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Congress Hasn't Completed Action Yet On Major Health Bills; Reauthorization Fight In 1988-89

The first session of the 100th Congress is more than half completed, with no significant actions on major health and cancer related legislation, other than completion of hearings on Dept. of Health & Human Services appropriations

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In Brief

Hammer Okay, Panel's Pittsburgh Meeting Rescheduled For Oct 23; Campbell Leaves AICR

PRESIDENT'S CANCER Panel meeting at the Univ. of Pittsburgh which was canceled last month when Chairman Armand Hammer was injured in a fall at his home has been rescheduled for Oct. 23. Hammer, 88, has recovered and is back on the job as chairman of Occidential Petroleum. . . . **COLIN CAMPBELL**, professor of nutritional biochemistry at Cornell Univ., has resigned as senior science advisor to the American Institute of Cancer Research and chairman of its grants review committee. Campbell said his involvement in nutrition studies in China has put heavy demands on his time, forcing him to relinquish his work with AICR, which supports research and education programs on diet and cancer . . . . **ROBIN SANDEFUR**, associate vice president for academic affairs at the Univ. of Texas System Cancer Center, has been named president elect of the Assn. of Biomedical Communication Directors. . . . **HARVARD UNIV.** has awarded honorary degrees to **Mary Lasker**, for her work which "changed the face of public health today," in the words of Harvey Fineberg, dean of Harvard's School of Public Health; and to **George Hitchings**, for "brilliant discoveries of his laboratories." Hitchings developed the drug 6-mercatopurine to treat leukemia and an analogue, azathiorprin, which made possible the first nontwin renal transplant. . . . **AMERICAN MEDICAL** Assn. has reelected **Joseph Painter** to a three year term on its board of directors. Painter is vice president for physician referral development and extramural programs at M. D. Anderson Hospital. **Charles McCall**, VP for patient affairs at M.D. Anderson, was named chairman of a special AMA commission which is reviewing the standards of medical education and training in the United States. . . . **CLEVELAND CLINIC** Foundation has dedicated its new, 50,000 square foot, four story cancer center, the result of a $3.8 million renovation that consolidates every component of cancer care and research at the foundation under one roof.

Cancer Act Renewal Battle Shaping Up For 1988-89, Money Fight This Year

(Continued from page 1)

bills. House and Senate Labor-HHS Appropriations Subcommittees may complete their markups of those bills before the end of the month.

The most important impending legislative battle relating to cancer programs probably will not surface until next year, or in 1989 in the 101st Congress. That's when the Biomedical Reauthorization Act is due for renewal, including the National Cancer Act.

If it goes into 1989, a new Administration will be on the scene to contend with, but if history means anything, it will not make much difference who is sitting in the White House. Except for Richard Nixon's initial support of the National Cancer Act of 1971, every President since (through his Office of Management & Budget and the various department secretaries) either opposed renewal of the Cancer Act or sought to dilute its key provisions.

The Reagan Administration actively opposed both the entire Biomedical Reauthorization Act and its Cancer Act provisions two years ago, and Congress had to override the President's veto to save them.

The Administration has given every indication it will oppose renewal legislation and Congress will have to once again provide the leadership.

Cancer Program advocates, on the other hand, will be seeking not only to keep the program intact but to restore certain authorities left out of the renewal, omissions which the Administration has been taking advantage of. Most important is the "apportionment" issue, which deprives the NCI director (and other NIH directors as well) of the authority to reprogram funds without the stifling restrictions imposed by OMB.

Meanwhile, the major effort on the legislative front at present involves the level of spending that NCI will have in the 1988 fiscal year, which starts next Oct. 1. Behind the scenes efforts have been going on to get the total as close to the bypass budget figure of $1.7 billion as possible. If that could be achieved, then the 1989 bypass request of $2 billion is well within the range of possibility and will put NCI right on track toward implementing efforts needed to meet the Year 2000 goal of reducing cancer mortality by 50 percent.

A host of health related bills have been introduced this year, although most have seen little movement.

