THE CANCER LETTER
RESEARCH EDUCATION CONTROL

Vol. 4 No. 5
Feb. 3, 1978

P.O. BOX 2370 RESTON, VIRGINIA TELEPHONE 703-620-4646

Subscription $100 per year

KENNEDY PLANS ONE YEAR ACT RENEWAL, FOLLOWED BY THREE YEAR BILL; HEARING SCHEDULED FEB. 8

Sen. Edward Kennedy has scheduled a hearing before his Senate Health Subcommittee on a one-year renewal of the National Cancer Act, along with other NIH research authorities, for Feb. 8, 9:30 a.m., in the Dirksen Senate Office Bldg., Room 4232.

Kennedy plans for the second consecutive year to seek only one year

(Continued to page 2)

In Brief

AMES TEST PINPOINTS PICKLES, CIGARETTES; AACR MAJORITY SUPPORTS CANCER CONGRESS

MUTAGENICITY TEST developed by Univ. of California biochemist Bruce Ames is becoming widely used as a means to check out etiological leads, possibly help in finding biological markers for screening. R.W. Miller, chief of NCI's Clinical Epidemiology Branch, told the National Cancer Advisory Board that the Ames test was used to identify pickles as a prime suspect in the high rate of esophageal cancer in certain regions of China. The Chinese, who have a high rate of lung cancer, argue that their cigarettes do not cause that disease. Chinese cigarettes were run through the Ames test and found to be as mutagenic as Japanese brands, Miller said. Charles Irving reported at the recent bladder cancer screening conference that, in the desperate search for biological markers and immunological detectors, the Ames test has been used to determine the mutagenicity of urine. There is a marked difference in the mutagenicity of urine from smokers as compared with non smokers, with that of the smokers significantly higher, Irving said. . . . **AMERICAN ASSN.** of Cancer Research polled its membership on the issue of whether they should attend the XIIth International Cancer Congress in Buenos Aires. A majority responded that they would go if they had the opportunity, despite the charges of terrorist activities against scientists in Argentina. . . . **NEW PUBLICATIONS:** "Breast Cancer Research," edited by Michael Brennan, and "Public Education About Cancer—Recent Research and Current Programs," edited by John Wakefield, have been published by UICC. Brennan's book developed from a workshop on breast cancer held in Geneva; Wakefield's is a collection of papers from seven countries. Single copies are available free from Managing Editor, UICC, Conseil-General 3, 1205 Geneva, Switzerland. A handling charge will be made for more than one copy. . . . **UICC ALSO** plans to update its International Directory of Specialized Cancer Research & Treatment Establishments, published in 1976. Information on nearly 500 centers in over 80 countries was compiled under the guidance of R. Lee Clark of the U.S. and S. Eckhardt of Hungary. Those who were left out of the first edition and would like to be included in the new edition should write to D.W. Reed, Directory Project, UICC, address as above.

ACCC MAKES PITCH FOR MORE NCI MONEY, INCREASED SUPPORT FOR COMMUNITIES

(Continued from page 1)

to seek only one year renewals for the Cancer Program and other NIH research, with no major changes. He intends to introduce additional legislation, probably in the spring, to renew the Cancer Act for three more years, and it is in this legislation that any substantive changes will be considered.

The one year renewal, for the 1979 fiscal year, will authorize a spending level of $1.01 billion for NCI (NCI has requested $1.036 billion, and the Administration requested $878.8 million).

Only Administration witnesses will be heard Feb. 8.

Kennedy does not intend to permit significant revisions of the Cancer Act in the one year renewal but may go along with some of the requests submitted by the National Cancer Advisory Board last year which were not included then in the one year extension that covered FY 1978. One such change that could go in now would be authorization for NCI to distribute reference chemicals free to grantees for carcinogenesis research.

Congressman Paul Rogers, chairman of the House Health Subcommittee, has not yet scheduled hearings on Cancer Act renewal or other biomedical research authorizations. Rogers is reported also to favor a one year extension now to be followed this year with a three year renewal.

