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Harkin, Hatfield Vow To Amend Health Reform To Include Trust Fund For Medical Research

Sens. Tom Harkin (D-IA) and Mark Hatfield (R-OR) last week said they intended to amend any health care reform plan that may be submitted by the Clinton Administration to include the creation of a Medical Research Trust Fund.

Under the proposal by the Senate Appropriations Committee chairman and the ranking Republican, the new funds would be generated through

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In Brief

Yale Names DeVita Center Director; Canellos, Antman Lead ASCO; Bresnick To Head AACR

VINCENT DEVITA JR. was named director, Yale Comprehensive Cancer Center, effective July 1. DeVita, NCI director during the Carter and Reagan administrations, succeeds **Alan Sartorelli**, who will retain an appointment in the cancer center and return to full-time research and teaching. DeVita moves to New Haven from Memorial Sloan-Kettering Cancer Center, where he served as physician-in-chief from 1988-1991 and holds the Benno Schmidt Chair in Clinical Oncology. "In 1965, Vince DeVita and I were medical residents together here at Yale under Dr. Paul Beeson, and during the intervening years he made many contributions to his nation, his profession and to his patients' lives," said **Gerard Burrow**, Yale School of Medicine dean. "We are delighted that he will bring his vast experience, clinical wisdom and management talents to our strong comprehensive cancer program." Speculation that Burrow was recruiting DeVita circulated this spring (**The Cancer Letter**, March 5). "Yale is one of those great universities, with such power in basic science, it offers the opportunity to take basic science to the clinic," DeVita said to **The Cancer Letter.** "I'm quite excited about it." . . . GEORGE CANELLOS, Dana-Farber Cancer Institute, succeeded **Bernard Fisher**, Univ. of Pittsburgh, as president of the American Society of Clinical Oncology at the society's annual meeting recently. KAREN ANTMAN, also of Dana-Farber, defeated **Bruce Chabner**, NCI, for president-elect. New board members: **Brian Lewis**, community oncology; **C. Norman Coleman**, non-hematology/oncology; **Ross Donehower** and **Nicholas Vogelzang**, undesignated specialties. Completing board terms were **Daniel Von Hoff, Nancy Kemeny,** and **Fred Applebaum**. . . . EDWARD BRESNICK was elected president-elect, American Assn. for Cancer Research, last month. Bresnick, Norris Cotton Cancer Center director, will succeed AACR President **Lee Wattenberg** in April 1994. Elected to the board were **Donald Coffey, Michael Sporn, Louise Strong** and **Daniel Von Hoff.**

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$5-A-Month Insurance Fee Proposed, Could Raise $6 Billion For Research

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a $5-a-month set-aside tacked on to every health insurance policy in the U.S.

Since about 100 million policies are expected to be issued under the Clinton Administration's health care reform plan, as much as $6 billion could be raised.

That would amount to a 50 percent supplement to the existing appropriations for medical research. Under the proposal, the new funds would be appropriated by Congress.

In a press conference last week, Harkin said the Clinton Administration appeared to be reserving judgment on the trust fund.

"The reaction was, 'This is an interesting idea,'" Harkin said. "It's just something that hadn't been in focus before."

"I hope it will be a part of the plan that they will present to us. If not, our approach would be to try to incorporate something like this into any plan that passes Congress," he said.

Endorsed By More Than 100 Groups

More than 100 groups representing patients and researchers endorsed the trust fund proposal.

"It's about time that medical research got its due and had a place at the health care reform table," said Terry Lierman, president of Capitol Associates, a lobbying group whose clients include the American Assn. for Cancer Research. "The leadership of Sens. Harkin and Hatfield can do more for medical research than we have been able to do through the appropriations process."

The cancer groups that support the proposal include AACR, American Cancer Society, National Breast Cancer Coalition, Albert and Mary Lasker Foundation, Assn. of American Cancer Innstitutes, Assn. of Pediatric Oncology Nurses, the Society of Surgical Oncology and Leukemia Society of America.

THE CANCER LETTER

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The House and Senate last week approved the NIH Revitalization Act of 1993, sending the bill to the President, who is expected to sign it.

