whose last minute letter objecting to various aspects of the RFA as reported to him stirred considerable controversy at NCI and among some ACCC members, said he was "impressed that many cancer control elements did end up in the RFA. I saw some happy things in it, some that I didn't understand, and some that I'm trying to interpret."

Johnson said the Aug. 23 deadline for letters of intent may not give some community organizations enough time. "By and large, it will be very difficult to meet that date. An enormous amount of work has to be accomplished. The big problems I see are putting together the CCOP organization to the point where you can write a description of it, and developing relationships with the research bases."

Johnson and other advocates of including more cancer control in the program had hoped that provisions for payment of administrative support might be loose enough to permit some of that administrative time to be spent on other control activities. The RFA spells out, however, that administrative support will be only for that "directly related to study activities."

"That's one real hooker," Johnson said.

NO ISSUES FOR AUG. 6, 13

***The Cancer Letter* will not be published during the next two weeks, while the staff vacations and the federal government wilts into its annual August malaise. The next issue—Vol. 8 No. 32—will be published Aug. 20. The Cancer Letter office will be closed from July 28 until Aug. 19. Phone messages to our tape recorder and mail requiring responses will be answered as soon thereafter as we can work our way through the accumulation.**

CARTER SAYS HE'LL INSIST GOVERNMENT ABIDE BY SPIRIT OF 1971 CANCER ACT

Tim Lee Carter is a country doctor who practices medicine in the same town in which he was born nearly 72 years ago, and who in his 16 years as a member of Congress became the most influential member of his party in health legislation. Among the important health bills enacted into law while Carter was the top ranking Republican on the House Health Subcommittee was the National Cancer Act of 1971.

"We wanted to make a strong effort to find the causes of cancer and better ways to treat it," Carter told ***The Cancer Letter*** in a telephone interview. "Some of us thought that those goals could be reached quicker if we took the National Cancer Institute out of NIH."

A bill passed overwhelmingly by the Senate, authored by Sen. Edward Kennedy, would have established NCI as an almost completely independent agency within the Dept. of Health, Education & Welfare, responsible only to the President and Congress. NCI would have been shielded from the competing demands of other health constituencies, which invariably outweigh the Cancer Program when it comes to influencing NIH and department leadership.

Carter's friend and colleague, Paul Rogers, did not agree that NCI needed all that much independence. The Florida Democrat, who was chairman of the Health Subcommittee, persuaded Carter and the rest of the committee to accept a more limited version of independence. The Senate went along, and the Act was signed by President Nixon—who had supported the Senate version—late in 1971.

The "independence" provisions of the Act included creating the President's Cancer Panel, charged with reporting directly to the White House on requirements of the National Cancer Program; providing for Presidential appointment of the NCI director and for members of the National Cancer Advisory Board; broadening the NCAB's power beyond that enjoyed by advisory councils of other NIH institutes; and establishing the "bypass budget" for NCI, designed to permit development of a budget which would provide optimal funding for the Cancer Program without having it whittled down by NIH and the department.

The Act also greatly increased budget authorizations for NCI, and the big infusion of additional money fueled the major advances in cancer research over the last 10 years. But the independence that Tim Lee Carter and Ted Kennedy thought was important and which they had hoped had been salvaged in the compromise bill soon became an illusion, especially the bypass budget.

The bypass budget submitted by NCI each year to the White House gets no more attention there than it would at the Kremlin. Instead, the Presidential budgets submitted to Congress include the scrawny requests submitted on behalf of NCI by the department—exactly what Congress had tried to avoid in creating the bypass.

Carter did not run for reelection in 1980, returning to his medical practice full time in Tomkinsville, Kentucky. It was a complete surprise to him, he said,

when he was asked a few months ago if he would accept an appointment to the NCAB, as chairman. Although he did not seek the job, now that he has it, he intends to use that position to restore some of the original intent of Congress expressed in the 1971 Act.

