DRS 8/1/83

THE CANCER LETTER

Vol. 9 No. 30
July 29, 1983

Subscription $125 year North America
$150 year elsewhere

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

NO DIET, NUTRITION, CHEMOPREVENTION CONCEPTS DUE FOR DRCCA BOARD IN OCTOBER, BUT MAYBE IN JANUARY

No new initiatives in diet and nutrition or chemoprevention will be presented to the Div. of Resources, Centers & Community Activities Board of Scientific Counselors for concept approval at its October meeting, but some may be ready for the Board's January meeting as DRCCA moves into implementation of plans it has developed for the two programs.

William DeWys, DRCCA associate director in charge of the Preven-

(Continued to page 2)

In Brief

MAUER TO LEAVE ST. JUDE FOR U. TENNESSEE AS CANCER PROGRAM DIRECTOR; HARVARD, MIT SHARE ACS AWARD

ALVIN MAUER, who said last year that 10 years as director of St. Jude Children's Research Hospital was all he thought he should serve and asked the institution's board to find a replacement, has accepted the position of chief of medical hematology and oncology and director of the Univ. of Tennessee Cancer Program at the university's Center for the Health Sciences in Memphis. The appointment will become effective next Jan. 1. Meanwhile, Mauer said he would remain at St. Jude until the new director has been appointed and is on board. . . . **AMERICAN CANCER** Society has awarded a $1 million special institutional grant to two teams headed by Brian MacMahon at Harvard and Gerald Wogan at Massachusetts Institute of Technology. MacMahon's epidemiologists and Wogan's genetic toxicologists will join forces to try to find out how cancer and genetic defects in humans are caused by environmental agents in the five year study. . . . **TWO PUBLICATIONS** produced by NCI's Office of Cancer Communications won first prizes in the 1983 Blue Pencil publications contest of the National Assn. of Government Communicators. "Young People with Cancer—A Handbook for Parents," written in cooperation with the National Candlelighters Foundation, won in one category; "Help Yourself—Tips for Teenagers with Cancer," produced in cooperation with Adria Laboratories, won in another category. The publications are among those distributed free by OCC. . . . **DENIS BURKITT**, the widely honored scientist who identified the cause of the lymphoma that bears his name and is now engaged in research on the assocation of diet and cancer, will present the annual Bernard Lee Schwartz Memorial Lecture at the Seventh Annual Scripps Cancer Symposium. The symposium, Oct. 31-Nov. 2, will include sessions on new concepts (tumor stem cell assay, monoclonal antibodies, NMR, lasers); GI, breast and gynecological cancer; hematologic malignancies; updates on testicular cancer, small cell lung carcinoma, and AIDS; and an overview of national cooperative group studies.

NUTRITION PROGRAM STRAYS FROM NCAB RECOMMENDATIONS, WITHOUT OBJECTIONS

(Continued from page 1)

tion Program, said that with the flurry of RFAs given concept approval at the last two meetings of the Board, proposals they have generated are moving through the system and are being or soon will be reviewed.

The need for more emphasis on diet and nutrition studies, and corresponding need for better planning and closer coordination of those studies, was pointed out in a report by an ad hoc committee of the National Cancer Advisory Board (***The Cancer Letter, May 28, 1982).***

DRCCA undertook the planning, with the help of Louis Carrese, NCI Associate Director for Program Planning & Analysis. The planning also included chemoprevention, which is a major program area under DeWys.

DeWys estimated that in the 1983 fiscal year, NCI would spend $37 million in the Diet, Nutrition and Cancer Prevention Program and Chemoprevention Program. That would increase to $50 million in 1984 and $60.7 million in 1985, DeWys said, with the qualification that the NCI budget and number and quality of grant applications could affect those numbers.

The NCAB recommendations included this statement:

The NCAB Ad Hoc Committee on Nutrition & Cancer recommends that the Board advise the director of the National Cancer Institute to give top priority to diet, nutrition and cancer research. The committee believes that an expanded effort in this field of research is necessary to increase the knowledge and understanding of such basic mechanisms as tumor promotion and anticarcinogenesis.

The committee came easily to the firm conclusion that the current NCI research emphasis in diet, nutrition and cancer is not sufficient.

Research in nutrition and cancer is at an evolutionary stage in its development. It needs to bring new sciences and scientists into the field and persuade them to apply their technologies to cancer research. It has to conceive and implement multidisciplinary research approaches and to prepare the way for community based trials of cancer prevention.

. . . Much of the grant supported research has the appearance of preliminary, exploratory inquiries. A more formal research plan is needed to capitalize on existing research and add to it.

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

The committee recommended that:

1. NCI earmark additional funds, specifically for diet and nutrition research related to cancer.

2. NCI should establish a time limited special administrative arrangement to plan and implement an NCI wide research program and recruit new scientific investigators into this field of research.

