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AUTHORIZATION LEGISLATION STILL ON CONGRESS' BUSY AGENDA, ALONG WITH RISK ASSESSMENT, APPROPRIATIONS

While Congress probably will not enact any legislation this year which could change significantly the National Cancer Program, there are holdovers from the 1983 session with a number of provisions affecting various aspects of the program, including some changes in the National Cancer Act. The prospect of those bills becoming law depends on the mood in both houses toward compromise, and on whether Congress

(Continued to page 2)

In Brief

FOUR TO SHARE IN $100,000 HAMMER PRIZE; OLDHAM TO HEAD NEW GENETIC ENGINEERING FIRM IN TEXAS

FOUR SCIENTISTS will split the second annual $100,000 Hammer Prize for Cancer Research, awarded by Armand Hammer, chairman of the President's Cancer Panel. They are Michael Bishop and Harold Varmus, both of the Univ. of California (San Francisco); Raymond Erikson, of Biological Labs, Cambridge, Mass.; and Robert Weinberg, of White Institute and Massachusetts Institute of Technology. They were selected for their individual discoveries relating to oncogenes. Hammer has pledged 10 such awards over 10 years, along with a standing offer of $1 million to anyone who finds a remedy for cancer comparable to Jonas Salk's polio vaccine. . . . **ROBERT OLDHAM,** former director of NCI's Biological Response Modifiers Program, becomes president this week of a new genetic engineering and biologicals firm, BioTex, in Houston. The company (full name: Biotechnology & Biotherapeutics of Texas Inc.) formerly was Immunomodulators Inc. In addition to managing the firm's research and development in biomedical and agricultural genetic engineering, Oldham will pursue his interest in monoclonal antibodies and will be adjunct professor of medicine at M.D. Anderson. . . . **PAPANICOLAOU CANCER** Research Institute, founded nearly 40 years ago by the late George Papanicolaou, is considering a merger with the Univ. of Miami. "We have hit hard times because of the recession," Julius Schultz, president of the institute for the past 16 years, told the "Miami Herald." "Reaganomics has cut grant programs. It makes it very difficult to maintain an institution based on people competing for grants. The days of a free standing, financially independent, nonprofit institute are gone." Gordon Zubrod, director of the university's comprehensive cancer center and a member of a university committee discussing the merger, quoted by the "Herald," said, "These discussions have ebbed and flowed over the years. Right now they are flowing again. They are certainly looking into the feasibility and what the problems would be. There is no proposal, nothing specific." Schultz said he would continue as president of the institute if the merger is accomplished. ue as president of the institute if the

HOUSE, SENATE BILLS AGREE ON MOST PROVISIONS OF CANCER ACT RENEWAL

(Continued from page 1)
will fit them into a crowded, election year schedule.

Foremost of these bills are those reauthorizing biomedical research, which include renewal of the National Cancer Act. After a year long struggle between Congressman Henry Waxman (D.-Calif.), chairman of the House Health Subcommittee, and Republican House members allied with the Administration, a compromise measure was approved late in the 1983 session (HR 2350). But even with the modifications, which eliminated many of the provisions considered objectionable by HHS, it still is considerably different from the measure authored by Sen. Orrin Hatch (R.-Utah), chairman of the Labor & Human Resources Committee, which has been awaiting final action in the Republican controlled Senate for months.

Senate action has been held up by Sens. Robert Packwood (R.-Ore.) and Jeremiah Denton (R.-Alab.), who are concerned about fetal research provisions. Sen. Robert Dole (R.-Kan.) may insist that his animal welfare bill, S.657, be included with Hatch's NIH bill, S. 773. Those roadblocks will have to be resolved before the bill can be brought to the floor. Even with Senate passage of an authorization bill, final action is not assured. When both houses approved vastly different reauthorization bills four years ago, they were so far apart and the possibility of agreement so remote that a conference was never held. Both bills eventually were dropped and a simple renewal of existing authorities adopted. The same thing could happen again.