Meanwhile, both opponents and advocates of the Cancer Program are beginning to put together their respective plans for killing, gutting, saving or enhancing the National Cancer Act. Opponents, some of them within the Administration and within NIH, reportedly are preparing a case to drop the Cancer Act completely and bring NCI back to the level of all other NIH institutes. Failing that, they will settle for taking away NCI's semi-independent budget authority, in which its budget requests go directly to the White House without being altered by NIH or HEW.

Various other authorities NCI has under the Act which are threatened include most of the key provisions in the Cancer Act—cancer center support (although the PHS Act does provide authority for centers), cancer control, the President's Cancer Panel, expanded information program, nutrition research, large scale production and distribution of biological materials and other therapeutic substances, support for cancer research outside the U.S., special manpower programs, the National Cancer Advisory Board with its grant review and advisory responsibilities, use of expert consultants by NCI and construction support grants.

Cancer Program advocates will argue to retain all those authorities and probably to add a few more.

The Assn. of Community Cancer Centers, which held its annual meeting in Washington last weekend, descended en masse on their congressmen, senators and Capitol Hill staff members Friday to present their suggestions for cancer legislation.

ACCC members first made a pitch for $250 million above the President's request of $878 million for NCI in FY 1979. Then they argued for continued support of comprehensive cancer centers, asked that Congress earmark appropriations for cancer control programs from centers, asked that two members of the National Cancer Advisory Board come from the ranks of community physicians who treat cancer patients, and pleaded for long term support of cancer control programs rather than consider them demonstrations with short term funding.

Following is ACCC's official position on the National Cancer Act:

1. We are beginning th see solid results in better patient treatment because of the passage of the National Cancer Act in 1971. We hope Congress will not delay in passage of another three year renewal with significant increases in overall funding. Now, seeing real progress, is not the time to slow down a good program. We recommend an additional $250 million be appropriated to exploit the recent breakthrough in clinical treatment.

2. We need a source for continual up-to-date education on new treatment methods for our patients. The comprehensive cancer centers, with scientists involved in the latest patient research, are the best source of this information. We hope Congress will continue to support the current centers, consider creating new ones, and designate specific appropriations for cancer control programs from cancer centers in its new budget. Our patients and your constituents desire the best care available.

3. The community physician is the ultimate recipient of much of the information on better treatment for cancer patients. NCI and the National Cancer Advisory Board need community input. We suggest Congress amend the National Cancer Act, designating two of the 18 National Cancer Advisory Board members as "community physicians actively engaged in the treatment of cancer patients." This will insure solid community input into NCI's outreach efforts.

4. Many good Cancer Control Programs are established, tested, proven, and then dismantled after they have been "demonstrated" as effective. We hope Congress will consider long-term support rather than just demonstration.

Following is the resolution on renewal of the Act approved by ACCC:

The Assn. of Community Cancer Centers Board of Trustees and House of Delegates recommend to Congress the following changes in the National Cancer Act:

1. Renewal of the National Cancer Act . . . from FY 1978 to 1981, during this session of Congress.

2. That in its "Findings and Declaration of Purpose" the Congress add after SEC. 2(b):

SEC. 2(c): "It is the purpose of this Act to encourage the continuing transfer of new knowledge to the public and to the community health providers who care for 85% of cancer patients."

Rationale: The association believes that the first five years of the National Cancer Act has shown that a major role of the National Cancer Program is the dissemination of new knowledge into the hands of community physicians who care for 85% of cancer patients. We recommend that this role be recognized.

3. That, to Congress' description of the duties of the director of the National Cancer Institute be added [after SEC. 407 (b) (9)] a new duty:

(10) "Support appropriate educational programs to community physicians and the public providing them with continuous information on cancer prevention, detection, diagnosis, treatment, and rehabilitation techniques."

