THE CANCER LETTER

Vol. 7 No. 19

May 8, 1981

Subscription $125.00 per year

P.O. Box 2370 Reston, Virginia 22090 Telephone 703-620-4646

NCAB MAY DETERMINE FATE OF NCOG, POSSIBLY OTHER REGIONAL GROUPS; SIMONE DENIES CCIRC PREJUDICE

The National Cancer Advisory Board, meeting on the afternoon of May 18 and morning of May 19 as a "special actions" subcommittee,

(Continued to page 2)

In Brief

HOUSE CUTS NCI RESCISION TO $7.73 MILLION; WEINHOUSE, ULTMANN NEW AACR, ASCO PRESIDENTS

HOUSE APPROPRIATIONS committee has slashed President Reagan's request for a $25 million rescision in NCI's FY 1981 budget to $7.73 million. If the Senate goes along, NCI will be able to restore much of the reductions projected for centers, cooperative groups and other programs the rescision hit hard, perhaps have more money available for new initiatives. The Senate Health Appropriations Subcommittee was scheduled to mark up its rescision bill this week. . . . **SIDNEY WEINHOUSE**, Fels Research Institute, and **JOHN ULTMANN**, Univ. of Chicago, took over last week as presidents, respectively, of the American Assn. for Cancer Research and the American Society of Clinical Oncology. **GERALD MUELLER**, McArdle Laboratory, was named vice president and president elect of AACR, while **SAUL ROSENBERG**, Stanford Univ., was named president elect of ASCO. New AACR board members are **GERTRUDE ELION, SAMUEL HELLMAN, JOHN LASZLO**, and **TERESA VIETTI**. New ASCO board members are **LAWRENCE EINHORN, SYDNEY SALMON, FREDERICK PHILIPS** and **NEIL MACDONALD** were reelected secretaries-treasurer of AACR and ASCO, respectively. . . . **FDA, NCI STAFF** members met last week to discuss the new impasse over the revised new drug toxicology guidelines. NCI reiterated its argument against requiring histopathology prior to phase 1 tests. FDA reps listened, offered no indication of their opinions, said they would respond later. NCI is pushing for an early decision, since the first IND developed under the new guidelines will be submitted June 1, and FDA has said it would not approve any until the histopathology issue is resolved. . . . **NCI'S FREE** distribution of commercially available drugs for use in clinical research protocols is being phased out. The move will save NCI about $2.5 million, nearly $2 million of which goes to the Cooperative Groups. NCI expects most of that cost to be picked up by third party payers. About $1.5 million of the total has been paying for adriamycin, which is being dropped immediately, with the others to follow as NCI's stocks are depleted. NCI will continue to supply investigational drugs free to the groups, contract supported trials, and through its Group A, B and C mechanisms. . . . **DIV. OF CANCER** Biology & Diagnosis Board of Scientific Counselors will meet May 14-16, with open sessions the first day from 1-5 p.m. and 7-10 p.m., and May 15 9-5 p.m.

NCI MAY ASK FOR "CCIRC B" TO REVIEW REGIONAL COOPERATIVE GROUP GRANTS

(Continued from page 1)

will consider the fate of the Northern California Oncology Group. The Board's decision could affect the entire concept of regional cooperative groups.

The Board will be asked by NCI staff and by NCOG Chairman Stephen Carter to overturn the decision of the Clinical Cancer Investigation Review Committee disapproving the group's grant. That decision rejected the site visit team's recommendation for approval and has led to charges by Carter and others allied with existing and newly forming regional groups that the CCIRC is dominated by persons affiliated with national groups and thus cannot give fair review to other groups competing for NCI clinical trials funds.

One other regional group is operating with a grant reviewed and approved by the CCIRC–the North Central Cancer Treatment Group. That grant is up for renewal this year and will be reviewed by the CCIRC at its June meeting.

The Div. of Cancer Treatment plans to publish a request for applications (RFA) soliciting applications from other regional groups, with the hope of funding at least three. There may be as many as 20 regional groups in various stages of development, and NCI expects at least 10 of them to compete for funding. If more than three come out with high priority scores, an effort probably would be made to support them in succeeding years.

