THE CANCER LETTER

Vol. 6 No. 38

Sept. 26, 1980

Subscription $125.00 per year

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

KENNEDY, WAXMAN DISAGREE ON AUTHORIZATION ISSUE; LEGISLATION FOR NIH, NCI THIS CONGRESS THREATENED

An impasse which has developed between Sen. Edward Kennedy and Congressman Henry Waxman over differences in bills passed by each house for biomedical research authorization threatens to block final passage of the legislation during this session of Congress.

Kennedy and Waxman, chairmen of the Senate and House health subcommittees, met last week to determine if they were close enough

(Continued to page 2)

In Brief

CONGRESS WORKING ON INTERIM FINANCING MEASURE TO FUND AGENCIES, INCLUDING NCI, THROUGH ELECTION

CONGRESS WAS preparing this week to complete work on a "continuing resolution" which would fund those agencies for which regular 1981 fiscal year appropriations bills have not been passed, including HHS. The 1981 fiscal year starts Oct. 1. The House approved last week a continuing resolution which would finance those agencies past the November election, over the objection of Republican members. The House resolution would permit agencies to spend at the levels included in House-passed appropriations bills; for NCI, that would be $1 billion, $1 million. The Senate Labor-HHS Appropriations Subcommittee has not scheduled a markup session for its 1981 bill and probably will not prior to the election. . . . **MARGARET SLOAN**, staff member of NCI's Div. of Resources, Centers & Community Activities, is on leave for six months to work with Irving Selikoff on occupational cancer at Mount Sinai. . . . **CHARLES MOERTEL**, director of the Mayo Comprehensive Cancer Center, has resigned from the FDA Oncologic Drugs Advisory Committee. Moertel would have needed a special exemption to serve on two advisory groups (he's a member of the DRCCA Board of Scientific Counselors). He decided that FDA's policy forbidding its advisers from participating in discussions of investigational drugs with which they have worked limited his effectiveness on that committee. . . . **SIMON KRAMER**, chairman of the department of radiation therapy and nuclear medicine at Thomas Jefferson Univ., will receive a gold medal from the American Society of Therapeutic Radiologists at its annual meeting in Dallas Oct. 22. **JUAN TAVERAS**, radiologist in chief at Massachusetts General Hospital, will receive a gold medal from the Radiological Society of North America at its meeting in Dallas in November. . . . **JOHN MONTGOMERY**, vice president and director of organic chemistry research at Southern Research Institute, received the Southern Chemist Award for 1980 from the American Chemical Society. Montgomery and his colleagues have played a major role in the development of anticancer drugs.

WAXMAN, KENNEDY NOT CLOSE ENOUGH TO CALL HOUSE-SENATE CONFERENCE

(Continued from page 1)

on the major issues to call for a meeting of the full conference committee. The answer: They are not.

If no agreement is reached before the present Congress ends, the bills would die. They could be reintroduced in the next Congress but would have to go through the entire legislative process again.

The major difference between Kennedy and Waxman is the provision in the House bill which specifically authorizes each NIH institute and requires new authorization after three years. Only NCI and the National Heart, Lung & Blood Institute have specific authorization now—the others were established under the general provision sof Section 301 of the Public Health Service Act.

NCI and NHLBI will not go out of existence, however, if their present authorizations are not renewed. They also were created under Section 301. But if the Waxman approach prevails, any of the institutes—including NCI and NHLBI—would be terminated without specific reauthorization every three years (the Waxman bill was amended on the floor to add a one year grace period).

Some members of Congress have argued that this would "politicize" NIH, placing scientists in the position of feeling they have to produce immediate, tangible results, the value of which is easily apparent to the public. The stability offered by Section 301 would be destroyed, they fear.

Waxman and his subcommittee have argued that the individual authorizations of each institute would provide Congress with increased oversight capability which they feel is needed to make NIH more responsive to public health needs.

The Waxman bill includes specific dollar authorizations for each institute. Only NCI since 1971 and NHLBI since 1974 have had funding limits written into authorizing legislation.

The Kennedy bill does not provide dollar authorizations for each institute. Such figures only establish the maximum levels, with the appropriations committees determining amounts appropriated for each institute (with concurrence of the full House and Senate, of course).

The Waxman bill also transfers some of the authority of the NIH director to the HHS secretary, a move Kennedy opposes.

