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Blood Cancers Advocacy Groups Seek DOD And NCI Funds, Medicare Coverage

Advocates for research in hematological malignancies are trying to stake out claims to the NCI and Department of Defense budgets.

The advocacy groups that represent leukemia, lymphoma, and myeloma asked Congress to start a DOD program to fund peer-reviewed research in these diseases.

The Capitol Hill push by the advocacy groups was timed to coincide with completion of the Progress Review Group report assessing NCI

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In Brief:

U of Pittsburgh Wins NCI Grant To Include End-of-Life Issues In Med School Curriculum

UNIVERSITY OF PITTSBURGH School of Medicine received a $750,000 grant from NCI to integrate end-of-life issues into its curriculum. A large number of dying patients and their families suffer needlessly, both psychologically and physically, because physicians are not adequately trained to care for people near the end of life, according to research. "We want to change not only the medical school curriculum but also the culture of medical education," said **David Barnard**, professor in the Department of Medicine, and director of Palliative Care Education, Center for Bioethics and Health Law at UPSM. "Physicians find caring for dying patients stressful, and their own attitudes toward emotional or psychosocial aspects of such care contribute to their avoidance of these issues. They report feelings of sadness, helplessness, failure, disappointment and loneliness when dealing with end-of-life patients, and many times this has a negative affect on patient care." The long-term goals of the new curriculum are to increase exposure to the scientific and humanistic knowledge necessary for excellent end-of-life care, to develop and implement learning experiences that provide students with prolonged exposure to dying patients, and to increase the number of faculty who have completed programs to improve their skills in teaching end-of-life care to medical students. Curriculum changes will be phased in over a period of several years. A new course beginning in the fall of 2001 for first-year medical students will allow visits to critically ill and dying patients in their homes over the course of an entire semester, said **Robert Arnold**, the Leo Criep, Professor in Patient Care and director of the UPMC Comprehensive Palliative Care Program. "With these in-home visits, students will learn directly from patients and

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PRG Proposes Translational Research Consortium

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programs in leukemia, lymphoma and myeloma.

The report is posted on the Institute's Web site: http://osp.nci.nih.gov/Prg_assess/PRG/LLMPRG/llm_rpt.pdf.

To magnify their efforts, three patient groups—the Multiple Myeloma Research Foundation, the Cure For Lymphoma Foundation, and the Leukemia and Lymphoma Society—pooled resources to hire the Washington law firm of Bennett, Turner and Coleman to carry out the push for hematological cancers.

In a curious twist on the PRG process, the law firm invited the patient advocates who worked on the PRG to join a steering committee for the Capitol Hill push. At this point, two patient groups—the International Myeloma Foundation and the Lymphoma Research Foundation of America—that were represented on the PRG joined the effort.

As a result, about 300 patients could be observed knocking on doors on Capitol Hill on June 21. The patients were advocating for four measures:

—The patients urged legislators to sign two letters seeking to establish the hematological cancers program at DOD. In the House, the sign-on letter was circulated by Reps. Phil Crane (R-IL) and Tony Hall (D-OH). In the Senate, the letter is circulated by Sens. Michael DeWine (R-OH) and Jack Reed (D-RI).

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"In the past, blood related cancer research has resulted in treatments for other cancers," the Crane-Hall letter states. "The most obvious example is chemotherapy, which was pioneered in blood-related cancers, and now is a standard part of treatment for for many other cancers."

Established in 1993 in response to a campaign by the National Breast Cancer Coalition, the DOD program established a new funding stream for cancer research. Over the past eight years, the DOD cancer research portfolio was expanded to include prostate, and ovarian cancers as well as neurofibromatosis.

—The groups urged Congress to require NCI to develop a plan for implementation of the PRG report no later than Dec. 31. Specifically, the implementation plan should include a strategy for drug development, including creation of the "Cancer Translational Research Consortium," an entity described in the PRG report.

—Enactment of the Access to Cancer Therapies Act (H.R. 1624), sponsored by Rep. Deborah Pryce (R-Ohio). The bill seeks Medicare reimbursement for oral therapies for cancer. Obtaining coverage is urgent, because many of the new cancer drugs, like the much-publicized Chronic Myologenous Leukemia therapy Gleevec are administered orally. The measure's Senate companion bill is S. 913.

