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NCI Plans To Expand R01 Grant Funding By $49 Million, Increase Other Grants Also

In an effort to place more money in the hands of extramural cancer researchers, NCI plans to increase funding for investigator-initiated research grants by about $49 million this fiscal year, **The Cancer Letter** has learned.

The increase would enable NCI to fund about 650 competing R01 grants this year, about 150 more than the number funded in fiscal 1995. The Institute plans to spend about $270 million on competing R01s this year, compared to $221 million last year, sources said.

The Institute also plans to expand funding for program project (P01)

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In Brief

Glantz, Waxman, Wigand Honored For Work Opposing Tobacco; CTRC Names Executives

SMOKE-FREE America Committee presented awards to three individuals for their work against tobacco. The awards went to **Stanton Glantz**, professor of medicine, University of California, San Francisco; **Rep. Henry Waxman** (D-CA); and **Jeffrey Wigand**, a former tobacco company executive who released documents damaging to the industry. . . . **JUDAH FOLKMAN**, professor of pediatric surgery at Harvard Medical School, delivered the annual Herbert J. Block Memorial Lectureship at the Arthur G. James Cancer Hospital and Research Institute at Ohio State University recently. . . . **CANCER THERAPY** and Research Center, of San Antonio, TX, has appointed two new executives to its clinical staff. **Diane Roberts** was named chief operating officer for clinical services and **Diane Bourgeois** was named director of clinical services. Both have been members of the CTRC staff since 1974. . . . **LOIS AYASH**, a physician at the Dana-Farber Cancer Institute, has sued the hospital and The Boston Globe, claiming she was unfairly singled out for the chemotherapy overdose that killed Globe columnist Betsy Lehman in 1994. The lawsuit claims breach of confidentiality, gender discrimination, defamation and libel on the part of the defendants. In its original story about the case, the Globe said Ayash was one of a number of doctors and nurses who signed the mistaken drug order. She was the only doctor named in that story. According to the lawsuit, Ayash did not sign the drug order and did not have clinical responsibility for the case when the drug order was given. In a correction published last June, the Globe acknowledged that Ayash did not sign the medication order.

Estimated NCI Grant Paylines Listed In Memo To Staff

(Continued from page 1)

grants, R29 grants for new investigators, R03 small grants and R21 exploratory grants, sources said.

NCI officials said the Institute's budget plans for fiscal 1996 have not received final approval from NIH, and plans for grants funding could change. However, in a memorandum to the Institute's staff, Director Richard Klausner outlined the grants funding targets set by the NCI Executive Committee at a meeting Feb. 8.

After peer reviewers rank grant applications by priority score, NCI sets the "payline" along the ranking beyond which grants cease to be funded.

In the memo, dated Feb. 13, Klausner listed the estimated paylines for funding various types of grants. In fiscal 1996, NCI plans to fund grants that fall within the following percentiles or priority scores:

—The payline for R01 grants will be the 23rd percentile. Last year, the payline was the 15th percentile.

—The P01 grants payline will be the 140 priority score. Last year, the payline was the priority score of 134.

—The payline for the R29 First Independent Research Support and Transition Awards will be the 30th percentile. Last year, the payline was the 27th percentile.

—The R03 small grants payline will be the 200 priority score. Last year, the payline was the priority score of 180.

—The R21 exploratory grants payline will be the 25th percentile. Last year, the payline was the 21st percentile.

—The payline for the R43 Small Business Innovation Research phase I grants will be the 175 priority score. Last year, the payline was in the low 200s.

—The payline for the R44 SBIR phase 2 grants will be the 175 priority score. Last year, the payline was the 160 priority score.

—The payline for the R41 Small Business Technology Transfer grants will be the 200 priority score. Last year, the payline was the 160 priority score.

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M.D. Anderson Closes Trials After FDA Requests Data

M.D. Anderson Cancer Center has closed three clinical trials using radiolabeled antiferritin antibodies for the treatment of advanced Hodgkin's disease after FDA raised questions about the conduct of the trials.

M.D. Anderson officials notified 79 patients and their families that the trials were closed Jan. 26 and that the cancer center officials were reviewing the manner in which the studies were conducted and data were collected. Patients in the studies were young adults whose disease had failed to respond to chemotherapy regimens and bone marrow transplantation.