The two chambers made no changes in the conference report (**The Cancer Letter,** May 28). The House vote was 290-130. The measure passed by unanimous consent in the Senate.

Medenica's Privileges Extended; Patients Sue Hilton Head Physicians

The controversial physician Rajko Medenica was expected to take a six-month leave of absence from Hilton Head (SC) Hospital June 1. He will not.

Last month, Medenica requested the leave of absence, which he said he needed to defend a medical malpractice suit (**The Cancer Letter**, April 30). However, in a letter last week to the hospital administration Medenica said he would not be taking a leave since his practice required continued hospital privileges.

In a special meeting last Thursday, the hospital board, the medical staff and the medical practice committee granted a 90-day extension of Medenica's hospital privileges, more than enough time for the physician to reapply for permanent privileges, sources said.

In their attempt to keep Medenica at the hospital, the physician's supporters struck at the hospital's medical executive committee, the 10-member board responsible for peer review.

Last week, the committee's chairman, neurosurgeon Alfred Higgins, was named in a suit in which a group of Medenica's patients claimed the peer review process was being inappropriately used to drive Medenica out of the hospital.

After the suit was filed in the U.S. District Court, Beaufort Division of South Carolina, Higgins removed himself from consideration of all matters involving Medenica, sources said. Higgins and another committee member were absent at last week's meeting.

Prior to recusing himself, Higgins wrote letters "in the capacity of the President of the Medical staff" in which he requested assistance in investigation of what he described as "questionable practices in the field of medical oncology."

The letters were sent to the American Cancer Society, the HHS Inspector General's Office, the South Carolina Board of Medical Examiners and Blue

Cross/Blue Shield of South Carolina, sources said.

In a letter a copy of which was obtained by **The Cancer Letter**, Higgins wrote that the two-year peer review of Medenica "suggested a number of questionable practices in terms of both medical and ethical issues."

"It is my belief the Medical Executive Committee is reaching the limits of its resources and abilities to further investigate or to seek appropriate settlement of these issues and therefore I am formally requesting your assistance in terms of more in depth study of the matter and recommendations for corrective action," Higgins wrote in the letter dated May 19.

Attached to the letters was an 8-page report by the MEC on Medenica's peer review status. A stamp on each page stated that the document was protected from "discovery, subpoena or introduction into evidence in any civil action."

The Patients' Suit

On May 24, Colorado businessman Charles Stevinson and 12 other Medenica patients filed a suit claiming that three Hilton Head physicians including Higgins interfered with Medenica's physician-patient relationship, invaded the patients' privacy and engaged in conspiracy and unfair trade practices (Case No. 9:93-1215-19).

Along with Higgins, the defendants include neurologist Daniel Howley and oncologist Jane Gehlsen.

Gehlsen, formerly a practitioner at Hilton Head Hospital, had written to a number of institutions to verify Medenica's training credentials listed on his curriculum vitae (**The Cancer Letter**, April 30). Contacted by **The Cancer Letter**, Higgins, Howley and Gehlsen said they were under legal advice not to discuss the case.

"I think there is a number of doctors on Hilton Head who are jealous and greedy, and losing patients, because Dr. Medenica is saving lives, wherein in their practices they cannot," Stevinson said to **The Cancer Letter.** "The court will have to decide whether placating their greed is more important than the lives of these patients, a lot of whom will die if Dr. Medenica is restricted from practicing medicine. I, for one, am not interested in forfeiting my life for the prosperity of a few doctors."

In the suit, Stevinson, who has Waldenstrom's Syndrome, said he was treated at a number of institutions before coming to Medenica in a "terminal condition" six years ago. According to the complaint, "as a result of the treatment, [Stevinson] is in complete remission and carrying on a normal life, but needs continuing therapy to maintain his present condition."

Other plaintiffs include Muhammad Ali, former world heavyweight boxing champion, whom Medenica is treating for a "neurological syndrome;" Anne Coors, wife of the vice chairman of the Adolph Coors Co., who, according to court papers, has responded to Medenica's treatment for unspecified conditions; Charles Kropp, chairman and principal stockholder in Waukegan Steel Corp., whose chronic myelogenous leukemia was brought into remission as a result of Medenica's treatment, the complaint states.

