THE CANCER LETTER

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Health Reform Bill Contains Unpleasant Surprises For Drug Manufacturers

The health reform bill submitted by the Administration to Congress last week contained a number of differences from the draft that had been leaked to the press a month ago.

Reimbursement for the care of patients enrolled in clinical trials made a safe transition from the draft to the 1340-page Health Security Act.

The surprises appear to be confined largely to the sections covering reimbursement of drugs purchased by the government through

(Continued to page 2)

In Brief

Krakoff Moves To Scotland; Salmon Wins Waldenstrom Award; ONS Endorses Reform

IRWIN KRAKOFF, head of the Div. of Medicine at M.D. Anderson Cancer Center, has taken a position as chairman of the Dept. of Medicine and director of cancer programs at Health Care International, Glasgow, Scotland. **Rosemary Mackey**, formerly senior vice president at St. Luke's Episcopal Hospital, Houston, is executive director, marketing and development, at the same institution. . . . **SYDNEY SALMON**, director of the Arizona Cancer Center, received the Waldenstrom Award from the International Myeloma Workshop last month, and delivered the Waldenstrom lecture. The award honored Salmon's contributions to research in multiple myeloma. . . . **ONCOLOGY NURSING** Society Board of Directors has endorsed President Clinton's health care reform plan. Key elements of a reform plan endorsed by ONS, developed by the American Nurses Assn., were contained in the President's reform package, the board said. ONS has more than 24,000 member nurses. . . . **JOHNS HOPKINS** Univ. School of Medicine has dedicated the Brassica Chemoprotection Laboratory—named after the genus of plants that includes broccoli, cauliflower and kohlrabi—to study anticancer substances found in fruits and vegetables. The lab is headed by **Paul Talalay**. . . . **GOLD MEDALS** awarded by the American Society for Therapeutic Radiology and Oncology at the society's annual meeting last month went to: **Eric Hall**, Columbia Univ.; **Theodore Phillips**, Univ. of California, San Francisco; and **John Laughlin**, Memorial Sloan-Kettering Cancer Center.

Health Reform Bill Differs From President's Draft

(Continued from page 1)
the Medicare and Medicaid programs.

The coverage of off-label indications, as described in the bill, would not be as broad-based as it appeared from the draft dated Sept. 7 (**Cancer Economics**, September 1993 and **The Cancer Letter**, Oct. 8).

The bill refers to the three compendia as a resource. However, an unexpected provision allows the carriers to determine whether additional off-label uses of a drug are medically acceptable.

That determination would be based on clinical evidence in peer reviewed medical literature and HHS guidance, the bill says.

Also under the bill, drug manufacturers would be required to give the government a rebate of 17% of the average manufacturer retail price on drugs purchased through the Medicare program. The earlier draft called for a 15% rebate.

Other drug pricing provisions, some of which were not contained in the draft report but contained in the bill, are:

- Manufacturers of generic drugs would not be required to give Medicare rebates to the government.
- In a provision that applies to drugs introduced after June 30, 1993, HHS would have the authority to negotiate the rebate amount if the drug's price is believed to be excessive or if the drug is available at a lower price on foreign markets.
- The government would compare the U.S. price of outpatient drugs to the prices charged in Western Europe, Japan, Australia and New Zealand. The comparison would continue throughout the life of the product, and higher rebates may be required if a drug's price in foreign markets dips below the U.S. price.

The rebate could be equal to the difference between the average manufacturer retail price and the price at which the drug is available to foreign wholesalers.

- The bill speaks of pharmacists as dispensers of drugs and does not address the pharmaceutical products being sold by physicians. The bill could affect Medicare coverage of drugs administered on an inpatient basis.
- Drugs will be reimbursed at a formula that includes an estimated acquisition cost (EAC) plus a pharmacy dispensing fee. The ceiling for EAC would be set at 93% of the average manufacturer non-retail price. In 1996, the dispensing fee would be set at $5 for the pharmacies.

HHS Secretary would have the authority to reduce the dispensing fees for mail order pharmacies, which have higher economies of scale.