Following is a summary of provisions in the two bills of special interest to the Cancer Program, as presented this week to the National Cancer Advisory Board by Mary Knipmeyer, NCI's congressional liaison officer.

HR 2350:

* Establishment of positions of assistant director for prevention in each NIH institute except the National Institute of General Medical Sciences and National Institute of Environmental Health Sciences.

* Permission to award cancer center core grants for up to five years (presently limited to three).

* Requirement for an NIH biennial report to Congress, including reports from all institutes.

* Authorization for centers for research and demonstration of health promotion and disease prevention.

* Requirement that each institution applying for NIH funding (1) have established an administrative process to review reports of scientific misconduct and (2) report to the HHS secretary any investigation of alleged scientific misconduct.

* Fetal research limitations, largely similar to current regulations which would restrict research or experimentation on a human fetus in utero or a living human fetus ex utero whether before or after induced abortion, unless (1) the research is done to ensure survival or otherwise meet the health needs of the fetus and the fetus will be placed at risk to the minimum extent necessary or (2) the risk is minimal and the purpose of the research is to develop important knowledge not obtainable by other means. The HHS secretary would be permitted to waive these restrictions after strict procedural guidelines, including approval of an ethics advisory board, are met.

* Ceiling of 5.5 percent on NIH administrative expenses.

* Requirement that the HHS secretary promulgate guidelines regarding the use of animals in research.

* Requirement that the HHS secretary, through the NIH director, arrange for a National Academy of Sciences Study of the use of live animals in biomedical and behavioral research.

* Requirement to expedite review and award for research relevant to a public health emergency.

* Establishment of a National Commission on Orphan Diseases and a President's Commission on Human Applications of Genetic Engineering.

The House bill leaves intact all provisions of the National Cancer Act, including the President's Cancer Panel, National Cancer Advisory Board, the Presidential appointment of members of those two bodies and of the NCI director, and NCI's bypass budget authority.

In the compromise, Waxman agreed to deletion of a line item authorization for cancer centers, long a major issue of the Assn. of American Cancer Institutes, in return for language guaranteeing that NCI will support a minimum of 55 comprehensive, clinical and laboratory centers (The Cancer Letter, Nov. 25).

The compromise bill authorizes for NCI $1.163 billion for research and $64 million for cancer control in FY 1984 (which is close to the actual amount NCI is getting); $1.221 billion and $74 million in FY 1985; and $1.3 billion and $84 million in FY 1986.

The Senate bill also includes the provisions renewing the National Cancer Act, along with these changes in NCI and NIH authorizations:

* The National Research Services Award payback requirement would be eliminated.

* The ceiling on direct support costs of grants which may be awarded by NCI and the National Heart, Lung & Blood Institute without approval by the NCAB or NHLBI advisory council would be increased from $35,000 to $50,000. The NCAB has been asking for

that change for about six years, and considering inflation, the figure probably should be even higher now.

* Extends from three to five years the length of cancer center core grants, agreeing with the House.

* Requires that the HHS secretary report annually to Congress on actions taken to improve the NIH review and award procedures.

* Requires that NIH establish an appeals process for grant and cooperative agreement applicants.

* Requires that each institute director notify his advisory board or council if any grantee is under investigation.

* Requires that the HHS secretary expedite review and award of research relevant to a public health emergency.

* Requires that the HHS secretary arrange for a study of the use, care and treatment of animals in research.

The last two items agree largely with similar House provisions, indicating they would be included in final legislation. The two houses also agreed on establishing a new National Institute of Arthritis & Musculoskeletal Diseases.

A surprise amendment offered on the House floor by William Madigan (R.-Ill.) was approved, creating a National Institute of Nursing at NIH. That had never come up in Senate hearings, so Hatch has scheduled one for this month.

Risk assessment:

Concerns among some members of the House that the Reagan Administration is sabatoging regulation of dangerous substances, particularly carcinogens, prompted introduction of three bills:

HR 3840, "Risk Assessment Research & Demonstration Act of 1983" sponsored by Don Ritter (R.-Pa) would establish an agency to coordinate research and demonstration projects for the study of risk assessment and its relationship to the regulatory process.