"The defendants have...attempted to defame and discredit Dr. Medenica, to deprive him of his right and license to practice medicine and to deprive him of his right to use Hilton Head Hospital," the suit alleges.

The suit claims that Howley and MEC chairman Higgins, who, according to the filing, practice together, "at all times acted in concert with each other with the act of one being the act of the other." The document refers to the two physicians collectively as "Howley."

The patients allege that:

▶ Howley had secured Medenica's patient files "through illegal and surreptitious means," then contacted those patients under fictitious names to elicit private information.

▶ Howley and Gehlsen communicated "false and defamatory statements" to the hospital administration, a number of state and federal agencies, insurance companies, the American Cancer Society and the press. As a result, a number of insurers denied reimbursement "thereby creating hardships and financial distress" to the plaintiffs.

▶ Howley and Gehlsen encouraged and advised the attorneys in a pending malpractice suit against Medenica, "with the result that the...attorneys became coconspirators."

▶ Howley and Gehlsen persuaded members of the hospital staff to initiate an "abnormal extraordinary 'peer review process,'" which included only Medenica's most difficult cases, involved the files of patients who were never admitted to the hospital, and supplied "files and defamatory information" to individuals involved in peer review.

"Ethically and legally, no group of so-called doctors and others should be allowed to intentionally and willfully invade the plaintiffs' and other patients' doctor/patient relationship," the compliant stated. "No group of so-called doctors and others should be allowed to create a procedure to disseminate willfully misleading disinformation and information. No group of so-called doctors and others should be allowed to intentionally invade the privacy of the...patients, let alone to do so and thereafter misstate the facts and

record."

The plaintiffs asked for an injunction against Gehlsen's and Howley's "interfering with the ability of Dr. Medenica...to use the Hilton Head Hospital" and correct all patient information on the files they illegally obtained and return all information to its proper place. The plaintiffs also asked for a jury to set the damages and the award of trebled damages under the Unfair Trade Practices Act.

This is not the first time Stevinson and other patients have come to Medenica's defense in federal courts.

In 1989, Stevinson and other patients obtained an injunction against Medenica's travel to stand trial on fraud charges in Switzerland (**The Cancer Letter**, April 30). In that case, Judge Sol Blatt Jr., agreeing that the plaintiffs would die if Medenica were to be unable to treat them, ordered the physician to turn in his passport to the court clerk.

The current case was assigned to Judge Dennis Shedd.

Stevinson also assisted in funding the Denver-based Medenica-Stevinson Center for Cancer and Immunology.

Medenica, who is licensed in Colorado, has provisional medical staff privileges at St. Anthony Hospital, operated by Sisters of St. Francis of Colorado Springs. Medenica's provisional status there is scheduled to come up for review within a month, after which he is expected to seek full privileges, sources said.

Privileged Information Released...Again

The Hilton Head Hospital's MEC report, dated April 1, states that it represents a summary of concerns raised by outside experts contracted by the hospital to conduct peer review of Medenica's practice.

In this specially designed peer review procedure, the oncology component of Medenica's practice was reviewed by Howard Ozer of the Univ. of North Carolina and Peter Weirnik of the Albert Einstein Univ. The neurology component was reviewed by Donald Costigan of Emory Univ. and immunology was reviewed by Joseph Bellanti of Georgetown Univ., the report stated.

The report was signed by Higgins, whose signature appeared above the printed list of seven other committee members.

A copy of the report was obtained by **The Cancer Letter.**

Earlier this year, Ozer's portion of peer review was mailed in an envelope without a return address to the attorneys representing a Medenica patient who claims to have developed hemolytic uremic syndrome as a result of the treatment (**The Cancer Letter**, April 30).

According to the MEC report, a number of problems remained unresolved after Medenica was given the opportunity to comment on the reviewers' findings.

The reviewers found Medenica's testing excessive and described his record-keeping as "confusing" and "untimely," the document said. Excerpts from the report follow:

▶ "Overly optimistic appraisal of patient conditions reflected in medical records suggest either lack of understanding or lack of regard for clinical basis for medical practice.