Huibert Vriesendorp, the principal investigator of the studies and an associate professor of radiotherapy at M.D. Anderson, disagreed with the center's decision to suspend the trials and said his program was unfairly targeted by FDA.

"We are in full compliance with all FDA rules and regulations," Vriesendorp said to **The Cancer Letter**. "FDA is threatening to close and audit all studies at M.D. Anderson unless they close this one."

Leonard Zwelling, M.D. Anderson associate vice president for clinical and translational research, said FDA made no such threat. "FDA is asking reasonable questions with regard to the trials, and we are focusing on getting them the answers," he said. "We felt there were enough questions about the documentation that we couldn't let things go on without getting some

answers."

Concerns about the studies surfaced last October when FDA requested routine information from M.D. Anderson, Zwelling said. The information was apparently requested when the University of Nebraska, which held the Investigational New Drug application for the radiolabeled antiferritin antibody, decided to withdraw the IND.

According to Vriesendorp, Nebraska researchers ran out of the agent and did not want to continue the research after Syed Quadri, a scientist who works with radioisotopes, moved from Nebraska to M.D. Anderson. Vriesendorp said he and Quadri began their collaboration on the agent when both held positions at Johns Hopkins University.

On Dec. 13, FDA informed M.D. Anderson that the reporting of "key information" in response to the inquiry was insufficient, the center said in a statement.

The center said it conducted a preliminary review of the studies last month. After a meeting with FDA officials Jan. 25, Zwelling said he made the decision to close the studies and conduct a more thorough audit.

Audit To Address Four Questions

Zwelling said Vriesendorp is required to submit a final report to FDA on the studies. If that report answers FDA's questions, an audit would not be necessary. If not, Eugene McKelvey, M.D. Anderson vice president for academic affairs, would form an independent faculty committee to conduct the audit.

Zwelling said the audit would address four questions:

—Did all the patients involved meet the eligibility requirements?

—Were adverse drug reactions documented and reported to FDA?

—Have response rates been documented?

—Did the patients receive only the specified therapy?

"The patient charts we have gone through are incomplete or difficult to go through," Zwelling said. "Given the situation, it's prudent to see where we are."

All the patients in the studies have advanced disease, and some died, Zwelling said. "There were deaths, but it is hard to know if the deaths were unusual," he said. "The question is, can we be absolutely certain there was no contribution to their deaths from the drug."

Patients who benefited from the treatment may continue to receive it under a compassionate use protocol, provided that M.D. Anderson would be able to document the benefit, Zwelling said.

Vriesendorp's clinical research privileges have been suspended, but he is permitted to treat patients, M.D. Anderson officials said.

Vriesendorp Cites Difficulty With Anderson, FDA

Vriesendorp said the closing of his studies is part of a larger problem between the M.D. Anderson administration and faculty.

"Over the last year or two there have been serious problems in interactions between the faculty and administration," he said. "Zwelling wouldn't mind having a ritual killing of someone like me so they can demonstrate to faculty what they will do."

"That's silly," Zwelling said. "I have been working with FDA to get these studies open and to treat patients. The idea that I'm doing anything but trying to get people treated is ridiculous."

Zwelling said M.D. Anderson internal politics had nothing to do with the situation. "This is not a witch hunt," he said. "These are issues of science and clinical medicine, and if the patient charts don't reflect the information needed, then we need to get it. If it's not on the charts, then show me where it is."

Vriesendorp, who is from Holland, said he began to study the antiferritin treatment at Hopkins in 1988 and continued his work when he moved to M.D. Anderson four years ago.

Over that time, he has treated 120 patients and published the results in journals that include the Journal of Clinical Oncology, September 1995 (Herbst, JCO 13, 2394-2400, 1995), and Cancer Research, December 1995 (Vol. 55, Supplement 1, pages 5888-5892). Another paper is expected to be published in the International Journal of Radiation Biology and Physics, Vriesendorp said.

"There is no indication or documentation that the studies we have been doing for the last eight years have suddenly turned sour," Vriesendorp said to **The Cancer Letter**.

Three out of four patients respond to the treatment, and responses last on average about six to eight months, Vriesendorp said. About half of the patients that do not respond to the treatment die within three months, he said.