3. NCI should establish a special administrative arrangement to:

—Plan a comprehensive interdisciplinary research program.

—Prepare a research agenda.

—Inform the scientific community of the plan and the agenda.

—Provide sheltered peer review until the state of the art of nutrition research stabilizes.

There were some who saw some irony in the Board's recommendation to establish a "Nutrition Task Force" with "sheltered peer review," coming at a time when the Board was in the process of dismantling the Organ Site Program task forces and throwing their "sheltered peer review" to an uncertain reception by NIH study sections.

The difference, as Committee Chairman Maureen Henderson pointed out, was the "time limited" arrangement of the Nutrition Task Force. As it developed, however, there is not now a Nutrition Task Force and probably will not be one.

DeWys, in explaining implementation of the NCAB recommendation at the Board's May meeting, said that NCI staff working groups have been established which cross branch lines and division lines, for the diet and nutrition and chemoprevention programs. They meet monthly, with the chemoprevention group functioning as a "decision network" committee charged with the responsibility of deciding which compounds to move from one stage to another. The diet and nutrition group is serving now more as an information exchange forum.

So it is an NCI staff and not an external advisory group which is developing recommendations for submission to the boards of scientific counselors for concept approval. Ideas can and do come from outside scientists unsolicited and from workshops, however.

The Henderson committee seemed to have in mind for "sheltered peer review" a review group with expertise in nutrition which would have as its sole responsibility the review of diet and nutrition grants. And the committee explicitly asked for a dedicated amount of money to be set aside.

DeWys said he feels the RFA system "is in some ways sheltered." An RFA does earmark a maximum amount of money which may be used for first year funding of grants awarded as a result of that specific RFA. Also with an RFA, program managers can go 20 priority score points beyond the NCI wide cutoff to fund desirable grants, and they can go even further with the approval of the NCI Executive Committee.

Thus, if study section members happen not to favor some new approaches or work which does not coincide with their biases, NCI still may support projects staff deems desirable, with the concurrence of the NCAB.

When DeWys presented the plans to the NCAB,

there were no objections from Henderson or other Board members over deviations from the Board's recommendations.

DeWys noted that an old controversy which has long confronted NIH still has to be considered, and that a balance would need to be struck between investigator initiated research vs. research according to a preconceived strategy. Investigators are still free to submit R01 and P01 applications, in diet, nutrition, chemoprevention, or anything else, without responding to the RFAs which may be sent out.

Objectives of the Diet, Nutrition & Cancer Prevention Plan are:

1. Identifying and characterizing dietary factors with proven activity in preventing carcinogenesis in animals.
2. Identifying dietary factors based on epidemiologic studies.
3. Determination of acceptability and biochemical effects of dietary manipulations.
4. Phase III clinical trials of potential dietary factors.
5. Application of research results to the general population.

Boundaries of the plan are:

1. Include identifying food constituents and dietary patterns.
2. Include determining which are helpful and which are harmful.
3. Include determining changes and modifications to be made (production and formulation).
4. Include determining bioavailability.
5. Include elucidating metabolic and other host/-environmental interactions.
6. Exclude nutritional methods used in therapy such as hyperalimentation.

Objectives of the Chemoprevention Plan include:

1. Identifying and characterizing agents with proven activity in preventing carcinogenesis in animals.
2. Identifying agents based on epidemiologic studies.
3. Pharmacologic and toxicologic testing of such agents to select the most promising agents.
4. Phase III clinical trials of potential chemoprevention agents.
5. Application of result results to the general population.

Boundaries of the Chemoprevention Plan:

1. Exclude studies of mechanism of action of carcinogens and inhibition of carcinogenesis.
2. Focus on applied research concerned with identifying and characterizing agents with proven activity in preventing carcinogenesis in the laboratory and/or suggested by epidemiologic studies.
3. Include pharmacology and toxicology needed for clinical trials.
4. Include large scale intervention trials and application to population at large.

Human intervention studies are grouped into five stages for both chemoprevention agents and dietary factors:

Stage I: Select and Evaluate Potential Agents

Formulate a research and development plan for agents based on a review of clinical, laboratory, and epidemiologic investigations including ongoing research and published literature.

—Consider the agent's inhibitory potential and safety.

—Perform efficacy and toxicity studies as necessary.

—Evaluate agents identified outside the program as to appropriate entry points for the NCI program.

(The entry point into the NCI program is based on the extent to which program criteria are met.)

Stage II (Diet & Nutrition): Conduct Initial Feasibility, Efficacy, and Toxicity Testing

—Design experimental and control diets to accomplish stage II work.

