THE CANCER LETTER

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Varmus Confirmation On Fast Track, Nominee Outlines Goals For Next Year

A Senate committee is likely to confirm Harold Varmus as director of the National Institutes of Health this week.

Sen. Edward Kennedy (D-MA), chairman of the Senate Committee on Labor and Human Resources, said the committee would expedite the confirmation of President Clinton's nominee for NIH director.

(Continued to page 2)

In Brief

Philadelphia Chromosome Discoveror Hungerford Dead; Oregon Recruits Scientists

DAVID HUNGERFORD, who described the Philadelphia chromosome in 1959, died Nov. 3 at age 66. He was a senior member emeritus of the Institute for Cancer Research at Fox Chase Cancer Center. Hungerford joined the institute in 1951 and collaborated with Peter Nowell on studies of human leukemia cells. This led to the discovery of a shortened chromosome 22, the defect later named the Philadelphia chromosome, in cells from patients with chronic myelocytic leukemia. In 1970, Hungerford described how the chromosome associated with Down's syndrome is derived. His contributions to the field of cytogenetics include the development of a DNA-preservation technique that has been used to located oncogenes on chromosomes. He retired in 1982, when multiple sclerosis limited his activities. He is survived by his wife, Alice, a sister, a brother, nieces and nephews. Contributions may be made to the David A. Hungerford Fellowship at Fox Chase to support predoctoral and postdoctoral research in cytogenetics. . . . **RONALD HERBERMAN**, director of the Pittsburgh Cancer Institute and professor of medicine and pathology at the Univ. of Pittsburgh School of Medicine, has been named the first Hillman Professor of Oncology. The endowed chair was created through a five-year, $1.5 million grant by Pittsburgh-based Hillman Co. . . . **BRIAN DRUKER**, associate professor of medicine at Oregon Health Sciences Univ., is the first investigator to occupy space in the Center for Cancer Research of the new Oregon Cancer Center. He was a member of the Oncology Div. at Harvard Univ. and is one of seven cancer researchers recruited to Oregon in the past year. Other new members recruited to the center include **Donald Austin, Maureen Hoatlin, Mike Liskay, Matthew Thayer, Richard Maurer,** and **Jay Nelson**. . . . **SALICK HEALTH CARE** Inc. and the **George Washington Univ.** Medical Center have agreed in principle to establish a comprehensive cancer center based in Washington, D.C., subject to board approval. Details in the November issue of **Cancer Economics** next week.

Varmus Seeks Staff, Plans Review Of Intramural Program

(Continued from page 1)

"Harold Varmus is an outstanding choice to lead the NIH," Kennedy said at the committee's hearing last week. "He has the vision and skill to lead this nation's biomedical research into the 21st century."

Goals For Coming Year

Varmus, responding to a question from Sen. Barbara Mikulski (D-MD), said he wanted to accomplish the following in his first year as NIH director:

- Search for directors for the NIH Office of AIDS Research, the National Institute of Neurological Disorders and Stroke, the National Institute on Drug Abuse, and the NIH Clinical Center.
- Conduct a "major evaluation" of NIH's $1.2 billion intramural research program.
- Improve the principles by which NIH resolves problems of equal opportunity and sexual discrimination.
- Address some encumbrances in the NIH peer review system.
- Develop ways to encourage more participation by the extramural community in NIH directions and programs.

Mikulski said she hoped a Senate vote on the Varmus nomination could take place by Thanksgiving. This would give Varmus the opportunity to take part in the preparation of President Clinton's FY95 budget request.

"I am concerned that NIH was really squeezed last year and not very well understood," Mikulski said. "We need to make sure the President's budget for NIH is robust."

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Kirschstein Named Deputy Director

Varmus announced that Ruth Kirschstein, acting NIH director since Bernadine Healy's departure, would continue as his deputy. Kirschstein, director of the National Institute of General Medical Sciences for the past 20 years, is respected by members of Congress and the scientific community. NIH directors often have called on her for difficult assignments. Last year, for example, Kirschstein organized the NIH Office of Research on Women's Health.

Sen. Dan Coats (R-IN) questioned Varmus about his apparent lack of administrative experience. Varmus said he was prohibited from taking on deanships at his institution while serving as an American Cancer Society Research Professor.