Rationale: New techniques in cancer care are continually being proven effective. This new information needs to be provided to community physicians and the public on a regular basis. This is not the case now. Many programs which have been developed to "demonstrate" educational techniques have been dismantled after they have been proven effective. In the meantime, new techniques have been discovered and not conveyed to the community. With cancer research progressing at a faster pace, our patients should be assured their physicians are continually being kept up-to-date.

4. That in its description of the "National Cancer Research and Demonstration Centers" the Congress amend SEC 408 (b) clarifying their description of: "(4) demonstration purposes" by adding the following wording: "(4) programs to demonstrate to physicians and the general public new techniques in cancer care."

Rationale: The centers remain the major source of new information to community physicians and the public. Findings of their efforts to educate community physicians and inform the public has been erratic. The association believes that Congress' intent was that the techniques be demonstrated, not the programs. With rapid changes in the technology of cancer care, established continuing programs are a necessity. Likewise, the centers are a source of information on care and resources to the public in their regions. This role should be continued and expanded.

5. That in its authorization of funds for "Cancer Control Programs," the Congress will restate its intent that the Cancer Control Program be used to speed up the transfer of life-saving treatment techniques and technology from the primary centers of excellence to the community physicians who are actively involved in the treatment of cancer patients. We believe to accomplish this without undo waste of time or money the major portion of Cancer Control funds should be channeled to the primary centers and to those secondary centers that are responsible for the development of new technology, the education of community physicians, and the lives of many, many cancer patients.

MAN ACCUSED OF PAYOFFS TO FLOOD SOUGHT NCI CONTRACTS IN 1973, 1975

Murdock Head, who was accused by a former aide of Congressman Daniel Flood (D.-Pa.) of making payments to Flood for assistance in getting government contracts, twice submitted unsolicited proposals to NCI for extensive film production contracts.

Both were turned down by NCI. In neither case, according to NCI records of congressional inquiries, which are maintained in detail, did Flood or any member of his staff attempt to intercede on Head's behalf.

Head first presented a proposal to NCI's Office of Cancer Communications in 1973 for a project involving development of a "film bank"—footage of cancer research and control projects which could be put together later for educational purposes. Head asked that a Sole Source contract be awarded. Head again made a proposal in 1975, also asking for a sole source award. NCI decided that sole source-ing was not justified for either proposal. In any case the projects were rejected because of funding limitations.

Unsolicited proposals in which the proposer seeks to get the job without being required to compete for it are prime candidates for influence peddling. The records show that in this case, for one, Flood made no effort on Head's behalf.

Flood denied all the charges made by his ex-aide, Stephen Elko. Elko was convicted last year of bribery charges. An affidavit filed in U.S. District Court in Los Angeles by Asst. U.S. Attorney David Hinden says Elko charged that he and Flood received $77,000 from Head between 1971 and 1973 in exchange for the congressman's assistance in securing government funds for a conference center in which Head has an interest. Flood allegedly got $59,000 and Elko $18,000.

The conference center is the Airlie House, in Warrenton, Va. NCI conducted the initial planning conference implementing the National Cancer Act of 1971 at the Airlie House in late 1971. Other NCI sponsored meetings have been held there. It is a first rate conference center. Head is the executive director of the nonprofit foundation which runs it.

Other charges of payments to Flood for intervention with government agencies were made by Elko in the affidavit.

Flood issued a statement denying Elko's allegations. "I emphatically state that these allegations are

not true and I have no further comment on the situation at this time," Flood was quoted as saying by *The Washington Post.*

Head also denied the charges. According to the *Post,* Head said, "The Airlie Foundation has made no contributions to any elected official, political party or political campaign. There have been no requests for assistance in return for support from any members of Congress or their representatives."

NCI TAKES ON TWO HOT ISSUES; MOERTEL ARGUES FOR LAETRILE CLINICAL TRIAL

NCI announced last week that it is undertaking two major retrospective studies which hopefully will provide some answers in two controversial issues—saccharin and laetrile.