HR 3976, the "Central Board of Scientific Risk Assessment Act of 1983," sponsored by James Martin (R.-N.C.) would authorize the National Academy of Sciences to establish a Central Board of Scientific Risk Assessment, to improve the review and evaluation of risk assessment made by federal agencies, with particular emphasis on risk assessment involving issues of chronic health hazards. This board would serve as a check on federal regulatory decision making based on risk assessment by reviewing regulatory documents by referral from the Office of Science & Technology Policy.

HR 4192, the "Risk Assessment Research & Demonstration Act of 1983," sponsored by Ritter, combines the other two into a single bill containing the provisions of both.

There has been no action on any of those bills.

President Reagan was scheduled to send his 1985 fiscal year budget to Congress this week. Congressman William Natcher (D.-Ky.), chairman of the House Labor-HHS Appropriations Subcommittee, will hold the hearing on NCI's portion of that budget on March 7.

ACS INDICATES IT PROBABLY WILL GO ALONG WITH HAMMER ON SURVEY FUNDS

The American Cancer Society probably will accept the offer of Armand Hammer, chairman of the President's Cancer Panel, to put up half the $150,000 cost of doing a survey of national cancer research construction needs if ACS will provide the other half.

Hammer told the National Cancer Advisory Board this week that he had not had a response yet to his letter in which he made the offer. An ACS spokesman told The Cancer Letter that the Society looked favorably on the proposal and had not sent its response to Hammer because "some details need to be worked out." The proposal will have to be approved by the ACS Board, which meets this month.

Hammer's offer was his solution to the dilemma faced by NCI in which the White House annually eliminates most of the budget request for construction and rennovation grants. NCI has hoped it could sell the President on a bigger budget for construction grants by documenting research facility needs. That effort was blocked by NIH, which refused to go along with permitting NCI to support such a survey.

"We (Panel members) are quite frustrated that we can't get the government's cooperation in this matter, and have to turn to the private sector," Hammer said.

Other items brought up at the NCAB meeting:

—NCI Director Vincent DeVita passed out certificates to the six retiring Board members, this being their final meeting unless the President does not appoint their successors prior to the May meeting. It would not be the final meeting, of course, for those who might be reappointed.

One who still might be reappointed is Roswell Boutwell, who is the only Reagan appointee among the six whose terms are up. Boutwell had informed DeVita that he would be spending the next two years in Japan and had asked not to be considered for reappointment (The Cancer Letter, Jan. 20). DeVita would not accept that, however, and convinced Boutwell that he could return at least for the three Board meetings which involve grant review, where his expertise as one of the few remaining scientists on the Board is badly needed. The new term would be for six years, so the major portion would not be affected by the time in Japan.

The retiring members, in addition to Boutwell, are Maureen Henderson, professor of medicine and

epidemiology at the Univ. of Washington; Janet Rowley, professor of medicine at the Univ. of Chicago; Irving Selikoff, director of the Environmental Sciences Laboratory at Mount Sinai School of Medicine; Sheldon Samuels, director of health, safety and environment for the AFL-CIO Industrial Union Dept.; and Morris Schrier, executive with MCA Inc. Samuels and Schrier held two of the six lay seats on the Board.

Selikoff and Samuels also fit the requirement of a 1978 amendment to the National Cancer Act which states that at least five Board members be involved in or knowledgeable about environmental or occupational causes of cancer or nutrition and its relation to cancer. Of the remaining members, only Boutwell, if he is reappointed, might fit that requirement. It will be interesting to see if the White House pays any attention to that segment of the law.