The regional group concept has been pushed strongly by NCI Director Vincent DeVita. He argued forcefully for expanding the program, adding three new groups, and won approval of the DCT Board of Scientific Counselors. A majority of that Board voted for the concept, but strong opposition from chairmen of national groups developed, and that opposition has continued.

The national chairmen argued that it does not make sense to create new groups at a time when existing groups are faced with level budgets and thus a decline in constant dollars. They said they would not mind competing head on with regional groups but did not like the proposal to earmark a certain amount of money ($1.5 million) for new regional groups which they said established a separate, favored category.

That money, and any other funds that might become available for clinical trials, should be put into the pot with existing Cooperative Group funds, with all groups competing for it under the same rules and with the same reviewers, the national chairmen argued.

Those allied with regional groups point to the NCOG decision as evidence that CCIRC review of their groups cannot be fair, that the deck is stacked against them. "The CCIRC is dominated by the national groups," one regional group member told ***The Cancer Letter.***

"I don't really blame them for being concerned about their own funding. I would feel the same way if I were in their place. There is going to be a limited amount of money for groups, and every time they let a new one in, existing groups will have to take cuts, or one will be bumped. Adequate, reasonable, fair review of regional groups is not possible with the CCIRC as it now exists."

NCI staff appears to agree with that position. DCT is preparing to ask for creation of a new group, a "CCIRC B," to review regional group applications. DCT will insist that its membership not include members of existing groups, or at least that they be in distinct minority.

The 24 member CCIRC has only three members who are not affiliated with a Cooperative Group. They are James Hanley, McGill Univ.; George Higgins, Veterans Administration; and Diane Komp, Yale Univ.

CCIRC Chairman Joseph Simone is vice chairman of the Pediatric Oncology Group. Other members and their affiliations are:

Laurence Baker, Southwest Oncology Group; Alfred Bartolucci, Southeastern Cancer Study Group; Clara Bloomfield, Cancer & Leukemia Group B; Norman Breslow, Wilm's Tumor Study Group; Ann Chu, Gynecologic Oncology Group; Hugh Davis, SWOG; David Decker, North Central Cancer Treatment Group; William Donegan, National Surgical Adjuvant Breast & Bowel Group; Joseph Eggleston, Eastern Cooperative Oncology Group; Richard Kempson, Northern California Oncology Group; Louis Leone, CALGB; Robert Lindberg, SWOG; Carl Mansfield, SWOG; Edward Mansour, ECOG; Harold Maurer, POG; Harvey Preisler, CALGB; Omar Salazar, Radiation Therapy Oncology Group and ECOG; Ralph Vogler, SEG; Janet Wolter, ECOG; and Roy Weiner, SEG.

Simone denies the CCIRC is prejudiced against regional groups. "Regionality was not an issue in any of our discussions (on NCOG's grant)," he said. "There are some things that a regional group can't do, but the fact they they can't was not held against NCOG."

Neither was the issue discussed about a proliferation of groups depleting available funds, Simone said. "That was never raised. We never touched on it."

The CCIRC "worked very hard on the NCOG review, and we had a lengthy discussion," Simone said.

Some skeptics of CCIRC's ability to render a fair and impartial decision on NCOG or other regional groups point to the fact that the site visit team had recommended approval. Simone pointed out that that is not unprecedented, that the CCIRC and other study sections have gone against site visit recom-

mendations in the past. A substantial number of CCIRC members were on the site visit team.

Simone noted that a "probation" category which had been available to CCIRC in the past is no longer in use. Groups in trouble when their grants were up for renewal frequently were placed on probation for a year or two, with the opportunity to strengthen their weak areas before the next review. Groups objected to being placed on probation, however. They felt it cast a pall over them, and that status was dropped. The CCIRC now either approves or disapproves a group.

Simone would not say whether he feels NCOG would have been given probation status had that option been available.

