THE CANCER LETTER

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# Committee Recommends FDA Approval Of Three New Drugs For Cancer Treatment

An FDA advisory committee last week recommended that three drugs receive FDA approval for the treatment of non small-cell lung cancer, ovarian cancer, and breast cancer.

*The Oncologic Drugs Advisory Committee* voted to recommend approval of Taxol (paclitaxel) as a first-line treatment for advanced ovarian cancer and for the treatment of non small-cell lung cancer. The committee also recommended approval of Gemzar (gemcitabine HCI)

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*In Brief:*

## ASCO Selects Four New Board Members; Mount Sinai's Shank To Move To California

**AMERICAN SOCIETY OF CLINICAL ONCOLOGY** elected four new board members: **Patricia Legant**, a practicing medical oncologist and co-founder of the Society of Utah Medical Oncologists; **Patrick Loehrer**, professor of medicine at Indiana University and co-founder and chairman of the Hoosier Oncology Group; **Monica Morrow**, professor of surgery and director of the Lynn Sage Comprehensive Breast Program at Northwestern University Medical School; and **Margaret Tempero**, professor of medicine at the University of Nebraska Medical Center and deputy director of the UNMC Eppley Cancer Center. They will begin their terms at the ASCO Annual Meeting in May. . . . **BRENDA SHANK** was named director of radiation oncology at the JC Robinson Regional Cancer Center in San Pablo, CA, effective July 1. Shank, chairman and professor of radiation oncology at Mount Sinai School of Medicine, also will join Marin Oncology Associates as a practicing oncologist. . . . **PATRICIA CARLSON KOEHLER** was named executive director and general counsel for the National Surgical Adjuvant Breast and Bowel Project Foundation Inc. Koehler is the former associate general counsel for the Allegheny Health Education and Research Foundation. . . . **PRESCOTT DEININGER** was named director for basic science programs and associate director at Tulane Cancer Center. Deininger also was named Marguerite Main Zimmerman Professor of Basic Cancer Research at Tulane University Medical Center, professor of environmental health sciences at the Tulane School of Public Health and Tropical Medicine, and adjunct professor in the Departments of Biochemistry, Pathology, and Laboratory Medicine, and a member of

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## Taxol, Gemzar, And Xeloda Recommended For Approval

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for the treatment of non small-cell lung cancer, and Xeloda (capecitabine) for the treatment of metastatic breast cancer.

### Taxol In Ovarian Cancer

The committee voted unanimously to recommend approval of Taxol in combination with cisplatin as a first-line treatment for stage III and stage IV ovarian cancer.

Taxol, sponsored by Bristol Myers-Squibb, is indicated as a second-line treatment for breast and ovarian cancers, and as a second-line treatment for Kaposi's sarcoma.

BMS presented data from a randomized phase III trial comparing paclitaxel-cisplatin to cyclophosphamide-cisplatin. The Gynecologic Oncology Group conducted the trial at 86 sites.

"The results of this trial are overwhelming," Stephen Williams, director of the Indiana University Cancer Center, said to the committee during the company's presentation. "For the first time in more than 15 years, we're seeing significant improvement in survival rates for patients with advanced ovarian cancer."

"From the GOG point of view, we no longer use chemotherapy that does not contain Taxol," Williams said.

The BMS analysis of data from the trial showed a median survival of 35.5 months for patients on the Taxol arm, compared to 24.2 months for patients receiving cyclophosphamide. FDA analysis of the trial showed the same median survival.

Median progression-free survival for patients receiving Taxol was 16.6 months with an overall clinical response of 60 percent, compared to 13 months and a 50 percent response rate in patients on the cyclophosphamide arm.

FDA analysis of the data showed a slightly lower median progression-free survival for both Taxol and cyclophosphamide, but a higher overall response rate than the BMS analysis showed. FDA calculated an overall response of 62 percent for patients receiving Taxol, and 48 percent for those receiving cyclophosphamide.

FDA reviewer Susan Honig said it was probably the first time FDA had calculated a better result than the sponsor did.

### Taxol In NSCLC

ODAC voted 5-2, with one abstention, to recommend approval of Taxol in combination with cisplatin for the treatment of NSCLC in patients who are not candidates for potentially curative surgery and/or radiation therapy.

The committee recommended approval for a 24-hour administration of 135 mg/m$^2$ of Taxol followed by cisplatin every three weeks. The committee recommended against approving a three-hour infusion of 175 mg/m$^2$ Taxol.