In the discussions between Waxman and Kennedy, those were the issues on which neither would back down. Other differences in the two bills apparently are negotiable. Kennedy's President's Council for Health Sciences, and Waxman's requirement for institute council (and in the case of NCI, National Cancer Advisory Board) approval of contracts over $500,000 are two of the most important. The Waxman provision for a budgetary line item for cancer centers would not be considered if an agreement is reached to drop all dollar authorizations. If funding levels are included, Kennedy probably would not oppose the line item for centers if Waxman insisted on it.

One possible compromise: Retain the dollar authorizations but drop the provision requiring reapproval of each institute every three years.

The National Cancer Act of 1971 has been renewed two times. Its renewal was included in the present legislation. If that legislation is not passed, the question arises, what impact would that have on the National Cancer Program?

Probably not much. The National Cancer Act and its renewals were in the form of amendments to the Public Health Service Act. There were no time limits placed on those amendments, except in the case of the dollar authorizations which have set spending limits for specific years. If no legislation is passed this year, there would be no limits and at least that aspect of Kennedy's bill would prevail.

All other provisions of the National Cancer Act would remain in place—the budgetary bypass, President's Cancer Panel, mandates for cancer control, cancer centers, nutrition research, information dissemination, international cooperation, etc.

Changes sought by NCI, NCAB and others which are in the House and Senate versions would not be made without the new legislation. These include increasing the amount in individual grants which could be awarded without NCAB concurrence from $35,000 to $50,000; and specific authority to award grants for five years.

If Kennedy and Waxman do agree to a full conference, they will be accompanied by:

—For the House, Democrats Harley Staggers, David Satterfield, Richardson Preyer, Andrew Maguire, Thomas Luken, Doug Walgren, and Barbara Mikulski; and Republicans Tim Lee Carter, James Broyhill, Samuel Devine, and David Stockman.

—For the Senate, Democrats Harrison Williams, Claiborne Pell, Gaylord Nelson, Alan Cranston, and Howard Metzenbaum; and Republicans Richard Schweiker, Jacob Javits, Orrin Hatch, and Gordon Humphrey.

NEW BOARD BALKS IN CONCEPT REVIEW; CIS, CYTOPATHOLOGY PLAN THREATENED

The new Board of Scientific Counselors for NCI's new Div. of Resources, Centers & Community Activities had not been formally established when it met last week, but that did not stop its members from asserting themselves immediately and forcefully. Asked to give concept approval for one major existing DRCCA program and a proposed new one, Board members indicated they might not approve either, at least under the terms requested.

Only the fact that the Board had not been formally constituted may have prevented negative notes on DRCCA's request to renew the Cancer Communications Network's contracts with comprehensive cancer centers next year and a proposal for contract supported cytopathology training at eight to 10 medical schools. DRCCA Acting Director William Terry said the Board could not vote on the issues but asked each member to individually express an opinion to him by letter.

Negative comments during discussion on the issues indicated a majority would not approve renewing the CCN contracts for the full five years requested, and perhaps not at all. Most of the criticism was directed at the toll free telephone service known as the Cancer Information Service.

CCN was established by the former Div. of Cancer Control & Rehabilitation to assist comprehensive cancer centers with their cancer control/outreach mandates. Nineteen of the 21 comprehensive centers were awarded contracts, and another program was established in Hawaii. The proposal was to renew all of the existing contracts and to bring in the two newly recognized comprehensive centers not previously included—Columbia Univ., and Michigan Comprehensive Cancer Center. All would be noncompetitive awards, at a cost of $220,000 per center for the first year.

Thomas Kean, NCI project officer for CCN, explained the program:

"The network is designed to assure that the most current information on cancer cause, prevention, early detection, diagnosis, treatment, continuing care, and rehabilitation is readily available to members of the lay public and health professionals. The network accomplishes its objectives through two mechanisms: (1) a system of toll free telephone services promoted under the name Cancer Information Service and (2) special projects designed to meet regionally identified information/education needs.

"Since its inception the network has steadily increased its services and service area until the 21 regional offices now cover 28 states and the District of Columbia or 69 percent of the nation's population. The Cancer Information Service portion of the network has responded to public inquiries from over 500,000 citizens and more than 80 special projects are under way or have been completed. Increasing utilization of the network's services indicates that the need for credible and accessible cancer information resources is ongoing."

Charles Moertel, director of the Mayo Comprehensive Cancer Center (one of the CCN contractors) questioned the cost effectiveness of the toll free phone service. NCI's support amounts to about $12-15 per call, Moertel said, "but that is a small part of the cost. The American Cancer Society contributes some support. Facilities are lent to us, and some publicity and advertising we get supposedly for free but in fact cost money. The total cost is closer to $25 to $30 per call. There are vastly cheaper ways to do this."