Some patients who receive the therapy are able to continue working, he said.

Vriesendorp said the answers to M.D. Anderson's four areas of inquiry have been addressed in documents sent to FDA. "The quality of the people at FDA is not high," Vriesendorp said. "These are not board certified cancer specialists, they are police officers. They have no expertise in the area, and no certification in the area. They are very disgruntled individuals and very difficult to work with, for any physician, and certainly for patients."

Vriesendorp said he hoped Congress would "expose" the intimidating tactics he said FDA uses against investigators. He said his patients have complained to their Congressional representatives about the closing of the studies.

Rep. Joe Barton (R-TX) has made inquiries with FDA about the studies, sources said. Barton, who is chairman of the Subcommittee on Oversight and Investigations of the House Commerce Committee, is conducting a series of hearings on FDA.

In Congress

Hatfield, Kennedy Propose To Invigorate Clinical Research

In a recently introduced bill, Sens. Mark Hatfield (R-OR) and Edward Kennedy (D-MA) suggested a way to invigorate clinical research in the US:

Establish a "President's Clinical Research Panel" under the Office of Science and Technology Policy, allocate more NIH money to funding young clinical investigators, stabilize funding at clinical research centers, mandate insurance reimbursement for clinical research, and institute a loan repayment program and career enhancement awards for clinical researchers.

While many of the features of the bill, called the Clinical Research Enhancement Act, provoke no controversy, several cancer groups point out that the bill does not call for establishing an NIH study section on clinical research.

Several advocates of clinical cancer research have described a study section as an essential feature of any meaningful change.

NIH and the Administration officials are reportedly unenthusiastic about the bill. The NIH clinical research effort is currently being evaluated by a committee headed by David Nathan, a researcher at the Dana-Farber Cancer Institute.

The bill is supported by 78 groups, including the Association of American Cancer Institutes and the American Society of Hematology.

"Unfortunately, many of our best and brightest don't see a future in clinical research," Hatfield said as he introduced the bill Jan. 26. "They question the national funding commitment and the institutional support at the NIH.

"My legislation seeks to ensure that our future in patient-oriented research is secure," Hatfield said.

According to observers, some of the features of the Hatfield bill could be reflected in several broader pieces of legislation, including the recently proposed insurance reform bill and the NIH reauthorization bill.

As it stands, the bill proposes establishing a 12-member panel representing a range of perspectives on clinical research. Panel members would be nominated by the president of the Institute of Medicine. At the same time, the NIH would create an advisory committee that would review clinical research at NIH. The committee would report to the NIH director and the President's panel.

Also, NIH would be directed to increase the number of FIRST grants and establish an intramural clinical research fellowship program.

Sources said Hatfield is considering reintroducing his twice-defeated proposal to establish a trust fund for biomedical research.

In the original proposal, the trust fund was to be funded through surcharges on insurance premiums. A year later, the funding was to come from a tax on tobacco products. If the bill is introduced again, it would not specify a funding source, sources said, aiming instead to keep the idea of a trust fund on the table, and ready to be picked up by others after Hatfield's retirement.

NIH Grant Supplements For Disabled Researchers

NIH has developed a program to encourage individuals with disabilities to pursue biomedical research careers. The program is designed to supplement research grant awards.

Supplemental awards are available to support individuals with disabilities from each of the following population groups: high school students, undergraduate students, graduate research assistants, individuals in postdoctoral training, investigators developing independent research careers, and established investigators who become disabled.

For all of the supplemental programs, the proposed research experience must be an integral part of the approved, ongoing research of the parent grant. Also, with the exception of the supplemental program for established investigators who become disabled, individuals with disabilities must be given the opportunity to interact with individuals on the parent grant, to contribute intellectually to the research, and to enhance his/her research skills and knowledge regarding the particular area of biomedical science.

Furthermore, the principal investigator must demonstrate a willingness and understanding that the purpose of the award is to enhance the research capability of the student or faculty member with a disability, and that the research experience is intended to provide opportunities for individuals with disabilities to develop into independent, competitive research investigators.