Using the department budget and not NCI's "is subverting the intent of Congress," Carter said. "I'm certainly going to push for the government to abide by the intent of our bill."

Carter feels special interest groups may have too much influence on the NCAB, a feeling shared by many who think that recent amendments to the Cancer Act mandating representation in certain fields (environmental carcinogenesis, practicing physicians) have distorted, if not corrupted, the Board.

"I think we will want to hear from all the brightest minds, to get the information we need to make decisions," Carter said. "We need to go in the directions that seem the most promising based on that information, and not allow our decisions to be influenced by narrow views."

Carter feels that the NCAB should be actively engaged in helping develop NCI programs and should work closely with the four division boards of scientific counselors.

Carter does have one special interest in the cancer field himself, the treatment of leukemia. His only son died of the disease in 1977.

Since great progress has been made in the last 10 years, were Carter, Kennedy, Mary Lasker and Solomon Garb wrong in pressing for an independent Cancer Program? That question might be answered by considering what the rate of progress would have been if:

- Assuming independence, or at least following the spirit of the bypass budget, would have resulted in increased appropriations, NCI had been able to fund 40-50 percent of approved grants, rather than the present level of 25 percent; and been able to pay program projects, cancer center grants, and cooperative groups at their recommended levels.
- NCI had been permitted to continue support of badly needed construction and renovation of cancer research facilities.
- NCI had not been forced to take the same cuts in personnel inflicted on the entire department.
- NCI had not been forced to wait for years to get new study sections for carcinogenesis, treatment research, nutrition, and epidemiology. Countless grants were rejected by study sections without expertise in those fields, while NCI's requests for new panels languished.

Carter and his fellow Board members may be hard pressed to help continue the momentum seen by their predecessors unless they can convince Congress and the White House that the Cancer Program needs a major increase in appropriations, after three years of a level budget.

Carter is no stranger to a fight, having survived eight terms in the House and four years as a combat medical officer in World War II. He was decorated for his service with the 30th Infantry Division in the Phillipines in action which recaptured Bataan and Corregidor. His unit treated as many as 217 casualties a day during those battles.

CLINICAL TRIALS MONITORING PROGRAM TO SITE VISIT PIs EVERY THREE YEARS

NCI's Div. of Cancer Treatment is in the process of implementing the new clinical tirals monitoring program which will involve periodic site visits to institutions conducting investigational drug studies under INDs held by NCI.

The plan is a modification of a proposal rejected by the division's Board of Scientific Counselors last February (***The Cancer Letter,*** Feb. 26). The new plan was approved by the Board at its June meeting.

A Board subcommittee consisting of Sharon Murphy, Philip DiSaia, and Theodore Phillips worked with DCT staff to develop the revised proposal. The subcommittee's report described the proposal:

"The program is based on three levels of concern. The first is existing regulations which require certain monitoring to meet FDA standards. The second is proposed regulations which are now followed closely by the drug industry. The third is desirable levels of review for protocols not involving investigational new drugs.

"Dr. (Daniel) Hoth (chief of the Investigation Drug Branch) reviewed the existing drug quality assurance programs and good clinical practices group arrangements among the pharmaceutical companies. These companies visit their contractors every four to 12 weeks, with 12 the longest interval between actual site visits and review of original data. It was felt that this was an admirable program, but more than necessary for DCT investigators who are frequently peer reviewed and who are in the academic community.

"Dr. Hoth also presented a review of the cooperative group quality control programs. Essentially all groups have quality control committees and quality review of the various modalities. Approximately half of them have already instituted on site audits and the other half are proposing them.

"The new program proposal outlines a system which will be economical and efficient and which will apply the same standard to the cooperative groups and to investigators conducting investigational new drug research under other sources of support. Review of all funded grants and contracts indicates that approximately 35 investigators are involved in phase 1 and phase 1-2 contracts in chemotherapy and biologic response modifiers. Review of these is already

covered by a clinical trials monitoring program as required by the FDA for phase 1 studies. An additional 101 investigators were identified who were funded under the former contract groups mechanism, i.e., brain, GI, and lung cancer or individual investigators, cancer centers, program projects, intramural NCI and drug studies mechanism investigators. Among the cooperative group full members, funded and unfunded, there are an additional 314 investigators, for a total of 415 investigator foci requiring monitoring. These institutions consist only of those involved with investigational new drugs not yet classified as category C.