Deputy Director Guy Newell is heading up both efforts. The saccharin study will involve interviews with 3,000 recently diagnosed bladder cancer patients and 6,000 randomly selected healthy persons living in the same areas. The study will make use of the population based cancer registries in Connecticut, Iowa, New Mexico, Utah and the metropolitan areas of Detroit, San Francisco-Oakland, New Orleans and Atlanta which are already participating in NCI's SEER Program. New Jersey will be included because it has the highest bladder cancer rate in the U.S.

Newell also is in charge of the retrospective study of cancer patients who who were treated with laetrile (***The Cancer Letter,*** Jan. 27). That study was attacked by Charles Moertel, director of the Mayo Comprehensive Cancer Center, in an article in last week's issue of the *New England Journal of Medicine.* An article by Newell in the same issue explained NCI's position.

Moertel, arguing for a clinical trial, wrote:

"The laetrile problem can only be successfully combatted if we fight on familiar grounds, using the tools we have known to be most trustworthy: a tightly controlled clinical trial performed in competent and experienced hands. This approach seems most ethical, and more important, it seems almost humane. . . . The case history review type of study proposed by NCI seems doomed to failure. No clinical pharmacologist would accept such evidence for the effectiveness of a drug."

NCI's position has been that any trial using humans, before any evidence at all that the substance has any anticancer activity, would be unethical.

Moertel proposes that only those patients who have received existing therapies be permitted to participate.

FDA Commissioner Donald Kennedy said that no information obtained through the study would be used against any physician or patient who might have violated the law in obtaining, using or administering laetrile.

NCI MUST PLAY MORE VIGOROUS ROLE IN PREVENTION, UPTON TELLS ACCC

"Prevention (of cancer) is happening and is saving lives but must be made more effective through intervention and avoidance," NCI Director Arthur Upton told members of the Assn. of Community Cancer Centers, speaking on "The National Cancer Institute: Future Directions."

"NCI must play a much more vigorous role in prevention," Upton said, "through research, education, demonstration, coordination with and support of regulatory agencies." Suggesting that the individual can do much to help himself in cancer prevention, Upton said "the strong cause and effect relationship of cigarette smoking and cancer is known. There is room for strong leadership here, and I'm delighted that (HEW) Secretary Califano has taken a strong stand" in proposing a variety of measures to reduce consumption of cigarettes.

Upton said other factors such as excess alcohol intake, diet, obesity, high intake of animal fat, the role of fibres, natural contaminants such as mycotoxins, nitrosamines and flavanoids are part of a "whole spectrum of questions that warrant followup and will turn up important leads in years to come . . . . The whole area of occupational carcinogenesis is of particular concern."

Chemoprevention is another area of great interest and increasing research activity, Upton said, mentioning retinoids, ascorbic acid and selective activation of P450 oxidases.

There are "exciting developments" in detection and diagnosis, Upton said. "I'm confident that in a few years mammography will be regarded as an enormous advance in detection of early breast cancer." Other new screening techniques in various stages of development include low cost, low risk methods, such as biological markers, and they need to be applied to high risk groups.

Turning to treatment, Upton said that reaching a 70% overall cure and 90% cure of early stage Hodgkins disease "is a fantastic achievement. There are those who say we'll never do that well with lung and breast cancer and other major tumor sites, but I don't believe they are right. We're just beginning to use intensive chemotherapy against those diseases. We're coming to the stage where we can customize treatment for individual patients. We're just beginning to see the results of the clinical trials machinery we have in place."

Upton said he was pleased by increasing attention "to the humanistic approach" in managing cancer patients, and that he expected to see the hospice concept developed on a much wider scale.

"The majority of cancer patients are your patients," Upton said to the community physicians. "Our job is to help you help them."

ACS SMOKING COMMISSION RECOMMENDS ALL OUT CAMPAIGN AGAINST CIGARETTES

HEW Secretary Joseph Califano recently proposed a stepped up effort by the government against cigarette smoking which included increased research and education efforts to cost $23 million a year, increased taxes on high tar and nicotine brands, and greater restrictions on smoking in public.