-- DeVita said that it now appears the FY 1984 budget will permit NCI to fund 31 percent of approved new and competing renewal grants, a total of 923. The grants budget increased 9.2 percent over 1983, largely because of the congressional directive that NIH fund a minimum of 5,000 new and competing grants, that they be paid at full recommended levels and cuts in noncompeting grants be restored to recommended levels. The cancer centers budget went up only 1.6 percent, despite the addition of $20 million by Congress over the President's request, the addition restoring enough to fund all competing renewals provided they compete successfully. Centers and clinical cooperative groups were not included among the grants mandated for funding at full recommended levels. The intramural research budget went up by 5 percent, and research contracts by 1.2 percent.

--In a change of NIH policy, grant pink sheets will be mailed to investigators along with priority scores when the review has been completed, DeVita said. That will permit applicants to submit rebuttal letters, with knowledge of whether they are close to funding ranges, prior to final actions by councils (or the NCAB in the case of NCI).

—The clinical trials budget, now at $48 million, has been level for the past two years and "we need to beef it up a little," DeVita said.

—When the Panel makes its swing around the country, taking a look at cancer centers, "We're not just going out to ask them how much more money they need. We're going to hold their feet to the fire a little," DeVita said. "We would like to know what plans they may have to take advantage of unique resources they have in their areas; what plans they have to help us meet our year 2000 goals; whether we need new criteria for developing centers; whether, (considering higher mortality rates for blacks) we need centers for blacks, with different criteria."

SEER GETS CONCEPT APPROVAL FOR FIVE MORE YEARS FROM AD HOC COMMITTEE

NCI's Surveillance, Epidemiology, and End Results (SEER) Program—recently transferred from what is now the Div. of Cancer Etiology to the Div. of Cancer Prevention & Control—has received concept approval for another five years, but not through the usual process.

DCPC concept review ordinarily is done by the division's Board of Scientific Counselors. Since two members of that Board—Charles Smart of the Univ. of Utah and Laurence Kolonel of the Univ. of Hawaii—are principal investigators for two of the SEER contracts, the Board was prevented by government regulations as intepreted by the Div. of Extramural Activities, from performing concept review. Instead, a six member ad hoc committee was w. organized for that purpose.

The ad hoc committee, chaired by Theodore Colton of Boston Univ., met one day prior to the Board's meeting, heard staff presentations on the program, and unanimously approved extending it for another five years. NCI had requested only three years, but Board members voted 5-1 to add the extra two years.

Although NCI (and most other federal agencies) has a policy of doing concept reviews in open meetings, the fact that SEER was being reviewed by an ad hoc committee was not made public. Ad hoc meetings do not have to be advertised since most of them involve technical review of proposals and thus are closed. It did not occur to NCI staff to announce the fact that the meeting was held, although it involved concept review of one of NCI's most expensive, visible, and sometimes controversial programs. The Cancer Letter objected, and later was permitted to listen to a tape recording of the meeting. DCPC Director Peter Greenwald said that the NCI Executive Committee has since determined that regulations do permit a board of scientific counselors to do concept review which involves one or more of its members as PIs provided they leave the room during the discussion. "That's the way it will be done from now on," Greenwald said.

NCI intends to seek JNCP (justification for noncompetitive procurement) approval for SEER, but that approval is not a foregone conclusion. If HHS determines that it should be opened up for recompetition, an RFP will be published.

The Board approved NCI's request for a total budget of $10.5 million for the program, with an annual inflation factor of six percent.

SEER contractors are located in San Francisco/Oakland, Connecticut, Detroit, Hawaii, Iowa, New Mexico, Seattle, Utah, Atlanta, Puerto Rico, and New Jersey. The contract with New Orleans has been phased out and New Jersey recently was added in a

competition to include an area with greater representation of blacks and Hispanics.

SEER currently is in its 11th year, with incidence data now available for the years 1973-82, mortality data from 1973-80, and survival data for patients diagnosed 1973-81 followed through 1982. The population within the SEER geographic areas represents 12 percent of the total U.S. population. Each SEER contractor maintains a cancer registration system such that all newly diagnosed cases of cancer are recorded within 11 months of the close of a calendar year. Demographic and medical information for each newly diagnosed case of cancer among residents of the geographic area are recorded and coded according to a prescribed format and submitted to NCI on an annual basis. No information identifying either the patient or the hospital making the diagnosis or rendering treatment is supplied to NCI since those data are considered proprietary by individual state laws. If patients are diagnosed and/or treated at facilities outside the boundaries of the geographic area of coverage, the contractor is expected to record information on those cases. Thus, some contractors obtain data from facilities located in other geographic areas as well as all local facilities.