"The proposed program will accept the adequate cooperative group site visit mechanism now in place in some of the groups and expand it into all of the groups. Only if a cooperative group elects not to perform its own site visits will it participate in the general NCI program. The only change will be that NCI staff will accompany the site visit teams on a percentage, i.e., about 20 percent, of the site visits. All cooperative group site visits will be carried out by peer members of the cooperative group who will have expertise in medical oncology or the oncology discipline under review.

"For the site visit monitoring of noncooperative group investigators NCI will organize a site visit team of qualified investigators in similar institutions, i.e., peers. These will be selected from the pool of qualified investigators in this class subject to site visiting. Each site visit team will be assisted by NCI staff, who will assist in setting up the visit and the data collection.

"For both types of site visits, it is planned that a similar or common set of review forms will be prepared and recommended.

"The minimum scope of the entire program is to site visit principal investigators conducting investigational drug studies at least once every three years. The visit will be conducted by a team of peers and will occur on a random basis, such that there is always the possibility of a visit during a given year. Two months warning of intent to visit and two weeks warning of specific case numbers will be provided.

"Items to be covered in the site visit include a sample of 10-20 charts with verification of IRB approval and consent forms signature. Procedures for storing and dispensing drugs will be evaluated, as will a number of items relevant to protocol adherence such as patient eligibility, protocol adherence in terms of dosage, evaluation of response, etc.

"After the site visit, a report will be provided to the institution's PI, the institution's IRB, and to NCI, as well as to the cooperative group headquarters.

"After the review there will be clarification of the problem in writing and, if necessary, by repeat site visit. The cooperative group may take immediate action to remedy the situation through reassessment of member status, i.e., probation, etc. The cooperative group chairman and his executive committee will, in conjunction with NCI, clarify the problem and if necessary recommend more stringent action.

"The total cost of this program is estimated now to be approximately $400,000 per annum which represents approximately $10/new case entered/year into all of the concerned new drug studies.

"The committee considered that this new proposal was an excellent one and had answered essentially all the major concerns about the proposal previously presented to the DCT Board.

NCI ADVISORY GROUP, OTHER CANCER MEETINGS FOR AUGUST, SEPTEMBER

Statistics in Chemistry & Chemical Engineering—Aug. 2-6, New Hampton, N.H. Gordon Research conference. Contact Dr. Alexander Cruickshank, Pastore Chemical Lab., Univ. of Rhode Island, Kingston, R.I. 02881, phone 401-783-4011.

National Cancer Advisory Board Subcommittee on Environmental Carcinogenesis—Aug. 10-11, Mt. Sinai School of Medicine, New York, Annenberg Bldg., 9 a.m. both days.

International Society for Experimental Hematology—Aug. 12-15, Baltimore, 11th annual meeting. Contact Dr. Lyle Heim, Dept. of Pediatrics, Texas Tech Univ., School of Medicine, 4800 Alberta Ave., El Paso 79905.

Regulation of the Immune Response—Aug. 14-17, Amherst, N.Y. 8th International Convocation on Immunology. Contact Dr. James Mohn, Ernest Witebsky Center for Immunology, Rm 21, Sherman Hall, SUNY Buffalo, 14214, phone 716-831-8345.

National Cancer Advisory Board Subcommittee on Activities & Agenda—Aug. 17, NIH Bldg 31 Rm 7, 8:30 a.m., open.

The Cancer Registry: An Educational, Epidemiological, and Evaluative Tool in Cancer Control—Aug. 18-20, Holiday Inn Parkway, Tallahassee, Fla. Contact Florida Cancer Council, American Cancer Society, John Carbonneau, 1001 S. MacDill Ave., Tampa 33609, phone 813-253-0541.