The National Commission on Smoking and Public Policy, established in 1976 by the American Cancer Society, this week announced its recommendations developed after a series of public forums held around the country. The commission's recommendations go far beyond Califano's in what would amount to the first all out, coordinated planned attack aimed at nearly every level of society which involve the production, manufacture, distribution, sale, advertising and consumption of cigarettes.

It also would produce one of the fiercest struggles in Congress in this century. Anti-cigarette legislation has fared poorly in the past against the tobacco lobby; a massive outpouring of public support would be needed to push any substantial part of the commission's recommendations into law.

The recommendations follow:

The Federal Government

A major federal initiative is required to reduce the toll of premature death and suffering related to cigarette smoking, to protect individuals from the risks associated with smoking, and to help slow the rapid rise of medical and hospital costs.

Executive Office of the President – Establish a cabinet-level Committee on Cigarette Smoking & the Health Status of the Nation. Members of this committee should include representatives from HEW, Agriculture, Defense, State, Labor, Commerce, Treasury, Federal Trade Commission, Environmental Protection Agency, and Consumer Product Safety Commission.

Congress – Place the interest of 218 million Americans above the intersts of six major cigarette-producing companies by passing legislation to:

1. Increase the federal excise tax of 8 cents per pack and replace it with a graduated uniform tax based on tar/nicotine content. This would provide a financial disincentive for those who smoke the high tar/nicotine cigarettes and a financial incentive to smoke the low tar/nicotine cigarettes.

2. Phase out, over a 10-year period, the present tobacco price support system which in effect is a tobacco subsidy and initiate a new program that demonstrates compassion for the economic needs of the tobacco farmer. We recommend that the 10 year program include:

- Full payment to farmers for not growing tobacco.
- Assistance to farmers while they continue to receive tobacco price support subsidies to help them grow the least harmful varieties of tobacco.
- Expanded research into non harmful alternative uses for tobacco, such as a potential source of protein.

3. Enact into law the Federal Trade Commission recommendations to make the health warning on the cigarette package more explicit. The label would read: "Warning: Cigarette Smoking is Dangerous to Health, and May Cause Death from Cancer, Coronary Heart Disease, Chronic Bronchitis, Pulmonary Emphysema, and other Diseases."

4. Eliminate tobacco products from the Food for Peace Program.

5. Direct FDA to safeguard the public interest by exercising its authority to regulate tobacco products, including the additives in cigarettes.

6. Review the protection it now affords the cigarette industry at the expense of the public health and welfare, and made certain that some appropriate agency of government, either FDA or the Consumer Product Safety Commission, holds the industry accountable for the safety of its product.

HEW – Act as a prime advocate of a federal initiative in cigarette smoking. The potential role spans public health education and information, research, regulation and financing.

1. The secretary should form an intra-agency council to assure a degree of cooperation and coordination among the many bureaus and offices within the department that have a potential to impact upon the cigarette problem. These include NCI, National Institute of Heart, Lung, and Blood Diseases; National Institute on Drug Abuse; National Clearinghouse on Smoking & Health; FDA, National Center for Health Statistics; Health Care Financing Administration, and the Office of Education.

2. The department should increase the priority of funds for education and information concerning hazards involved in cigarette smoking; increase, manyfold, the funds made available to the National Clearinghouse on Smoking & Health.

3. Prepare in cooperation with the major voluntary health agencies, a large-scale, paid antismoking campaign, using all media.

4. Support a thorough study of the net costs to society of cigarette smoking, so that these costs can be more equitably distributed, with smokers bearing far more of the economic burden than is now the case.

5. Support high-quality research on the impact of passive smoking.

6. Increase funds for epidemiologic studies of social, behavioral, and biological factors in cigarette smoking.

7. Support a study of the addictive qualities of nicotine, and recommend maximum levels of use in cigarettes.

Federal Trade Commission – Pursue a purposeful and practical tack in regulating cigarette advertising.