Each patient recorded in the data base from 1973 forward must be followed annually until death. A variety of active and passive methods are utilized by the contractors to ascertain the vital status of the patients in their data base, and these data are submitted to NCI on an annual basis. These data are then used to monitor cancer patient survival. Each contractor is expected to utilize and analyze data at the local level, to feed back appropriate data to participating hospitals, and to use data for local health planning purposes.

Extensive quality control over the data are exercised by NCI staff in conjunction with the staff of the Univ. of California at San Francisco. Each contractor is visited semiannually for purposes of quality control. Problems identified during such visits form the bases for further education and training of contract personnel. Semiannual workshops are held for contract personnel. Also, two week training sessions for new cancer registry personnel are held three times a year at UCSF.

The ad hoc committee also gave concept approval to continuing the SEER contract with the Israel Tumor Registry for three more years. This contract, which will cost an estimated $150,000 a year, permits SEER to obtain cancer incidence and survival data among the various immigrant groups in Israel, including Americans and Canadians who have moved there, and to compare data between U.S. and Israel. Incidence trends are monitored, searching for common etiologies.

Members of the ad hoc committee enthusiastically supported continuing SEER but expressed interest in broadening the representation of ethnic groups, particularly blacks and Hispanics. Some reservations were made concerning the additional numbers of Hispanics being added through the New Jersey registry, since most of those will be of Puerto Rican and possibly other Carribean origins. Only the New Mexico registry among SEER contractors has any significant numbers of Hispanics of Mexican origin within its geographic area, possibly leaving that large group of Americans under represented.

Some members also were concerned about how the change from New Orleans to New Jersey would affect the program's data base. John Young, NCI's project officer for SEER, said that the change strengthened the program and brought it more into balance. "The weakness may be that New Jersey was a little naive in knowing what it will take to do the job," Young added, an indication that perhaps the New Jersey registry did not ask for enough money.

Greenwald discussed at the meeting of the full Board of Scientific counselors the new procedures relating to concept review.

The key change requires that concept ideas be reviewed by a BSC committee before coming to the full Board," Greenwald said. "Although at times, for efficiency on less expensive proposals or for other reasons, we may want to do this by mail and phone. Ad hoc members will assist BSC committees as needed, and committees will look at whether we are getting sufficient participation from non NCI experts in the review of major research plans."

Greenwald said that David Joftes, chief of the Contracts Review Branch in the Div. of Extramural Activities, had advised that, "in a formal sense, the concept review refers only to our presentation to the full BSC, the discussion at that time, and the vote. The seven purposes (of concept review) pertaining to consistency with mission, purpose, feasibility, resources, mechanisms, etc. will be considered by the full BSC."

In addition, Board committees will be asked for programmatic advice before concepts are brought to the full Board. "Since the ideas are evolving at this time, this differs from the formal concept consideration, and committees should delve deeply into importance to the program, merit in relation to other research in the field, alternative approaches, costs, the necessary number of studies, priority, whether we are getting sufficient expert advice in development of the idea, and any other issues you think are important," Greenwald said.

Members of the SEER ad hoc committee were, in addition to Colton, Philip Archer and Lewis Kuller, members of the DCPC Board; Tom Chin, Univ. of Kansas

Medical Center; Lois Dow, St. Jude Children's Research Hospital; and Genevieve Matanoski, Johns Hopkins Univ.