"I'm no stranger to the issues," Varmus said. He has held a number of leadership positions dealing with scientific issues such as research integrity, indirect costs, funding and training of young scientists, and science education for the public. He has served on many advisory groups, including, earlier this year, the Institute of Medicine panel that advised the Dept. of Defense on its 1993-94 breast cancer research program. At NIH, Varmus said, "I do have a big team of deputies and institute directors."

Coats told Varmus that an NIH director needs "a lot of steel" to withstand pressure from members of Congress who would pressure him to direct funds to certain areas based on the health needs of their families or constituents.

Varmus said he would see that NIH maintains a balanced portfolio of clinical research on specific disorders as well as undirected basic research.

Sen. Nancy Kassenbaum (R-KS) asked Varmus how he plans to strengthen the role of NIH director. Varmus said he is working with HHS Secretary Donna Shalala on several administrative measures that would give the NIH director more authority to make appointments and provide salaries commensurate with those of academic institutions. There also should be more trans-NIH initiatives, Varmus said.

In his statement to the committee, Varmus said the "qualities and aspirations" he will bring to the job include:

"As a working scientist, I will bring to discussions of science policy an intimate knowledge of how science is done and a firm commitment to scientific excellence.

"As an investigator who has seen the pursuit of an obscure chicken virus create a new vision of human cancer, I will defend open-ended basic science

against the calls for restricted applications of what is already known.

"As a fair-minded citizen concerned with the role of science in our society, I will try to improve science education at all levels and to promote the careers of women and minority scientists.

"And as a medically trained custodian of federal funds, I will encourage NIH investigators to extend their biological discoveries to clinical settings."

Committee members referred to Varmus as a "Renaissance man" because of his background in literature and science, and in Varmus' words, his "indecision about careers." Varmus' early interests were a fascination with the brain, tropical health, and internal medicine. Varmus said his mentor at NIH, Ira Pastan, converted him to "an enthusiastic bench scientist" by showing him "how to use a simple model organism—the bacterium E. coli—to understand a complex phenomenon, hormone action."

Varmus said he was a candidate for NIH director because, "With NIH funding I have worked unimpeded by anything other than my own limitations. I have known the joys of discovery, nurtured brilliant students, and received public accolades for work that was largely an act of love. The indebtedness I feel towards the NIH is one of the reasons I am sitting before you today."

NIH Responds To IOM Report On Women's Health Initiative

NIH and the advisory groups and principal investigators involved in the Women's Health Initiative have responded to an Institute of Medicine report critical of some aspects of the $625 million research program.

Among other suggestions, the IOM report, requested by the House Appropriations Committee, said the WHI clinical trial should be redesigned to remove the breast cancer-dietary modification hypothesis, and completed sooner than planned.

"The WHI Group disagrees with this recommendation. We believe that the clinical trial has clear potential to produce much-needed information about the role of diet in preventing breast cancer and that the dietary modification-breast cancer component of the trial should remain a primary hypothesis," according to a statement released by the NIH Office of Disease Prevention, the WHI Advisory Committee, the WHI Executive Committee and principal investigators at the WHI clinical coordinating center and vanguard clinical centers.

In addition, the statement said:

Clinical Trial: The group said it agreed with the IOM recommendation to outline the consent process for the trial more carefully. "We believe that the WHI informed consent document and procedures are already more comprehensive and informative than those of comparable ongoing trials, but we are striving to improve the process further."

IOM recommended that the clinical trial be scheduled to end in 2002 rather than April 2005. "The WHI Group agrees with the concept of interim looks at the data and making decisions regarding stopping of all or some components of the study based on recruitment, retention, and incidence experiences. However, the WHI Group believes that the IOM is underestimating the risk of drawing erroneous conclusions and losing important information through early stopping of the trial."

Observational Study: The WHI Group said it agreed with the IOM recommendation that this component be treated as a precious investment and monitored carefully to ensure high data quality.

"The IOM also recommends that the NIH make data from this component of the WHI available to qualified investigators outside of the WHI network. There is a policy and mechanism in place for outside, ancillary investigations. The IOM recommends that NIH consider the implications for the observational study if the clinical trial portion is stopped early. The WHI Group anticipates that stopping the clinical trial or components of it would have minimal or no effect on completing the observational study as planned."