—Enactment of the "Access to Cancer Clinical Trials Act," (H.R. 967), a measure that seeks to remove reimbursement barriers to accrual to clinical trials.

The Hutchison Bill

In a move that appears to confound Capitol Hill observers, Sen. Kay Baliey Hutchison (R-TX) introduced a bill to authorize at least $250 million for NCI research as well as $25 million in CDC programs in blood cancers in fiscal 2002.

To begin with, the Hutchison bill, (S. 1094), which was developed without participation of the patient groups, the bill seeks $5 million *less* than the $255 million that NCI says it expects to spend on hematological cancers in the current fiscal year.

The bill relies on the largely symbolic authorization mechanism, which is intended to guide appropriators, but is, in fact, barely relevant in the heat of appropriations battles. Finally, it is unclear how CDC, a public health agency, would spend $25 million on diseases where screening is not feasible.

"When I first started looking into the federal commitment to the deadly blood cancers, leukemia,

lymphoma, and multiple myeloma, I was really amazed to know that 11 percent of all cancer deaths come from these blood diseases, but only 5 percent of the research funding from the NCI is going to find the cure," Hutchison, whose brother has multiple myeloma, said at a hearing of the Senate Labor, HHS and Education Appropriations Subcommittee June 21.

A Hutchinson staff member said the bill would represent a substantial increase for NCI since the Institute's coding system double-counts some projects. However, the legislation does not address coding.

NCI officials say that generally funds spent on cancer sites are not double-counted. Yet, since research directions in hematological cancers may overlap, it is possible that some small amount of double-counting occurs when projects are coded, Institute officials say.

The PRG Report

Presenting the PRG report at the appropriations subcommittee hearing, NCI Director Richard Klausner said the group's recommendations dovetailed with the research programs his reforms have launched at the Institute.

"One of the things I felt about the PRG group, which was very satisfying, was the very nice alignment between their recommendations or where we need to go and the dozens of new programs that we have put in place at NCI to capture the possibilities of new science, new ways of asking questions, to direct them specifically to blood malignancies," Klausner said.

"I think the PRG recognized that we had set up these structures, and we were really set to go. And with these exquisite recommendations, we already are working with the members of the PRG, within the NCI, to figure out what needs to be initiated, what needs to be expanded, and what we'll be able to afford to do," he said.

The PRG has identified ten areas for research that would alter the prevention, diagnosis, treatment, and care of individuals with these cancers. A number of these priorities would be achieved through a new initiative, the Cancer Translational Research Allied Consortium (C-TRAC), which can serve as a model for the rapid development of new therapies for many kinds of cancers, the report says.

A summary of the PRG recommendations follows:

Etiology:

· **Understand the interaction among genotype, immune function, infectious agents, environmental toxins, and lifestyle factors that can lead to hematopoietic malignancy.**

The etiology of leukemia, lymphoma and myeloma is not well understood, yet the development of behavioral and pharmacological interventions for prevention of these diseases requires that we know what causes them. Prior epidemiological research has focused almost entirely on a single or limited group of hematological cancers and precursor conditions. Case-control and cohort investigations are needed.

Pathobiology:

· **Identify the basic mechanisms responsible for genome instability, chromosome translocations, and other mutations in hematological malignancies.**

Reducing the incidence of leukemia, lymphoma and myeloma will require a better understanding of (1) how various types of DNA damage occur in hematopoietic cells, (2) the impact of various genetic factors on susceptibility to DNA damage, (3) repair capacity and other types of cellular responses to DNA damage, and (4) the role of environment in the broadest sense.

· **Define the relationship between the development of hematological malignancies and the host biological environment.**

The stromal microenvironment and the overall host environment are critical determinants of tumor initiation, progression, migration, and response to therapy. In light of the remarkable research tools that have been developed in the past few years and the considerable progress in understanding the biology of normal and tumor cells, it is time to make a major effort to study the complex problem of tumor-host interactions in hematological malignancies.

· **Provide molecular characterization of hematological malignancies, including the characterization of global patterns of genetic and epigenetic alterations and RNA and protein expression, as well as the validation of the molecular targets necessary for the survival, proliferation, and evolution of hematological malignancies.**

Rapid migration to a molecular definition of cancer will have a dramatic impact on diagnosis and treatment. We recommend the expansion of several current NCI initiatives to promote the application of novel technologies to each of the hematological cancers, including both common and less prevalent

subtypes.