<>H.R. 671, by Rep. Mary Rose' Oakar (D-OH), Breast Cancer Treatment Informed Consent Act. Requires states to enact laws requiring physicians to notify breast cancer patients of alternative forms of treatment. Many states have already done this, and others are in the process.

<>H.R. 391, by Rep. Claude Pepper (D-FL), Breast Cancer Screening Act. Mandates establishment of breast cancer screening centers at NCI supported cancer centers.

<>S. 79, by Sen. Howard Metzenbaum (D-OH), and H.R. 162, by Rep. Joseph Gaydos (D-PA), establishing a federal program to notify individual employees within populations at risk of occupationally induced disease that they are at risk because of exposure to an occupational health hazard. Hearings on the Senate bill have been completed and final markup by the Labor & Human Resources Committee is expected momentarily. The American Cancer Society supports the measure, the Administration opposes it. Opposition is based on what is claimed as the time and expense involved for small businesses to carry out notification, potential for litigation, impact on workmen's compensation insurance costs, costs of establishing a new bureaucracy to administer the law.

<>H.R. 1470, by Rep. Henry Waxman (D-CA), and Sen. 143, by Sen. Daniel Inouye (D-HI), Compassionate Pain Relief Act. Establishes programs for making heroin available for intractable pain caused by cancer or pain experienced by terminally ill cancer patients. NCI has opposed heroin pain relief bills in the past on the grounds that other equally effective measures are available and that any loosening of heroin control could lead to greater abuse of the drug.

<>H.R. 1546, prohibiting employment discrimination based on a history of cancer, by Rep. Mario Biaggi (D-NY).

<>H.R. 1944, by Rep. Norman Lent (R-NY), to limit liability in malpractice claims. Similar bills have been introduced by Inouye and by Sen. Claiborne Pell (D-RI). These appear to be the most feasible measures of those aimed at rectifying what has become an almost impossible situation regarding malpractice judgments and cost of physician liability insurance.

A host of animal welfare bills have been introduced which would limit or impact in

various ways use of animals in research. Most of these measures were introduced in the last Congress but failed after receiving various degrees of consideration. Congress is too attuned to the needs of biomedical research to enact a law that would seriously restrict most legitimate use of animals. Most likely to succeed are those that would ban or restrict use of animals acquired from animal shelters or from dealers involved in theft of animals.

<>H.R. 1905, by Rep. Robert Roe (D-NJ), the University Research Facilities Revitalization Act. Authorizes a program by the National Science Foundation for the repair, renovation, or replacement of laboratories and other research facilities at universities and colleges. It would require that such grants be awarded on the basis of merit and that the federal share of the total cost of a project not exceed 50 percent. Grant proposals would be judged on the basis of the quality of the institution's research and training, "congruence" with the NSF mission, and impact on university research and training.

<>H.R. 164, by Rep. Frank Guarini (D-NJ), and S. 169, by Sen. Don Riegle (D-MI), authorizing federal grants for programs related to exposures to DES.

<>H.R. 651, by Rep. William Goodling (R-PA), providing that effectiveness requirement provisions of the Food, Drug & Cosmetics Act not apply to laetrile in certain cases, easing restrictions against it.

Several bills have been introduced that would increase the excise tax on cigarettes, and others that involve protection against secondary smoking. One, H.R. 1532, by Rep. Robert Whittaker (R-KS), would prohibit all consumer sales promotion of tobacco products. Rep. Anthony Beilenson (D-CA) introduced a resolution directing the President to call upon radio and television broadcasters to educate, in cooperation with public health organizations, the public about the dangers of cigarette smoking.

On the other side of the tobacco front, Sen. Mitch McConnell (R-KY), introduced S. 969, which would impose trade sanctions against South Korea if it failed to take action to open its markets to U.S. manufactured cigarettes.

Various other bills have been introduced in nutrition, including food labeling, nutrition monitoring and research; radiation protection, mostly for compensation of veterans for health impairment due to radiation exposures; and family medical leaves and job protection.

DeVita: No Decision Yet On Award Of FCRF Operations/Support Contract

NCI Director Vincent DeVita informed **The Cancer Letter** last week that he had not yet made the final decision on which firm will receive the $60 million plus operations/support contract for Frederick Cancer Research Facility.