Moertel then dropped his bomb.

"Last evening when I returned to my hotel, I decided to play the role of a Washington bus driver who upon returning home from work is confronted by his wife who is panicked because she has just discovered a lump in a breast. Responding to promotions of the cancer network people on the availability of the toll free service, I looked in the phone book for a number. The first number I saw was listed under the name 'Cancer Answers.' When I dialed it, a recording came on that the phone had been disconnected.

"I next called a number listed under 'Cancer Information and Referral,'" Moertel continued. "I got a recording that the office was open only from 9 to 5. The third call was to a 'Cancer Information Center.' A sympathetic lady answered, and when I told her my wife might have breast cancer, she urged me to take her to a place called 'Vitality House' where she would receive the best treatment—laetrile, vitamins, etc. She said it would not be necessary for my wife to be cut open, or to be burned with radiation or poisoned with chemicals.

"Here we are in the nation's capitol, where this program originates, and this is the kind of advice I got."

"I'm horrified," Kean said when he recovered from the shock. "We are deeply concerned about the quality of service. If that response was obtained from a Cancer Information Service number, it will be taken care of immediately."

"Certainly it was not," Moertel said. "But in essence it was. It was your promotion which led me to look for cancer information in the phone book."

Kean later checked out the numbers Moertel had called and found none was a CIS listing. The Georgetown-Howard Comprehensive Cancer Center CCN office recently was moved to the Howard Univ. campus, and the phone number was inadvertently omitted from the current D.C. phone book.

"We know CIS is not functioning optimally," Terry said. "Kean's job is to upgrade it. The issue of what appears in the phone book is not an easy one. We have no control over that. But it doesn't negate the value of the service. We think we can make it a high quality one."

Kean agreed with Moertel, that "there are mass media techniques to provide information to large numbers of people, but that does not fill the immediate need for someone who is suddenly confronted with cancer."

Board member Peter Greenwald, director of epidemiology for the New York State Health Dept., questioned whether cancer centers "are the best places for dissemination of information."

NCI considers the CCN contracts as "resource contracts" rather than "research." Resource contracts are not reviewed by nongovernment peer review groups but rather by NCI staff, occasionally with the help of outside consultants. Moertel and others challenged that aspect of the program.

Board member Harry Eagle, director of the Albert Einstein Cancer Research Center, said the program "is still developmental. It is a valuable service and should have the funds to continue development." But Board member Charles Cobau, Toledo practicing oncologist, pointed out that the $4 million annual cost amounts to eight percent of the cancer control budget.

Margaret Sloan, acting chief of the Occupational Medicine Branch, presented the cytopathology training proposal to the Board. Contracts would be awarded to eight to 10 institutions, either medical schools or major hospitals, with support of $120,000 to $150,000 per year for five years. The awards would be competitive, to institutions already training pathologists and which have a strong cytopathology program. They would be able to hire, as a maximum, the equivalent of an additional cytopathologist, an additional cytotechnologist and a part time secretary. They would be funded for the production of additional teaching slide sets and the improvement of their present collections.

In addition, they would be supported to offer three month stipends at $5,000 each for four to eight pathologists per year who have just completed their residencies and wish to become prepared to direct cytopathology laboratories in the future. The same course could also be provided for pathologists who may be sent to these institutions for training by state or federal agencies at the agencies' expense. For cytopathologists in practice and for cytotechnologists, opportunities should also be made available for continuing education in cytology for which appropriate tuition would be charged.

"We would propose to accompany this type of institutional support with a fellowship program of one year's duration which would be awarded from NCI on a competitive basis, but which would have to be taken at one of the institutions participating in this program," Sloan said. "Each institution would be responsible for one of these fellowships. Stipends would be at a level of approximately $25,000 per year."

Sloan said the need for the program was based on the fact that 5,000 laboratories in the U.S. provide cytology services but only 40 have been approved by the American Society of Cytology, which offers a voluntary inspection and accreditation for a fee. Labs involved in interstate commerce must be inspected periodically by the Center for Disease Control. Labs operating entirely within a state are licensed by state health departments, but the quality of those inspections varies and many labs operate without adequate inspection or supervision, Sloan said.

Recommendations from NCI state of the art conferences involving cytology procedures have been that the institute should take whatever steps it can to improve the performance level of cytology labs, Sloan noted. NCI commissioned the American Society of Cytology to prepare a report on cytology lab problems. That report found that the most important need was for improvement in the qualifications and experience of the directors of the 5,000 clinical labs which provide cytology services.