The average manufacturer retail price is defined as the price paid to the manufacturer for the drugs distributed to retail pharmacies. The average would exclude the rebates to Medicare.

The average manufacturer nonretail price is defined as the price paid to the manufacturer by hospitals and other institutional purchasers for their own use. Both average prices would be calculated quarterly.

The Administration plans to implement its reforms by Jan. 1, 1996.

Report Urges Bypass Funding For Breast Cancer Programs

The report of the President's Cancer Panel's Special Commission on Breast Cancer presented to the White House last week calls for funding breast cancer programs at no less than $500 million per year.

That amount is consistent with the NCI bypass budget for fiscal 1995.

"The report serves as the basis for an action plan to deal with breast cancer," said Nancy Brinker, chairman of the special commission, former member of the President's Cancer Panel and founder of the Susan G. Komen Breast Cancer Foundation.

In recent months, Brinker found herself competing for the Administration's attention with another group, the National Breast Cancer Coalition, which is calling for making breast cancer one of the top national priorities and the formulation of another

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strategic plan (**The Cancer Letter**, Oct. 8).

In mid-December, HHS Secretary Donna Shalala will hold a hearing to formulate a plan for the federal government's breast cancer programs.

"Past investments in basic science and breast cancer research have brought us to a point where numerous opportunities exist to advance our ability to prevent and treat breast cancer," the special commission's report states, calling for an interagency effort that would be led by NCI.

The 26-page report recommends two broad goals in combatting breast cancer:

--Development of methods to cure and prevent the disease and,

--Making current and future methods of early detection available to all population groups.

"At this time there are no proven methods of preventing breast cancer," the report says. "Determination of dietary, hormonal, environmental, genetic and other causes of breast cancer is required for the development of effective preventive strategies."

According to the report, physicians need to promote the use of screening mammography and clinical breast examinations for all women, paying particular attention to the underserved populations.

The report calls for inclusion of patient advocates into decisionmaking on optimal use of breast cancer research funds; greater research on newer imaging techniques; the development of a breast cancer blood test that identifies biomarkers of early disease; the development of less invasive and less toxic therapies and the implementation of the 1992 Mammography Quality Standards Act.

The advocates of Brinker's plan include John Dingell (D-MI), chairman of the Committee on Energy and Commerce and Sens. Connie Mack (R-FL) and Dianne Feinstein (D-CA), cofounders of the Senate Cancer Coalition.

"The commission report can serve as a blueprint for [a plan to combat breast cancer] and assist those whom Secretary Shalala will call together in December to discuss national strategies for eradicating breast cancer as a life-threatening disease in our lifetime," Dingell wrote in a "Dear Colleague" letter accompanying the report for other House Members.

In a letter to Senate members, Mack and Feinstein similarly endorsed the report. "We believe the recommendations of this report should be carefully considered in the development of a national strategy to eradicate breast cancer," they wrote in a joint letter.

NCI is expected to spend $262.9 million on breast cancer in fiscal 1994. Other NIH Institutes will spend additional $36.5 million and the Department of Defense will spend another $210 million over the next five years.

Wiernik Admits Cover-up, Loses Posts At Albert Einstein

Peter Wiernik was removed from his posts as chairman of the oncology department and associate director of the cancer center of the Albert Einstein Medical Center after admitting that he had provided interleukin-2 to two neurosurgeons conducting unauthorized trials with brain tumor patients and subsequently covered up his actions.

The incident occurred six years ago, and, according to federal prosecutors, there was no evidence that patients had been harmed in the unauthorized experiments.

Wiernik was removed from his posts effective July 1, after the prominent cancer researcher admitted to federal prosecutors that he had provided the agent for the experiments and covered up his actions for five years.

Wiernik, who remains a professor at Montefiore Medical Center, an institution affiliated with Albert Einstein, was also censured by the medical staff.