The Source Evaluation Group, which has completed its evaluation of proposals for the contract, had its report ready for him but he had not yet seen it as of July 10, DeVita said through a spokesperson. DeVita and other NCI senior executives were in Annapolis for their annual July retreat, during which they formulate research and budget plans for the following fiscal year.

According to information obtained by **The Cancer Letter** (July 10 issue), companies competing with the incumbent contractor, Program Resources Inc., had been led to believe that PRI would receive the award. Those who made it to the final round with PRI were EGG and the consortium of Bechtel Corp. and Battelle Memorial Institute.

ACS Research, Fellowship Budget Hits $81 Million In 86-87, All-Time High

The American Cancer Society has approved over 800 research projects and postdoctoral fellowships for the 1986-87 fiscal year amount to over $81 million in support, John Laszlo, vice president for research, announced. That sum represents nearly one third of the total ACS budget.

Those research commitments are in addtion to the Society's extensive programs of epidemiological research, its support of an ongoing program to evaluate interferon, and a program of large, five year institutional grants for investigation of cancer cause and prevention.

This is the largest amount devoted to support of research in the Society's history, Laszlo said.

A major target of research funded by ACS is that of cancer prevention. Studies in biochemistry and chemical carcinogenesis, looking at environmental agents and lifestyle factors which may contribute to cancer risks, received over $9.5 million in support.

Cell and developmental biology projects were awarded $8.8 million. Researchers in the field of nucleic acids and protein synthesis were awarded over $11 million. Microbiology and virology studies will receive over $11 million. Many of the basic science grants deal with the molecular mechanisms that govern development of cancer cells.

Awards for clinical investigations in immunology, immunotherapy, chemotherapy, hematology, prevention, diagnosis and therapy added up to $22.5 million.

Psychological and behavioral research in cancer, a new and growing field of interest of ACS, Laszlo said, had $1 million earmarked for projects. Some of these grants address problems of smoking and other cancer avoidance behaviors.

An additional $16 million was awarded for personnel in research.

Laszlo noted that some scientists awarded ACS support may be unable to accept it because they have been granted support from other institutions. Alternative grants may be made to a number of highly rated but unfunded applications, requiring nearly $10 million, if these funds become available.

All ACS research grant applications are peer reviewed by appropriate advisory groups. The Board of Directors makes the awards on recommendations of its Research & Clinical Investigation Committee.

The ACS research program, funded entirely by public donations, is second only to that of the U.S. National Cancer Institute.

USC Study Finds Increased Leukemia Risk For Children From Pesticides

A link between household pesticides and childhood leukemia has been shown in a study reported in the July issue of "Journal of the National Cancer Institute."

Investigators at the Univ. of Southern California found that children whose parents use pesticides in the home have a 3.8 times greater risk of leukemia. If garden sprays are used, children have a 6.5 times greater risk.

The risk was 2.5 times greater among children whose fathers have worked in industries manufacturing aiarcraft and other transportation equipment or machinery.

The results are based on a case control study of children 10 years of age or younger in Los Angeles County, involving 123 diagnosed with acute leukemia from 1980-84.

NEW PUBLICATIONS

New Cancer Atlas Published By NCI Offers Risk Factor Research Leads

"Atlas of U.S. Cancer Mortality Among Whites: 1950-1980," which pinpoints geographic areas with average, below average and above average cancer death rates, is intended for use as a research tool, NCI Director Vincent DeVita said when it was released last month.

The first atlases for whites and non-whites, published in the mid-1970s covering death rates from 1950-1969, generated leads for in depth research on risk factors. "We hope the new atlas will continue to stimulate research and provide a tool that can help in reaching the Institute's goal to reduce the nation's cancer death rate by up to 50 percent by the year 2000," DeVita said.

The atlas contains color coded maps that illustrate variations in the average annual U.S. cancer death rate for adult white men and women for the three decades, 1950-59, 1960-69 and 1970-80. Rates were calculated for all cancers combined and separately for 33 types of cancer. Other maps are color coded to indicate the trends for death rates.