Board member Lester Breslow, dean of the UCLA School of Public Health, said, "I fail to see why the government has to subsidize the pathologist establishment. . . . It would be better to support strong, regular state inspections."

Board member Anthony Miller, director of epidemiology for the National Cancer Institute of Canada, said, "The proposed solution is the wrong solution. The right solution would be mandated quality control. I realize that may not be possible. The appropriate solution might have to come through legislation, maybe not at the federal level. We need to consider priorities in the cancer control budget, and I would expect this to be very low."

Board member Kaye Kilburn, professor of medicine at the Univ. of Southern California, said, "The problem may solve itself. I think people are coming out now supertrained in cytology. It's a fascinating field," he insisted, which is attracting increasing numbers of young pathologists in training. He conceded "there is a generation gap but it soon will close."

"There is a generation gap, but we felt this program would close it," Sloan said.

Board Chairman Stephen Carter, director of the Northern California Cancer Program, noted the $1 million a year cost of the program. "Considering all the negative aspects, it is hard to justify," Carter said.

NRC UNDERTAKES STUDY OF DIET, CANCER, SCHEDULES PUBLIC MEETING FOR NOV. 6

A National Research Council committee beginning a broad study of what is known about various dietary constituents and their possible links to cancer cause and prevention will hold a public meeting in Washington Nov. 6. The meeting, to hear comments on where the committee might best focus its efforts, will be in the auditorium of the National Academy of Sciences, 2100 C St. N.W., from 10 a.m. until 3 p.m.

Convened at the request of the National Cancer Institute, the Committee on Diet, Nutrition, and Cancer will attempt to assess the state of knowledge on the subject a develop a series of recommendations for future research. The committee will examine individual components of the diet—nutrients, food additives, and contaminants—as well as dietary pat-

terns for possible roles in causing or preventing cancer. It will also attempt to assess the effects of changes that may occur during the processing, preparation, storage, and consumption of foods. Evidence will be sought from a variety of sources, including epidemiological studies, laboratory animal experiments, and in vitro tests of the potential mutagenicity of food substances.

An interim report evaluating present knowledge is expected in two years, with the final report on research objectives planned for a year later.

Those who wish to present material to the committee should prepare their comments in written form and submit them to Committee on Diet, Nutrition, and Cancer, Room 353, National Academy of Sciences, 2101 Constitution Ave. N.W., Washington D.C. 20418, telephone 202-389-6906. The written comments may be any length; multiple copies should be provided if public distribution at the meeting is desired. Persons wishing to make oral presentations should submit their written comments by Oct. 6. All presenters will be given a specified amount of time to summarize their views, depending upon the number of presenters and the need to assure a balanced presentation of views. Time will be provided at the end of the meeting for discussion.

The committee is chaired by Clifford Grobstein, Univ. of California (San Diego). The vice chairman is John Cairns, Mill Hill Laboratory of the Imperial Cancer Research Fund, London, U.K. Other members are: Robert Berliner, Yale Univ.; Selwyn Broitman, Boston Univ.; Colin Campbell, Cornell Univ.; Joan Gussow, Columbia Univ.; Laurence Kolonel, Univ. of Hawaii; David Kritchevsky, Wistar Institute; Walter Mertz, U.S. Dept. of Agriculture; Anthony Miller, Univ. of Toronto; Elizabeth Miller, Univ. of Wisconsin; Michael Prival, Food & Drug Administration; Thomas Slaga, Oak Ridge National Laboratory; Lee Wattenberg, Univ. of Minnesota.

Robert Neal, Vanderbilt Univ., and Takashi Sugimura, National Cancer Center Research Institute, Tokyo, will serve as advisors to the committee.