▶ "Transcending areas of recognized competence (neurology) without maintaining documentation of patient conditions, progress related to treatment, or consultation with certified specialists in the field indicates lack of respect for boundaries of competence.

▶ "Treatment of quasi- or nonmalignant conditions with antineoplastic therapy (pseudomyxoma) is not justified by patient testimonial alone. This is also true for treatment of other conditions. Use of testimonials suggests lack of understanding of the need for scientific discipline and documentation.

▶ "Issues of offering or continuing therapy to patients and families beyond reasonable hope suggests motivation other than the best medical interests of the patient, or lack of understanding of ethical practice.

▶ "Cloaking last effort therapy with pseudo-scientific procedure, thus providing false hope for patients, suggests misconception of the responsibilities of the clinical scientist to the patient beyond the benefit of realistic optimism.

▶ "Disclosure of possible serious side effects or death as a result of therapies described in Dr. Medenica's 'informed consent' documentation does not appear realistic or complete.

▶ "Statements of patients' personal financial responsibility for treatment and related diagnostics described as 'off-label' or for the purpose of 'research' in 'informed consent' documents does not appear to be consistent with the usual ethical intent of such documents."

MEC Claims "Intimidation"

In the report, the MEC said Medenica's response to peer reviewers' comments "is to assume an adversarial position that neither MEC nor the reviewers are intellectually capable of understanding the significance of his clinical and scientific achievements and contributions.... He also resorts to thinly veiled intimidation in the form of instituting litigation against the reviewers and presumably the MEC despite

our efforts to perform this peer review process...in good faith and according to the principles of fairness and confidentiality," the report stated.

As a result, the report said the MEC found itself at a dead end:

In-house peer review of Medenica's practice was not feasible because of reticence by hospital staff members to perform such reviews and because of Medenica's claims that such reviews would reflect "personal prejudice," and "ignorance of the highly sophisticated nature of his practice," the report said.

Outside reviews, too, proved to be not feasible, since they "failed to satisfy Dr. Medenica or his supporters as to the merits of or the seriousness of the reviewers' criticisms and the need to modify the conduct of his practice....

"Any...efforts to establish a remedial program would require extensive input from recognized authorities in the fields of oncology, immunology and hematology who currently represent the state of the art with regard to practice standards, research standards and medical ethics. Such a program would necessarily require Dr. Medenica's participation and compliance. It would also require his willingness to acknowledge fiscal responsibility and propriety as this applies to his patients and to the available health care resources of the community," the report said.

In a related development, last month Judge Gerald Smoak of the Beaufort County Court of Common Pleas, in an unusual ruling, sealed the court files in the malpractice case against Medenica.

The files include Ozer's peer review analysis of Medenica's treatment of Gayle Taylor, a breast cancer patient.

Granting a motion by Medenica's attorneys, Smoak also imposed a gag order on all parties in the Taylor litigation.

DCPC Advisors Okay Five New RFA Concepts, Worth $33.6 Million

Advisors to NCI's Div. of Cancer Prevention & Control have given concept approval to five new grant programs that will result in set-asides of approximately $33.6 million over the next three to four years to fund research project grants or cooperative agreements.

The DCPC Board of Scientific Counselors, at its meeting last month, also gave concept approval to the continuation of an interagency agreement with the Centers for Disease Control's Office of Smoking and Health. NCI provides $75,000 a year for funding the Assn. of State and Territorial Health Officials Tobacco Prevention and Control Contact Network.

Following are excerpts of the concept statements:

Interactive research project grants for clinical/metabolic studies in nutrition and breast cancer prevention. Proposed RFA, total $10 million over four years, six to nine awards per year. Program director: Carolyn Clifford, Diet & Cancer Branch.

This concept seeks to encourage the coordinated submission of related and integrated research project applications from investigators who want to collaborate on the development and conduct of clinical/metabolic studies relevant to nutrition and breast cancer prevention. Applicants will be responsible for the planning, direction and execution of the proposed projects. Once principal investigator from the group submitting a package will be identified as the program coordinator and applications submitted as a package should be tightly focused on a specific research theme.

Several typical examples of research areas relevant to the dietary intervention clinical/metabolic studies for nutrition and breast cancer prevention are:

--Identification, evaluation, and validation of specific molecular, cellular, metabolic and endocrine biomarkers that are associated with initiation and/or promotion of preneoplastic transformation which may be responsive to dietary constituents.