The atlas covers the 48 contiguous states and the District of Columbia. Data for Alaska and Hawaii were not avaible for the 30 year period.

The atlas was prepared by NCI Epidemiology & Biostatistics Program scientists Linda Pickle, Thomas Mason, Robert Hoover and Joseph Fraumeni, and by Neil Howard of ORI Inc. under contract to NCI.

"The geographic patterns of death rates seen in the earlier atlas generally have persisted in the new atlas with its 10 more years of data," said Fraumeni, who is director of the Epidemiology & Biostatistics Program. "The most notable new pattern is the emergence of elevated death rates for lung cancer among women in areas of Florida and along the mid-Atlantic and West Coasts. The lung cancer pattern for women is strikingly different from that for men. The reason for the new pattern is not certain, but cigarette smoking may be the main factor. Further research will be needed, however, before this is certain."

Available from the Supt. of Documents, U.S. Government Printing Office, Washington DC 20402. Also, data tapes may be purchased from the National Technical Information Service, 5285 Port Royal Rd., Springfield,

VA 22161. Maps on cancer death rates for the black population will be available in about a year.

Other new publications:

From the Candlelighters Childhood Cancer Foundation, Suite 1011, 2025 Eye St. NW, Washington DC 20006, phone 202/659-5136--"Making Contact: A Parent to Parent Visitation Manual," by Erna-Lynne Bogue and Barbara Chesney. Developed in collaboration with the Assn. of Pediatric Oncology Social Workers, it supplies guidelines for selection and recruitment of parent visitors, development of referral systems, training to stregthen visitor-parent contacts and support resources for visitors responding to the impact of meeting others' needs. Free to parent groups, health professionals and agencies planning or running parent to parent visitation programs for parents of children with cancer. $5 ($7 outside the U.S.) to noncancer parent grooups. Also, "Candlelighters Childhood Cancer Foundation Bibliography and Resource Guide," by Julie Russem, Lucy Gritzmacher and Minna Nathanson. $1 ($2 outside U.S.)

"A Synopsis of Cancer Chemotherapy," by Richard Silver, David Lauper and Charles Jarowski. Second edition (first published in 1977). Yorke Medical Books, Box C-757, Brooklyn, NY, 11205, $35.

"Adjuvant Therapy of Cancer V," edited by Sydney Salmon. Proceedings of the Fifth International Conference of Adjuvant Therapy of Cancer held last March in Tucson. Grune & Stratton Inc., Promotion Dept., Orlando, FL 32887, phone toll free 1-800-468-8671, $39.50 prepublication price.

"Surviving Cancer, A Practical Guide for Those Fighting to Win," by Danette Kauffman. Acropolis Books, 2400 17th St. NW, Washington DC 20009, 202/387-6805, $7.95.

"An Introduction to Alternative Health Care Delivery Systems for Radiologists," a new monograph by the American College of Radiology. ACR Publications, 1-800/227-7762.

"Pharmacologic Treatment of Tobacco Dependence: Proceedings of the World Congress," edited by Judith Ockene. Harvard Univ., 79 John F. Kennedy St., Cambridge, MA 02138, $10 per copy for orders of less than five, $7.50 each for five or more.

"Rodent Tumor Models in Experimental Cancer Therapy," edited by Robert Kallam. Pergamon Press, Maxwell House, Fairview Park, Elmsford, NY 10523, $55.

DCE Board Gives Concept Approval To Recompetition Of Two Contracts

Two large contracts were given concept approval for recompetition by the Div. of Cancer Etiology Board of Scientific Counselors, for studies on environmental cancer utilizing prepaid health plans and for laboratory support for processing and storage of biological specimens from persons at high risk of cancer.

The Board also gave concept approval to the noncompetitive continuation for five more years of a contract with the Assn. of Veterinary Medical Data Program Participants for animal morbidity/mortality surveys of colleges of veterinary medicine. The cost of this continuation was estimated at $195,000 a year.

The Board of Scientific Counselors of the Div. of Cancer Biology & Diagnosis also gave concept approval to the noncompetitive continuation for five more years of the contract with the Univ. of Minnesota for study of hemoccult screening techniques as a means of detecting early cancer of the bowel. Estimated total cost of this continuation is more than $8.5 million over the five years.