—Determine whether the intake of these diets and their biochemical effects can be satisfactorily monitored.

—Establish efficacy of the experimental dietary factor or combinations of factors in at least one of a battery of model systems.

—Determine toxicity at levels required for inhibition.

—Determine the identity of the dietary factor.

—Determine the mechanism of action.

Stage II (Chemoprevention): Conduct Initial Efficacy and Pharmacology/Toxicity Testing

—Acquire and/or produce agent in sufficient amount to accomplish stage II work.

—Conduct pharmacology disposition studies in appropriate standardized systems.

—Establish efficacy of single agents or combinations of agents in at least one of a battery of model systems.

—Determine toxicity at levels required for inhibition.

—Determine identity of agent.

—Determine mechanism of action.

Stage III: Conduct Human Trials for Efficacy and Safety in Defined Populations

—Select study populations.

—Develop protocols considering agent's effectiveness, adverse effects, and safety.

—Perform ongoing analysis and evaluation to assure that side effects can be detected, remedial action can be taken, and trial can be terminated early if benefits of the intervention are established.

Stage IV: Conduct Research on Intervention for Target Populations

—Select study populations.

—Conduct research on methods for large scale applications of preventive measures.

—Develop strategies for implementing demonstration programs in target populations.

—Determine amount of agent required for demonstration programs.

—Re-evaluate available monitoring systems.

—Identify valid methods for outcome assessment.

Stage V: Implement Demonstration Programs in Target Populations

—Produce and formulate required amounts of preventive agents.

—Develop protocols.

—Conduct demonstration program in target populations.

—Monitor population receptivity to the intervention.

—Identify possible adverse effects.

—Establish followup procedures.

DeWys listed one further stage, VI, without elaboration—introduction to the general population.

The planners listed two stages for the epidemiology research flow:

Stage I: Identify Agents, Populations, and Natural Experiments for Further Study

—Review clinical, laboratory, and epidemiological investigations to determine inhibitory potential of agents.

—Identify appropriate populations for further study by means of descriptive studies using aggregate data and considering cancer incidence and mortality rates.

—Identify and study natural experiments.

a) Identify patterns of population intake of agent.

b) Examine the relationship between intake and subsequent cancer incidence and mortality rates.

Stage II: Refine and Test Hypotheses Regarding Agents in Target Populations Required for Case Control and Noninterventive Defined Population Studies.

—Conduct analytic epidemiologic studies, using combinations of case-control and prospective studies.

—Determine preventive effects, including those within important subsets of target populations (e.g., sex, age).

PROSPECTS FADING FOR FUNDING MORE CCOPs IN FY 1983; POSSIBLY IN 1984

The prospect of funding some additional Community Clinical Oncology Programs, above the 59 already awarded, appeared to be fading this week, at least for the 1983 fiscal year.

The staff of NCI's Div. of Resources, Centers & Community Activities had hoped to be able to make some additional awards to fill in geographical gaps, using the balance of the $10 million NCI had committed to the program. The 59, with their research bases, would use about $8 million, according to earlier estimates.

However, negotiations with the centers and cooperative groups which are participating as research bases have not been completed. DRCCA now feels that those costs will be somewhat higher than the previous estimates.

DRCCA also is taking a closer look at some of the budget cuts imposed by the review committees on several of the funded CCOPs. For some, the cuts may make it impossible for them to go ahead with the program, and DRCCA is considering adjusting their budgets upward. With budget adjustments and higher research base costs, the "extra" $2 million may dwindle considerably.

NCI can't carry forward into the 1984 fiscal year any of the $10 million not committed prior to Oct. 1, but there probably won't be anything left in the NCI budget anyway. Although Director Vincent DeVita did commit that amount to CCOP, where the entire amount would come from in the desperately hard pressed NCI budget had never been identified. If the total cost of funding the 59 programs does reach $10 million, DeVita will find it somewhere. And if it does not, NCI probably will fund a few more in the 1984 fiscal year, to reach the $10 million level.

NCI is not planning, at this time, to allocate more than $10 million to CCOP in FY 1984.

The issue of whether a few of the unsuccessful CCOP proposals will be rereviewed because of deficiencies in the first review still has not been settled. If they are and a new score pushes them into the funding range, they will be funded. It does not seem likely that that could be accomplished before the end of this fiscal year, however.

DRCCA has definitely decided it would ask the NCI Executive Committee to permit cooperative groups which are losing some of their cancer control outreach community satellite hospitals to CCOP to use that money to fund new satellites. DRCCA may insist that the new satellites be recruited from the ranks of approved but unfunded CCOPs.