Community Prevention Study: IOM recommended that more definitive plans be developed for this portion of the WHI.

The concept for the community prevention study was approved recently by the NCI Div. of Cancer Prevention & Control Board of Scientific Counselors. The board was asked to review this portion of the study, because the NIH director's office has no grant-making authority.

The IOM report said NIH was to spend only $25 million on this study. Carrie Hunter, chairman of the community prevention study in the NIH Office of Research on Women's Health, said that figure was incorrect. NIH plans to spend $45.75 million over five years on the study.

"NIH will be undertaking further review of the Women's Health Initiative in the near future," Acting NIH Director Ruth Kirschstein said in a statement.

HHS Appeals Board Finds No Misconduct By Popovic

Former NCI researcher Mikulas Popovic did not commit scientific misconduct in the work that led to the development of a blood test for the HIV virus, an HHS appeals board found last week.

In the Nov. 3 decision, the panel was highly critical of an earlier proceeding by the HHS Office of Research Integrity which concluded that Popovic had falsified datapoints and written a misleading sentence in a landmark 1984 paper published in Science.

According to his attorneys, Popovic has been virtually shut out of research in the U.S. and is working as a visiting scientist at Karolinska Institute in Sweden.

After reviewing the preceding decision, the three-member appeals panel wrote: "One might anticipate that after all that sound and fury there would be at least a residue of palpable wrongdoing. There is not in this case. We find that ORI was simply unable to prove by a preponderance of evidence that Popovic is guilty of scientific misconduct."

The panel said that early in the investigation, the Popovic case became misconstrued because it was initially intertwined with the controversies surrounding the conduct of other scientists and the U.S.-French patent dispute over the HIV screening test.

Interpretation Of A Sentence

The case against Popovic rested on the interpretation of a single sentence in the Science paper. OSI read that sentence as evidence of scientific misconduct. The appeals panel did not.

The sentence in question appears underlined in the following paragraph:

"The cell line HT was tested for HTLV before being infected in vitro and was negative by all criteria including lack of proviral sequences. Continuous production of HTLV-III was obtained after repeated exposure of parental HT cells ... to concentrated culture fluids harvested from short-term cultures of T-cells (grown with TCGF) obtained from patients with AIDS or pre-AIDS. The concentrated fluids were first shown to contain particle-associated reverse transcriptase (RT). When cell proliferation declined, usually 10 to 20 days after exposure to the culture fluids, the fresh (uninfected) HT cells were added to the cultures. Culture fluids from the infected parental cell line were positive for particulate RT activity."

ORI findings of misconduct were based on a reading that Popovic tested individual patient samples for RT activity before pooling those samples to infect the cell line. Based on this reading, ORI concluded that Popovic had falsified the data since, according to other tests, individual samples from the patients were not uniformly positive for RT.

Appeals Panel's Conclusions

The appeals panel concluded:

- "ORI's finding depends on a reading of the disputed sentence which is not the only reasonable reading. ORI's reading that 'concentrated fluids' means individual patient samples ignores unrebutted testimony and other evidence that the fluids from the patient samples were first pooled and then concentrated. Moreover, in context, the 'first' can reasonably be read as intended to convey that the RT activity was associated with the concentrated patient fluids (and therefore a virus had been transmitted from the fluids to the cell line).
- "ORI's reliance on its experts' opinions on the meaning of the sentence is misplaced since, for the most part, the experts did not independently determine the meaning of the sentence. Their testimony as a whole supports a conclusion that, in context, the statement is merely ambiguous.
- "We find Popovic's testimony about what he in fact did to be credible since that testimony is consistent with the laboratory notebooks, is corroborated by others' testimony, and is unrebutted.
- "ORI did not show either that Popovic added the sentence in question or that in the editing process he was made aware of the addition of the sentence and should have known it may have been misinterpreted.
- "ORI overrated the significance of the sentence in arguing that Popovic had a motive to falsify it. ORI did not establish that the paragraph was the key methodological section of the paper, nor that Popovic would have viewed what he in fact did as illogical and lied about it to make his experiment appear more rigorous."