· **Further develop research on stem cells, both multi-lineage and single lineage.**

Our understanding of how specific outcomes are determined at a molecular level in different types of normal blood cell precursors is still limited. As a result, it is still not possible to anticipate how specific molecular changes produce disease. Such information is essential to designing therapies that are curative and nontoxic.

Drug Development and Therapeutics:

· **Develop the required resources to translate "lead" structures and molecules into effective therapeutic agents. Hasten the translation of candidate validated targets to lead compounds and subsequent clinical trials and support the development of orphan therapeutic agents and diagnostics, including FDA approval.**

Target discovery, validation, and clinical translation for hematological diseases will form an important basis for future drug development in all cancer types. Consequently, the NCI needs to magnify its efforts to offset the cost of drug development for relatively rare cancers, including leukemia, lymphoma, and myeloma.

· **Foster partnerships between the NCI and academia, advocates, cooperative groups, FDA, and industry to expedite drug development and availability of therapies.**

As lead agency for implementing the National Cancer Program, NCI should form a working group of equal partners to enhance cooperation and efficiency in developing new cancer treatments.

Education, Communication, and Survivorship Research:

· **Determine how to provide accurate, timely, and tailored information to patients to improve medical decision-making, access to clinical trials, quality of care during active treatment and follow-up, and quality of life.**

Effective health communication narrows the enormous gap between discovery and applications and reduces health disparities among our citizens. However, much of the available information on communicating with patients does not address the specific circumstances of those affected by the hematological cancers.

· **Develop education and training programs for certification of physicians and centers for diagnosis, treatment, and clinical trials in hematological malignancies.**

Certification will lead to significant improvement in the treatment of hematological cancers, not only through optimization of current treatment approaches but also through the channeling of patients to specialized physicians and centers where state-of-the-art treatments may be investigated and applied in cooperative group trials.

· **Identify and target individuals and populations at high risk for adverse long-term outcomes to define the biological basis of identified associations and facilitate the design and testing of intervention and prevention strategies.**

We do not know which patient populations are at high risk for adverse outcomes of treatment for leukemia, lymphoma and myeloma. Long-term outcomes research on these diseases has often been characterized by small sample sizes, lack of heterogeneity in the study populations to allow for adequate assessment of risks, and potential bias in study populations resulting from selection influences, such as incomplete follow-up. However, identification of high-risk individuals and populations is essential to the rational development and testing of intervention and prevention strategies.

A New Initiative – The Cancer Translational Research Allied Consortium (C-TRAC):

· C-TRAC will bring together experts across multiple disciplines and institutions to participate, within a formalized infrastructure, in the rapid discovery and development of cancer therapies. This initiative will encompass the whole spectrum of drug discovery and development: identifying, validating, and credentialing targets; discovery and preclinical testing of agents directed against these targets; and scale-up and testing of promising agents in clinical trials.

The ultimate goal of the C-TRAC will be to shorten drug development time from five to ten years to two years through a novel alliance among academia, industry, government, and patients.

Together, leukemia, lymphoma, and myeloma constitute the fourth most common form of cancer. More than 60,000 people will die of these diseases this year. These cancers represent a large number of diseases that vary in their cause, molecular makeup, pathophysiology, treatment, and care.

NCI has completed PRG reviews of cancers of the breast, prostate, colon, lung, brain, and pancreas as well as gynecologic and hematological cancers.

Cancer Centers:

UPCI To Lead Clinical Trials Of Eli Lilly's Oncology Agents

The University of Pittsburgh Cancer Institute and Eli Lilly and Co. announced a precedent-setting arrangement that would allow the cancer center to conduct and coordinate clinical trials of Lilly agents.

While the company's principal priority is to accrue patients in clinical trials that would support drug approval by FDA, the arrangement also covers pre-clinical and early clinical research.

According to observers, the Pitt-Lilly deal may suggest a strategy for cancer centers and cooperative groups to tap into funds for drug development and receive access to new agents.