1. Seek to obtain a voluntary agreement with the cigarette industry to eliminate the use of models in all advertising.

2. Seek an agreement under which cigarettes above a specified tar-nicotine content would not be advertised. We recommend maximums of 10 mg. tar and 0.7 mg. nicotine in cigarettes for which advertising would be permitted. These levels should be reduced, however, on a gradual basis.

3. Require that tar-nicotine and carbon monoxide content be prominently printed on every cigarette package.

4. Require that the warning label be displayed on every package and in all advertisements, particularly billboards, at a size that is readily visible.

Dept. of Labor – Support the general policy that the workplace should be a smoke-free environment. "No smoking" should be the general rule. Special areas should be set aside in places of employment for those who want to smoke. The Occupational Safety & Health Administration should begin a major study of the impact of cigarette smoking in the workplace, particularly in closed environments. Based on its findings, it should recommend and enforce appropriate standards.

Dept. of Defense – Discontinue its practice of encouraging cigarette smoking through the sale of tax-free cigarettes; taxes should be added to the price of cigarettes sold at all military establishments. The department should not permit the illegal sale of cigarettes to minors. It should make cessation programs widely available. Educational and informational campaigns on the risk of cigarette smoking to the individual should be added to the current Information and Education programs. The secretary should direct each of the Armed Forces to examine their policies with respect to smoking in public facilities, and assure adequate nonsmoking areas.

State and Local Governments

Government, at all levels, should view smoking as harmful and destructive and should provide smoke-free environments for its employees and guarantee nonsmoking areas in all government facilities open to the public.

1. "No Smoking" should be the general rule in all public places; a smoking area should be provided where appropriate.

2. The ban on the sale of cigarettes to minors minors should be enforced. Vending machines should be allowed only in places where they can be supervised or monitored. Penalties for violation should be made more severe.

3. State legislatures should enact legislation to eliminate "contributory negligence" on the part of smokers as an industry defense in legal actions against cigarette companies.

4. A portion of cigarette tax revenues accruing to the states should be earmarked for the training of competent health educators and for public information and education campaigns about smoking. This should include school health education as well as purchase of antismoking ads.

Public and Private Schools

1. Smoking should not be permitted in elementary or secondary schools.

2. Highest priority should be assigned the development of a comprehensive health education program stressing health maintenance to be taught kindergarten through 12th grade as a part of the required curriculum.

3. Smoking cessation clinics, appropriate for various grades, should be part of school health services. Funds for such activities should be made available at the state level.

The Health Care Community

Health professionals, particularly dentists, obsttricians, pediatricians, general practitioners, should set exemplar roles by not smoking. They should inform patients about the risks of smoking, should counsel them on quitting techniques, refer them to smoking cessation clinics whenever desirable, and should make a patient's smoking history and status part of the medical record.

Hospitals should prohibit smoking in nonprivate rooms and public areas.

PETERS TO LEAVE NCI FOR POSITION WITH CYSTIC FIBROSIS FOUNDATION

James Peters, former director of NCI's Div. of Cancer Cause & Prevention, has accepted the position of medical director of the Cystic Fibrosis Foundation. He will leave his present job as special assistant to NCI Director Arthur Upton Feb. 15.

As medical director of the Foundation, which is headquartered in Atlanta, Peters will be responsible for research in cystic fibrosis, professional education and training, patient registration and epidemiology, the 130 cystic fibrosis centers, and a young adult program. He will head a 12-person staff with a research budget of $2.5 million a year.

ENVIRONMENTAL CARCINOGENESIS STUDY SECTION PUSHED; NIH SAYS IT'S ON WAY

One of the major problems NCI has encountered in attempting to support more research in environmental carcinogenesis is that the NIH Div. of Research Grants, which reviews the traditional (R01) investigator initiated research grant applications, has never had a study section with the expertise to adequately review that type of grant.

The National Cancer Advisory Board's Subcommittee on Environmental Carcinogenesis more than two years ago recommended that the NCAB ask NIH to establish a new stuyd section. The Board agreed, the request was submitted, NIH agreed and sent the request on to HEW headquarters. That's where it ended.