The appeals board's decision was signed by Cecilia Sparks Ford, Norval Settle and Judith Ballard.

Popovic, formerly a visiting associate in the NCI Laboratory of Tumor Cell Biology would like to return to NIH, his attorneys said.

Advisors OK Grants Program In Reducing Tobacco Use

Advisors to NCI's Div. of Cancer Prevention & Control approved in concept a new grants program for research in strategies to reduce tobacco use.

The DCPC Board of Scientific Counselors agreed to set aside up to $4 million over the next four years to fund three to five awards. The board also gave concept approval to a new grants program in cancer and rural health, and a program announcement for intervention research to change the dietary habits of African-Americans.

Two large contracts for technical support for chemoprevention research and a chemopreventive agents repository also were approved for recompetition. Each was approved at a level of $7 million over the next five years.

The board also gave concept approval to:

—An interagency agreement in which NCI would provide $5 million over the next five years to the Beltsville Human Nutrition Research Center of the USDA to conduct collaborative human studies of diet and nutrition.

—Continuation of a sole-source contract with the National Public Health Institute of Finland for follow-up of the Alpha-Tocopherol, Beta-Carotene Lung Cancer Prevention Trial, at a cost of about $2.8 million over the next seven years. The trial enrolled more than 29,000 male smokers aged 50-69 between 1985-88. The preliminary analysis of intervention results has begun, and a paper will be submitted for publication early next year, the concept statement said.

Following are the concept statements for the proposed RFAs, PA, and competitive contracts:

Research in Innovative Strategies to Reduce Tobacco Use. Concept for new RFA for R18 grants, total $4 million over four years, three to five awards. Program director: Public Health Applications Research Branch, Marc Manley.

The goal of this research is to better understand strategies to develop, implement, and disseminate effective tobacco control interventions. Tobacco control interventions are those interventions which can influence large populations to reduce tobacco use. These interventions include, but are not necessarily limited to, restrictions on sales of tobacco to minors, restrictions on indoor smoking, increases in tobacco excise taxes, and restrictions on tobacco advertising.

This program is intended to stimulate innovative behavioral, public health, and economic research on tobacco control policy interventions, including the analysis of their feasibility, effectiveness and consequences of implementation. Below are examples of research questions that could be addressed.

Tobacco Pricing and Taxation: What would be the effect on consumption of very large increases in tobacco taxes? What are the consequences of earmarking tobacco tax revenues for specific programs? What are the most effective strategies for increasing tobacco excise taxes?

Restrictions on Indoor Smoking: What is the effect of smoking bans in schools on the smoking behavior of students? What are the most effective strategies for implementing clean indoor air policies? What strategies facilitate and accelerate compliance with policies that restrict smoking? What are the economic costs and benefits of ordinances and policies that restrict smoking?

Tobacco Marketing and Promotion: What is the role of advertising in: recruiting new smokers, reducing the cessation rate among current smokers, and increasing the relapse rate in former smokers? What are the consequences of restricting tobacco advertising, for example, through the removal of billboards near schools or in sports stadiums? How are youth, women, and minority populations targeted by tobacco advertising?

Access to Tobacco Products: What are the most effective interventions to reduce tobacco sales to minors? What effects do restrictions on vending machine sales have on youth access to tobacco? What strategies can be used to increase enforcement of existing laws banning sales to minors? What are the effects of penalties directed at retailers, minors, or parents?

Cancer Prevention and Rural Health. Concept for a new RFA for R01 grants, total $4 million over four years, three to five awards, Program director: Nancy Simpson, Prevention & Control Extramural Research Branch.

The Cancer Prevention and Rural Health RFA will address the need for targeted cancer prevention and early detection education programs in rural populations. Investigators will be encouraged to submit proposals for public and health professional cancer education research in the following two areas:

Prevention—Cancer prevention research projects should address those cancer concerns of special relevance to rural populations such as protection from lip and skin cancer, control of pesticides and other occupational and environmental carcinogens, tobacco use and diet and nutrition. They may also address psychosocial concerns around the adoption of risk reduction behaviors. Public education strategies may include developing a community-wide, multi-media educational campaign on lip and skin cancer, use of tobacco products such as cigarettes and smokeless tobacco, or family financial and social concerns of adopting a diet that is high in fruits and vegetables. Health professional strategies may include such

things as training physicians and/or other health care providers to address diet during patient visits or to assess and counsel patients about their cancer risk status.