NCI ADVISORY GROUP, OTHER CANCER MEETINGS FOR OCTOBER, NOVEMBER

Trends in Oncology for the New Decade—Oct. 1-2, Roswell Park continuing education in oncology.
Div. of Cancer Treatment Board of Scientific Counselors—Oct. 2-3, NIH Bldg 31 Rm 10, open 8:30 a.m.–5:30 p.m. both days.
New Approaches to Cancer Therapy—Oct. 2-3, EORTC symposium, Madrid.
Piedmont Oncology Assn. & Piedmont Oncology Nurses Assn. Annual Conference—Oct. 3-4, Winston-Salem, N.C.
American Thermographic Society—Oct. 4-5, New Orleans.
Research Methodologies in Terminal Care—Oct. 5, to be followed Oct. 6-7 by Third International Seminar on Terminal Care in Montreal, sponsored by the Royal Victoria Hospital and McGill Univ. Contact Post Graduate Board, Royal Victoria Hospital, 687 Pine Ave. West, Montreal, Quebec H3A 1A1.
National Cancer Advisory Board Organ Site Subcommittee—Oct. 5, NIH Bldg 31 Rm 4, 7:30 p.m., open.
National Cancer Advisory Board—Oct. 6-8, NIH Bldg 31 Rm 6, open Oct. 6, 8:30 a.m.–3 p.m., Oct. 8, 9 a.m.-adjournment.
National Conference on Gynecologic Cancer—Oct. 9-11, Los Angeles Hilton, sponsored by the American Cancer Society.
Div. of Cancer Biology & Diagnosis Board of Scientific Counselors—Oct. 9-11, NIH Bldg 10 Rm 4B36 Oct. 9 for open sessions 1–5 p.m. and 7–10 p.m., and Bldg 31 Rm 7 for open sessions 9 a.m.–5 p.m. Oct. 10 and for closed session Oct. 11.
Cancer Control Grant Review Committee— Oct. 13-14, NIH Bldg 31 Rm 8, open Oct. 13, 8:30–9 a.m.
Symposium on Carcinogenesis & Biological Effects of Tumor Promoters—Oct. 13-16, Castle of Elmau, Bavarian Alps.
Western European Workshop on Cancer Education in Schools—Oct. 13-15, Madrid.
National Toxicology Program Board of Scientific Counselors—Oct. 15-17, NIH Bldg 31 Rm 6 & 7, 9 a.m., all open. Review of draft technical reports of bioassays from the Carcinogenesis Testing Program will be conducted Oct. 15 on C.I. acid orange 10, C.I. acid red 14, D(2-ethylhexyl)phthalate, 11-aminoundecanoic acid, bisphenol A, 2,6-dichloro-p-phenylenediamine, and locust bean gum. The agenda for Oct. 16-17 includes a review of pathology quality assurance, preliminary review of statistical analyses and experimental design in carcinogenesis bioassays, discussion and development of recommendations concerning content of human risk statements based on animal carcinogenesis data; development of recommendations for the NTP chemical nomination and selection process, status report on the automated data processing study, and a briefing on toxicology development activities.
Management of Patients with Cancer Pain—Oct. 17, Holiday Inn French Quarter, Perrysburg, Ohio.
Third Annual Conference on Unresolved Questions in Oncology—Oct. 17-18, Golden Gateway Holiday Inn, San Francisco, sponsored by the Children's Cancer Research Institute at Pacific Medical Center. Speakers will include Donald Pinkel, Arthur Ablin, Agnes Alikpala, Joseph Castro, Sharon de Wit, Sarah Donaldson, Bertil Glader, Michael Harrison, Oscar King, Joseph Kushner, George Lee, Mark Nesbit, Beverly Raney, Ronald Rooney, Gerald Rosen, Margaret Sullivan, Melvin Tefft, William Wara, and Jordan Wilbur. Contact CCRI, 2352 Clay St., San Francisco 94115, phone 415-563-8777.
American Society of Therapeutic Radiologists—Oct. 21-25, Dallas.
Swiss Cancer Congress—Oct. 24-25, Zurich.
Present Concepts in Leukemia Pathophysiology—Oct. 24, Shamrock Hilton, Houston.
Cancer & Enzymes—Oct. 24-26, Vacation Village Hotel, San Diego, sponsored by the VA Medical Center, San Diego; Univ. of California (San Diego); and the International Society for Clinical Enzymology. Contact UCSD, Office of Continuing Education, School of Medicine, S-005, La Jolla 92093.
International Tutorial on Clinical Cytology— Oct. 25-Nov. 1, Vienna.
4th Annual Scripps Memorial Hospital Cancer Center Cancer Symposium—Oct. 27-29, Vacation Village Hotel, San Diego.
International Symposium on Fundamental Mechanisms in Human Cancer Immunology—Oct. 27-29, Galveston. Sponsored by the Univ. of Texas Medical Branch and Univ. of Montpellier. Contact Margie Taylor, UTMB Cancer Center, 111-A Basic Science Bldg. Galveston 77550, phone 713-765-2981.
Forum for Death Education and Counseling Third National Conference—Oct. 31-Nov. 2, Kansas City, Mo. Workshops for death educators and counselors are scheduled for Oct. 27-30. Contact Forum for Death Education & Counseling, P.O. Box 1226, Arlington, Va. 22210.