HEW refused to act on the request, probably because of the Administration's determination to reduce the number of advisory committees.

DRG attempted to fill the need by using ad hoc committees to review environmental carcinogenesis grants but quickly learned that the lack of continuity still produced inadequate review.

The NCAB subcommittee last week decided it had waited long enough, and suggested to Director Arthur Upton that he consider establishing an environmental carcinogenesis review committee within NCI. Upton agreed that "this might be possible, in the light of the reorganization" that he is implementing. The committee would be among the increased review responsibilities of the Div. of Cancer Research Resources & Centers (whose name probably will be changed to something like Div. of Research Review & Evaluation).

"To do it ourselves would be a fallback position," Upton said, indicating he preferred that NIH retain that responsibility if a new study section could be authorized.

Thaddeus Domanski, chief of DCRRC's Cause & Prevention Branch, said that Stephen Schiaffino, chief of the Scientific Review Branch of DRG told him he had repeatedly asked HEW for permission to form a new study section, with no response.

Subcommittee member David Hogness asked, "If the new committee is formed to operate within NCI, where would you go for that authority?" Upton answered, "I haven't encountered this question before."

The answer is, probably to the same office at HEW that has turned down DRG's requests.

Subcommittee Chairman Henry Pitot said, "I agree with Phil (Shubik, former chairman of the subcommittee), that a new study section is badly needed. I have looked over some of the pink sheets (of environmental carcinogenesis grant applications). Some people are not getting fair review."

Schiaffino, who was not at the subcommittee meeting, later told ***The Cancer Letter*** that he was preparing to resubmit a charter for the new study section "and I'm confident this time it will go through."

The new study section, which will be called the Chemical Pathology Study Section, will review applications in that field assigned to the National Institute of Environmental Health Sciences as well as NCI. Schiaffino said there has been a substantial increase in the number of applications for such studies. He expects HEW to grant the new charter by early spring.

The NCAB at its November meeting asked that the subcommittee undertake the project of drafting a statement explaining the limitations of bioassays and difficulties in applying bioassay data to an assessment of risk to humans. Board members felt such a statement would be useful in explaining to Congress and the public why it is neither simple nor inexpensive to find all the carcinogens in the environment, nor to prove that they are carcinogens to the satisfaction of the regulatory agencies.

The subcommittee undertook a similar task in 1975 when then NCI Director Frank Rauscher asked it to "better define in functional terms a chemical carcinogen" and to develop "general guidelines which can be used for interpreting carcinogenicity data."

Nearly a year later, after a series of meetings of the subcommittee with 17 consultants, a report was issued entitled "General Criteria for Assessing the Evidence for Carcinogenicity of Chemical Substances."

"In effect, we redefined cancer," said Pitot, who was one of the consultants.

"This (latest request) strikes me as a massive undertaking," Hogness commented. "It is," Pitot agreed.

Pitot submitted an outline of what he felt the proposed statement should include:

A. Data analysis

1. In vitro studies—mutation, DNA repair, chromosome abnormalities, mutation, dose response data, transformants, metabolic characteristics, toxicity.

2. In vivo studies—mutation, chromosome abnormalities, tumor production, dose response, tumor types, natural history.

3. Human data where available—epidemiology, dose response characteristics, metabolism in humans or other primates.

B. Analysis of inherent limitations in data analysis of bioassays, both in vitro and in vivo.

C. Human risk estimate on basis of data

1. Mathematical estimates of human risk (e.g. linear non-threshold or log-probit models), including dose response and metabolism extrapolation to humans.

2. Exposure patterns in human population—extrapolation of experimental mode of exposure to the human situation.

3. Risk estimate based on data and evaluation of human situation with respect to the agent.

Pitot proposed that consultants again be called upon and asked subcommittee members to submit names of individuals who would be asked to serve in that capacity.

"This will be controversial, probably far more than the other," said subcommittee member William Powers.