As a part of these awards, funds may be requested to make changes or adjustments in the research setting that will make it possible for an otherwise qualified employee with disabilities to perform the essential functions associated with his/her role on the project. The accommodations requested under this program must be directly related to the performance of the proposed role on the research project and must be appropriate to the disabilities of the individual. Some types of accommodations that might be provided under these awards include: specialized equipment, assistive devices, and personnel such as readers, interpreters, or assistants. In all cases, the total funds for accommodations requested from the supplement must be reasonable in relationship to the direct costs of the parent grant and the nature of the supplemental award.

Principal investigators at domestic institutions who hold an active R01, R10, R18, R22, R24, R35, R37, P01, P20, P30, P40, P41, P50, P51, P60, U01, or U10 grant are eligible to submit a request for an administrative supplement to the awarding component of the parent grant for any of the supplemental programs. Principal investigators holding an active First Independent Research Support and Transition (FIRST) Award (R29), an Academic Research Enhancement Award (R15) or a Small Grant Award (R03) also may apply for a supplement under this program.

The parent grant must have support remaining for a reasonable period at the time of a supplemental award. Principal Investigators are encouraged to submit an application no later than three months before the anniversary date of the last two years remaining on the parent grant.

Usually, each parent grant may have only one supplement for a person with disabilities. Appointment of more than one individual to a single grant depends on the nature of the parent grant, the circumstances of the request, and the program balance of the awarding component. Supplemental awards under these programs do not preclude a separate supplement to support an underrepresented minority.

Application procedures: A request for a supplement may be submitted at any time. In making requests, the grantee institution, on behalf of the principal investigator of the parent grant and in cooperation with the individual with disabilities, must submit the request for supplemental funds directly to the awarding component that supports the parent grant. The request is not to be submitted to the NIH Division of Research Grants.

The decision to fund a supplement will take approximately eight weeks from receipt of a completed application. Applicants for summer-only research appointments must submit early enough to ensure that funding and accommodations are in place by the time the summer experience is scheduled to begin.

Principal Investigators interested in participating in any of these supplemental programs are encouraged to contact NIH staff administering the parent grant.

For general information about the Supplements for Individuals with Disabilities, NCI grantees may contact: Paulette Gray, Deputy Director, Division of Extramural Activities, Executive Plaza North, Suite 600, Bethesda, MD 20892, tel: 301/496-4218, fax: 301/402-0956, e-mail: grayp@dea.nci.nih.gov

NIH Offers Grant Supplements For Support Of Minorities

NIH has announced that principal investigators holding research grants that funds are available for administrative supplements to existing grants for the support and recruitment of underrepresented minority investigators and students.

The aim of these supplements is to attract and encourage minority individuals to enter and pursue biomedical and behavioral research careers.

In awarding supplements, the NIH will give priority to projects involving African American (Black), Hispanic American, Native American and Alaskan Natives, and Pacific Islander or other ethnic or racial group members who have been found to be underrepresented in biomedical or behavioral research nationally.

Supplements are available to support minority high school students, minority undergraduate students, minority graduate research assistants, minority individuals in postdoctoral training, and minority investigators.

In all cases, the proposed research experience must be an integral part of the approved ongoing research of the parent grant. As part of this research experience, the minority individual must be given the opportunity to interact with individuals on the parent grant, to contribute intellectually to the research, and to enhance her/his research skills and knowledge regarding the particular area of biomedical science.

Furthermore, the Principal Investigator must demonstrate a willingness and understanding that the purpose of the award is to enhance the research capability of the minority student or faculty member and that the research experience is intended to provide opportunities for minority individuals to develop as independent, competitive research investigators.

Principal Investigators at domestic institutions who hold an active R01, R10, R18, R22, R24, R35, R37, P01, P20, P30, P40, P41, P50, P51, P60, U01, U10, U41, or U42 grant are generally eligible to submit a request for an administrative supplement to the awarding component of the parent grant for any of the supplemental programs. Principal Investigators holding an active First Independent Research Support and Transition (FIRST) Award (R29), an Academic Research Enhancement Award (R15) or a Small Grant Award (R03) also may apply for a supplement under this program. An R29 awardee may apply only when the minority candidate is a high school, undergraduate, or graduate student.