13th Annual Malignant Disease Symposium–Oct. 31-Nov. 1, Univ. of North Carolina, Chapel Hill.
Clinical Cancer Education Committee–Nov. 5-6, NIH Bldg 31 Rm 4, open Nov. 5 8:30–9:30 a.m.
25th Annual Clinical Conference–Gastrointestinal Cancer–Nov. 5-7, Shamrock Hilton Hotel, Houston.
39th Annual Meeting Japanese Cancer Assn.–Nov. 5-7, Tokyo.
Cancer & Risks–Nov. 5, Miami Valley Hospital, Dayton.
Pancreatic Cancer Review Committee– Nov. 5, Ambassador West, Chicago, open 8:30–10 a.m.
Advances in Head and Neck Oncology–Nov. 6, Roswell Park continuing education in oncology.
Prostatic Cancer Review Committee– Nov. 6, Omni Hotel, Atlanta, open 8–8:30 a.m.
Diet, Nutrition & Cancer–Nov. 6, National Academy of Sciences, Washington, D.C., 10 a.m.–3 p.m.
Cancer Special Programs Advisory Committee– Nov. 6-7, Bethesda Marriott, open Nov. 6, 9–10 a.m.
Cancer Prevention & Screening– Nov. 7-8, Holiday Inn Union Square, San Francisco. Contact Office of Continuing Education, Mount Zion Hospital & Medical Center, P.O. Box 7921, San Francisco 94120, phone 415-567-6600.
Prevention of Colorectal Cancer–Nov. 8, 13th annual Special Pathology Program Shamrock Hilton, Houston.
Pain Management in Cancer Patients–Nov. 8, Univ. of Delaware, Newark, Del.
President's Cancer Panel–Nov. 12, NIH Bldg 31 Rm 11A10, 10 a.m.
Cancer Centers Support Grant Review Committee–Nov. 13-14, NIH Bldg 31 Rm 6, open Nov. 13, 8:30–10 a.m.
Bone Marrow Transplants– Nov. 13, Roswell Park continuing education in oncology.
Committee on Cytology Automation–Nov. 13-14, NIH Bldg 31 Rm 10, open Nov. 13, 8:30 a.m.–5:30 p.m. and Nov. 14, 8:30–10:30 a.m.
Caring for the Care Giver–Nov. 14, Dallas, sponsored by American College of Radiology, American College of Surgeons and St. Paul Hospital.
Radiological Society of North America–Nov. 16-21, Dallas.
National Cancer Advisory Board–Nov. 17-19, annual program review.
Relation of Carcinogen Action on DNA to Cell Transformation–Nov. 18, Jefferson Medical College, Philadelphia.
2nd Asia & Oceania Congress of Nuclear Medicine–Nov. 24, 28, Manila.

NCI CONTRACT AWARDS

Title: Operation of a genetic production center for rodents in biocontainment environments, 52 month renewals
Contractors: Charles River Breeding Laboratories, $8,672,807; Simonsen Laboratories, $3,354,383; Harlan/Sprague Dawley, $2,283,544; and Leo Goodwin Institute for Cancer Research, $3,340,578.

Title: Preparation and purification of viral components
Contractor: Litton Bionetics, $448,200.

Title: Protocol toxicology prime contractor
Contractor: Battelle Memorial Institute, Columbus Laboratories, $394,502.

Title: Carcinogenicity studies in rodents, task order
Contractor: Battelle Columbus, $1,186,601.

Title: Statistical support for NCI serum panel
Contractor: Ebon Research Systems, Washington, D.C., $75,033.

REQUEST FOR GRANT APPLICATIONS

RFA NIH-NCI-TRCCB-80-7

Title: *Cancer patient compliance with therapeutic regimens*
Application Receipt Date: *Jan. 15, 1981*

In the most general sense, compliance may be understood as the extent to which a person's behavior (for example, taking medications, following diets, or changing life style) coincides with medical or health advice. Lack of patient cooperation with diagnostic, treatment, or rehabilitation efforts across chronic disease states is a major and growing concern for health care providers. Although there is no reason to assume that the problem of noncompliance is less acute in cancer patient populations, to date only one careful investigation of cancer patient compliance has been carried out. That research, as well as widespread clinical evidence, suggests that across the whole gamut of cancer control activities, noncompliance is a major problem for this group, also.