Though a federal complaint against Wiernik was filed, prosecution was deferred and the complaint is scheduled to be dismissed next month, as a result of an agreement with the prosecutors. Wiernik's role in the incident is under review by the New York State Board for Professional Medical Conduct.

In June, the office of the U.S. Attorney's for the Southern District of New York issued a press release on the case. However, the issue did not come to light until last week, when a story about it appeared in The New York Daily News and, later, in The New York Times.

"I have spent 30 unblemished years seeking to assist others to find new and better ways to treat cancer," Wiernik said in a written statement to **The Cancer Letter**. "Consistent with these goals, I sought to assist colleagues whose integrity and qualifications I had no reason to doubt at the time and subsequently erred in misrepresenting those circumstances.

"I am deeply sorry for my complicity. I hope that it does not curtail my future efforts in cancer research and treatment. I played no role in administration of

the recombinant IL-2 to the brain tumor patients or in the related trials."

According to Ty Cobb, an attorney with Hogan & Hartson, a Washington firm, who represents Wiernik, the IL-2 Wiernik provided to the neurosurgeons was not diverted from any of his own patients and was slated to be discarded.

Wiernik's former associate, Elisabeth Paietta, also signed a statement admitting to having provided the agent for unauthorized experiments. The neurosurgeons were not named in the court papers.

Nadia Adler, general counsel for Montefiore, told **The Cancer Letter** that Wiernik's loss of the two posts was the result of his admission of his role in the coverup.

According to Adler, the two neurosurgeons conducted their experiments in 1987, after coming to Montefiore from NIH. Their experiments at Montefiore were a continuation of their NIH studies, Adler said.

The neurosurgeons, while seeking FDA approval for the experiments, asked Wiernik to give them a small quantity of the agent, attorneys involved in the case said. Wiernik was using IL-2 in his experiments with renal cell carcinoma.

According to court documents, 16 brain cancer patients were treated by the neurosurgeons. Wiernik was not involved in their treatment, court documents say.

"The neurosurgeons claimed that [they] would be receiving [their] own supply of rIL-2 shortly," Wiernik wrote in a statement to the court.

According to the statement, the oncology department had a residual supply of the agent, which was slated to be discarded. "Although I knew at the time that there were regulatory restrictions on the use of the residual rIL-2, I agreed," Wiernik wrote.

Later that year, the neurosurgeons told Wiernik that FDA had demanded that they identify the source of rIL-2 they had been using, Wiernik wrote.

"After much discussion, we all agreed not to disclose that the oncology department had consented to the department of neurosurgery's use of the residual r-IL-2 from our laboratory, because that usage violated FDA regulations.

"I was afraid that if I acknowledged that I had permitted the department of neurosurgery's use of residual rIL-2, I and the department of oncology would be severely penalized, and our contributions to the treatment of current and future patients and to the important cancer research to which we had been devoted every day since I first arrived would be jeopardized.

"I was also concerned about the unintended consequences to the staff of top rate physicians and clinicians I had attracted to Montefiore. Following the meeting, I advised Dr. Paietta that I agreed to tell a story, if asked, that was not true: that a technician in the oncology laboratory supplied the residual rIL-2 to the department of neurosurgery without either my knowledge or Dr. Paietta's.

"I asked Dr. Paietta if she was willing to join this untrue story and she agreed, motivated, in my view, by her dedication to our patients and the importance of our ongoing research," Wiernik wrote.

According to the statement, Wiernik told this story in a letter to NIH, in communications with HHS investigators and during an internal inquiry conducted by Montefiore.

"I was never comfortable or enthusiastic about telling these lies or about participating with others in what amounted to a cover-up," Wiernik wrote.

"I became increasingly uncomfortable as the FDA and institutional investigations proceeded producing a host of surprising revelations about the qualifications, conduct and misrepresentations of others involved, which magnified the gravity of falsehoods to which I had agreed and thereafter sponsored."

The investigations continued, with the most recent inquiry involving the U.S. Attorney's office and FDA.

In May 1992, Wiernik authorized his attorney to tell the entire story to the U.S. Attorneys, the physician wrote.