Screening and Early Detection—Cancer screening and early detection research projects should also address those cancer concerns of special relevance to rural populations. Public education strategies may include working with rural women's organizations to develop messages and materials about the importance of breast self exams, health professional breast exams, and mammography or community education projects that lesson fears and delay to followup from positive Pap tests or mammograms. Health Professional education strategies may include developing special training modules in conjunction with rural health training centers such as rural Area Health Education Centers for physician extenders on breast exams, mammography; or addressing ways for health care professionals to more effectively motivate patients to regularly obtain cancer screening tests according to recommended schedules.

Researchers should develop intervention strategies that are specifically designed for rural populations. Census and/or survey data will be used to define the target area and population. High priority will be given to research projects that are applicable to rural communities nationwide and produce cost effective strategies that can be easily replicated and disseminated.

Culturally Sensitive Intervention Strategies for Implementation of NCI Dietary Guidelines Among African Americans. Concept for program announcement.

The objective of this research initiative is to develop, implement, and evaluate innovative culturally sensitive dietary/behavioral change intervention strategies for African Americans. The overall goal is to develop effective intervention strategies that could serve as models for promoting diet and health behavior change at the community level. The proposed project will focus specifically on implementation of the NCI dietary guidelines among low socioeconomic African Americans 18 years and older.

Applicants will be required to develop dietary/behavioral intervention strategies for achieving dietary modifications to reduce fat intake and to increase the intake of dietary fiber, fruits, and vegetables. Other dietary guidelines can be included if adequate justification is provided.

The development of culturally relevant intervention strategies should take into account sociocultural and situational factors as well as attitudes and beliefs that may affect African Americans food choices and their interest in health and modifying dietary habits.To maximize cultural relevance and motivation for behavioral changes, the applicants will be required to seek the advice and participation of indigenous leaders and focus groups in the development and implementation of the intervention strategies. In addition, the intervention strategies should include a combination of approaches that integrate nutrition education, behavior modification techniques, and education on the role of dietary factors in cancer risk reduction. Intervention channels may include various African American religious, professional, medical/nursing, social, public housing organizations, community health centers as well as worksites, businesses, etc. Interventions may target individuals, households, groups, and/or organizations.

Outcome measures may include: 1) the ability to recruit and retain study subjects; 2) measures of change in the intake of dietary fat, fiber, and fruits and vegetables; 3) predictors of change including knowledge, attitudes, and behaviors; 4) stages and processes of change; 5) identification of barriers and motivators of dietary change; 6) measures of sustained dietary and behavioral changes; and 7) biochemical and anthropometric parameters.

Multidisciplinary Technical Information Resources and Support for Chemoprevention Research. Recompetition of a contract, total $7 million over five years, one award. Project officer: Gary Kelloff.

The goal of this initiative is to provide the Chemoprevention Investigational Drug Unit with necessary information supply and management support required for the multidisciplinary research planning, analysis, and decision making activities in cancer chemoprevention drug development.

Chemoprevention research support services shall include data review and analysis of a) scientific data generated by NCI's chemoprevention drug development program studies, b) results generated by the worldwide scientific community relevant to chemoprevention research, c) mechanisms of chemoprevention action, d) new test systems and protocol modifications, e) intermediate biomarkers, f) individual agent or class studies. It will also include the updating and maintenance of program databases including the "Master List of Chemopreventives," the "Desktop Database," and the "Summary Desktop Database" computer files.

Drug discovery technical support identifies, documents and prioritizes new chemopreventive agents for preclinical testing through literature searching, class studies, program and outside agent nominations, and qualitative structure/activity relationships. Part of this function will be to provide quality assurance activities required for clinical trials. The contractor will assist program staff in the development of criteria for data collection and formats for uniform data reporting to meet FDA requirements for various levels of drug approval.