"Is one of the purposes to get across to Congress the complexity of the problem? To help persuade Congress not to write laws demanding simple answers?" Hogness asked. Upton replied that it was.

NCAB Chairman Jonathan Rhoads said that the statement previously developed by the subcommittee "was so carefully qualified that it is not likely to reach anyone outside the scientific community. A

congressman reading the 13th qualification would just say the hell with it."

Benno Schmidt at last week's Board meeting asked that "someone as knowledgeable as anyone can be take a look at what we're doing with the $150 million (that NCI is spending on environmental carcinogenesis) and tell us what we ought to be doing that we're not, if we had more money. Or how we can better spend the $150 million.

"I think what these people (the critics who say NCI is not doing enough in environmental carcinogenesis) are really saying is that we ought to change the world we live in. If so, that's something more than the Cancer Institute can handle."

Rhoads asked that the subcommittee include in the report a response to Schmidt's suggestions. "The subcommittee might like to contemplate what we could do with another $150 million," Rhoads said.

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. Some listings will show the phone number of the Contract Specialist, who will respond to questions. Listings identify the respective sections of the Research Contracts Branch which are issuing the RFPs. Their addresses, all followed by NIH, Bethesda, Md. 20014, are:

Biology & Diagnosis Section – Landow Building
Viral Oncology & Field Studies Section – Landow Building
Control & Rehabilitation Section – Blair Building
Carcinogenesis Section – Blair Building
Treatment Section – Blair Building
Office of the Director Section – Blair Building
Deadline date shown for each listing is the final day for receipt of the completed proposal unless otherwise indicated.

RFP NCI-CM-87195-26

Title: *Clinical trials monitoring service*
Deadline: *March 13*

The Cancer Therapy Evaluation Program (CTEP), Div. of Cancer Treatment (DCT), NCI, is seeking an organization having capabilities and facilities to provide a clinical trials monitoring service for phase I and certain phase II clinical studies of investigational new agents.

This service will have two components: (a) providing a central data management resource for both the CTEP and for the investigators conducting these studies and (b) providing a monitoring resource to meet FDA regulatory requirements and to complement the data management objective. The contractor selected shall establish and maintain a computer based system of detailed records of phase I and phase II clinical trials, provide the procedures and resources for obtaining the required data, monitor investigator compliance with FDA regulations, prepare monthly status reports on ongoing clinical studies, and final reports on completed studies.

The contractor's principal investigator and key personnel must have experience with data management systems, monitoring clinical drug evaluations, (particularly cancer chemotherapy) and with FDA regulations concerning investigational new drug trials.

It is anticipated that an incrementally funded contract will be awarded for a period of three years. The level of effort must be sufficient to monitor from 40 to 80 active clinical trials. Each trial requires 20-30 patients (a total of approximately 1,000-2,000 patients annually). Trials will be performed by 15-20 separate institutions.

Contracting Officer: C.L. Swift
Cancer Treatment
301-427-8125

CONTRACT AWARDS

Title: Demographic Cancer Research Program in Hawaii, continuation
Contractor: Univ. of Hawaii, $1,681,615.

Title: Support of cancer surveillance system in the state of Washington, continuation
Contractor: Fred Hutchinson Cancer Research Center, $486,087.

Title: Developing virus-cancer test systems and production of viruses, continuation
Contractor: Pfizer, Inc., $1,818,317.

Title: Study environmental factors on endogenous MMTV expression
Contractor: Baylor College of Medicine, $434,442.

Title: Cervical Cancer Screening Program, renewal
Contractor: Minnesota Dept. of Health, $350,112.

Title: Breast Cancer Detection Demonstration Project, continuation
Contractors: Wilmington Medical Center, $256,501; and Albert Einstein Medical Center, Philadelphia, $282,880.

SOLE SOURCE NEGOTIATIONS

Proposals are listed here for information purposes only. RFPs are not available.

Title: Programming services in support of the Contract Management System, modification
Contractor: Sigma Data Computing Corp., Rockville, Md.

The Cancer Letter –*Editor* JERRY D. BOYD

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