NCI DEVELOPING POLICY ON RELATIONS BETWEEN INDUSTRY, DCT CLINICAL TRIALS

NCI's Div. of Cancer Treatment is in the process of developing a policy on relationships between the pharmaceutical industry and NCI supported clinical trials. A draft statement of the policy has been presented to the division's Board of Scientific Counselors and to cooperative group chairmen, and most agreed in principle, although one potentially complicated problem was pointed out.

Saul Schepartz, DCT deputy director, has been coordinating development of the policy. The draft statement follows:

"As a part of its mission of developing new cancer

therapies, NCI recognizes the importance of collaboration with the pharmaceutical industry in the clinical development of new anticancer agents. It is the policy of NCI that such collaboration should be fosteredwherever possible. The role of NCI in clinical drug development should be to serve as a catalyst, a coordinator, and a facilitator of research in new anticancer drugs and biologics. In addition to the goal of supporting clinical research for the purpose of developing new programs of cancer treatment, NCI recognizes that it shares with the pharmaceutical industry the important goal to conduct clinical trials which define the precise contribution of a new drug in the treatment of cancer. This policy statement pertains to research with drugs or biologics conducted within clinical trials cooperative groups supported by NCI.

"The following statements define the general terms under which this collaboration is taken.

I. INDs

"It is recognized that the needs of both NCI and the pharmaceutical firm are best served where each holds an IND. Therefore, it is expected that in most cases either NCI or the pharmaceutical firm will file an IND which references an IND or master file held by the other.

"In certain instances, and when mutually agreeable, clinical trials within cooperative groups may be conducted under the IND of the pharmaceutical firm. As a general rule, all information in INDs will be fully shared between NCI and the pharmaceutical firm. However, certain information pertaining to manufacturing processes may be held in confidence by the private sponsor. Nevertheless, all quality assurance data concerning the manufacturing process will be shared with NCI. NCI and the pharmaceutical firm will exchange all information submitted to its IND including but not restricted to protocols, annual reports, adverse drug reactions, and other materials. NCI will maintain the confidentiality of all materials derived from private sponsors' IND.

II. Clinical Trials – Planning, Protocols

"Wherever possible, the planning of the clinical phases of drug development should be a joint venture between the pharmaceutical firm and NCI. As stated above, NCI recognizes the need of a private sponsor to focus on clinical trials which lead to a new drug application. This goal is also important to NCI, since an NDA is the vehicle through which new drug therapies become widely available to cancer patients.

"In addition to areas of mutual clinical interest, NCI and the pharmaceutical firm may independently pursue clinical studies of particular interest to each. As a practical matter, this would involve meetings with the staff of the Cancer Therapy Evaluation Program to discuss clinical trial design strategy. There should be frequent and full interchange between staff members of CTEP and the private sponsor. Furthermore, the planning of a particular clinical trial should be a joint venture involving the cooperative group, the pharmaceutical firm, and NCI.

"All protocols for investigational drug research, regardless of the IND sponsor, will not be activated without review and approval by the Protocol Review Committee of CTEP. Protocols developed under NCI IND will be sent to the pharmaceutical firm at the time of submission for review and comment.

III. Resources Proved to Cooperative Group by Private Sector

"NCI supports and encourages pharmaceutical industry support of clinical research in cancer drug trials. Funds may be provided directly to the cooperative group. Funds provided to a cooperative group for additional monitoring beyond the standard practices of the group will be regarded as supplementary funding. In all cases, resources, financial or otherwise, provided to a cooperative group by a pharmaceutical firm should be a matter of record as described in Section V.

"Alternatively, other types of resources may be provided, such as support personnel to perform additional monitoring, computer resources, etc.

IV. Data, Rights and Confidentiality

"All data derived from clinical trials done by an NCI sponsored group will be made fully available to NCI. Similarly, this data will be fully available to the private sponsor. It is recognized that the data remains the property of the grantee.

"The grantee maintains the full right to publish the data at such time and place as he/she sees fit. When mutually agreeable, it is appropriate for manuscripts to have an advisory review by private sponsor prior to submission.

V. Cooperative Agreement

"Clinical trials conducted with agents from a pharmaceutical firm irrespective of IND sponsorship or funding arrangements should be included in the progress reports and competitive renewal applications of the group.

"Progress reports and renewal applications should clearly indicate the IND sponsor, if other than NCI, and the resources (funding, personnel, etc.) which have been provided by private sponsor."

Schepartz said that cooperative group members expressed concern about the reporting of resources provided by all sponsors.

"The problem is rather complicated," Schepartz said, "since it is essentially impossible to separate clearly resources provided by NCI vs. those from industry. In particular, the statistical and operations offices will be providing support to all studies, and we believe it would make no sense to attempt to segregate the costs of these activities, much less the activities of the various staff who may be involved with each protocol. Thus we felt that the best ap-

proach would be to consider all studies and all resources of the groups together. This, of course, becomes important in particular at the time of peer review when productivity must be evaluated as a function of available resources.