--Determine the relation between dietary intake and gene expression in breast epithelial cells and breast cancer cells.

--Evaluate interactions such as nutrient-nutrient, nutrient-drug and genetic-environment interactions.

--Define dose-response relationships for macronutrients, micronutrients and non-nutrient dietary constituents on molecular and cellular events and alterations in metabolic pathways.

--Characterize individual variability in the biological activities of specific dietary interventions.

--Identification of biochemical markers as quantitative measures of dietary intake, digestion, absorption, metabolic breakdown or nutritional status.

--Bioavailability of dietary nutrients and non-nutrients at various intakes and from different food sources.

--Determine the relation between dietary intake of environmental carcinogens, i.e., pesticides and dioxins, and breast cancer, including potential effects of contaminants in the food and water supply.

NCI anticipates that there will be set-aside funds for the initial year's funding and will consider for funding all IRPG applications in a package if all are related by peer review as having significant and substantial scientific merit. NCI will also consider funding meritorious individual IRPG applications if it is not possible to fund the IRPG package as a whole.

Economic studies in cancer prevention, screening and care. Proposed RFA, total $6 million over four years, three to six awards. Project officer: Martin Brown, Applied Research Branch.

The objective of these studies is to provide NCI with knowledge on economic aspects of cancer care in order to develop new directions for health care policy and cancer prevention and control interventions. Three broad topics are: the cost of cancer treatment and care in various organizational settings; cost-effectiveness of cancer prevention and screening

trials and interventions; and collection of economic data in the context of clinical trials and the use of economic data and analysis in the design of trials.

Suggested cancer sites to be studied are breast, prostate and colorectal, though other sites would be considered.

A. The cost of cancer treatment and care in various organizational settings. Research goals:

--To develop and validate methods for collecting reliable and representative data on longitudinal patterns of health care resource use, expenditures and costs for cancer prevention, screening, diagnostic, treatment and care in various organizational settings.

--To develop and validate methods for collecting reliable and representative data on the cost of continuing care for cancer patients.

--To explore alternative proposed and existing models outpatient and home based continuing care for cancer patients in order to determine efficient modes of organization which provide access to and meet the continuing care needs of cancer patients and their families.

Proposed studies initially would include methodological and feasibility studies. The purpose would be to explore ways of overcoming the barriers that have made this type of study difficult to conduct to date: How does the researcher obtain access to a representative population of newly diagnosed cancer patients in a fee-for-service? How does the researcher obtain access to reliable and complete data on health service utilization and costs for these patients? How can such a study be organized efficiently so as to make the data available at a reasonable level of cost to NCI?

Other studies would include actual data collection in fee-for-service settings as well as continuing studies in the HMO setting and in emerging organizational settings such as managed care, preferred provider organizations, etc., including comparative studies across settings.

In the area of continuing care costs, proposed study areas include:

--Additional studies to develop aggregate level estimates of the economic burden of cancer on families, including the relative contribution to this burden by cancer site and by phase of the disease and treatment process.

--Methodological studies to determine sampling strategies, methods for analyzing censored data, methods for constructing summary economic burden measures, methods for measuring nonmonetary costs, and developing standardized survey instrumentation that can be applied to this area.

--Patterns of care studies focusing on the experience of cancer patients after the initial treatment phase, including home care are important to determine the frequency and timing of interviews.

--Data collection studies based on the methodological studies and using one or more SEER registries as a sample frame or other sample frames such as non SEER cancer registries, cooperative groups and CCOPs.

B. Cost effectiveness of cancer prevention and screening trials and interventions.

Research goals are to determine the prospective cost effectiveness of NCI sponsored cancer prevention and screening trials and the health system interventions which might eventuate from these trials. Proposed studies:

--Methodological studies to address how well efficacy, cost and quality of life data obtained in the trial setting will generalize to expected community practice and to develop methods for adjusting parameter estimates or generating plausible ranges of uncertainty in cases where such data is not expected to generalize well.