Details of the competitive concept proposals follow (concept proposals for new contract and grant supported projects approved by the DCE Board appeared in **The Cancer Letter** July 3 and July 10. Concepts for program announcements approved by the DCBD Board were in **The Cancer Letter** July 3):

Laboratory support for processing and storage of biological speciments from persons at high risk of cancer. Recompetition of a contract currently performed by Biotech Research Laboratories Inc., for five years at an estimated total cost of $450,000 a year.

The Epidemiology & Biostatistics Program has emphasized the use of laboratory probes as measures of exposure and/or susceptibility in epidemiologic studies. This effort has substantially expanded in recent years with the advent of major programs of retroviral and biochemical epidemiology.

As a result of program wide studies, the repository currently houses over 250,000 serum and plasma samples, 46,000 viably frozen lymphocyte samples, and 12,000 samples of other types, including tumor, stool, urine and other materials. Over 175,000 samples have been disseminated in the past four years of this contract to 177 collaborators for laboratory analysis. On a monthly average, between 5,000 and 10,000 samples (primarily serum and plasma) are accessioned, and between 30 and 150 lymphocyte transfer packs are processed per month. Approximately one half of these specimens are entered for long term storage and one half are sent for testing (e.g., retroviral testing, virus culture, molecular analysis). While approximately 85-90% of the effort of this contract supports AIDS, retroviral and family studies research, the

repository has also provided support to intramural staff throughout the Epidemiology & Biostatistics Program involved in collaborative research projects with laboratory scientists at NCI and elsewhere.

Objectives of this contract are to provide services necessary for accessioning and processing biological specimens for epidemiologic studies; to organize, aliquot and disperse samples to collaborating investigators for testing; to maintain the existing repository of samples and add new samples in an organizated way; and to maintain accurate information on the quality, quantity and location of samples, and to provide these data in a timely manner for the computerized sample inventory.

Samples come to the repository with different requirements. A portion are fresh unprocessed samples. Other samples are already processed and submitted for inventory and long term storage. Included with these samples are materials collected and processed under the biochemical epidemiology contract which does not include provision for long term storage.

The contractor provides services necessary for sample processing and inventory. These services will be tailored to the needs of different investigators. Standard protocols for processing different types of samples will be followed to ensure that biological materials are suitable for their intended use. This will include procedures for separating and viably freezing lymphocytes for cell culture, tissue typing, cell surface markers, and genetic polymorphism analysis. Other materials requiring specialized processing include red blood cells, urine, feces, tumor tissue, semen, exudates and transudates. Serum and plasma will be processed, aliquoted and stored at the time of sample receipt. A portion designated by the NCI staff investigator will be set aside for specified analysis, and the remainder will be aliquoted for long term storage in the repository. For each sample, records of internal freezer location as well as external destination will be developed, and these data entered into the computerized inventory system. Samples will be stored at suitable temperatures in mechanical or liquid nitrogen freezers, and 24 hour per day monitoring will be maintained to guard against sample loss due to equipment failure.

Computerization for this repository will continue to be supplied through the program wide computer support services resource. This computer support is essential to maintaining records of inventory location, as well as providing a mechanism for computer based approaches to integrating collection of laboratory results.

Paul Levine is the project officer. In response to Board member Janet Butel's question on whether materials in the repository are available to NIH grantees, Levine said they were.

"It strikes me that the cost is high for the number of samples," Board member Roy Shore commented.

Levine said that some of the material has to be processed, which increases the cost. William Blattner, chief of the Family Studies Section and an assistant project officer, added that the repository eventually will be moved to the Frederick Cancer Research Facility, which will reduce costs. DCE Director Richard Adamson said that the recompetition of the FCRF contracts had delayed the move. "This likely won't go the full five years," Adamson said.

Studies on environmental cancer utilizing prepaid health plans. This is recompetition of three contracts with Kaiser Foundation Research Institutes in Portland, OR, Oakland and Los Angeles. The new contract period will be four years, with an estimated total cost of $600,000 a year.