The decision against NCOG was not unanimous, although ***The Cancer Letter*** has learned that a sizeable majority supported that decision. The minority report will be presented to the NCAB, which has the option of (1) letting the majority decision stand, (2) accepting the minority report, (3) referring the issue back to CCIRC and asking for another review, (4) referring it to an ad hoc committee for re-review. Precedents exist for all those options.

The best guess now is that the NCAB will accept the minority report. If that is the decision, NCI will recommend funding of NCOG at about 70 percent of its current level, disallowing the budget increase requests. "Since groups which have been approved by CCIRC are being funded at 75 percent of recommended levels, we feel that NCOG should be cut back some, and should not prosper in the face of the adverse review," one staff member said.

How will cutting back on the financial support help strengthen NCOG?

"It will force them to get rid of their weaker elements. Leaner will be better."

A CCIRC member who voted for NCOG and helped write the minority report agreed with Simone, that the regional group/dilution of funds issues played no part in the majority decision.

"There certainly was no discussion along those lines," he told ***The Cancer Letter.*** "And I don't think it had any part in the individual decisions. The decision was made on its merits. I happened not to agree with it."

ACCC COMMITTEE HEARS HOW FOUR GROUPS DO CLINICAL TRIALS; WILL MEET AGAIN

The Assn. of Community Cancer Centers Clinical Research Committee last week opened its efforts to help NCI devise a new program to bring more community physicians and their patients into clinical trials by listening to descriptions of four existing programs along that line.

Rodger Winn described the Memorial Sloan-Kettering outreach program in which MSK trained oncologists practicing in the Greater New York area have organized to cooperate with the comprehensive cancer center in clinical studies.

Twenty-four physicians are participating, Winn said. They participate in protocol development (all protocols must be approved by NCI, but no NCI money is as yet involved in supporting the group). Most patients on protocols are treated in the communities, but some are referred to MSK. Examples of those, Winn said, are those referred for phase 1 interferon trials and for the national testicular cancer protocol.

The program is working, Winn said, although "Memorial had to shed some of its paternalism and we had to shed our paranoia about big brother."

Winn said the community physicians can do phase 2 trials "easily. . . . Phase 3 trials with randomization can be done at the community level. We shouldn't be excluded from those."

One problem, he said, is that "we cannot run a no-treatment arm at the community level. Internists will refer patients to us because we assure them they will receive new and hopefully better treatment. If we go back and tell them their patients were randomized to no treatment, they will never refer to us again."

MSK contributed computer time and some space to the program, an $8,000 grant from a patient went into it, Lilly contributed $13,000 for a phase 2 trial, and the members were assessed $150 each to participate. The group probably will compete for support from NCI as a regional group.

Winn said "the biggest bugaboo" has been quality control and computerized data collection. Randomization and registration is done at Memorial. Patients must be registered before they go on drugs.

"Memorial found a solution for itself," commented William Terry, director of NCI's Div. of Resources, Centers & Community Activities. "They've taken their grads, put them with protocols, without NCI money."

Winn said that one of the requirements for membership is that at least one member of each practice has to have been trained at Memorial. "Memorial didn't rush into this. They had to be dragged in. They were greatly concerned about quality control. We had to break down that rule. There are some oncologists I would love to bring in who are not Memorial trained."

Paul Edsel reported on the North Central Cancer Treatment Group which is affiliated with the Mayo Comprehensive Cancer Center. The group was organized to bring in oncologists in the upper midwestern states where many communities are located considerable distances from either university or community cancer centers.

Edsel said 1,600 patients have been entered on the group's protocols, at an average cost of $250. Group members pay travel costs out of their own pockets.

It has had a working arrangement with the Eastern Cooperative Oncology Group, and started using ECOG protocols for the most part. As it has developed its own protocols, those from ECOG have been dropped. The group also works with the Childrens Cancer Study Group.

Edsel said that his group does have some protocols with no-treatment arms, "but that has taken a lot of education."