--Cost effectiveness evaluations of NCI sponsored prevention and screening trials based on prospective expectations about trial outcomes and about the effect of trial outcomes on clinical practice and (in the case of prevention) population behavior.

--Cost effectiveness evaluations of other cancer related interventions based on clinical trial evidence, other clinical evidence and health care system database records (such as SEER/Medicare database). Examples of such studies include the comparative cost-effectiveness of alternative cancer prevention approaches (e.g. what is the optimal combination of tax policy, health education and physician intervention to reduced lung cancer through reduced consumption of tobacco products?); alternative modalities of cancer screening and diagnostic follow-up (e.g. fecal occult blood test and sigmoidoscopy for colon cancer screening; what is the most cost effective strategy of diagnostic follow-up to non-normal mammography?) and the comparative cost effectiveness of alternative approaches to clinical surveillance of cancer patients.

C. Collection of economic data in the context of clinical trials.

Research goals: To determine the cost of the health care intervention (e.g. cancer prevention, control, treatment or rehabilitation) in NCI sponsored trial settings compared to standard cancer control and treatment settings. To determine the feasibility of collecting data on direct and indirect lifetime costs in the context of clinical trials. Proposed studies:

--Methodological studies addressed to measurement and analysis problems inherent in chronic disease studies.

--Methodological studies to determine the mechanisms for and feasibility of collecting economic information of various levels of scope and detail in the context of clinical trials.

--Methodological studies on how economic data and analysis might be incorporated into the optimal design of clinical trials.

--Studies which actually collect economic data within the context of a clinical trial, either on a retrospective or a prospective basis.

Cancer surveillance using health claims-based data systems. Proposed RFA (cooperative agreement), total $3.6 million over three years, up to three awards. Project officer: Larry Kessler, Applied Research Branch.

This concept seeks research projects to determine the potential utility and limitations of reimbursement claims systems for tracking cancer incidence, the use of new early detection and diagnostic tests, and cancer related health care utilization. This initiative is designed to address the following research questions:

1. How do incidence rates generated from health claims or other medical contact data compare with SEER registry rates including temporal trends in the rates? Are any differences systematic in nature?

2. Do comparisons of data collected by health claims versus registries differ depending on the reimbursement system? Can standard exchange data sets now under development be used to extract information relevant to cancer

surveillance? Can techniques or artificial intelligence be use to define cases, determine matches between data sources, determine extent of disease, and other relevant surveillance data using information from health claims and other nonregistry data?

3. What data are currently unavailable using health claims that are available in SEER? What are the barriers including cost that must be overcome to add these data to a claims data base? How necessary for research and surveillance are these data?

4. How can claims data be used to track the emergence of new technologies for detecting, diagnosing or treating cancer or precancerous conditions?

5. To what degree can an expanded claims based registry system enhance NCI's ability to examine environmental causes of cancer?

6. To what extent does an expanded claims-based registry system provide information of additional value compared to nationwide cancer mortality data obtainable from the National Center for Health Statistics?

7. What are the confidentiality issues associated with the use of claims based data, as well as any other data bases proposed, in addressing any of the above questions?

This initiative encourages interdisciplinary approaches to address these research questions.

Research will be carried out in areas with high quality existing cancer registries.

Cancer pain management in the outpatient setting. Proposed RFA, total $6 million over four years, five awards. Program director: Claudette Varricchio, Community Oncology & Rehabilitation Branch.

Objectives are to 1) test interventions to promote the transfer of technology in a variety of health care delivery systems to improve knowledge about pain management for cancer patients living at home, 2) evaluate interventions to address patient and health care provider factors that are barriers to effective transfer and use of state of the art cancer pain management techniques, 3) improve the acceptability and use of the pain control strategies through improved management of the side effects of analgesics and/or modifications of attitudes towards the use of narcotics for pain management.

This is a request for applications for research that will develop and test interventions for the delivery of appropriate and effective pain management to cancer patients outside of acute care and hospice settings. The settings where this intervention could be tested include in home care, out patient based care for patients experiencing chronic pain from metastatic disease or the sequelae of disease or therapy, or acute pain episodes during a more stable course of disease.