In competition for drug development money, for-profit contract research organizations have had the advantage of not being encumbered by academic bureaucracy and peer review, and have been able to run circles around cancer centers and cooperative groups.

Cooperative groups have been more successful in competing for pharmaceutical company-sponsored trials designed to support supplemental NDA applications than for trials intended to support NDAs. Cancer centers have been attracting pharmaceutical contracts, but they have been doing this one contract at a time.

Usually, the cancer centers' arrangements with pharmaceutical companies are made for specific agents, one agent at a time.

"It's a precedent to have a cancer center have such a specific commitment with a pharmaceutical company," said Ronald Herberman, UPCI director and associate vice chancellor for health sciences research at Pitt.

"With the cancer centers in general, or with us before this agreement, it's all been on a study-by-study basis," Herberman said. "This is a broader agreement, where we have agreed that we will seriously consider playing a significant role on a regular basis."

The UPCI-Lilly deal cuts out, or at least limits, the role usually performed by the CROs. UPCI will provide project management oversight for clinical trials involving patients enrolled through Pitt's network, Herberman said.

"Even for the phase III trials, we expect that this will be a direct relationship between us and Lilly," Herberman said.

The Lilly-Pitt deal was done through the university's for-profit spin-off, the Pittsburgh Clinical Research Network.

Formed three years ago, PCRN has contracting authority that allows it to bypass the university bureaucratic procedures.

"That organization is serving for us as the single point of contacts for our industry trials," Herberman said. "What we've worked out with Lilly is to have essentially some dedicated staff just to focus in the partnership with that company."

"Taken together, this package held tremendous appeal for us, given the aggressive agenda we have set for our oncology franchise," Alan Hatfield, medical director of Lilly Oncology' U.S. affiliate, said in a statement.

"We have an infrastructure at UPCI by which we can evaluate potential medications in a more timely manner, something we hope to build with other institutions across the country as well," Hatfield said.

The terms of the collaboration were not disclosed.

"The point of doing this with a cancer center like ours is that this combines both the ability to accrue but also to have thought leaders add value to protocol development and innovative ideas and approaches," Herberman said.

"The idea is that at least half the trials that will be done will be investigator-initiated protocols with Lilly agents," Herberman said.

The agreement is renewable annually.

UPCI has more than 60 faculty investigators, and a community-based network that includes over 50 oncology practices throughout western Pennsylvania.

Herberman said the deal with Lilly is the first of several such agreements with pharmaceutical companies.

The cancer center plans to establish a small number of such preferred partnerships, he said.

To expedite the trials-management process, UPCI and PCRN have devoted the last six months to streamlining their respective administrative procedures under the direction of Donald Trump, UPCI deputy director for clinical investigations, and PCRN executive director, Peter Small.

NIH Programs:

Fogarty Leads Grant Program On World Tobacco Research

The Fogarty International Center of NIH has established a program to address the growing incidence of tobacco-related illness and death in the developing world.

FIC and five partners within the NIH, in cooperation with the World Health Organization's Tobacco Free Initiative, have issued a call for research and training proposals for the new International Tobacco and Health Research and Capacity Building Program.

The combined commitment from FIC and the NIH partners is $3.5 million for the first year of these five-year awards. Total support is expected to be about $17 million over the next five years.

"On my first day on the job, I indicated that this department would be committed to U.S. support and technical assistance on global health, including tobacco control," said HHS Secretary Tommy Thompson. "This new NIH program offers an important opportunity to learn more about effective ways to prevent or reduce smoking rates worldwide, especially in developing nations."

According to WHO, tobacco consumption is the leading cause of preventable death and disability in adults globally. Each year, about 4 million people worldwide die from tobacco-related causes.

If current smoking patterns persist, the number of tobacco-related deaths will rise to 10 million annually by the year 2025, surpassing the death toll from AIDS, tuberculosis, automobile accidents, homicide, suicide, and childbirth combined.

Seventy percent of this increase will occur in the developing world, where health care systems are inadequate to address current needs and will be strained to the brink by the burdens imposed by the expected magnitude of tobacco-related illness.

The goal of the new research and training program is to reduce the burden of tobacco consumption in low- and middle-income nations by conducting observational, intervention, and policy research of local relevance and building capacity in these nations in epidemiological and behavioral research, prevention, treatment, communications, health services, and policy research.