The Board gave concept approval to two sole source contract supported projects. One, for an information resource and management system for chemopreventive agents, involves supplementing the Div. of Cancer Etiology's existing contract with SRI Inc. SRI performs that service now relating to DCE's carcinogenesis program. The additional work for chemoprevention would add an estimated $170,000 a year to the contract. The other sole source contract concept was for an economic analysis of cigarette smoking by the year 2000 which NCI would do through an interagency agreement with the HHS Office of Smoking & Health at an estimated cost of $150,000 a year for two years.

The Board disapproved unanimously the concept of a validation study of an evaluation handbook on smoking published by the Center for Disease Control, which would have cost an estimated $150,000 a year for 30 months. "This is a backwards approach," Kuller said. "This may not be worth $150,000 (and, considering that it is one of seven such handbooks being published by CDC), "it sure ain't worth $1 million."

The Board tabled a concept on paying $300,000 to the National Academy of Sciences for a report on a "critical assessment of studies giving risk estimates of asbestos related diseases and of the efficacy of secondary prevention methods in dealing with asbestos related diseases." Staff was asked to prepare a work plan on how the division's effort in this area would be related to those of other agencies.

Concepts approved by the Board, in addition to those published in the last two issues of The Cancer Letter, were:

Evaluation of Outreach Consultation Through Tumor Conferences (Tumor Boards)

Anticipated number of awards: Part A, one; part B, up to eight (Part A a contract, part B grants)
Duration of awards: Part A, one year; part B, three years
Estimated annual budget: Part A, $105,000 direct costs, $150,000 total; part B, $400,000 direct cost, $650,000 total

Major objectives are to characterize the outreach consultation process through tumor conferences as it exists in community cancer programs, university hospitals, and cancer centers; and to assess the extent of the contribution from outreach consultation and the tumor conferences on patient management, including referral patterns and place of management of complex medical problems.

Many university and community cancer centers are presently involved in a variety of outreach activities including tumor boards and on site consultation. Yet there are no data describing or evaluating these efforts in terms of the effectiveness of transferring information on the latest methods of cancer management. Improved management might be possible using existing resources with specific changes in the local consultative and referral activities. Resources required by the American College of Surgeons have not been examined. An assessment is in order. Improvements in patient management particularly in some areas of the country could have significant public health impact.

Part A. It is apparent that a large number of community hospitals can and are being brought into national cancer control efforts. In 1983 the American College of Surgeons had approved 1,015 hospital cancer programs in the U.S. One required component of these programs is a tumor board which meets either weekly or monthly depending on the number of cancer patients seen at that institution. The ACOS Commission on Cancer has data which demonstrate geographic variations in five year survival rates for cancer patients by site. Tumor boards as generally constituted are heterogeneous multidisciplinary forums for the discussion of patients with cancer. Thus the primary focus would be to gather information on the types of conferences in existence, ACOS approved and others, on their organization, participants, and activities (i.e. didactic or case discussion). Information based on surveying samples of the ACOS approved programs and others should be readily obtained. These surveys would elicit information on organization structure, staff participation, preparation and dissemination of a written record, and the process of case presentations.

Part B. Study of the effectiveness of cancer outreach consultation is more challenging. Studying concordance between recommendations and actual management for presented and nonpresented patients with similar diseases (type and stage) provides an intermediate assessment of tumor conference influence. Targeted over time reviews of diseases known to be managed differently now than a decade ago will be important for assessing secular differences. One intervention possible at the tumor conferences may be the focusing of attention on peridiagnostic mortality for a specific disease to see if management practices change. Disease free intervals in testicular cancer and acute myelogenous leukemia may be signals of suboptimal management. Other strategies may be employed.

Board member Charles Smart, who headed the ACOS Commission on Cancer for many years, noted that 85 to 90 percent of cancer patients are treated in community hospitals. All ACOS approved programs have tumor boards, and "there are probably an equal number with tumor boards which are not approved (programs by ACOS)," Smart said. "That means this is a process which influences treatment of 60 to 70 percent of cancer patients. It is important to know if this is worthwhile. We have an opportunity to

measure changes in behavior better than before, not did they leave anything out but did they change the treatment. I have a gut feeling it is worthwhile, but I would like to know." Smart estimated tumor boards cost a total of $10-15 million a year.