Jules Lodish described his group's program in Milwaukee, run out of the Mt. Sinai Medical Center which is affiliated with the Univ. of Wisconsin. "All oncologists want to be linked with some programs that give them a sense of participating in clinical research," he said. "We can give them something—facilities, the link to research."

The number of patients treated by the group is rising, and the group is starting to develop its own protocols.

"We talk with patients when their physicians let me, and we never had a problem with a no-treatment arm," Lodish said. "You can be positive about it, and people feel that maybe the doctor is using his judgment, not just giving poison to everyone."

James Borst reported on his experience with the NCI cancer control contract as a satellite of the Southwest Oncology Group. The budget is $660,000, and 490 community physicians are involved.

The group has practically unlimited access to SWOG protocols, and participates in phase 2 studies, Borst said. "One problem is that nonmembers (i.e., the satellite members) are excluded from SWOG decision making. I recommend that this structure be changed. We need to get community physicians on disease committees."

Edward Moorhead, chairman of the ACCC committeee, added that "it is hard to cooperate with SWOG when they consider community physicians as second or third class citizens."

The committee was established by ACCC in response to NCI Director Vincent DeVita's suggestion that the Institute would be interested in supporting some new program aimed at developing and expanding clinical trials in community hospitals and channeling more patients into national clinical trials where appropriate. It was referred to as an extension or expansion of the Community Hospital Oncology Program (CHOP), but with a mandatory clinical trials component added.

What eventually comes out may bear little resemblance to CHOP. Terry said after the committee meeting that the way may be left open for several approaches—regional groups, center outreach, large community hospital with smaller satellites, smaller hospitals in consortium, expansion of the Cooperative Group satellite program. "We may want to select from the best of these and apply them where they will work," Terry said.

Most of the community physicians participating in the discussions have indicated a willingness to enter patients on protocols and refer them to centers when appropriate. That is the "quo" in the "quid pro quo" condition set forth by DeVita for further NCI support of clinical oncology programs in communities. But the community people want to be assured that the "quid" is not lost. That consists of NCI support for elements of community cancer programs not directly related to clinical trials—professional and public education, psychosocial and other support.

The bottom line is improvement in the quality of care for cancer patients in the community. Since all money for the new effort will come from Terry's division (and not the Div. of Cancer Treatment), it must include some cancer control components.

The commitee is planning a two day meeting, probably to be scheduled for August, to continue its deliberations.

AACR OPPOSES SENATE HUMAN LIFE BILL; ASCO BACKS CANCER ACT, REIMBURSEMENT

Members of the American Assn. for Cancer Research overwhelmingly approved last week at their annual meeting a resolution opposing S. 158, the bill which would establish in law that human life starts from the moment of conception.

Van Potter, who had been attending a meeting of the National Academy of Sciences where a similar resolution had been approved, offered the resolution because the bill "cannot stand up to the scrutiny of science."

The resolution reads:

"It is the view of the American Assn. for Cancer Research that the statement in Chapter 101, Section 1, of U. S. Senate Bill 158, cannot stand up to the scrutiny of science. This section reads 'The Congress finds that present day scientific evidence indicates a significant likelihood that actual human life exists from conception.' The bill further proposes that the term 'person' shall include 'all human life.' These statements purport to derive their conclusions from science, but they deal with questions to which science can provide no answer.

"Defining the time at which the developing embryo becomes a 'person' must remain a matter of individual moral or religious values.

"The Association reaffirms support for the concept of utmost protection for human life, but recognizes major religious and ethical differences on the characterization of the onset of personhood.

"The membership expresses its concern that the Congress is attempting to define by legislation what constitutes science and what does not."

Michael Brennan, director of the Michigan Cancer Foundation, opposed the resolution. "I cannot lend my support to any resolution that denies that the fertilized human ovum is not a human life," Brennan

said. "It is life of some form, and cannot be other than human. This scientific society is not competent to determine what the extension of human life is."

A vote by a show of hands displayed very little support for Brennan's position, and most of the members present approved the resolution.