Gordon Research Conference—Cancer Section—Aug. 23-27, New London, N.H. Contact Dr. Cruikshank, address above.

Cancer Epidemiology in Latin America—Aug. 24-27, Washington D.C. Contact Dr. Elaine Millner, NCI, DCCP, Landow Bldg. Rm 8C16, Bethesda, Md. 20205, phone 301-496-9600.

International Assn. for Comparative Research in Leukemia—Sept. 2-4, Beverly Hills. Contact R. Davis, UCLA Jonsson Comprehensive Cancer Center, 1100 Glendon Ave. Suite 844, Los Angeles 90024.

7th World Congress Collegium International Chirurgiae Digestivae—Sept. 6-9, Tokyo. Sessions on total and limited resection for gastric cancer, surgical techniques for sphincter preserving surgery for rectal cancer, radical surgery for pancreatic cancer, etc. Contact T. Aoki, 7th World Congress of CICD, 2nd Dept. of Surgery, Jikei Univ. School of Medicine, 25-8 Nishi Shinbashi 3-chome, Minato-ku, Tokyo, 105 Japan.

Coagulation, Cancer & Inflammation—Sept. 8-10, Airlie House, Airlie, Va. Workshop sponsored by NCI and two other NIH institutes. Contact Dr. Anne Ball, Div. of Blood Diseases & Resources, NHLBI, Federal Bldg. Rm 5A12, Bethesda, Md. 20205, phone 301-496-5911.

Tetracarcinoma Cells—Sept. 8-12, Cold Spring Harbor, N.Y. Contact meetings office, Cold Spring Harbor Lab, New York 11724.

XIIIth International Cancer Congress—Sept. 8-15, Seattle. Contact Secretary General of the Congress, Fred Hutchinson Cancer Research Center, 1124 Columbia St., Seattle 98104.

Approaches to Management of Pain–Sept. 9, Goodman's Hall, Oakland, Calif. Contact Despina Johnson, 2844 Summit St. Suite 204, Oakland 94609, phone 415-465-8570.
4th Annual Pharmacy Symposium on Cancer Chemotherapy–Sept. 12-14, Houston Shamrock Hilton Hotel. Contact Sharon Bronson, Dept. of Pharmacy, M.D. Anderson Hospital & Tumor Institute, 6723 Bertner Ave., Houston 7703-, phone 713-792-2870.
President's Cancer Panel–Sept. 14, Westin Hotel, Seattle, 7:30 p.m., open.
Papilloma Viruses–Sept. 15-19, Cold Spring Harbor. Contact same as above.
Chemical Emergencies in Laboratories–Planning & Response–Sept. 15-16, Frederick Cancer Research Facility. Contact Linda Kesselring, Environmental Control & Research Laboratory, NCI-FCRF, P.O. Box B, Frederick, Md. 21701, phone 695-1451.