"The problem suggested by at least one of the groups," Schepartz continued, "is that the HHS auditors may not agree with this comingling of resources, in that it complicates the allocation of personnel costs, overhead, and probably other factors as well. We believe this point is well taken, and therefore we intend to initiate discussions as soon as possible with HHS auditors. We are anxious to develop final guidelines and hope we can resolve these issues before the end of the summer."

Schepartz noted that an NIH committee is considering overall guidelines for all institutes. "Although specific approaches currently followed by the individual institutes vary widely, it may be possible to develop general principles that will apply to all."

SELF TEST DETECTION MARKET LIMITED, BUT INCREASE SEEN FOR NEW TECHNOLOGY

A report from International Resource Development Inc., a Connecticut research firm, casts doubt on the growth potential of the market for self test cancer detection devices. But the report forecasts strong sales of simplified digital x-ray and ultrasound systems to physicians and physician groups; predicts a "new wave" of imaging equipment sales to hospitals; and suggests that a single "super system" will combine different imaging technologies.

An announcement from the company summarized the report:

"Faberge and BCD Products are both marketing inexpensive devices which rely upon thermography to detect possible breast cancer in women (the devices fit inside a bra, and provide a profile of the heat emission pattern from the skin). However, these devices are currently available only through a physician's prescription; and the Food & Drug Administration is probably not going to hurry to provide approval for direct marketing to the public on a nonprescription basis. FDA has doubts about the efficacy of the devices, and also about the users' ability to interpret the results obtained from them.

"Although most medical imaging systems bought today are large and expensive (up to $2 million each) and are bought by hospitals, the IRD study predicts strong future sales of simplified digital x-ray systems, as well as ultrasound systems, to individual physicians and physician groups. The productivity and precision of these imaging systems will be enhanced by interfaces to advanced microcomputers, such as the IBM PC-XT, which will assist both with the image processing and with the diagnosis.

" 'Physicians have discovered that there are big profits to be made from straightforward imaging electronics,' according to Lawrence Gasman, a consultant on the IRD research team. 'The trend is for physicians to acquire modestly priced imaging equipment, and to handle as many patient tests as possible on these systems—they can be real money machines for the physicians.'

"Meanwhile, in the hospital segment of the market, a 'new wave' of imaging equipment sales is forecast, with particular emphasis on digital x-ray systems and nuclear magnetic resonance equipment. Long term, the trend will be towards the 'imaging center of the future,' in which a single super-system will combine several different types of imaging technologies (x-ray, NMR, ultrasound, etc.) coupled with very advanced and powerful image-processing computers.

"The medical imaging business is a risky one. Apart from some x-ray equipment, the market for equipment that is other than state of the art is small. Therefore, companies must invest large sums of money in research and development activity. Also, the industry appears to have something of a history of unfulfilled expectations with regard to new technologies. For example, CT scanning has matured much faster than most observers expected as new imaging technologies have emerged. In addition to expenditure on R & D are the financial and other types of resources that must be devoted to training a highly educated and highly paid sales force; the cost associated with regulatory activity; and the certification of equipment by FDA and others. The result of all this is that it is a difficult market for many smaller companies to enter—one false move by such a company could prove fatal.

"Nevertheless, small companies do compete in the medical imaging market. However, much of the action goes not just to big companies but to multinationals and their subsidiaries who are active in numerous other areas of electronics. These include not only American companies such as General Electric, but giant European companies, such as Siemens, and Japanese electronics companies, such as Toshiba. Smaller U.S.-based firms which have recently had success in the medical imaging field include ADAC Laboratories, Diasonics, Omnimedical, and Xonics. Medical imaging equipment can bring substantial profits to the vendor, not only from the initial sales of the equipment but also from servicing, sales of add-ons and supplies."

The report estimates that convention and digital x-ray equipment, including fluoroscopy and angiography, will total $1.12 billion in sales in 1983 and will more than double, to $2.61 billion in 1993. Sales of CT scanners will drop, from $310 million this year to $150 million in 1993; nuclear medicine, from $180 million to $155 million; NMR, from $60 million to $70 million, and thermography, from $20 million to $30 million.

International Resource Development Inc. is a 12-

year-old research firm which specializes in the analysis of new technological advances and their commercial implications. A free description and table of contents for the $1,285 report (No. 562) on "Medical Imaging Markets" are available from IRD at 30 High St., Norwalk, Conn. 06851; phone 800-243-5008. In Connecticut or outside the U.S. call 203-866-6914; telex 64 3452.