BMS presented data from three phase III trials conducted by the Eastern Cooperative Oncology Group, the European Organization for the Research and Treatment of Cancer, and by the company.

Overall, the company said, Taxol combined with cisplatin produced a superior response rate, prolonged time to progression, and advantages in quality of life compared to cisplatin-etoposide, cisplatin-teniposide, and cisplatin alone.

According to the FDA review of the BMS data, Taxol-cisplatin did produce a higher response rate, but showed no statistically significant survival advantage. FDA also found a higher incidence of hematologic toxicity, specifically in incidences of grade IV neutropenia.

FDA analysis of data from the ECOG trial found that 135 mg/m$^2$ of Taxol over 24 hours produced a 21 percent response rate, compared to a 12 percent

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response in patients treated with cisplatin-etoposide. BMS said the data showed a 26 percent response rate for Taxol, and a 14 percent response for etoposide.

In an analysis of results from the EORTC trial comparing 175 mg/m$^2$ of Taxol over three hours to teniposide, FDA found that Taxol produced a response rate of 33 percent, compared to 21 percent in the teniposide arm. BMS said the data showed an overall response rate of 36 percent in the Taxol arm, and 25 percent in teniposide.

BMS study number 208 compared 175 mg/m$^2$ of Taxol over three hours to high-dose cisplatin. FDA analysis found that Taxol produced a response rate of 26 percent, compared to a 17 percent response in the cisplatin arm. BMS analysis of the data showed the same response rate as the FDA analysis did.

*FDA did not find a statistical difference in time to progression or median survival time in any of the three trials.*

"I think it's a tough call," said ODAC member Richard Simon, chief of the NCI Biometric Research Branch. "But I believe there is some small survival benefit, although I would have liked to have seen a stronger statistical demonstration of it."

"I guess I have been persuaded that there is clear clinical benefit associated with platinum-Taxol," said ODAC member Richard Schilsky, director of the University of Chicago Cancer Research Center. "It was interesting to me that in the [quality of life] graphs shown by the sponsor, there was a progressive decrement in each of the parameters displayed for the cisplatin-etoposide arm over time. However, there was a relative stability in the Taxol-cisplatin arm, indicating that there was at least a better preservation of quality of life for patients receiving that treatment."

*The committee said data presented from the EORTC and BMS trials did not show that 175 mg/m2 of Taxol administered over three hours had a significant clinical benefit.*

The committee voted 5-2, with one abstention, not to recommend approval of the higher dose therapy.

**Gemzar For NSCLC**

The committee voted 9-1 to recommend approval of Gemzar, sponsored by Eli Lilly and Co., in combination with cisplatin for the palliative treatment of stage III and stage IV NSCLC.

The company presented data from three phase III trials comparing Gemzar-cisplatin to cisplatin alone and to cisplatin-etoposide, and Gemzar alone to cisplatin-etoposide.

FDA analysis of the results showed that patients enrolled in the trial comparing Gemzar-cisplatin to cisplatin alone had a median response rate of 23.2 percent on the Gemzar arm compared to 6.5 percent on the cisplatin arm. The median survival time of patients receiving Gemzar-cisplatin was 8.7 months compared to 7.5 months for patients receiving cisplatin alone. The company presented data from 309 patients.

An updated survival analysis of 522 patients in the study showed a median survival time of 9 months for patients receiving Gemzar-cisplatin, and 7.5 months for those receiving cisplatin alone.

Data from the Gemzar-cisplatin vs. cisplatin-etoposide trial showed a 1.7 month increase in median survival time for patients receiving Gemzar. Patients on the Gemzar-cisplatin arm had a median survival time of 8.7 months and a response rate of 33.7 percent, compared to a seven-month survival time and 13.6 percent response rate for patients receiving cisplatin-etoposide.

The committee said Gemzar's efficacy when combined with cisplatin outweighed its increased toxicity. Patients treated with Gemzar had a significantly higher incidence of grade III/IV hematologic toxicities.

The committee was less convinced about the drug's efficacy when used alone. In a vote of 9-1, the committee said the trial comparing Gemzar alone to cisplatin-etoposide did not show the drug to be safe and effective for the palliative treatment of NSCLC.

"I think all the data are fairly conclusive that the drug has activity as a single agent, and I think it's pretty clear that we agree that the drug adds something to cisplatin chemotherapy," Schilsky said. "But whether by itself the drug actually produces meaningful clinical benefit for patients, I don't think we've seen data to suggest that that is the case. I don't think we have sufficient evidence to make a judgement either way."