There are two major reasons for measuring compliance behavior in cancer patients. First, in the development of new forms of treatment, the compliance distribution for subgroups of patients and types of treatment should be taken into account in order to interpret the effects on disease course and outcome. Interpretation of the results of clinical trials is not possible without taking in to the account the proportion of patients not complying with the protocol. Unfortunately, this distribution of compliance behavior for cancer treatment protocols has not been systematically assessed.

Second, in clinical application aimed at control of the disease (ranging from diagnostic procedures and follow-through to post-primary treatment rehabilitation), patient cooperative behavior needs to be monitored. Patient cooperation may be enhanced by application of such procedures as behavioral modification techniques, including stimulus control and reinforcement of appropriate behavior.

Whether compliance measurement is an essential part of therapeutic trials and the development of more effective treatments, or whether such measurement is utilized in monitoring cooperation with proven treatment and enhancing the latter–valid and reliable methods of measuring compliance are essential. Findings in the current compliance literature are inconsistent, and study results are noncomparable because "compliance" is not adequately defined, different measures of compliance response to the same regimen are utilized, and these same measures are not accurate indicators of the criterion behavior.

Research Goals and Scope

1. One aim of research supported in this area will

be to develop valid direct and indirect measures of cancer patient compliance to diagnosis, treatment, and rehabilitation recommendations. Direct methods of measuring compliance to self-administered treatment regimens include, for example, the assessment of level of drug in the blood, or the measurement of urinary excretion of medication, metabolites, or drug markers. Assays for methotrexate, hexamethylmelamine, allopurinol, L-phenylalanine mustard, tamoxifen, and prednison, for example, already exist, and behavioral investigators would need to collaborate with pharmacologists in the further development and utilization of such measures for these self-administered treatments. Studies of compliance using drugs for which assays are not available will be excluded from consideration. In addition to the development and/or utilization of reliable drug assays, investigators should consider individual pharmacokinetic variations (for example, differential bioavailability of medication, genetically determined variations in metabolism and effects of repeated dosage on metabolic rate) in order to assess patient compliance to treatment. This RFA will not support the development of assay technitues for assessing drug levels independent from a behavioral study focus which addresses the nature of compliant behavior in cancer patients. Investigators proposing to measure drug compliance with new forms of treatment currently being developed, and for which no reasonably valid assay technique exists, should emphasize the development of indirect measures of compliant behavior.

Indirect methods of measuring compliance to diagnostic, treatment, or rehabilitation recommendations include the assessment of therapeutic outcome, utilization of interview reports, and the use of other forms of patient and/or family self-report. While these latter, indirect methods have proven difficult to develop as accurate indices of patient behavior (for example, outcome is determined by other factors than patient cooperation), it is still possible to assess objective, but indirect signs of compliance (such as clinical evidence of self-care activities). As direct measurement of compliant behavior is less feasible with regimens that do not involve medication, it is imperative to develop broader tools with which to assess the extent of patient cooperation in a therapeutic endeavor.

Creative research is therefore needed to develop valid measures of cancer patient compliance. Such measurements will provide the methodologic tools for assessing compliance variance as it relates to the development of new treatment, as well as for monitoring compliance behavior in those patients at high risk for noncompliance with accepted forms of treatment.

2. A second aim for research supported by this RFA initiative is to foster research into the nature of cancer patient compliance which will lead to a greater understanding of the sources of individual and group variation in compliance behavior. The distribution of compliance behavior by treatment, patient subgroup, and treatment setting needs to be determined in conjunction with both randomized, treatment trials, as well as in the clinical application of standard treatment techniques. In addition, sources of variance in compliance behavior related to diagnostic follow-through, adjunct health recommendations, after care and rehabilitation regimens need to be systematically assessed. Such knowledge will allow for more valid interpretation of outcome in clinical trials, including the development of more accurate dose-response curves for different subpopulations of patients. Better understanding of the nature of noncompliance in cancer patients will also allow for the prediction of noncompliant behavior in order to intervene with those at high risk for noncompliance.

3. A third aim of this research area will be to develop techniques that effectively modify compliant behavior for subpopulations of patients. The most effective techniques can then be applied by care givers in the health delivery system to high risk noncompliers in order to optimize cooperation in these patient groups.