NCI ADVISORY GROUP, OTHER CANCER MEETINGS FOR AUGUST, SEPT., FUTURE

Fundamental Tumor Registry Operations—Aug. 1-4, Memphis, Methodist Hospital School of Nursing. Contact Sue Sumner, phone 901-726-7780.
American Society for Pharmacology & Experimental Therapeutics—Aug. 7-11, Philadelphia. Contact Dr. Warren S. Chernick, ASPET '83, Hahnemann Univ., Broad & Vine Sts., Philadelphia 19102.
Interageancy Collaborative Group on Environmental Carcinogenesis—Aug. 10, NIH Bldg 31 Rm 4. Contact Dr. Herman Kraybill, phone 301-496-1625.
National Cancer Advisory Board Committee on Activities & Agenda—Aug. 11, Fred Hutchinson Cancer Center, Seattle. 2 p.m., open.
Oncology in 1983—Aug. 16-19, Norris Cotton Cancer Center, New Hampshire. Contact Jane Bassick, Projects Coordinator, NCCC, Dartmouth-Hitchcock Medical Center, Hanover, N.H. 03756, phone 603-646-5546.
Expanding the Capabilities of the Tumor Registry: A Collaborative Effort—Aug. 17-19, Tampa Marriott Hotel.1983 Florida Registry Workshop. Contact Florida Cancer Council, 1001 S. MacDill Ave., Tampa 33609, phone 813-253-0541.
2nd International Congress of Reproductive Immunology—Aug. 18-20, Kyoto, Japan.
Early Breast Cancer Detection/Nutrition & Cancer—Aug. 19, Denver. Contact Ms. Midge Cullis, Director of Professional Education, American Cancer Society, 1809 E. 18th Ave., Denver 80218.
5th International Congress of Immunology—Aug.21-27, Kyoto. Contact Japanese Society for Immunology, Inst. of Virus Research, Kyoto Univ., Kawaracho Shogoin, Sakyo-ku, Kyoto 606, Japan.
Viral Oncogenesis, Cellular Interactions, Cancer Biology, Immunology, Treatment—Aug. 22-26, New London, N.H. Contact Dr. Alexander Cruickshank, Gordon Research Conferences, Colby-Sawyer College, New London 03257, phone 603-526-2870.
Biology & Epidemiology Contract Review Committee—Aug. 24, NIH Bldg 31 Rm 2, open 9-9 a.m.
13th International Conference of Chemotherapy—Aug. 28-Sept. 2, Vienna. Contact Prof. Dr. K. Karrer, President, Institute for Cancer Research, Univ. of Vienna, Borschkegasse 8a, A-1090, Vienna, Austria.
Radiolabeled Cellular Blood Elements: Achievements, Challenges, & Prospects—Aug. 29-Sept. 9, Maratea, Italy. Contact Prof. M.L. Thakur, Div. of Nuclear Medicine, Dept. of Radiation Therapy & Nuclear Medicine, Thomas Jefferson Univ. Hospital, 11th & Walnut Sts., Philadelphia 19107.
2nd International Conference on Gynecologic Cancer—Aug. 30-Sept. 2, Edinburgh, Scotland. Contact Dr. Paul Morrow, Women's Hospital, 1240 N. Mission Rd., L903, Los Angeles 90033, phone 213-226-3397.
NCAB Committee on Cancer Control & the Community—Sept. 2, Chicago, site to be announced.
8th International Meeting on N-Nitroso Compounds—Sept. 4-9, Banff, Canada. Contact International Agency for Research on Cancer, 152 cours Albert-Thomas, 69372 Lyon Cedex 08, France.
European Congresses of Radiology, Radiotherapy, and Oncology—Sept. 5-10, Bordeaux. Contact P.M.V., Congres de Radiologie, 100 avenue Charles de Gaulle, B.P. 246, 92205, Neuilly Sur Seine, France.