The American Society of Clinical Oncology heard without discussion a statement on a number of issues. Denman Hammond, chairman of the ASCO Public Issues Committee, presented the committee's recommendations, for consideration by the Society's Board of Directors:

—Endorsement, for transmission to Congress at appropriate times, renewal of the National Cancer Act and approval of adequate budgets for NCI.

—Endorsement of H.R. 2101, a bill that would provide 100 percent reimbursement by Medicare and Medicaid for anticancer drugs administered under proper supervision.

—Recommendation that physicians accept assignment of drugs at cost plus 10 percent.

—Provision to the membership of copies of correspondence from the HHS legal counsel on entitlement of patients to reimbursement for experimental anticancer drugs under certain conditions, with the intention that this be used to influence other third party payers.

—Continued opposition to the proposal for reimbursement for persons injured in clinical research.

—Opposition to House resolutions which would legalize laetrile, exempt blood products from FDA regulation, and restrict FDA to regulating for safety only, dropping the efficacy requirement for drugs.

ACS URGED TO SUPPORT MORE RESEARCH ON PSYCHOSOCIAL ASPECTS OF CANCER

A line item in the American Cancer Society budget for psychosocial research, core funding of specialized psychosocial research, and development of a needs assessment in the field were among recommendations of one speaker at the ACS sponsored National Conference on Human Values & Cancer.

Joseph Cullen, deputy director of the UCLA Jonsson Comprehensive Cancer Center, said that "because the American Cancer Society has always excelled in the tradition of service to the public, it is my bias that they should be the agency that champions the support of psychosocial cancer research and other activities to support that research. They can do so by considering implementation of the following:

"(1) Development of a consensus and systematic needs assessment for psychosocial research priorities over the next decade. Actually with the proposed working conference to be held this summer in Minneapolis on 'The Psychological, Social and Behavioral Medicine Aspects of Cancer: Research and Professional Education Needs and Directions for the 80s,' this recommendation will be implemented.

"(2) Establishment of a national advisory and review committee to prioritize research solicitations and review proferred proposals. The members of this committee should be experts in the broad dimensions of psychosocial research with a sprinkling of clinical and basic scientists from oncology and the life sciences to guarantee perspective and feasibility in the research objectives and designs.

"(3) Allocation of a line-item budget for the support of psychosocial research, the amount and distribution of such to depend on the needs assessment described under (1).

"(4) Core funding of specialized institutions which already have potential or demonstrated resources of excellence for psychosocial research.

"(5) Support of post-doctoral fellows in psychosocial research within institutions with the necessary resources and commitment.

"(6) Convention of state of the art conferences at periodic intervals to guarantee implementation of the advancements being made and their integration into cancer medicine as a whole."

Cullen said that "if one thinks of the cancer management spectrum as a horizontal vector in time, proceeding chronologically with interventions from prevention through detection, diagnosis, treatment, rehabilitation and continuing care, these interventions are vectors intersecting the management continuum and subtending a complex of psychosocial considerations, issues, needs, implications, and so forth, wherein the health care system and and public interface."

As an example, Cullen noted, "If 25 to 35 percent of cancer mortality in the U.S. male population and 5 to 10 percent in the female population (and increasing rapidly) are mainly due to the smoking of tobacco products and cigarettes; and if 3 percent of all U.S. cancers in 1974 were attributable to excessive alcohol consumption; and if at least 5 percent of all cancers can be accounted for by occupational exposures, one must recognize and seize the opportunity to support research and interventions to reduce these preventable relationships. I submit without qualification that most of the research/interventions here will emanate from the laboratories of the psychosocial scientist."

Jimmie Holland, chief of psychiatry service at Memorial Sloan-Kettering Cancer Center, discussed "The Humanistic Side of Cancer Care: Changing Issues and Challengers." A summary of her presentation:

"Biomedical research aimed at increasing survival from cancer has been the appropriate primary goal of those interested in cancer. Human values were regarded as intrinsic 'givens' in a caring medical community which required no special attention or dis-

crete focus. Human values and the 'human' morbidity of cancer were clearly 'everybody's business' but as such, they received little direct attention and suffered the consequences of becoming 'nobody's business.'