"We've been grasping for ways to change the way community physicians manage cancer patients," Board member Charles Cobau said. "I believe tumor boards are a very important way to share information with physicians. I look at tumor boards as a link between community hospitals and university centers. One of the things which can be looked at in part B is how effective is it to have professors go out and take part in tumor conferences. It is appropriate to fund as a cancer control activity if it is effective; we can save some money if it is not."

"Although I was not enthusiastic about the concept, it is an important issue," Board member Virgil Loeb commented. "I'm terribly concerned that we will wind up with a lot of data from part A that will not be useful in part B."

The concept was approved by a unanimous vote.

Continuing Care Research: Identifying and Reducing Obstacles for Patients with Cancer

Anticipated number of awards: Six (cooperative agreements)

Duration of awards: Four years

Estimated annual budget: $300,000 direct costs, $420,000 total (for all six)

The purpose of research to be conducted under this effort will be to design, implement, and evaluate existing innovative programs whose purpose is to provide resolution of concrete needs of patients with cancer. Specific aims are:

Stage 1—Develop prospective and accurate data related to the incidence of resolved and unresolved living problems; document and characterize existing and/or potential solutions; identify the special circumstances which suggest the needs for practical interventions.

Stage 2--Use the existing resources and develop or improve upon systematic interventions in a coordinated manner.

Disordered and nonintegrated efforts at continuity of care are an inherent problem to any health care delivery system that relies on multiple care sites and providers. In general, the solution of the problems associated with the successful continuing care of the cancer patient and/or their families will vary as a function of the severity of the disease, its reversibility, and the patient setting.

Surveys of demands for specific services or patient need assessments confirm that continuity of cancer care is, at times, inefficient or ineffective. Biases resulting from the type of data (often retrospective analyses), and type of quesionnaire (perceptual assessments) are major hazards of these data. The interpretation of this information often fails to address the survival differential for types of cancers resulting in distorted prevalence rates for perceived needs and service demands. For example the administrative, economic, and daily living problems of patients with lung cancer living only months will differ greatly from those encountered by patients with metastatic but treatable breast cancer often living years. These studies do, however, provide leads for in depth exploration, and justify more systematic investigation. The contribution of inadequate social networking, referral procedures, discharge planning, and patient tracking to these data can also be inferred from these studies.

The demand for and implementation of continuity of care activities occurs at every major transition point (admission, discharge, reentry) faced by cancer patients and/or their families. Of major oncological interest are the continuity of care activities which occur at time of diagnosis, treatment success or failure, cure or death.

The removal of obstacles to the resolution of the daily living problems, or concrete needs, cancer patients face could relieve the pressures of the illness and its treatment. However, the quality and nature of the programs, which facilitate access to services, which deal with these problems can be highly variable depending on local resources, available expertise, and the extent of planning for such delivery. The efficiency and effectiveness of such programs are of current concern to NCI because these disordered efforts are likely to continue. The dissemination of reliable information about solutions using existing resources may bring about efforts where they don't presently exist.

Studies are sought which utilize existing programs which are able to identify the salient features which lead to the resolution or failure to resolve the problems cancer patients and their families face. Grantees will be asked to describe their existing research efforts, to use a common problem oriented needs assessment, and to cooperatively develop a resource index. They will also be expected to survey a common assortment of outcome variables.

The research program will be divided into two stages. During stage 1 investigators will be expected to successfully estimate the incidence of resolved and unresolved problems, and document existing and potential solutions to barriers to the resolutions of concrete needs. In preparation for program merit review, investigators will be expected to carefully describe how the information generated in stage 1 justifies an intervention program. After review, investigators will either phase out their research activities (complete data analysis and prepare final reports), or implement an intervention program. Evaluation of the impact of the intervention will include statements concerning the generalizability of the research findings.