The program encourages applications linking behavioral science, social science, and basic science with clinical and operational aspects of health care research. It targets five key research areas: epidemiological and surveillance research, susceptibility and risk for smoking uptake, biobehavioral and social research, intervention research, and policy-related research.

In addition to support for basic science, including the study of addiction, this program may provide support for projects that examine tobacco tax policies, marketing and advertising strategies, campaigns that promote a smoke-free norm, and prevention strategies targeted at youth.

FIC led the development of the program in collaboration with NCI, the National Institute of Child Health and Human Development, National Institute on Drug Abuse, National Institute of Mental Health, and National Institute of Nursing Research.

Scientists and health professionals from the developing world were consulted at all stages. "Our consultation with scientists from the developing world was crucial in helping us understand where the needs are most critical," said FIC Director Gerald Keusch.

"Our aim in launching this program is to provide a framework of support for the development of data necessary to inform decision-making," Keusch said. "As developing countries begin to grapple with the major toll that tobacco will take on individuals, families, and communities, and to establish national tobacco-control programs, it is essential that they have access to the best data."

Although smoking among girls and women is relatively low in developing countries, there is evidence that it is on the rise.

"One of the most important public health opportunities we have is in preventing a rise in international smoking rates among girls and women," said NCI Director Richard Klausner.

"Since the United States is a mosaic of populations, our expectation is that this international program will yield results to inform prevention, intervention, and policy strategies at home as well as abroad," Klausner said.

The World Bank estimates that 80,000 to 100,000 young people around the world become addicted to tobacco every day.

"Prevention programs that target youth are a must if any progress is to be made in addressing the tobacco pandemic," NIDA Director Alan Leshner said. "It has been proved that the earlier in life one starts smoking, the more difficult it is to stop. Since tobacco companies market their product to young people, the handwriting is on the wall in terms of the toll that we

can expect if the course continues unchecked."

Training of young scientists is an integral feature of this new program and applicants are required to include a significant capacity and infrastructure-strengthening component in their proposals.

Applications are due by Oct. 26, and the deadline for receipt of Letters of Intent to apply is Sept. 4. The Request for Applications for this program may be found at http://grants.nih.gov/grants/guide/rfa-files/RFA-TW-02-005.html.

Funding Opportunities:

Flight Attendant Institute Offers Research Awards

The Flight Attendant Medical Research Institute was formed after a successful class action suit brought against the tobacco industry by flight attendants and their survivors for the diseases and death caused by exposure to environmental tobacco smoke.

Class members established an endowment of $300 million to support the non-profit foundation. U.S. Surgeon General Julius Richmond is the chairman of the board of the foundation.

FAMRI invites applications for three awards:

—Young Clinical Scientist Award supports clinical investigators with a Ph.D. or M.D. and is limited to research in smoking-related disorders.

FAMRI is particularly interested in providing a bridge between the clinic and the laboratory for the critical translation of basic findings into diagnostic and therapeutic approaches. The YCSA is offered to two groups of scientists: research fellows and junior faculty members.

—Clinical Innovator Award supports medical and clinical scientific research studies on environmental tobacco smoke.

With this award, FAMRI is interested in high-risk projects that are not generally funded by government and non-government sources that will lead to breakthroughs and creative collaborations. The award is available to investigators with an M.D. or a Ph.D.

—Center of Excellence Award Program links physicians and scientists from various disciplines into multidisciplinary programs in patient care and research.

The aims of the FAMRI CoE include enhancing the knowledge base on the exposure to ETS. The program was developed on an institutional basis, with comprehensive research plans, including research endeavors from basic to clinical research and community outreach.

Inquiries: FAMRI, c/o Stanley and Susan Rosenblatt, Class Counsel, 66 W. Flagler St, 12th Floor, Miami, FL, 33130, phone 305-374-6131; fax 305-381-8818; Web site http://www.famri.org.

AACR Honorary Awards

American Association of Cancer Research is accepting nominations for the following awards.

Winners will present a scientific lecture at the 93rd AACR annual meeting in San Francisco, April 6-10, 2002.

—American Cancer Society Award for Research Excellence in Epidemilogy or Prevention supports achievements in the fields of epidemiology, biomarkers and prevention.