8th Biannual Morris Hepatoma Symposium–Sept. 16, Westin Hotel, Seattle. Contact Dr. Wayne Criss, Cancer Center, Howard Univ., Washington D.C. 20060, phone 202-636-6351.
Fundamental Problems in Breast Cancer–Sept. 17-18, Univ. of Alberta, Edmonton, contact Cross Cancer Institute, 11560 University Ave., Edmonton, Alberta, Canada T6G 1Z2.
The Oncology Nurse: Challenges of the '80s–Sept. 20-25, Brugge, Belgium. Lung carcinoma in Europe. Contact Secretary, 1st. Conv. SEP, Dept. Pneumology, AZ Sin-Jan, Ruddershove, 8000 Brugge, Belgium.
Poxvirus–Sept. 20-23, Cold Spring Harbor. Contact above.
Carcinogenesis Studies Using Cultured Human Tissues & Cells–Sept. 20-24, Aspen, Colo. contact Dr. Curtis Harris, DCCP, NCI, Bldg. 37 Rm. 3A17, Behesda, Md. 20205, phone 301-496-2048.
International Society of Pediatric Oncology–Sept. 21-25, Bern, Switzerland. 14th meeting. Contact Dept. of Child Health, Royal Hospital for Sick Children, St. Michael's Hill, Bristol BS2 8BJ, UK.
2nd International Congress on Viral Oncology–Sept. 23-26, Naples. Contact Dr. Enrico de Lorenzo, Organizing Secretary, Via Le Elena 17-B, 80122 Naples, Italy.
National Cancer Advisory Board Subcommittee on Environmental Carcinogenesis–Sept. 23, NIH Bldg. 31 Rm 4, 9 a.m., open.
IVth International Symposium on Nasopharyngeal Carcinoma–Sept. 27-29, Kuala Lumpur, Malaysia. Contact Secretariat, NPC International Symposium, Dept. of ENT, Faculty of Medicine, Univ. of Malaysia, Kuala Lumpur, 22-11, Malaysia.
Society for Immunology–Sept. 27-29, Munster, West Germany. 14th annual meeting. Contact Prof. Dr. E. Macher, Universitat, Hautklinik, Von-Esmarch-Strasse 56, 4400 Munster, Fed. Rep. of Germany.
NCI Div. of Cancer Cause & Prevention Board of Scientific Counselors–Sept. 29-30, NIH Bldg. 31 Rm 10, 9 a.m. both days, open.
5th Oncosurgical Symposium–Sept. 29-Oct. 1, Brno, Czechoslovakia. Czechoslovak Stomatological Society. Problems of metastasizing malignant tumors in the face, complications of jaw and face oncology. Contact J. Bildre, Czech Medical Society, Vitezueho umora 31, 120 26 Prague, Czechoslovakia.
American College of Epidemiology–Sept. 30-Oct. 1, O'Hare Inn, Chicago. Annual meeting. Contact Dr. Curtis Mettlin, Secretary, American College of Epidemiology, Roswell Park Memorial Institute, 666 Elm St., Buffalo N.Y. 14263.
Tumor Registrars Assn. of New England–Sept. 30-Oct. 1, Sheraton-Regal Inn, Hyannis, Mass. Contact Mary Anderson, Cancer Registry, St. Vincent Hospital, 25 Winthrop St., Worcester, Mass. 01604.

FUTURE MEETINGS

Advances in Pediatric Oncology, Care of the Child & Family–Oct. 7-8, New York City. Assessment and management of pain in children, alternative strategies of coping with pain and chronic illness, long term psychological effects of illness in children. Sponsored by the Assn. of Pediatric Oncology Nurses. Contact N. Houlihan, RN, APON Program, 511 E. 80th St., New York 10021.
Cancer Invasion & Metastasis–March 1-4, 1983, Houston Shamrock Hilton. 36th Annual Symposium on Fundamental Cancer Research. Recent developments in the biology of tumor metastasis formation and possible contributions of these developments to cancer treatment. Contact Office of Conference Services, Box 18, M.D. Anderson, 6723 Bertner Ave., Houston 77030, phone 713-792-2222.

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-CO-33854-41

Title: *Management information system support service (programming*
Deadline: *Sept. 13*

NCI is soliciting proposals for a small business firm to provide communications services to support the Office of Cancer Communications.

This proposed procurement is a total set aside for small business concerns. Small business size standard: A small business, for purposes of this procurement, is a firm, including its affiliates, that is independently owned and operated, is not dominant in the field of operations in which it is bidding on government contracts, and its average annual receipts for its preceding three fiscal years do not exceed $4 million (FPR 1-1.701.1(f)(10). This

This project is for a three year period. Offerors will be limited to those firms having operating facilities within a 40-mile radius of Bethesda, Md. as daily person to person contact is required.

Contracting Officer: Patricia Rainey
RCB, Blair Bldg. Rm. 332
301-427-8877

The Cancer Letter Editor Jerry D. Boyd

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