Centralized Chemopreventive Agent Repository and Drug Regulatory Support. Recompetition of a contract, total $7 million over five years, one award. Project officer: Gary Kelloff.

The goal is to provide DCPC with an efficient centralized drug repository and regulatory support opera-

tion. A major responsibility is to identify sources, procure, and store bulk supplies, measure chemical quality, maintain material and safety data sheets, aliquot, package, track and distribute agents to user labs. The preclinical drug evaluation program tests approximately 30-50 new chemical agents each year. Currently over 250 agents in bulk supply are in the repository for preclinical use. Maintaining drug supply for the more than 40 ongoing clinical trials involving 21 agents under clinical trials is also a major part of this concept.

The second objective is to provide specialized technical program support for meeting drug regulatory requirements.

The contractor would actively participate in DCPC's Agent Development Committee. Specialized technical support will be applied in the area of analytical methods development for monitoring drug purity and stability. Continuing chemical analysis will be required for quality assurance monitoring of drugs during the actual clinical trial.

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-CB-33053-60

Title: **Master agreement for cancer vaccine development**

Deadline: Approximately Jan. 4

NCI is soliciting proposals from offerors with the capability to provide needed support services in the emergent cancer vaccine field. The required support will be defined by Master Agreement Orders issued during the period of performance. The MAOs will be awarded based on competition between members of the Master Agreement pool. MA holders selected for award shall provide one or more of the following: clinical grade recombinant vaccinia virus CEA constructs, other recombinant tumor associated antigen vector constructs, and/or monoclonal antibodies and peptides for use in clinical protocols to elicit specific active immunotherapy responses in colorectal carcinoma, mammary carcinoma, and lung carcinoma patients. Specific tasks may include one or more of the following: production of clinical grade recombinant CEA and other tumor associated antigen constructs including pox virus vectors, baculovirus vectors, purified peptides, monoclonal antibodies, and testing of constructs in rodent and non-human primates for immunogenecity and safety. Separate, complete proposals are required for each task. Master Agreements will be awarded to all firms whose technical proposal is considered acceptable. This is a resolicitation of an existing Master Agreement. Any organization which now has a Master Agreement for a specific task under this Master Agreement Announcement need not reapply for that task. If any organization wishes to qualify for another task(s), the organization need only propose on the task(s) not previously awarded.

Contract specialist: Barbara Birnman, Tel. 301/496-8611, RCB Executive Plaza South Rm 620.

RFA Available

RFA CA-94-006

Title: **Patterns of care in radiation oncology**

Letter of Intent Receipt Date: Dec. 1

Application Receipt Date: Jan. 24

The Radiation Research Program of NCI's Div. of Cancer Treatment invites applications for Patterns of Care Studies in Radiation Oncology. The objective of this RFA is to focus on those factors in radiation oncology that are most likely to affect patient outcome, such as failure to control local-regional neoplastic disease, treatment related morbidity that negatively impacts a patient's quality of life, or failure to implement new methods and treatment strategies that have been shown to be advantageous for the patient.

Applications may be submitted by domestic and foreign for-profit and non-profit organizations. NCI anticipates awarding one to two R01 grants, with total costs not to exceed $650,000 for the first year. Approximately $650,000 in total costs per year for three years will be committed to fund grants.

The major goal of this research initiative is to support clinical investigations that 1) document and evaluate patient survival and outcome as a function of radiation oncology practice and methodology, 2) coordinate with the leadership of the Cooperative Groups for the optimal design of protocols and clinical trials based on data received from patterns of care studies, 3) examine the patterns of care for minorities vs non-minorities, and 4) present the findings of the patterns of care studies to the radiation oncology community to achieve both the goals of information and education. The evaluation and documentation of the acceptance and implementation of new treatment strategies in the radiation oncology community where a benefit for the cancer patients has been shown is also of interest. New studies of interest are prospective patterns of care and/or patterns of fractionation studies that will support and enhance on-going protocols for cancers of the prostate and cervix. Prospective studies that show patterns of total care for breast cancer are of special interest.

Inquiries: Dr. Sandra Zink, Radiation Research Program, NCI, Executive Plaza North Suite 800, Bethesda, MD 20892, Tel. 301/496-9360, Fax 301/480-5785.