The committee said aggregate results from the trials were a better indicator of Gemzar's efficacy as a single agent, than from the one trial alone. The committee voted 6-4 to recommend approval of Gemzar as a single agent for the palliative treatment of NSCLC.

"I think it comes down to availability and choice," said ODAC member Robert Ozols, senior

vice president of medical sciences at Fox Chase Cancer Center.

Gemzar is indicated for the treatment of locally advanced or metastatic pancreatic cancer.

**Xeloda In Metastatic Breast Cancer**

ODAC voted to recommend accelerated approval of Xeloda, an oral therapy for the treatment of metastatic breast cancer that is resistant to paclitaxel and an anthracycline-containing chemotherapy regimens.

The drug, sponsored by Hoffman LaRoche, belongs to a class of agents called fluoropyrimidine carbamates.

Accelerated approval may be granted for a drug that is indicated for a life-threatening disease for which an adequate therapy does not exist. The drug must demonstrate therapeutic gain on the basis of a well-controlled trial, and the applicant must agree to continue trials after approval of the drug.

Hoffman LaRoche presented data from a non-comparative, multicenter trial in 162 woman who had failed treatment with paclitaxel.

The response rate in the 135 patients with measurable disease was 18.5 percent with a median duration of 154 days.

In the 43 patients with disease resistant to both paclitaxel and anthracycline, the response rate was 25.6 percent with a median duration of 154 days.

The committee, in a vote of 11-1, said the 25.6 percent response rate was evidence of a meaningful therapeutic benefit over existing treatments.

Adverse events associated with Xeloda include diarrhea, stomatitis, and hand-foot syndrome. The committee said that the toxicity profile was acceptable for women whose disease is resistant to both paclitaxel and anthracycline.

The committee voted 10-2 to recommend accelerated approval of Xeloda for metastatic breast cancer patients resistant to paclitaxel and anthracycline.

The committee voted 8-3 with one abstention to recommend approval of the drug for patients resistant to paclitaxel who have received a minimum cumulative dose of 400 mg/m$^2$ of doxorubicin equivalents.

**The Cancer Letter** invites readers attending the American Association for Cancer Research annual meeting March 28-April 1 to stop by our exhibit in the Morial Convention Center, booth #810, to talk to the editors.

*In Congress:*

## Human Genome Project Ahead Of Schedule, Collins Says

The Human Genome Project is ahead of schedule and under budget in its goal to completely sequence the human genome by the year 2005, National Human Genome Research Institute Director Francis Collins said at a Congressional hearing last week.

"Now at the halfway mark, progress in the 15-year Human Genome Project, its impact on health research and even public policy has surpassed the most ambitious expectations," Collins said at a March 12 hearing of the House Labor, HHS and Education Appropriations Subcommittee. "If you look at the milestones that were set for this project, in every instance we have exceeded those goals."

President Clinton requested $237 million for NHGRI in the Administration's fiscal 1999 budget proposal. The proposed budget would be a 10.4 percent increase over the fiscal 1998 appropriations.

Subcommittee Chairman John Porter (R-IL) asked Collins to comment on an article in the March 10 issue of The New York Times that reported the Human Genome Project to have completed only three percent of the planned sequencing.

Collins said the article presented an overly simplistic view of the Human Genome Project. "While it is true that we have done about 3 percent of the total sequence, the original plan was at this point to have less than 1 percent," Collins said. "The first half of the project was to be devoted to the development of genetic and physical maps, the sequencing of model organisms, and the improvement of technology to bring down the cost of sequencing.

"Once you step beyond the superficial level of what has been accomplished and how much time has gone by, it is clear that the goals are being met quite handily," Collins said.

To keep the price of the project within the planned budget, project costs will have to be reduced by a factor of two over the next seven or eight years, Collins said. To accomplish that goal, new cost-cutting technologies will have to be developed, and the price of sequencing base pairs will have to be reduced from $0.50 per pair to $0.49.

The human genome contains three billion bases.

The original predicted price for the genome project was $200 million per year for 15 years, for a

total of $3 billion in 1990-dollar equivalents, Collins said. Collins said that including the fiscal 1999 budget the project has spent $1.5 billion. The projected cost for the first nine years was $1.8 billion.

"So it might cost us as much as $3 billion," Porter said. "Four B-2 bombers to map the entire human genome?

"Well, I think it is probably going to go down as the best money we have ever spent," Porter said.

**Genetics and Prostate Cancer**

NHGRI has initiated a nationwide study that will focus on genetic reasons for the higher incidence of diabetes and prostate cancer in African Americans.