One of the primary goals of the Environmental Epidemiology Branch is to evaluate rapidly hypotheses concerning potential environmental causes of cancer. These hypotheses may arise from clinical observations, epidemiologic studies, or from laboratory experimentation. A relatively rapid way to accomplish this for some environmental exposures is to utilize already recorded information in a prepaid health plan on large groups of patients with a particular cancer and a comparable series of persons without the disease. This sort of record linkage capability is taking on increasing importance, since it involves review of collected information and therefore avoids many of the problems associated with issues of privacy and confidentiality. Because of the nature of prepaid health plan records, the primary hypotheses that can be tested involve those associated with the use of therapeutic drugs, medical conditions, surgical and radiologic procedures, occupation, location of residence and exposures that are highly correlated with any of these variables. Utilizing longitudinally record information concerning demographic and specific exposure characteristics of cases, and controls representatitive of the group from which the cases are drawn, is a valuable way to determine whether a more extensive study is required.

A secondary type of investigation that is appropriately done within prepaid health plans is the hypothesis generating type of investigation, utilizing the same approaches outlined for testing hypotheses. Here also, because a substantial amount of specific information has already been recorded for substantial numbers of cases and controls, these resources provide a relatively cost efficient way of exploring variables for associations that can then be tested in other populations.

Finally, in large prepaid health plans in existence for many years, a number of data banks and other resources have been developed for a wide variety of reasons (e.g., multiphasic screening, serum banks, computerized pharmacy files, data from other ad hoc studies). Exploration of plans for such potential epidemiologic resources can result in the identification of opportunities to test current hypotheses with respect to environmental carcinogenesis.

Over the last three years, the Environmental Epidemiology Branch has been collaborating with three separate large prepaid health plans that have been in existence for 20 or more years.

The general aims continue to be the establishment of a collaborative research project which would provide the Epidemiology & Biostatistics Program with resources that can be used to promptly evaluate new hypotheses about environmental causes of cancer. This would be accomplished by the analysis of information in a prepaid plan utilizing data recorded over many years on large groups of patients having particular cancers or exposures and comparable individuals without the cancer or exposure, to uncover previously

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The dollar estimates with each concept brought before the various boards of scientific counselors or other advisory groups are not intended to represent maximum or exact amounts which will be spent on those projects. They are intended as guides for board members to help in determining the value of the projects in relation to the resources available to the entire program or division. In the case of RFAs, the amounts cited are the maximum that will be set aside to fund those particular grants, the final amount depending on NCI's budget and program priorities. Responses should be based on workscope and description of goals and methods included in the RFPs (contracts) or RFAs (grants and cooperative agreements). Availability of the RFPs and RFAs will be announced when NCI is ready to release them.

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unrecognized associations which deserve further study. Another objective has been to explore the numerous resources for record linkage within these plans in order to exploit unique opportunities to use the collected data for epidemiologic assessment of cancer risk.

The main value of these resources is to provide a framework where new hypotheses can be evaluated rapidly. To some extent, the specific objectives for the next four years will depend upon the nature of these hypotheses as they emerge. Currently, the specific objectives to pursue in the first two years of the project would be:

1. An evaluation of the relationship of second primary malignancies to treatment, particularly chemotherapy, for a first primary cancer. This project will have two main aspects. Firstly, all second primary nonlymphocytic leukemias occurring among individuals with a first primary cancer of any site will be identified, and controls matched with these cases on the basis of age, first cancer diagnosis, year of diagnosis, and survival. The therapy records will be abstracted, with particular attention paid to radiation and alkylating agent therapy in an attempt to develop dose-response relationships. Secondly, the plan is to evaluate the solid tumor experience of long term survivors of a first primary cancer, particularly when chemotherapy was given. Any associations noted will be evaluated further via the case control methodology described.

2. The cohort of DES exposed mothers will be expanded in efforts to conduct appropriate followup to assess the risk of breast and other malignancies. Pilot studies will be initiated to evaluate the feasibility and statistical power of any efforts to evaluate the cancer experience of the offspring of these women.