Letter to the Editor

Montefiore Oncology Dept. Expresses Support For Wiernik

To the Editor:

The Dept. of Oncology at Montefiore Medical Center is writing in response to your recent article regarding Dr. Peter Wiernik (**The Cancer Letter**, Nov. 5). We are writing to express the unanimous support and respect that the department maintains for Dr. Wiernik.

We are cognizant of the problems that have arisen and the infractions that have occurred and we acknowledge that some level of punishment must be extracted. Nevertheless, we feel strongly that this anomalous episode should not detract from nor destroy the significant and consistent accomplishments that have been achieved by this man and his major contributions to the field of oncology and the development of new cancer therapy.

Dr. Wiernik has worked in the field of oncology, hematologic malignancies and the development of new anticancer agents for more than 25 years. He has played an instrumental role in the development of almost every new antitumor agent, participating in the Phase I/II Working Group from its inception. Agents credited to his efforts include daunorubicin, doxorubicin, mitoxantrone, and more recently, Taxol. In fact, had he not devised the premedication formula for Taxol administration, the drug was doomed to oblivion, in the words of the NCI (Life, May 1992). It was his years of experience in drug development and his courage in attempting to make this drug work (among others) and not being fearful of its initial toxicity that allowed this drug to become a major new player in oncology. Dr. Wiernik is unique in his ability to observe new clues and expend energy and creativity on forcing the clues to become new therapies. It seems that this enthusiasm for pressing for the development of promising new leads and attempting to benefit the hapless patients involved was at the root of Dr. Wiernik's current difficulties. Clearly there was no personal or professional gain from these efforts, but as on numerous previous occasions, a sincere desire to improve therapy. We would also like to clarify that the protocols referred to in the article were approved by the IRB at Montefiore and had previously been approved at the NIH.

Dr. Wiernik, in his 11 years at Montefiore Medical Center, has fostered a first-rate clinical and laboratory investigative effort, has attracted outstanding investigators from other institutions, and trained and developed investigators arising from within his own fellowship program. Much of the substance of the program has been directed toward so-called "translational research," in which basic research skills and findings are utilized to address clinical applications. Dr. Wiernik has a unique ability to engender cooperation between clinicians and laboratory scientists, and his vision, leadership, and support have been successful in developing funded research in a variety of areas key to translational research. This program has been key to furthering the development of the Albert Einstein Cancer Center, providing a strong clinical research and translational research base.

Additionally, Dr. Wiernik has developed a highly creditable academic program in oncology, such that all of his faculty as well as fellows seek him out as a mentor. Under his guidance of the department, the number of faculty has increased six-fold, the amount of federal and private funding has increased 33-fold, and the fellowship program has tripled. The growth of the Oncology Program is a direct reflection of Dr. Wiernik's unusual combination of clinical, academic, and administrative skills.

Dr. Wiernik is dedicated not only to high academic standards, which are not in question, but insists on an environment which provides high-quality patient care. This has engendered strong support for him from the nursing staff, the voluntary medical oncology staff, and the patients. Dozens of letters of support have arrived from his patients as well as other patients seeking a physician who will try to help them. The patients clearly understand what is at stake if this man is no longer able to contribute to the development of new and better cancer therapy.

Dr. Wiernik is respected by his staff as a critical thinker and a tough leader, but as one whose word is a firm commitment. To those of us who work with him on a daily basis, his integrity is unquestioned and his honesty in matters of clinical research, patient care, and administrative issues are a given. It thus seems ironic that he and his work be jeopardized by the so-called "cover-up" that seems so out of character to all of us. It is from this perspective that it seems unjust to us that Dr. Wiernik be required to forfeit so many of the fruits of his career over a single regrettable mishap.

In summary, the Dept. of Oncology at Montefiore Medical Center strongly supports Dr. Wiernik and looks forward to additional years working with him in his battle against cancer. The department feels that Dr. Wiernik is an essential part of its role in this effort.

Dept. of Oncology
Montefiore Medical Center

(Representing some 100 members of the department including clinical and laboratory faculty, clinical fellows, oncology nurse associates, physician assistants, social workers, oncology unit nursing staff, ancillary personnel, and data management.)