"Although humiliated, I was greatly relieved," Wiernik wrote. "I am fully responsible for my actions and extremely sorry for my conduct."

Hospital To Renew Medenica's Privileges, With Conditions

After four months of devising peer review procedures, the board of directors of Hilton Head Hospital offered to renew the hospital privileges of Rajko Medenica, a controversial South Carolina physician.

The offer is contingent on Medenica's acceptance of "certain conditions," hospital officials said. The deadline for meeting those conditions is Nov. 16, Steven Caywood, hospital administrator, said to **The**

Cancer Letter.

Caywood declined to identify the issues that remain to be resolved. However, sources familiar with the negotiations said the hospital is demanding that Medenica's patients drop a suit against three physicians, two of whom are practicing at Hilton Head Hospital (**The Cancer Letter**, June 4).

In the suit, filed last May, the patients claimed that the physicians, all of whom had at various times looked into Medenica's practice methods, were endangering the plaintiffs' lives by their attempts to interfere with Medenica's practice.

One of the three physicians named in the patients' suit, Alfred Higgins, is president the medical staff and chairman of the medical executive committee at the hospital. Until the suit was filed, Higgins was responsible for peer review of Medenica's practice.

Charles Stevinson, a Denver businessman and one of the plaintiffs, confirmed to **The Cancer Letter** that he expects to meet with the hospital board later this week to discuss the possibility of settling the suit.

Over the past four months, hospital officials struggled to devise a system for ongoing peer review of Medenica's practice. Though no details have been announced, knowledgeable sources told **The Cancer Letter** that a physician picked by the hospital would be asked to review Medenica's patient records.

According to sources in academic institutions, hospital officials have been recruiting an oncologist whose duties would include reviewing Medenica's patient files and making regular site visits to Hilton Head Hospital.

Sources familiar with the negotiations told **The Cancer Letter** that Medenica and the hospital would hire a nurse and a physician's assistant to assist Medenica with maintenance of patient records.

At the hospital Medenica would be required to use standard protocols only, sources said. It was unclear whether Medenica would be similarly restricted in his office-based practice.

DCE Advisors OK Expansion Of Chernobyl Workers Study

NCI plans to expand support for a study of leukemia and thyroid disease among Estonian workers who participated in the clean-up of the 1986 Chernobyl nuclear reactor accident.

Advisors to NCI's Div. of Cancer Etiology approved spending $300,000 to expand a study by the Finnish Cancer Registry under contract with NCI. The study will, over the next three years, extend the biological dosimetry to estimate radiation doses received by all 4,845 Estonian clean-up workers, rather than a sample of 1,000 workers as originally planned. The reason for this, NCI staff said, was that the dosimetry badges worn by the workers were found to be "inadequate indicators of radiation exposure." In addition, dose records were missing for more than a quarter of the workers.

The expansion also will allow for a study of thyroid nodularity of 1,000 workers.

The board gave concept approval to recompetition of two competitive contracts and one new grants program in AIDS-associated malignancies, a three-year noncompetitive contract to the Chinese Academy of Medical Science for cellular and molecular studies of hepatocarcinogenesis in China, and a noncompetitive contract to the National Academy of Sciences for a second mortality survey of cancer in Navy Korean War microwave (radar) workers.

The board turned down a proposed NCI-National Institute of Occupational Safety and Health interagency agreement for the study of workers exposed to sulfuric acid aerosols. Board members said further animal studies were needed prior to investigations in humans.

Following are the concept statements for the recompetitions and the RFA:

Studies Using Primate and/or Other Animal Models for AIDS Vaccine Research. Recompetition of a contract held by Bioqual Inc. $1.2 million over four years. Project officer: Genoveffa Franchini.

The Laboratory of Tumor Cell Biology established this contract in 1991 to provide animal facilities, including biohazard containment (P2) for the housing and veterinary care of up to 50 nonhuman primates. These animals have been available for immunization with live recombinant vectors and HIV subunit proteins. The cellular and humoral immune response has been methodically measured in the immunized animals using diagnostic and functional assays (ELISA, Western blot, CTL and neutralization assays).