3. The cases of breast cancer occurring among women under age 45 over the past 15 years will be identified, and controls matched to these women on the basis of age and duration of health plan membership will be identified. Data relating to prescriptions of oral contraceptives along with other breast cancer risk factors will be abstracted. If these efforts yield any evidence of the recently reported relationship between the duration of oral contraceptive use at a young age and risk of breast cancer among young women, cases and controls will be approached to obtain more complete information on breast cancer risk factors.

4. Among plans having computerized pharmacy records, attempts will be made to evaluate the feasibility of identifying cohorts of women treated for menopausal symptoms with estrogens and with combinations of estrogens and progestins and following these women while in the plan to assess the risk of various outcomes, including cancer, heart disease and osteoporosis related conditions. The practicality of obtaining information on relevant covariants for these diseases on either a case control basis within the cohort or in a case-cohort manner would also be assessed.

5. The feasibility of establishing cohorts to evaluate a variety of nutritional hypotheses about cancer etiology will also be pursued. Specifically, the feasibility of obtaining information via self administered questionnaire and biological specimens (e.g., nail clippings) from those receiving routine physical exams at selected facilities will be explored.

This project will continue to focus on the utilization of information existing in health records, to obtain new insights into cancer etiology. However, more efforts will be directed towards the assessment of complementing these record based studies with additional information obtained for specific study purposes.

Robert Hoover is the project officer.

Board member Maureen O'Berg expressed concern whether those enrolled in the health plans are representative of the general population.

"The plans are large, they cover huge populations, over large areas," Hoover said. "They are not necessarily representative, but the groups we study within the plan are comparable. They are becoming more representative."

"Have you thought of adding some routine basics, such as collection of blood and serum?" Board member Moyses Szklo asked.

"Yes, and we hope to add that on," Hoover said. "We hope to take advantage of the opportunity, to have them fill out questionnaires, take samples of blood. But we need to determine the feasibility and cost."

"I strongly endorse collecting biological specimens," Board member Thomas London said.

Hoover said that Kaiser did at one time, but "they didn't know what they were storing it for" and stopped.

Board member Lawrence Fischer noted that "you have no control over the reliability of the information. Is this a serious deficit?"

"No, although there may be some misclassification that could dilute findings," Hoover said. "But the abstractors are trained. The levels of risks from abstracting records is almost identical to levels obtained from intensive interviews by trained people."

RFPs Available

Requests for proposals 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 20892. 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-CP-71112-55

Title: Inter-intra species identification of cell cultures

Deadline: Approximately Sept. 1

The Div. of Cancer Etiology is seeking proposals for a research support service facility capable of performing an inter-intraspecies cell culture identification service. The offeror shall maintain a facility which can rapidly and successfully respond to the needs of investigators for characterization and identification of many diverse cell lines. The offeror shall serve to monitor the proper identification of cell lines used in cancer and biomedical research through cytogenetic, immunofluorescent, and isoenzyme testing services and through expertise in cell identification.

Offerors shall demonstrate their ability to provide for identification of up to 30 cultures per month. Other minimum facility, equipment and personnel requirements will be included in the RFP. A five year contract is anticipated.

This is a recompetition of the contract currently being performed by Children's Hospital of Michigan.

Contract Specialist: Mary McGarvey
RCB Blair Bldg Rm 114
301/427-8888

Sources Sought Announcement 87-05

Title: Clinical trial of the efficacy of intravenous gamma globulin in the treatment of symptomatic

children infected with the human immunodeficiency virus

The National Institute of Child Health & Human Development, in collaboration with the National Institute of Allergy & Infectious Diseases, is conducting a randomized double blind, placebo controlled clinical trial of the efficacy of intravenous gamma globulin in the treatment of children infected with HIV.

Currently, approximately 500 children under age 13 have been diagnosed nationwide with CDC definition AIDS. However, clinicans in the major centers of pediatric AIDS report that the number of children with symptomatic HIV disease far exceeds this number. It is clear that this number will continue to increase. Seroprevalence surveys conducted in two New York metropolitan area hospitals examined the occurrence of HIV antibody in the serum of women delivering on their obstetric service. After a months long surveillance period, one hospital documented a prevelance rate of 2% while the rate of seropositivity in the other hospital approached 3.5%.