The project is coordinated by Howard University in Washington, DC.

Over the next three years, the prostate cancer project plans to accrue 100 families with at least five affected members.

Blood samples will be taken by grantee institutions nationwide, and sent to Howard for DNA analysis. Genotyping of all samples will be done at NHGRI, Collins said.

"This is a truly exciting opportunity for the joining together of an NIH institute and a institution with a great deal of credibility and capability, which is hungry for a presence in genetics and genomics as applied to minority illnesses," Collins said. "Of the things we are doing in our intramural program, this is one of the most exciting."

The project, supported by the NIH Office of Research on Minority Health with some funding from NCI, will focus heavily on chromosome 1, which recent studies have shown to be linked with prostate cancer in African American men.

Collins said the institute plans to expand the program to include breast cancer and other diseases. Project coordinators are applying for further NIH funding for the expanded program and recruiting investigators, he said.

## Health Disparities Between Minorities Too Large: Shalala

The overall health of Americans is improving at a steady rate, but the disparity between the health of minority and white Americans is still too large, HHS Secretary Donna Shalala said last week in a speech at Howard University.

"Think of two nearly parallel lines slanting upward," Shalala said during the March 13 speech. "The two lines represent the generally improved health of whites and minorities, including African Americans, Hispanics, Asians, Pacific Islanders, and Native Americans. But the gap between whites and non-whites that exists for many diseases remains about the same."

"It's that gap that we must close," she said.

Shalala delivered the keynote address at a ceremony marking the 10th anniversary of the Patricia Roberts Harris Public Affairs Program at Howard. Shalala worked for Harris as an assistant secretary for policy development when Harris was the Secretary of Housing and Urban Development in President Jimmy Carter's administration. Harris, who died of cancer, also served as HHS Secretary.

Closing the gap between minority and white health includes fighting poverty, improving access to quality health insurance, and improving personal behavior, Shalala said.

"The fact is, the vast majority of preventable deaths are linked to just three personal behaviors: smoking, poor diet, and lack of physical activity," Shalala said. "That means that people from every race and ethnic group can lower the risk of premature death by kicking tobacco out of their lives, eating right, and staying active."

Shalala described a plan developed by the Clinton Administration to eliminate health disparities between minority and white Americans by the year 2010. President Clinton first announced the plan during a Feb. 21 radio address (**The Cancer Letter**, Feb. 27).

The plan is designed to eliminate disparities in cancer screening and management, infant mortality, diabetes, HIV/AIDS, and child and adult immunizations.

"Making prevention a public health priority, fighting poverty, and increasing access to health insurance are all important steps toward eliminating racial and ethnic health disparities, but they won't get us across the finish line," Shalala said. "That's going to take bold new moves—the kind of moves the President outlined when he announced his goal of eliminating these disparities by 2010."

Shalala said the Administration's plan includes an education and outreach program led by Surgeon General David Satcher, grants for community-based programs designed to improve minority health, a conference to explore ways to build public-private partnerships to improve minority health, and a committee and work groups that will develop a long-

term plan to help end health disparities.

Clinton has requested an appropriation of $150 million to fund 30 grants to develop programs to improve minority health, and $250 million to strengthen existing public health programs. No funding has been specified for the remaining pieces of the Administration's plan.

The Administration has set interim goals toward the improvement of minority health, to be completed as part of the Healthy People 2000 program, Shalala said.

Those goals include increasing to 60 percent the number of minority women who have received a clinical breast exam and mammogram within the last two years, cutting infant mortality among African Americans by 22 percent, cutting the death rate of African Americans from heart disease by 25 percent and stroke by 40 percent, and assuring access to health care and drug therapies for at least 75 percent of low-income people infected with HIV/AIDS.

*Funding Opportunities:*

## NIH To Fund New Awards For Clinical Research Careers

NIH has created three new types of career development awards aimed at increasing the participation of clinical researchers in medical research and enriching the pipeline of people properly trained to do clinical research.

The new awards, which NIH expects to begin funding in FY 1999, will support young investigators who have just completed specialty training and mid-career investigators. Institutional curriculum awards will be offered to help teach the essentials of clinical research to young trainees and junior faculty.

The awards will be used by every NIH Institute, and will serve as additions to NIH strategies to enhance and expand clinical research training and career development.

The Mentored Patient-Oriented Research Career Development Award (K23) was developed for investigators who have recently finished specialty training. The award is focused on providing both didactic training and mentored research experience for up to five years.