"Several issues, however, did receive attention in the 1960s. The consequences of surgical cancer therapy which resulted in colostomy, laryngectomy and finally, mastectomy, were highlighted by the American Cancer Society for training of nurses and for use of patient volunteers who had been through the experience and who could teach firsthand about adaptation to altered function. Reasons for delay, how to teach the seven danger signals of cancer, and whether to tell or not to tell the diagnosis of cancer, were additional subjects of study.

"The National Cancer Plan led to a mandate which demanded the 'transfer of new therapies and technology to the bedside.' The responsibility was given to the Div. of Cancer Control—with a task to apply current knowledge in prevention, screening, diagnosis, treatment rehabilitation and continued care. This mandate immediately brought study of how to bring new concepts of care to patients, and the behavioral, psychological, social and ethical issues were included in the domain of cancer control.

"This event resulted in the first support of psychosocial research, which was confounded by requirements to provide demonstration models as opposed to behavioral and psychosocial research; in addition, investigators in the field had to develop new assessment techniques appropriate to study patients with life-threatening illness; new multidisciplinary research groups had to be developed. The 1970s also saw changes in social attitudes which questioned the 'caring' side of medicine, demanded more participation of patients in their own care, and placed increased emphasis on the human and legal rights of patients.

"Psychosocial and psychiatric oncology have been the outcome of this new focal area in oncology. Emerging as accepted areas for scientific inquiry and for significant contribution to patient care, innovation and increasing higher quality research is evolving."

LAETRILE CLINICAL STUDY OFFERS SOLID EVIDENCE – THE SUBSTANCE IS USELESS

The NCI supported clinical study of laetrile, reported at last week's American Society of Clinical Oncology meeting, for the first time has provided definitive, clinical, scientific evidence that the substance is useless in the treatment of cancer patients.

Although laetrile proponents—those involved in the emotional "freedom of choice" issue and those who make money on it—indicated they do not agree with the validity of the study, the results may help to defuse the drive to legalize it.

The study was conducted at Mayo Clinic by Charles Moertel, UCLA Jonsson Comprehensive Cancer Center by Gregory Sarna; Univ. of Arizona Health Sciences Center by Stephen Jones; and Memorial Sloan-Kettering Cancer Center by Charles Young. Mayo coordinated the data from all four institutions with Thomas Fleming as statistician. Moertel presented the report at ASCO and fielded most of the questions at a press conference which followed.

Results are based on data from a core group of 156 patients of the 178 enrolled in the study. Of the remaining 22: 14 patients were recently placed on very high doses of laetrile and only preliminary data are available; one patient was considered ineligible because the initial diagnosis of cancer was not confirmed; four patients are currently being evaluated; and three others were not evaluable because one left the study after only eight days and two died within three days of starting treatment from causes not directly related to cancer.

The clinical trial with laetrile followed the same approach used by NCI to test other compounds for effectiveness in treating cancer. Criteria for selecting patients for the laetrile study were similar to the criteria used for all initial studies of other compounds. Informed consent was required.

The laetrile study included cancer patients for whom no other treatment had been effective, or for whom no proven treatment existed. All patients had tumor masses that could be regularly measured for growth or shrinkage by x-ray or other types of examination.

Laetrile was given to patients with a broad spectrum of tumors including the most common types of of cancer, such as lung, breast, and colorectal.

The great majority of the 178 patients entering the laetrile study were in good general condition. Seventy percent were able to work full or part time. None was totally disabled. Thirty-four percent had not received any previous chemotherapy. Median age of the patients was 57. One hundred men and 78 women were enrolled.

Treatment design for the trial was patterned after current laetrile usage—based on the writings of some laetrile practitioners and on direct consultation with several others. Laetrile was given for 21 days by intravenous injection at an average daily dose of 8 to 9 grams and then continued by mouth at a dose of 0.5 grams three times daily. Treatment was stopped if a patient showed progressive disease.