It is expected that six to eight high quality applications will be supported in the area of cancer patient compliance, and approximately $1 million over a three year period for direct costs, plus an amount for allowable indirect costs, has been set aside for this research effort. In order to assure research support for projects examining a broad spectrum of cancer control activities, 50 percent of the awards will be made to projects concerned with the indirect measurement of compliant behavior, and 50 percent of awards will support studies concerned with the direct measurement of medication compliance. These initial applications should not cover a period of longer than three years, and it should be noted that renewal applications will compete with all research grant applications received by NIH. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

Applications responding to this RFA will be reviewed by a standing or special Div. of Research Grants study section.

Criteria specific to this RFA include an operational definition of cancer patient compliance appropriate to the cancer patient subpopulation and regimen being studied, the correspondent development and/or utilication of a valid and reliable measurement(s) of compliant behavior, and the utilization of an experimental or quasi-experimental research design in the study of cancer patient compliance. Pharmacological studies in which the investigator proposes to develop assay techniques independently from an investigation into the nature of cancer patient compliance and/or its enhancement will not be considered responsive to this RFA. Applicants without a history of research

with cancer patients must for this project demonstrate a collaborative research effort with investigators in relevant biomedical specialties.

Applications should be submitted on form PHS 398, which is available in the business or grants and contracts office at most academic and research institutions or from the Div. of Research Grants, NIH. The phrase "Prepared in Response to RFA: Cancer Patient Compliance with Therapeutic Regimens: should be typed across the top of the first page of the application. Additionally, a brief covering letter should accompany the application indicating that it is being submitted in response to this RFA announcement. The original and six copies of the application should be sent or delivered to: Application Receipt Office, Div. of Research Grants, NIH, Room 240 Westwood Blvd., Bethesda, Md. 20205.

In addition, one copy of the application should be sent to: Dr. Sandra M. Levy, Div. of Resources, Centers & Community Activities, NCI, Room 621, Blair Bldg., Silver Spring, Md. 20910.

For further information, investigators are encouraged to contact Levy at the above address or by telephone: 301-427-8656.

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. Address requests to the Contracting Officer or Contract Specialist named, Research Contracts Branch, National Cancer Institute, Blair Building, 8300 Colesville Rd., Silver Spring, Md. 20910. Deadline date shown for each listing is the final day for receipt of the completed proposal unless otherwise indicated.

RFP NCI-CN-15534-04

Title: *Development of monographs on basic radiation criteria and mammography*

Deadline: *Approximately Oct. 15*

The Div. of Resources, Centers & Community Activities, NCI, is soliciting proposals from organizations which will develop one or more handbooks concerning radiobiological aspects of basic radiation protection criteria and another handbook concerning radiation protection in mammography. The mammography handbook shall be suitable for serving as a reference for the medical community involved in diagnostic radiology.

The basic radiation protection handbook shall be suitable for serving as a more general reference for the scientific community at large and those serving in public health. The contract is anticipated to be a two-year, cost-type completion contract. Applicable general provisions shall be either Form HEW-315, 315A, or 316. Copies of the general provisions may be obtained from the contract specialist.

Contract Specialist: Jacquelyn Carey
Control & Rehabilitation
301-427-8747

SOURCES SOUGHT

Project No. NCI-CB-14338

Title: *Support for the Smoking, Cancer and Health Program*

Deadline for Statement of Capabilities: *Oct. 15*

Support contractor to assist NCI staff in the logistics and management of the Smoking, Cancer & Health Program. The selected contractor will provide a wide range of support activities. The workscope contains 5 tasks: (1) conference support, (2) technical document development, (3) data processing and computation support, (4) liaison, and (5) preparation of informational materials.

The support activities are concerned with research and demonstration activities in toxicology, epidemiology, prevention, behavior, attitudes, pharmacology, education, information, training and other areas appropriate to Smoking, Cancer & Health. It is anticipated that one award will be made as a result of a subsequent RFP and that a contract will be awarded for a period of one year.

Organizations possessing the necessary capabilities and who can meet the criteria listed below must supply the following required information: (1) The contractor must have flexibility to phase staff in and out of the project depending on the needs of the NCI, SCHP. (2) The contractor must supply evidence of previous experience in carrying out the range of the type of activities. (3) Must provide information on the scientific consultants knowledgeable in smoking and health available to the contractor during the performance of this contract. (4) Organizations submitting proposals for this project must have (or be willing to establish prior to contract award) regular office facilities within a 35-mile radius of the NIH facilities, Bethesda, Md.

Ten copies of the resume of experience and capabilities must be submitted.

Contract Specialist: Daniel Abbott
Biology & Diagnosis
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.