Investigators will commit at least 75 percent of their time to the program.

NIH estimates that there will be 80 new K23s each year.

The Mid-Career Investigator in Patient-Oriented Research Award (K24), was developed for mid-career clinical scientists. Because of the demands placed on their time, the opportunity for these investigators to have dedicated research time and to be mentors to other investigators is scarce. To address these concerns, the K24 relieves investigators from patient care and administrative responsibilities. Investigators will receive support for up to five years, with the possibility of a one-time renewal.

NIH estimates that 50 to 80 awards will be made each year.

The Institutional Curriculum Award (K30) is designed for institutions with a substantial clinical research portfolio and a critical mass of individuals in clinical research training and career development. It is meant to stimulate the inclusion of high quality, comprehensive courses in the fundamentals of clinical research, as part of the career development of clinical investigators.

The maximum award for a program, which may not exceed five years, will be $200,000 per year. NIH expects to fund about 20 such programs in the first year.

## NCI Offers 5-Year Program Of Cancer Prevention Training

NCI is accepting applications for the Cancer Prevention Fellowship Program.

The program is designed to train individuals from a variety of health science disciplines in the field of cancer prevention and control.

The program provides for Master of Public Health training at accredited one-year university programs, participation in the Cancer Prevention and Control Summer Academic Course, mentored research training in cancer prevention and control at NCI, and brief field assignments at other institutions.

Fellows will be accepted for up to five years of training.

Eligible candidates must hold an MD, DDS, or DO degree from a US, territorial, or Canadian Medical School or PhD or other doctoral degree in a related disipline. Foreign applicants must have current USMLE or ECFMG certification and appropriate experience. Applicants must be citizens or resident aliens of the US eligible for citizenship within four years.

The Cancer Prevention and Control Summer Academic Course is also open to physicians and

scientists who are interested in specialized instruction on the principles and practice of cancer prevention and control. The course is divided into eight modules that can be attended individually.

Application deadline is Sept. 1. The program begins July 1, 1999.

Contact Barbara Redding, tel: 301/496-8640, fax: 301/402-4863, email: br24@nih.gov.

## RFPs Available

***RFP N01-CN-85080-70***

Title: **Phase I Clinical Studies Of Chemopreventive Agents**

The Chemoprevention Branch of the NCI Division of Cancer Prevention is expanding the existing Master Agreement pool with the objective of conducting phase I clinical trials to evaluate the pharmacokinetics, pharmacology, and toxicology of chemopreventive agents, as well as to evaluate the modulation of biological markers of carcinogenesis.

MA holders receiving a contract award will be selected through this pool, based on technical merit and on budgetary considerations for specific tasks involved. Any MA awarded as a result of this solicitation will be in effect to Feb. 15, 2003. Due dates for receipt of proposals June 1 and December 1 (or the next business day) of each year. MA holders already in the existing master agreement pool need not respond to this announcement.

The RFP may be accessed through the Research Contracts Branch Home Page by using the following Internet address: http://rcb.nci.nih.gov/RFP.HTM.

Contact: Erin Lange, Contracting Officer, NCI, RCB, PCPSS; 6120 Executive Blvd, Executive Plaza South, Room 635, Rockville, MD 20852; tel: 301-435-3828; fax: 301-402-8579; email: el45g@nih.gov.

**RFP N01-CN-85077-57**

Title: **Phase II—Clinical Trials Of New Chemopreventive Agents**

The NCI Division of Cancer Prevention intends to expand the existing Master Agreement pool for "Phase II Clinical Trials of New Chemopreventive Agents."

Any MA awarded as a result of this solicitation will be in effect to Oct. 30, 2002. Due dates for receipt of proposals June 1 and December 1 (or the next business day) of each year. MA holders already in the existing ma pool need not respond to this announcement.

The RFP may be accessed through the Research Contracts Branch Home Page by using the following Internet address: http://rcb.nci.nih.gov/rfp.htm.

Contact: Desiree Sylver-Foust, Contract Specialist, NCI, RCB, PCPSS; 6120 Executive Blvd, Executive Plaza South, Room 635, Rockville, MD 20852; email: ds154o@nih.gov.; tel: 301-435-3833; fax 301-402-8579.