The contractor shall: 1) provide proper housing and husbandry for the maintenance of healthy nonhuman primates, rhesus macaques for HIV-1/HIV-2/SIV vaccine studies and possible Japanese macaques for HTLV-I study), 2) ensure that space and equipment (caging) are dedicated to the contract, 3) provide environmental enrichment for the animals as requested by law, 4) inocu-

late animals with reagents provided by NCI and collect whole heparinized blood and sera upon request, and 5) collect and preserve tissues by freezing or fixation. We wish to contract for the use of 30 nonhuman primates with the option to increase the number to a total of 50.

Purification and Characterization of HIV Viral Proteins. Recompetition of a contract held by Advanced BioScience Laboratories Inc. $1.2 million over four years. Project officer: Carl Saxinger.

The overall objective of the Laboratory of Tumor Cell Biology is the understanding of the growth and differentiation of human blood cells in health and disease. This contract will provide the ability to purify, characterize by biochemical and chemical means, and to provide biologically active proteins from viruses, cells, biological, expression systems or as specified by the Project Officer. Functional assays will be performed to assay biological activities of the proteins by measurements of activation, repression or toxic effects on B or T-lymphocytes or neuronal cells. Assays will also be performed to measure binding to CD4, proliferation of endothelial cells, or proliferation of tumor cells, e.g., KS cells, depending on which protein is being tested. Reagents, such as polyclonal antibodies will be generated in limited number from the purified or partially purified materials.

The contractor will provide all laboratory materials and support, including BL2/BL3 laboratories, where necessary, and trained personnel to achieve the objectives of the contract. Proteins of viral and cellular origin or as provided by LTCB will be purified and characterized by multiple systems of electrophoresis and/or chromatography including HPLC. The contractor will also provide amino acid sequence analysis for a limited number of samples at the option of LTCB. In vitro bioassays necessary for protein characterization of purified proteins will be suitable for each individual protein. A limited number of polyclonal antibodies prepared against proteins of interest will be characterized and provided.

Studies of the Viral Etiology of AIDS-Associated Malignancies. New RFA or Program Announcement, proposed first-year funding $1 million, five years. Program director: Kenneth Cremer.

The goal of this program announcement will be to stimulate research on the role of viruses and other biological agents in the etiology and biology of AIDS-associated malignancies, including but not limited to Kaposi's sarcoma and AIDS non-Hodgkin's lymphomas. Herpesviruses, such as Epstein-Barr virus, cytomegalovirus and other human herpesviruses, human papillomaviruses, human T-lymphotropic viruses or unknown but suspected retroviruses or other microbes are among the potential oncogenic or etiologic agents that might interact with HIV. Studies might also focus on etiologic agents functioning as a co-factor(s) in the context of HIV infection or on HIV serving as a co-factor in the context of other viral or microbial infections. Proposed areas of investigation might include but are not limited to: 1) the role of viruses and/or biological factors and/or co-factors in the etiology of AIDS-associated malignancies; 2) interactions between viral and cellular genes and/or proteins which might be involved in the initiation and progression of AIDS-associated malignancies; 3) the role of direct and indirect processes, such as autocrine and paracrine mechanisms and effects, by which single or multiple viral or microbial infections play a role in the initiation and progression of AIDS-associated neoplasms; 4) the use of currently available animal models to investigate the molecular basis of AIDS-associated malignancies; and 5) investigations of the alteration of pathogenesis and oncogenesis as a consequence of the immune status of the patient.

Radiation Dosimetry for Epidemiologic Studies. Recompetition of a contract held by M.D. Anderson Cancer Center. $1.25 million total over five years. Project officers: John Boice Jr., and Ruth Kleinerman.

The accurate estimation of radiation dose to specific organs following ionizing radiation exposure remains an essential part of our program of radiation studies. A comprehensive approach to physical dosimetry permits the accurate quantification of risks and dose-response relationships. Since 1979, radiation physicists at M.D. Anderson Cancer Center have worked closely with the Radiation Epidemiology Branch to provide radiation dosimetry for epidemiologic studies. An important part of our program are studies of populations exposed to radiation in medical settings.