The proposed interventions should build on current knowledge and research findings that indicate appropriate pain management approaches in different types of pain etiology (i.e. bone pain from metastatic disease or neurogenic pain from surgery, other therapy or disease progression) as well as using different drug combinations for optimum effect.

The cultural, ethnic, and developmental aspects of the population targeted for study must be considered in designing interventions. Validation of established assessment guides in low literacy and non-English speaking populations should be considered as part of a broader intervention where appropriate. Biological and behavioral variables should be included as appropriate to the research question. The inclusion of biological variables that can be measured directly is encouraged. This will require collaboration across disciplines and the inclusion of community care givers and primary care providers on the research team.

Examples of target areas for the development of interventions could be:

--Effects of patient concerns, patient choices, decision making strategies, and care giver values on effective pain management.

--Impact of systematic use of clinical practice guidelines and documentation of the effect of the intervention on patient care outcomes.

--Overcoming barriers to application of state of the art knowledge about cancer pain management.

--Interface of ethical and legal codes and the effect of adherence to each on the quality of pain management outside of the acute care setting.

Rehabilitation and psychosocial research in younger women with breast cancer. Proposed RFA, total $8 million over four years, five to six awards. Program director: Susan Nayfield, Community Oncology & Rehabilitation Branch.

The objectives of this concept are: To identify and describe the medical and psychosocial sequelae of breast cancer diagnosis and treatment in younger women, and to explore factors contributing to the occurrence of these problems; and to develop and test interventions directed at decreasing morbidity associated with breast cancer and improving quality of life for younger breast cancer patients.

This concept invites applications which address specific health issues and psychosocial problems faced by women diagnosed with breast cancer during early adult life. Research projects will focus on developing, implementing, and evaluating interventions directed at young women with breast cancer. Problems targeted by these interventions include issues such as career development and employability, marriage and family planning, medical sequelae of treatment, and living with the uncertainty of recurrent disease.

Projects will include two phases of research: 1) a descriptive phase, in which baseline data is collected and descriptive analyses are performed, and 2) an evaluative phase, in which the impact of the study intervention on physical and psychological morbidity and quality of life of younger women with breast cancer is assessed.

For purposes of this concept, younger women are defined as women under age 50 at the time of diagnosis of breast cancer and at entry into the research project. Population subgroups for specific focus may be identified by medical, social, or cultural characteristics or needs. Proposals should address at least one of the following aspects of care for younger breast cancer patients: 1) medical sequelae of therapy, 2) body image and sexuality, 3) interpersonal and family relationships, 4) concrete needs (e.g., assistance with child care), 5) employment and insurance, 6) medical uncertainty, and 7) special needs of younger patients during terminal care.

For formal evaluation of efficacy, a study design including random assignment to control and intervention groups is recommended. A quasi-experimental design may be considered if this approach provides reasonable assessment

of efficacy. Required outcome variables include the patient's global health-related quality of life and QOL domains reflecting medical and psychological morbidity. Outcomes assessment strategies and analyses must be based on established health research methods and utilize standard measures of QOL and QOL domains with demonstrated reproducibility, validity, and responsiveness.

Because of the complexities of the problems faced by younger women with breast cancer, a multidisciplinary research approach is recommended. Expertise from areas of medical and surgical oncology and oncology nursing, health psychology and psychiatry, endocrinology and reproductive medicine, health economics and health services research, and other social science disciplines should be included as appropriate for the target problem and population.

RFPs Available

Requests for proposals described here pertain to contracts planned for award by the National Cancer Institute unless otherwise noted. Address requests for NCI RFPs, citing the RFP number, to the individual named, the Executive Plaza South room number shown, National Cancer Institute, Bethesda MD 20892. Proposals may be hand delivered to the Executive Plaza South Building, 6130 Executive Blvd., Rockville MD.

RFP NCI-CP-40509-13

Title: In vitro screening and evaluation of chemicals and preclinical drugs for in vivo toxicology selection

Deadline: Approximately July 26

The Office of the Director, NCI Div. of Cancer Etiology, is soliciting proposals for contracts to perform work associated with the Mouse Lymphoma Assay and the Salmonella Typhimurium Assay. Under the Mouse Lymphoma Task, offerors must document their ability to induce mutations in the mouse lymphoma assay. Up to five samples per year will not be coded samples of chemical compounds but will be human urine specimens. A number of compounds tested have unusual and hazardous properties including extreme acute toxicity, high reactivity, explosive or pyrrophoric potential, or high volatility. Both the safe handling of compounds and the generation of accurate and defensible data are critical.