2nd International Workshop on Design & Application of Tumor Prostheses for Bone & Joint Reconstruction—Sept. 5-8, Vienna. Contact Secretariat, Workshop, Wiener Med. Akademie, Alserstr. 4, 1090 Vienna, Austria.
Progress and Controversies in Oncological Urology—Sept. 8-10, Noordwijkerhout, The Netherlands. Contact Prof. Dr. F.H. Schroder, Dept. of Urology, Erasmus Univ., PO Box 1739, Rotterdam.
11th Annual Meeting of the International Society for Oncodevelopmental Biology & Medicine—Sept. 11-15, Stockholm. Contact ISOBM Congress, c/o RESO Congress Service, S-10524, Stockholm.
Breast Cancer Task Force—Sept. 12-14, NIH Lister Hill Center, 8:30 a.m. each day. Presentations Sept. 12 on new methods for early detection and diagnosis of breast cancer. The Task Force will consider new initiatives in breast cancer on Sept. 13 and 14.
International Conference on Cutaneous Oncology—Sept. 12-16, The Hague, The Netherlands. Contact Dr. Richard Dobson, Dept. of Dermatology, Medical Univ. of South Carolina, Charleston, S.C. 29425.
International Congress of Urological Cancer—Sept. 14-16, Sydney, Australia. Contact Dr. Derek Raghavan, Conference Secretary, Ludwig Institute, Univ. of Sydney, Sydney 2006.
International Symposium on Human Choriogonadotropin—Sept. 15-16, Cassis, France. Contact Secretariat, Laboratoire de Hormones Proteiques, Faculte de Medicine, F-13385 Marseille Cedex 5, France (91) 78 68 55.
Third National Seminar on Community Cancer Care—Sept. 16-18, Hyatt Regency, Indianapolis. Contact Office of Continuing Medical Education, Methodist Hospital of Indiana, 1604 N. Capitol Ave., Indianapolis 46202.
2nd International Conference on Hormones & Cancer—Sept. 18-23, Monte Carlo. Contact Dr. S. Iacobelli, Laboratorio de Indocrinologia Molecolare, Universita Cattolica del S. Cuore, Largo Gemelli 8, 00168 Rome, Italy.
UICC Latin American Conference on Clinical Oncology—Sept. 18-22, Lima, Peru. Contact E. Caceres, Inst. Nacional de Enfermedades Neoplasicas, Av. Alfonso Ugarte 825, Lima.
Soft Tissue Tumor Symposium—Sept. 19-21, New York. Contact Dr. Steven Hajdu, Dept. of Pathology, Memorial Sloan-Kettering Cancer Center, 1275 York Ave., New York 10021.
European Assn. for Cancer Research—Sept. 19-21, Copenhagen. Contact Dr. J. Kieler, Danish Cancer Society, Lab. of Environmental Carcinogenesis, Ndr Frihavnsgard 70, DK-2100, Copenhagen O, Denmark.
9th European Congress of Pathology—Sept. 19-24, Hamburg, Germany. Contact Hamburg Messe und Congress GmbH, Cong. Orgn., Postfach 30 23 60, 2000 Hamburg 36, Fed. Rep. Germany.
NCI Div. of Cancer Cause & Prevention Board of Scientific Counselors—Sept. 14-15, NIH Wilson Hall, 9 a.m. both days; closed Sept. 14 9 a.m.-noon.
American College of Epidemiology-Centers for Disease Control—Sept. 22-23, Atlanta. Annual meeting. Contact Dr. Philip Brachman, CDC, 1600 Clifton Rd. NE, Atlanta 30333.
6th Annual Diagnostic Cytopathology Course—Sept. 22-24, New York. Contact Marilyn Black, Course Secretary, Cytology Services, Memorial Sloan-Kettering Cancer Center, 1275 York Ave., New York 10021.