The contractor will provide the support necessary to make measurements on patients, anthropomorphic or water phantoms, and use computerized treatment planning programs, when appropriate in order to reconstruct radiation doses to specific organs following medical exposures. The contractor will: 1) determine the manner in which physical dosimetry can be best applied to the epidemiologic studies of interest; 2) coordinate dosimetry data collected or prepared by other medical physicists who are participating in our studies; and 3) compare measured doses with calculated organ doses to validate consistency and accuracy of simulation models. Measurements will be made to allow a partition of

organ doses into the contribution from a) head-leakage and collimator scatter, and b) scatter within the patient from the useful beam. In addition, each dosimetry determination will be evaluated and ranked according to the completeness and quality of information available for estimating organ doses. 4) Based on all available dosimetry information, the contractor will also assess and determine exposure categories for occupational groups, incorporating knowledge on job classifications, questionnaire responses, dosimetry records, and medical x-ray histories. Contract funds would be used to support personnel, including the principal investigator, a computer programmer, dosimetrists and radiologic physics technicians. In addition, materials and dosimetry supplies, such as thermoluminescent dosimeters, would be purchased as necessary.

It is anticipated that dosimetry support would be required at the same level during the next five years, although there would be a greater emphasis on occupational and environmental exposure assessments. Ongoing studies requiring organ-specific dose estimates include:

1) cancer risk in young girls receiving repeated spinal x-rays to monitor scoliosis during the growth spurt (n=5,000); 2) second cancers in children treated with radiotherapy for retinoblastoma (n=1,000); 3) second cancers in patients treated for non-Hodgkin's lymphoma (n=500); 4) cancers following total body radiotherapy for bone marrow transplantation (n=1,000); 5) x-ray technologists occupationally exposed to radiation (n=143,000); and 6) studies of thyroid cancer following medical x-ray exposures (n=500). Anticipated new studies include 1) second cancers among patients given radiotherapy for endometrial cancer (n=1,000); 2) second cancers among long-term survivors of cervical cancer (n=1,000); 3) persons living at very high altitudes exposed to increased cosmic ray and neutron radiation; and 4) workers employed in nuclear industries.

ASCO Seeks Nominations For Two Awards, Due Dec. 15

The American Society of Clinical Oncology is soliciting nominations for two research awards: the Clinical Research Career Development Award and the Young Investigator Award. The application deadline is Dec. 15 for both awards.

The Clinical Research Career Development Award is intended to provide clinical investigatros in the early years on a clinical faculty with the support and protected time needed to establish an independent clinical cancer research program that is competitive for national funding

The applicant must be a physician who at the time of grant submission is in the first or second year of a full time, primary faculty appointment in a clinical department of an academic medical institutuion. The award is $50,000 a year for three years.

The Young Investigator Award provides seed grant funds to promising young clinical investigators to encourage research in clinical oncology.

The applicant must be a physician who at the time of grant submission is either in the final year of training in an oncology subspecialty post graduate training program or has completed fellowship training within the past year and is planning an investigative career in clinical oncology. The award is $25,000 for one year.

Contact ASCO headquarters, phone 312/644-0828, fax 312/644-8557 for application information.

RFP 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 to the individual named, Executive Plaza South Room number shown, NCI, Bethesda, MD 20892. Proposals may be hand delivered to the Executive Plaza South Building, 6130 Executive Blvd., Rockville, MD.