Under the Salmonella Typhimurium Assay, offerors must document their ability to induce mutations in Salmonella Typhimurium. Up to five samples per year will not be coded samples of chemical compounds but of human urine samples. One of the major questions to be investigated concerns the dose dependency effects of high levels of mutagens in the test system and whether high concentrations of S9 gives dose dependent formation of unusual metabolites of known mutagens and carcinogens. NCI shall consider proposals from all responsible small business firms qualifying under SICC #8731, size standard 500 employees. Offerors must meet three mandatory requirements. Offerors must possess a facility in compliance with Good Laboratory Practice for Nonclinical Laboratory Studies found in CFR Title 21, Part 58; must have examples of Salmonella and/or Lymphoma studies carried out under Good Laboratory Practices which have been or are capable of being submitted in support of a regulatory application to FDA or EPA; and the proposed principal investigator must have documented experience in utilizing these specific microbial and/or mammalian cell mutagenicity assays on human urine specimens. Multiple contract awards anticipated. Cost reimbursement contracts, for a four year period.

Contracting officer: Sharon Miller, RCB Executive Plaza South Rm 620, phone 301/496-8611.

In Brief

Schafer, Johnson Lead ONS; Neel Wins AACR's Gertrude Elion Award

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. . . **SANDRA LEE SCHAFER**, Shadyside Hospital, Pittsburgh, succeeded **Carol Curtiss** as president of the Oncology Nursing Society last month. **LINDA JOHNSON**, Arthur James Cancer Hospital and Research Institute, Columbus, OH, was elected president-elect. New directors are **Linda Sveningson** and **Roberta Anne Strohl**. . . . **BENJAMIN NEEL**, Harvard Medical School, received the first Gertrude Elion Cancer Research Award sponsored by the American Assn. for Cancer Research. The $30,000 award, supported by Wellcome Oncology, is to be given annual to a nontenured scientist. Neel's research proposal was titled, "Tyrosine Phosphatases in Cell Life and Death." . . . **ONCOLOGY NURSING** Society awards presented last month included: **Judith Johnson**, Minneapolis, Distinguished Service Award. Most recognized of her accomplishments is the "I Can Cope" program she began through the American Cancer Society. **Jeanne Quint Benoliel**, Univ. of Washington, Distinguished Researcher Award. Benoliel pioneered research in women undergoing mastectomy. **Erma Bombeck**, the writer and columnist, ONS Public Service Award. **Donna Berry**, Seattle, **Marylin Dodd** and **Suzanne Dibble**, San Francisco, Excellence in Cancer Nursing Research Award. Berry also received the Quality of Life Award. **Launa Lamkin**, Denver, Excellence in Cancer Nursing Administration Award. **Eileen Sharp**, Franklin, TN, Excellence in Biotherapy Nursing Award. **Sharon Ritchey**, Altoona, PA, Excellence in Patient/Public Education Award. **Suzanne Mahon**, St. Louis, Excellence in Breast Cancer Education Award. **Alice Longman**, Tucson, Excellence in Cancer Nursing Education Award. **Margaret Hull**, Columbus, OH, Excellence in Writing Award in Nursing Research. **Nessa Coyle**, New York City, Excellence in Writing Award in Clinical Practice. **Tish Knobf**, New Haven, CT, Excellence in Scholarship Award. **Linda Scott**, Beckley, WVA, Excellence in Oncology Nursing in Private Practice Award. **Debra Wujcik**, Vanderbilt Univ., delivered the ONS/Schering Clinical Lecture, titled "An Odyssey into Biologic Therapy." . . . **ELLYN BUSHKIN**, recipient of the ONS Mara Mogensen Flaherty award and former clinical director of nursing, Mount Sinai Medical Center, died weeks prior to the ONS congress. Her husband, Bernard Bushkin, delivered her lecture, "Signposts of Survivorship: A Universal Travel Guide."