In addition, patients were treated with a so-called "metabolic therapy" program. The diet emphasized fresh fruits and vegetables and whole grains. It was severely restricted in meat, animal products, refined flour, refined sugar, and alcohol. Patients also received pancreatic enzymes and large doses of vitamins A, C, and E, as well as vitamin B complex and minerals.

During the study, patients were carefully monitored for side effects, especially for signs of cyanide toxicity. Levels of cyanide in the blood showed consistent elevations with the oral treatment. Usually these were within safe limits but occasionally were dangerously high. In one patient, treatment was discontinued for this reason.

Toxic effects noted in the study that may have been associated with treatment included nausea, vomiting, headache, dizziness, mental confusion, and skin rash. In the main, these were mild and subsided quickly when therapy was discontinued.

Moertel stated that some laetrile practitioners employ larger oral doses of amygdalin than that in the NCI-sponsored studies. Such practices, carried on outside a carefully monitored research study, must be considered extremely hazardous and carry a risk of producing fatal drug reaction.

Data based on the core group of 156 patients indicate the following:

- Within one month of beginning laetrile treatment 50 percent of the patients showed evidence of disease progression and 90 percent had progressed within three months.
- Fifty percent of the patients died before five months and only 20 percent were alive by eight months. (The survival experience would be consistent with that expected if patients had received no treatment.)
- Only one patient showed a partial reduction in tumor size. This persisted for only 10 weeks. Thereafter, the tumor progressed although the patient had continued on laetrile therapy. The remaining patients failed to improve. (Researchers generally expect to see a tumor regression rate of from 0 to 5 percent in studies in inactive drugs. In this study, the regression rate represented less than one percent of patients in the study.)
- From the standpoint of general benefits, six percent of the patients showed weight gain at some time during the study. Only three percent of the patients were still on therapy and maintaining weight gain at 10 weeks.
- In performance scores (a measure of patients' ability to be physically active), only six percent of the patients ever showed improvement and only three percent of the patients were still on therapy and maintaining this improvement at 10 weeks.

Among the 140 patients who had symptoms from their disease before laetrile therapy, 19 percent claimed improvement in how they felt at some time during the study; at 10 weeks, only five percent of the patients were still on therapy and claiming improvement in symptoms. This degree of symptomatic benefit is within the range of that anticipated with placebo (inactive medication) treatment.

"The findings of the laetrile tests with cancer patients present public evidence of laetrile's failure as a cancer treatment," NCI Director Vincent DeVita said. "The question of laetrile's effectiveness has been a significant public health issue for years. The hollow promise of this drug has led thousands of Americans away from potentially helpful therapy of scientific validity. Now the facts speak for themselves."

Moertel said in his presentation that amygdalin (the generic name of the drug) "in combination with so called metabolic therapy does not produce any substantive benefit in terms of cure or improvement of cancer per se, slowing the advance of cancer, improving symptoms or general condition of the cancer patient, or in terms of extension of life span.

"We fully realized as we began this study that if we achieved negative results, this would not be convincing to the laetrile zealots, but it was not our intention to convince the zealots. We do hope, however, that these results will be helpful to thoughtful cancer patients and their families as they consider therapeutic alternatives. Heretofore they have been badly confused. We also hope these results will be helpful to the physician as he counsels his cancer patients. Laetrile has been tested—it is not effective."

At a press conference following Moertel's presentation, Sydney Salmon told reporters that amygdalin was tested in the in vitro assay he and his colleagues have developed at the Univ. of Arizona. In 29 separate assays, it was inactive in all 29.

Asked whether he felt that patients still should have "freedom of choice," Moertel said, "Fine. I agree with freedom of choice but not with freedom to exploit desperate cancer patients."

A laetrile advocate at the press conference said that the amygdalin supplied by NCI for the trial was not the same formulation used by laetrile practitioners. Moertel displayed a statement by Ernest Krebs, foremost proponent of the drug as an anticancer agent who coined the name "laetrile" and registered it as the trade name for amygdalin. Krebs said in the statement that he was satisfied the amygdalin used by NCI was the same used by laetrile practitioners.