An R15 awardee or an R03 awardee may apply only when the minority candidate is a high school or an undergraduate student. However, exceptions to these rules may be made. Applicants should check with their awarding component. Minority supplements to R29, R15 and R03 awards may provide support above the established dollar limits. The P20, P30 and P60 award mechanisms are eligible for supplements only when they contain research components.

Principal investigators are encouraged to submit an application no later than three months before the anniversary date of the last two years remaining on the parent grant. Usually, each parent grant may support only one minority supplement. Appointment of more than one individual to a single grant depends on the nature of the parent grant, the circumstances of the request, and the program balance of the NIH awarding component. Minority individuals may receive support from only one of these supplement programs at a time, but may be supported by more than one minority supplement during the development of their research careers.

The decision to fund a supplement will take approximately eight weeks from receipt of a complete application.

Principal investigators interested in participating in these programs are encouraged to contact NIH staff administering the parent grant. For general information about the Research Supplements for Underrepresented Minorities, NCI grantees may contact Paulette Gray, Deputy Director, Division of Extramural Activities, Executive Plaza North, Suite 600, Bethesda, MD 20892, tel: 301/496-4218, fax: 301/402-0956, e-mail: grayp@dea.nci.nih.gov

Annual Conference Planned On Laboratory Animal Care

The HHS Office for Protection from Research Risks, Public Responsibility in Medicine and Research and Tufts University School of Veterinary Medicine announce the annual conference on the care and use of laboratory animals in research.

Keynote speakers include Judith Vaitukaitis, director, National Center for Research Resources; Dr. Bill Raub, science advisor for the HHS Assistant Secretary for Planning and Evaluation, Nancy and Gerald Jaax, central figures in the response and management of disease outbreak storied in "The Hot Zone."

Among other forefront issues, the conference will address the search for alternatives to painful procedures, and the ethics, science, and risk of animal-to-human xenotransplantation.

Inquiries: PRIM&R, 132 Boylston St., Boston, MA 02116, tel: 617/423-4112, fax: 617/423-1185, e-mail: primr@delphi.com

Foundation To Fund Grants On Care Of Chronic Conditions

The Robert Wood Johnson Foundation is accepting grant applications under a $13 million program that funds demonstration and evaluation projects intended to improve the systems of care for patients with chronic conditions.

According to the foundation, the money is to be awarded over the next five years.

The program seeks to fund projects in medical, mental health, and supportive services, emphasizing non-institutional services.

The foundation said two types of projects will be considered:

—Demonstrations of new service systems that enable more appropriate, integrated services, improve patient satisfaction, and contribute to better health outcomes, greater efficiency, and reduced costs, and

—Evaluations of initiatives already in place to determine their impact on outcomes, service costs, and the quality of care.

No Restrictions On Populations

The foundation imposes no restrictions on the populations to be served.

However, the foundation said the following principles should be reflected in the proposals submitted:

—Health care providers need to recognize the special needs of people with chronic conditions across care settings and integrate clinical and non-clinical supportive services.

—Changing the acute care-oriented system to one more suited to the chronically ill requires comprehensive strategies that look for leverage points, particularly those that would alter how existing resources can be used.

—Proactive intervention is essential, so that a person's condition does not deteriorate before services are obtained; in most cases, people prefer to stay in their homes and communities as long as possible, which requires a system that fosters independence.

—A system of care for people with chronic conditions can be more effective when patients and caregivers play a role in its design and implementation.

The foundation said it is especially interested in supporting projects in the following areas: (1) integrating health care delivery in the acute care setting and the community for chronically ill children; (2) establishing efforts to link health care services with housing and community support services for the elderly; (3) giving people with disabilities the option to live in the community rather than institutions; (4) establishing services and delivery systems that reflect consumer preferences.

Additional information is available from Jay Wussow, Center for Health Care Strategies, 353 Nassau St., Princeton, NJ, 08540. Tel.: 609/279-0700, Fax: 609/279-0956.

RFPs Available

MAA-N01-CN-65008-70

Title: **Phase I studies of new chemopreventive agents**

Deadline: Approximately April 10

The NCI Div. of Cancer Prevention and Control, Chemoprevention Branch, in its annual requirement to seek new sources, is soliciting proposals for Master Agreement Holders for the phase I studies of new chemopreventive agents. The objective of these studies is to determine the parameters and characteristics of toxicity in humans, the safely delivered dose, and the basic clinical pharmacokinetics of agents emerging from the NCI chemoprevention agent development program so that subsequent phase III risk reduction trials can be appropriately designed.