In a survey carried out in the northeastern U.S. in over 7,000 births, samples of infants' blood were documented to contain antibody against HIV with prevalence varying from 7.0/1,000 births in an urban area to 1.0/1,000 births in suburban-rural areas. This study is ongoing and is being conducted outside the New York-New Jersey area. Thus, it is clear that pediatric HIV disease is a major problem which will continue to increase.

The children who have AIDS have been documented to have both the opportunistic infections seen in adult AIDS patients as well as severe recurrent bacterial infections. Studies have shown not only defective cell mediated immunity but also impaired humoral immunity. The picture of infectious disease in young children with perinatally acquired AIDS is further complicated by their lack of natural exposures to infectious agents and their developmentally immature immunologic systems.

In the absence of available antiviral and immunomodulator therapies, support for these patients includes a number of nonspecific interventions including substantial nutritional support. In order to respond somewhat more specifically to the problems of these children a number of clinicians treated their patients with intravenous gamma globulin administered on a regular schedule. Calvelli and Rubinstein, in a study conducted at Albert Einstein in the Bronx, reported a significant reduction in bacterial infections in their treated patients. Currently at least two major pediatric AIDS centers administer this therapy to a number of their highly symptomatic AIDS patients. Other centers, however, recognize the essentially unproven nature of this treatment and, in general, do not administer this therapy or use it only in highly selected situations. Thus, the trial proposed in this announcement will provide definitive evidence with regard to the efficacy of this treatment.

The specific aims of the study are to test the following hypotheses in a multicenter trial of the use of intravenous gamma globulin in the treatment of young children with HIV disease:

1. Intravenous gamma globulin (when compared to an identical appearing intravenously administered placebo) administered on an every 28 day schedule in a dose of 400 mg/kg will be demonstrated to increase the survival time of children infected with HIV.

2. This same therapy (when compared to its placebo) will be demonstrated to decrease the number of documented severe bacterial infections in the treated group.

3. This therapy will decrease the number of hospitalizations and the number of hospital days in the treated group.

4. This therapy will limit or interrupt the antigenic stimulation of HIV infected children (stimulation which may cause lymphocyte replication and more rapid progression of the HIV disease) and thus slow the progression of the disease.

This trial will enroll children who are infected with HIV disease and randomize them to receive either gamma globulin (Cutter product) or placebo. Children will be treated as outlined above and outcome assessed by the determination of (1) number of documented severe bacterial infections (2) number of hospitalizations and hospital days, (3) T-cells and T-cell subsets, (4) specific responses to antigens and mitogens and (5) length of survival. Approximately 100 children will be enrolled over a six month period in each arm of the study and each will be followed for one year from entry or until death or study termination. An independent safety committee will periodically monitor study results and consider the early termination of the study if serious adverse effects occur or if substantial efficacy of treatment is demonstrated.

Responses to the announcement by interested clinical investigators should provide the following:

1. Name and CV of all professional staff who will participate in the conduct of this trial.

2. Documentation specifying how many HIV infected children under age 13 are currently being followed at the investigator's institution including specification of their current clinical status as defined by CDC's new pediatric classification system.

3. Documentation of total number of children under age 13 with HIV disease treated by this institution over the last five years.

An estimate of number of patients who would likely meet the entry criteria noted above over the next six months and who would participate in the trial.

The mechanism for support for this trial will be through individual subcontract between those institutions elected for participation and the data center selected under a current competitive procurement which will result in a contract with NICHD. The data center will manage all data generated by the trial and will analyze these data for monitoring by the safety committee and for the steering committee which will direct the analyses and report the results. The steering committee will be composed of investigators from each participating institution, and scientific/programmatic officials from NICHD and NIAID. The subcontract between the data center and each individual institution will fully support the conduct of the clinical trial at that institution.

Any institution which wishes to participate and is already a participant in the AIDS treatment and evaluation unit (ATEU) network can apply to participate in this trial through the ATEUs. This study will be conducted in collaboration with NIAID and the ATEUs.

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