RFP NCI-CP-40541-13

Title: Record linkage studies utilizing resources in population-based tumor registries

Deadline: Approximately Jan. 3

NCI's Div. of Cancer Etiology wishes to contract with population-based tumor registries in the U.S. and in other countries in order to collaborate in the conduct of record-linkage and subsequent analytical investigations. The duties required in support of the record-linkage studies include: develop a study plan which includes the evaluation of existing records that are potentially valuable for record-linkage; develop or apply the appropriate record-linkage procedures to link a "population file" with the cancer registry files; and provide results of the record-linkage study to the Project Officer either on computer tape or in tabulated form as requested. After the record-linkage study has been completed, it may be desirable to consider additional analytical investigations that require data beyond that found on computer tapes. Offerors should have cancer inci-

dence data for all patients diagnosed within a defined geographic locale for at least 5 years during the previous decade, 1980-1989, and have the ability to ascertain all cancer cases within the registries catchment area of women of all age groups and U.S. minority populations, as appropriate. The offerors must have experience in the collection of cancer data from a variety of medical sources and multiple institutions, and must have legal authority to collect medical data within the given geographic area or be able to demonstrate the willingness of all medical facilities within that area to participate in data collection and patient follow-up activities. Master areements will be awarded to all respondents whose technical proposal is considered acceptable. The intial Master Agreement award is nonmonetary, and is exclusively for the purpose of establishing a pool of contractors who are qualified to perform services for epidemiological studies of cancer utilizing the resources of population-based tumor registries. Each Master Agreement holder will be eligible to compete for awards of Master Agreement Orders to carry out specific record-linkage studies.

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

Letter to the Editor

A Prayer For Sen. Harkin And NIH Research Funding

To the Editor:

The 30 research grants awarded by the NIH Office of Alternative Medicine to study alternative medical practices (**The Cancer Letter**, Oct. 15) will cause rejoicing among the hucksters of quackery, but they are an affront to every research scientist who has been turned down for grant support after laboring to satisfy every requirement for scientific excellence.

Joseph Jacobs, director of OAM, repeatedly states that NIH study sections apply the same criteria for evidence of scientific excellence in applications to the OAM as they do for applications to NIH agencies.

However, one look at the subject titles on this list of OAM grant awards is enough to show that "special standards" were imposed on the study sections doing these evaluations.

Consider the grant to Scott Walker of the Univ. of New Mexico to investigate "intercessory prayer." Did the study section that evaluated that application ask Walker whose God would the prayers be offered to? Would it be Allah? Jehovah? Jesus? Buddha? Who would write the prayers? How would the investigator prevent the controls from praying secretly? Would sinners be included in or excluded from the experimental and control groups? What published evidence indicates this investigation has a rational basis?

These questions seem facetious, but they are the questions a scientific study section would ask of any applicant for a research grant.

Last July, Sen. Tom Harkin (D-IA), the father of OAM, announced to a packed subcommittee hearing that he cured all his allergies in about two weeks by swallowing 250 bee pollen pills (USA Today, July 22). As a result of this revelation, I fully expected to see the award for grant funds to study the curative properties of the bee pollen in those pills. Don't allergy sufferers throughout the USA deserve the same chance for a cure that has been afforded to the Senator?

Fifteen minutes with a child's encyclopedia turned up some fascinating facts about bee pollen. Pollen collected from bees comes from the hairs on their hind quarters. It consists of 40% plant carbohydrate, 5% plant fat and 5% plant protein. The remaining 50% is fungus, bacteria, insect body parts and hairs, mites and bee fecal material.

Since Sen. Harkin's allergies were cured by this mixture, isn't it the duty of OAM to fund a "rigorous scientific research project" to identify the component in the mixture that cured Harkin? It is entirely conceivable that the active ingredient was the bee fecal material. After all, goat feces are used in Ayurvedic medications (OAM funded this modality with two grants.)

Americans who suffer from allergies should demand that Harkin, Jacobs and OAM take immediate steps to find out whether feeding bee shit to the public would be more healthful than the bull shit they are currently dishing out.

Saul Green
New York, NY

Editor's note:

OAM is conducting a field investigation of therapeutic benefits of bee pollen. It is one of four investigations underway.

Green, a biochemist, is the author of a paper on the immunoaugmentative therapy originated by the late Lawrence Burton of the Bahamas. The paper appears in the Oct. 13 issue of the Journal of the American Medical Assn.