Current MA holders for this program are not required to submit a proposal.

Inquiries: Erin Lange, contract specialist, RCB, PCCS, 6120 Executive Blvd., EPS Room 635, Bethesda, MD 20892, tel: 301/496-8603, fax: 301/402-8579, e-mail: langee@nih.gov.

MAA-N01-CN-65015-63

Title: **Evaluation of chemopreventive agents by in vitro techniques**

Deadline: Approximately March 25

The NCI Div. of Cancer Prevention and Control, Chemoprevention Branch, in its annual requirement to seek new sources, is soliciting proposals for the evaluation of chemopreventive agents by in vitro techniques to increase the number of Master Agreement holders. Current MA holders for this

program are not required to submit a proposal.

This Master Agreement Announcement is issued to solicit MA holders who have adequate capabilities and technical expertise to screen and evaluate the activity of chemopreventive agents in various in vitro assays of cell transformation.

Agents with potential chemopreventive activity are identified by epidemiologic surveys, initial laboratory findings, observations in the clinical setting, or structural homology with agents having known chemopreventive activity. A rigorous and systematic evaluation of these candidate agents is necessary before their efficacy can be examined in clinical trials for cancer prevention.

The contractor must have or be able to obtain all the equipment necessary to accomplish the studies, including but not limited to: laminar flow hoods, C02 incubators, equipment for sterility testing, isotope counters, spectrophotometer, hazardous chemical storage cabinets and refrigerators, equipment such as microscopes and miscellaneous laboratory equipment.

The period of performance of the MA pool will be three years. Up to four MA orders per year will be issued.

Inquiries: Tina Huyck, contracting officer representative, NCI, RCB, PCCS, EPS Room 635, 6120 Executive Blvd. MSC 7226, Bethesda, MD 20892-7226, tel: 301/496-8603, fax: 301/402-8579.

RFA Available

RFA ES-96-004

Title: **Linking Of Environmental Agents And Disease**

Letter of Intent Receipt Date: April 5

Application Receipt Date: May 8

The goal of this Small Grants Program (R03) is to encourage research that will establish whether there is sufficient evidence either mechanistically or from epidemiologic studies to justify further investigations into the role of environmental agents in the initiation or exacerbation of human diseases. Research is specifically encouraged to determine the sound scientific connection between environmental agents and the initiation or progression of disease. The total estimated funds available for support of this program is $750,000, which will support approximately 10 to 12 awards.

Inquiries: Jerry Heindel, Organs and Systems Toxicology Branch, National Institute of Environmental Health Sciences, PO Box 12233, MD 3-02, 104 Alexander Dr., Building 3, Room 316, Research Triangle Park, NC 27709, tel: 919/541-3319, e-mail: heindel_j@niehs.nih.gov

NCI Contract Award

Title: Support services for genetic epidemiology
Contractor: Westat Inc., $3,502,471

Letter to the Editor:

Letter Insulted Ethnic Group, Traditional Indian Medicine

To the Editor:

As a person of Indian origin, I was deeply offended by the "Letter to the Editor" you chose to print in your Jan. 26 issue. In trying to make a point regarding the role of the FDA, Saul Green and Jack Raso use traditional Indian medicine as an example. By the derogatory tone of their letter and their references to "healers in turbans," "goat feces" and "ass urine," they insult an entire ethnic group, and display their ignorance of the ancient practice of Ayurvedic medicine.

Shame on **The Cancer Letter** for being so insensitive. An apology is in order.

Roshan Bastani
Associate Director
Div. of Cancer Prevention & Control Research
UCLA Jonsson Comprehensive Cancer Center

The Editors reply:

An apology is indeed in order.

The letter, by Saul Green and Jack Raso, was a "modest proposal" that presented a vision of the US without the FDA. Green and Raso state that many practitioners of alternative medicine refer to the "time-honored" healing traditions of India in place of presenting clinical evidence supporting the safety and efficacy of their treatments.

We should have foreseen the range of interpretation of several statements in the letter. We take full responsibility for the problem and thank Dr. Bastani for pointing it out.