—Joseph H. Burchenal clinical Research Award was established by Bristol-Myers Squibb for achievements in clinical cancer research.

—Bruce F. Cain Memorial Award was established by the Warner-Lambert Company for achievements of an individual or research team in the fields of medicinal chemistry, biochemistry, or tumor biology as related to drug discovery. The award encompasses anticancer, antiviral and antifungal agents.

—A. Clowes Memorial Award was established by Eli Lilly Co. for achievements in basic cancer research, encompassing both laboratory research and epidemiological investigations.

—Cornelius P. Rhoads Memorial Award was established by an anonymous donor for achievements by an individual in cancer research. The award winner must be an early career investigator not more than 40 years of age at the time the award is given (April 2002.)

—Richard and Hinda Rosental Foundation Award is given for promising contributions to clinical cancer care. It is restricted to individuals who are engaged in the practice of medicine, who reside in the Americas, and who will not be more than 50 years of age at the time the award is given (April 2002.)

—DeWitt S. Goodman Memorial Lecture. Nominees should be scientists who have made significant contributions to the general field of cancer prevention.

For further information, see http://www.aacr.org. Nomination deadline is Sept. 10.

NIH Program Announcements

PA-01-113: Therapeutics Research on AIDS-Associated Opportunistic Infections and Malignancies

Application Receipt Dates: Jan. 2, May 1, and Sept. 1

The PA encourages investigator-initiated grant applications for preclinical research of state-of-the-art technologies to advance new or improved therapies. No clinical trials will be supported under this PA, which is being issued by NIAID, and co-sponsored by NCI and the National Institute of Dental and Craniofacial Research.

The National Heart, Lung, and Blood Institute, and the National Institute of Diabetes and Digestive and Kidney Diseases also have an interest in and support research on opportunistic infections associated with AIDS. The mechanism of support will be the NIH individual research project grant R01 and the exploratory/developmental grant R21 mechanism. A sound rationale and a well-designed research plan with limited preliminary data are required for a R21. The R01 supports more advanced projects.

The PA is available at http://grants.nih.gov/grants/guide/pa-files/PA-01-113.html.

Inquiries: Kenneth Cremer, Division of Cancer Biology, NCI, Rm 5016, 6130 Executive Blvd., MSC 7398, Bethesda, MD 20892-7398, phone 301-496-6085; fax 301-496-2025; e-mail kc47i@nih.gov.

PA-01-115: Management of Chronic Pain

National Institute of Nursing Research, NCI and co-sponsoring Institutes and Centers encourage research proposals to determine the most effective interventions in removing barriers to effective treatment, to determine the most effective pharmacological and non-pharmacological therapies including complementary and alternative therapies, to identify assessment tools for patients unable to verbalize their pain, and to identify effective pain management strategies for individuals with disabilities and underserved populations.

This PA will use the NIH research project grant R01 award mechanism.

The PA is available at http://grants.nih.gov/grants/guide/pa-files/PA-01-115.html.

Inquiries: Claudette Varricchio, program director, Division of Cancer Prevention, NCI, 6130 Executive Blvd. EPN 300, Bethesda, MD, 20892; phone 301-496-8541; fax 301-496-8667; e-mail varriccc@mail.nih.gov.

In Brief:

NCI Grant To Help Pitt Include Teaching End-of-Life Issues

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their families what it is like to have a life-threatening illness, and it will help the students to develop skills in listening to patients about the impact of illness on life," Barnard said. Additional course material will be introduced into the required first- and second-year curricula beginning in the fall of 2002. Barnard and Arnold are national leaders in palliative care education. The Palliative Care Service at UPMC was established in 1998 and provides comprehensive, coordinated services to terminally ill patients and their families. The service emphasizes relief from pain and other distressing symptoms, integration of physical, psychological and spiritual aspects of patient care, and development of a support system, both to help patients live as actively as possible until death and to help the family cope during the patient's illness and in bereavement. . . . **JOANA ROSARIO** was appointed the first international program director of the National Center for Complementary and Alternative Medicine at NIH. Rosario will develop a long-range plan for CAM research on a global scale, and direct and oversee a multifaceted international portfolio of research grants and contracts. She was previously at the National Institute of Neurological Disorders and Stroke.

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