These research programs are expected to be institutionally based and involve the entire cancer population over a specified period of time for a particular institution. Longitudinal studies are encouraged where feasible and efficient. Demographic and geographic factors will be considered in the final selection process.

"I don't understand this as a research program," Board member Harry Eagle said. "It is easy to identify five, 10, 15 points at which care of the elderly could be improved. It doesn't come into focus."

"Problems that occur are repetitive," DCPC Associate Director Jerome Yates said. "It seems to me you can collect information on a prospective basis, then design an intervention."

"Is the agency prepared to deal with a problem once the information is in?" asked Board member Erwin Bettinghaus. "If you're not ready to deal with a problem in some cases, you're better off if you don't have the data."

"What I see coming out of this is a better definition of problems," Yates said.

"This is an extraordinary, innovative project," Board member Doris Wilkinson said. "The investment is meager and is well worth it." Her motion to approve was passed unanimously.

Clinical Trials Using 4-Hydroxyphenyl Retinamide (HPR)

Anticipated number of awards: One or two contracts to study prevention of bladder cancer and one or two contracts to study prevention of breast cancer.r two
Duration of awards: Initially three years with potential extension to six.
Approximate annual budget per award: $250,000

HPR is an amide derivative of retinoic acid that has been shown to exert a chemopreventive effect against the development of rat mammary tumors and mouse transitional cell bladder cancer. In preclinical toxicology tests it has been shown to have very low toxicity compared to more standard retinoids such as vitamin A or the retinoic acids. HPR has been under development by McNeil Pharmaceuticals and early phase 1 testing in human subjects in England is nearly complete. Plans are to file an IND to conduct clinical trials in this country in March or April.

Animal studies suggest that retinoids should be effective in preventing the development of bladder cancer. Preliminary human studies in Europe with the relatively toxic retinoid etretinate show an effect in preventing late recurrence of bladder cancer. Early recurrences, believed due to already established cancer foci were not affected. In this country, one study has been attempted using 13-cis retinoic acid. That study had early recurrence as an endpoint and was discontinued without looking for possible inhibition of late recurrences. There is need for a properly structured and carefully conducted study in the chemoprevention of bladder cancer with a potentially effective low toxicity retinoid.

Retinoids have been shown effective in preventing breast cancer in animal model systems. Risk factor analysis can be used to define a population of women at risk for development of breast cancer. A low toxicity retinoid can be given to these women for the prolonged period of time necessary to test its preventive potential.

Under separate RFPs, offerors will be asked to submit proposals to conduct randomized phase 3 trials for chemoprevention of bladder cancer or breast cancer with HPR.

RFPs AVAILABLE

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

RFP 200-84-0706(P)

Title: Interviewing--Selected cancers study
Deadline: Approximately March 20

The Centers for Disease Control contemplates awarding multiple contracts to identify cases of selected cancers and to interview both cases and controls.

In order to be considered for this procurement, an offeror must be able to identify, in a defined geographic area, at least 95 percent of males with birth dates from Jan. 1, 1929 through Dec. 31, 1953, who have been diagnosed as having soft tissue sarcoma, lymphoma, nasal and nasopharyngeal cancer, or primary liver cancer between July 1, 1984 and June 30, 1988; must have an established mechanism for identifying cancer cases within 30 days of diagnosis, reviewing (abstracting) hospital medical records, and obtaining tissue blocks/slides from hospitals and pathologists; and must be able to document its ability to conduct epidemiologic studies utilizing data from its population based cancer registry including interviewing of cancer patients or next of kin.

Scheduled issue date is approximately Feb. 10.

Contracting Officer, PGO
Centers for Disease Control
255 E. Paces Ferry Rd.
Atlanta, Ga. 30305

RFP Amendment
RFP NCI-CP-EBP-41010-65

Title: Operation of a computerized death certificate procurement and management system and tracing using other vital records systems

Date of receipt of proposals has been extended to Wednesday, Feb. 29, to allow the government additional time to make necessary RFP modifications.

The Cancer Letter _Editor Jerry D. Boyd

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