Another laetrile proponent insisted that "30,000 cancer patients" have been treated with laetrile, with "80 percent results."

If so, very few of them or the people who treated them responded to NCI's appeal in 1978 for data on cases of positive response to laetrile. Although the appeal was widely publicized and NCI sent out letters to over 450,000 individuals, only 93 cases were submitted for evaluation. A review by 12 clinical oncologists found four partial and two complete responses but could not verify whether laetrile was responsible for those responses.

The negative results from the clinical study, the retrospective analysis, the in vitro test, and extensive animal tests made over the years should be convincing enough to reasonable persons. Laetrile zealots are not reasonable; whether members of the

state legislatures, including the 23 which have legalized the substance, are reasonable remains to be seen.

A report on psychosocial attitudes of cancer patients treated with laetrile was presented at the ASCO meeting.

The study at the Univ. of Arizona Cancer Center, by Karen Redding, Larry Reutler, Stephen Jones, Frank Meyskens, and Tom Moon, found few differences between 17 patients who received laetrile and another 17 who received other phase 2 drugs as to clinical or demographic features, attitudes, expectancies, concerns, coping strategies, and levels of depression, anxiety, or stress.

There was a highly significant difference, however, in the patient-doctor relationship. Only two of the patients choosing laetrile said they had received emotional support from their physicians, whereas 59 percent of those receiving other drugs felt they had received such support from their physicians.

Most revealing, 76 percent of the laetrile patients had been told by their physicians "there was no hope—nothing left to be done." Only two patients in the control group had been told that by their physicians, although the nature and stage of the diseases and overall health status of the two groups were the same.

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-17494

Title: *Establishment and operation of rodent production centers for inbred and hybrid rodents*

Deadline: *Approximately June 16*

The animals will be produced under maximum barrier and modified conventional environmental conditions. NCI is seeking organizations with the capability and facilities for producing and supplying rodents primarily for hybrid mouse production and as hosts for maintaining experimental tumor lines. To be considered for award of a contract, respondents must meet the following criteria:

1. Have existing facilities for maximum barrier and/or modified conventional environmental conditions. 2. Principal investigator must have experience with animal production, inbreeding procedures and maximum barrier and/or modified conventional environmental conditions. 3. Organizational experience in the production of high quality laboratory animals.

A total of eight tasks is anticipated which will include cage levels of 2,000, 4,000, 7,000 and 8,000 cages. One task will include the requirement of a modified conventional facility. Another task will include the requirement of a physical location so that truck delivery is available to the NIH, Bethesda, Md. area.

Still another task will include a requirement of access to an international airport which can expedite animal shipments to the Philippine Islands, Japan and other Far Eastern areas. Finally, still another task will include the requirement for access to an international airport which can expedite shipments to Western European areas.

It is anticipated that multiple awards will be made as the result of this RFP. It is also anticipated that awards will be for a three year incrementally funded period of performance.

Contract Specialist: Charles Lerner
RCB Blair Bldg. Rm. 232
301-427-8737

RFP N01-CB-14351-40

Title: *Human tumor cell line bank for diagnostic studies*

Deadline: *June 22*

NCI is seeking an organization with the technical capabilities and interest in continuing the maintenance of a human tumor cell line bank, which carries over 200 cell lines of various neoplasms and distributes samples useful for research in cancer diagnosis, to investigators throughout the United States and abroad.

The organization must have the following: (1) experience and demonstrated proficiency in maintaining tumor cells in tissue culture; (2) the ability to freeze and retrieve viable tumor cells; (3) the expertise for characterization of established cell lines of human tumors and for sensitive detection of mycoplasma and other possible contaminants, and (4) adequate space and equipment to maintain the proposed resource.

A five year contract is anticipated.

Contract Specialist: Maria Valltos
RCB Blair Bldg. Rm. 332
301-427-8877

The Cancer Letter _Editor Jerry D. Boyd

Published fifty times a year by The Cancer Letter, Inc., P.O. Box 2370, Reston, Virginia 22090. Also publisher of The Clinical Cancer Letter.