4th National Conference on Cancer Nursing—Sept. 22-23, Anaheim, Calif. Contact Marian Frerichs, Programs Committee, American Cancer Society, 777 Third Ave., New York 10017.
Modifiers of Carcinogenesis—Sept. 22-23, Copenhagen. For information, see above under European Assn. for Cancer Research.
4th Asian & Australian Conference of the International Society of Radiographers & Radiological Technicians—Sept. 22-26, Yokohama. Contact L. Morimoto, Japan Assn. of Rad. Techn., 1-26-27 Shinkawa Chuo-Ku, Tokyo 104, Japan.
2nd Annual Antibody Techniques Workshop—Sept. 23-25, East Lansing, Mich. Contact Joan Allam, Michigan State Univ., College of Human Medicine, phone 515-353-7822.
Joint Autumn Meeting of the Royal College of Radiologists—Sept. 23-24, Liverpool. Contact British Institute of Radiology, 36 Portland Pl., London W1N 3DG, UK.
American Assn. of Oral and Maxillofacial Surgeons—Sept. 23-27, Las Vegas. Contact B. Degen, AAOMS, 211 E. Chicago Ave., Suite 930, Chicago 60611.

Sexuality & the Cancer Patient: Nurse, Where Are You?—Sept. 24, Widener Univ., Chester, Pa. Contact Vivan Middleman, Widener Univ. School of Nursing, Pennsylvania Campus, Chester 19013.
American College of Radiology—Sept. 26-29, Denver. Annual meeting. Contact S. Aubin, ACR, 20 N. Wacker Dr., Rm 1660, Chicago 60606.
6th Asia-Pacific Cancer Conference—Sept. 27-30, Sendai, Japan. Contact Conference Secretariat, Japan Convention Services, Nippon Press Center Bldg, 2-2-1, Uchisaiwaicho, Chiyoda-ku, Tokyo 100, Japan.
Hematological Histochemistry Meeting—Sept. 27-29, Cambridge, UK. Contact Royal Microscopical Soc., 37/38 St. Clements, Oxford OX4 1AJ, UK.
NCI Div. of Cancer Treatment Board of Scientific Counselors—Sept. 29-30, NIH Bldg 31 Rm 10, 8:30 a.m. both days, closed Sept. 29, 5 pm-adjournment.
Nutrient Data Base Applications—Sept. 29-30, Marriott Hotel Astrodome, Houston. Contact Jeff Rasco, Conference Services, HMB Box 131, UT M.D. Anderson Hospital, 6723 Bertner Ave, Houston 77030, phone 713-792-2222.

FUTURE MEETINGS
Forum for Death Education & Counseling—Oct. 20-23, Holiday Inn Mart Plaza, Chicago. 6th annual conference. Contact Vickie O'Sullivan, Continuing Education, Rush-Presbyterian-St. Luke's Medical Center, 600 S. Paulina, Chicago 60612, phone 312-942-7095.
Childhood Cancer: Current Controversies—Nov. 17-19, Caribbean Gulf Resort Hotel, Clearwater Beach, Fla. Contact Cindi Butson or Randy Kraft, Seminar Coordinators, Florida Assn. of Pediatric Tumor Programs, PO Box 13372, Gainesville 32604, phone 904-375-6848.
Clinical Cancer Chemotheraphy—Dec. 12-16 in Delhi, India, and Dec. 18-22 in Madras, India. Postgraduate courses sponsored by UICC. Contact David Reed, UICC, 3 rue du Conseil-General, 1205 Geneva, Switzerland.
Cancer and AIDS—March 2-3,1984,Sheraton Palace Hotel, San Francisco. 19th annual San Francisco Cancer Symposium. Contact West Coast Cancer Foundation, 50 Francisco St. Suite 200, San Francisco 94133.
National Tumor Registrars Assn.—May 15-18, 1984, Chicago. 10th annual meeting. Contact Suzanna Hoyler, PLrogram Chairman, American College of Surgeons, 55 E. Erie St., Chicago 60611.

RFPs AVAILABLE

Requests for proposal described here pertain to contracts planned for award by the National Cancer Institute unless otherwise noted. NCI listings will show the phone number of the Contracting Officer or Contract Specialist who will respond to questions. Address requests for NCI RFPs, citing the RFP number, to the individual named, the Blair building room number shown, National Cancer Institute, NIH, Bethesda, MD. 20205. Proposals may be hand delivered to the Blair building, 8300 Colesville Rd., Silver Spring, Md., but the U.S. Postal Service will not deliver there. RFP announcements from other agencies will include the complete mailing address at the end of each.

RFP NCI-CM-37622-19
TITLE: Study of the clinical pharmacokinetics of anticancer drugs
DEADLINE: Approximately Sept. 1

The Cancer Therapy Evaluation Program, Div. of Cancer Treatment, NCI, is seeking organizations with capabilities and facilities to collect pharmacokinetic data on new and established antitumor agents in patients undergoing treatment for malignant disease during phase I studies in order to help establish the most effective dosage schedules.

This project will be primarily concerned with the measurement of drug and/or metabolite(s) levels in the plasma, tissues, urine, and feces in order to determine the distribution, metabolism and elimination as well as the absorption if the drug is administered orally to patients. Measurement of the bile should be done when possible and measurement of other fluids (e.g., cerebrospinal fluid) may be necessary.

The apparent volume of distribution and plasma protein binding shall also be measured. The drug and/or metabolite(s) levels shall be determined with time (mg/ml x min) after standardized doses (expressed as mg per square meter of body surface area) and routes of administration of the drug on different schedules.

Approximately 30 patients per drug will be required to provide adequate statistical documentation of individual variability in pharmacokinetic behavior. Approximately two drugs will be evaluated annually and these shall be selected by NCI program staff.

The analytical methodology for the measurement of the drug and/or metabolite(s) in body fluids and tissues shall be the responsibility of the contractor, although it will be provided, if available, for specific drugs by NCI. The method which is developed will be concerned with recovery, specificity, sensitivity and reproducibility.

One organization will be selected for award of this project. The contract will be for a period of three years. The project will require approximately 8,400 professional hours, which shall include MDs, PhDs, and laboratory technicians.
CONTRACT SPECIALIST: Kristina Mott
RCB, Blair Bldg. Rm. 228
301-427-8737

The Cancer Letter _Editor Jerry D. Boyd
Published forty-eight times a year by The Cancer Letter, Inc., P.O. Box 2370, Reston, Virginia 22090. Also publisher of The Clinical Cancer Letter.