**RFP N01-CN-85027-57**

Title: **Prostate, Lung, Colorectal And Ovarian Cancer Cancer Screening Trial Expansion**

Deadline: Approximately May 8

The NCI Division of Cancer Prevention, Early Detection Branch, is expanding the Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial and is interested in soliciting proposals from organizations for two new screening centers, each focusing on a different population group and each recruiting no less than 5,000 participants (2,500 subjects and 2,500 controls) to the Trial. One screening center will target Hispanic communities and recruit at least 1,500 Hispanic Americans (or 30 percent of their total enrollment goal) and the other will target the general U.S. population. Female subjects will be screened for colorectal, lung, and ovarian cancers. Male subjects will be screened for colorectal, lung, and prostate cancer. Following the initial screen, screening will be performed annually for three years for prostate, lung, and ovarian cancers and only at the initial and third annual screen for colorectal cancer. Subjects and controls will be followed for at least ten years. The PLCO Cancer Screening Trial was established in 1992 with 10 screening centers, a Coordinating and Data Management Center, a Steering Committee, and a Monitoring and Advisory Panel. During its 2-year pilot phase protocols and biomedical data management procedures were established.

The RFP may be accessed through the Research Contracts Branch Home Page by using the following Internet address: http://rcb.nci.nih.gov/RFP.HTM.

Contact: Desiree Sylver-Foust, Contract Specialist, fax: 301-402-8579, tel: 301-435-3833, email: ds154o@nih.gov.

**Sole Source RFP N02-BC-81038-21**

Title: **Laboratory Support For Structural Studies Of Membrane Proteins By Electron Microscopy**

The NCI Division of Basic Sciences proposes to issue a Sole Source RFP to the Johns Hopkins University School of Medicine for laboratory support for structural studies of membrane proteins by electron microscopy awaiting completion of an electron microscopy facility on the NIH campus. Authority for this action is 41 USC 253(c)(1), as set forth in FAR 6.302-1(b)(1).

In February 1998, NCI selected Sriram Subramaniam as a Section Chief in the Laboratory of Biochemistry, DBS, NCI. This selection resulted from a nationwide search. Subramaniam will report aboard the NCI in May 1998, as a full time government employee and will continue his independent research which was initiated several years ago while he was an employee of the Johns Hopkins University School of Medicine, Department of Biological Chemistry. Because this facility will not be completed in time for Subramaniam to continue his research on-site and in order to allow the continuation and progress of the on-going studies, NCI proposes to

provide him with research support during the interim period. The proposed contractor will provide support for studies on understanding the biogenesis, structure and mechanisms underlying the activation of rhodopsin, the G-protein coupled light receptor in vertebrates and in invertebrates. The experimental goals are to obtain molecular "snapshots" of the structure and environment of newly synthesized rhodopsin and to understand the structural basis of steps in light transduction by rhodopsin. This is one of the few laboratories world-wide that is actively pursuing high resolution electron crystallographic studies of membrane proteins. Further, the existing staff has acquired an expertise and familiarity with the research which cannot be duplicated without years of working on the project. Based upon the above, the government believes the Johns Hopkins University School of Medicine is the only source that can provide the necessary resources to continue the research without substantially reducing the progress and without a loss of the data which it has acquired over the years.

This contract is being solicited as a cost-reimbursement, level-of-effort contract with a base period of 18 months and three one-month options. This is expected to be sufficient time to allow for the construction of the on-site laboratory.

Contracting Officer: Barbara A. Shadrick ESS, RCB, OEM, NCI, 6120 Executive Blvd Rm 620H, Rockville, MD 20892-7224, tel: 301-435-3787, fax: 301-480-0241, email: bs92y@nih.gov

## PA Available

**PA-98-042**

Title: **Exploratory Grants For Correlative Laboratory Studies And Clinical Trials**

The NCI Division of Cancer Treatment and Diagnosis invites research grant applications from interested investigators to conduct innovative therapeutic clinical trials or new correlative laboratory studies using patient specimens from therapeutic clinical studies.

The exploratory/developmental (R21) grant mechanism is utilized for pilot projects or feasibility studies to support creative, novel, high risk/high payoff research that may produce innovative advances in science. The objective of this PA is to encourage applications from individuals who are interested in testing novel or conceptually creative ideas that are scientifically sound and may advance progress in human health. This PA supersedes PA-96-040, Exploratory Grants to Stimulate Correlative Laboratory Studies and Innovative Clinical Trials. The exploratory grant program provides limited funds (maximum of $100,000 direct costs per year not including indirect costs of any collaborating institutions) for short-term (up to two years) research projects.

The goal of this initiative is to promote translational and clinical research through the support of two types of studies: 1) new therapeutic clinical trials or 2) new correlative studies relevant to therapeutic clinical studies. Applications should be focused on integrating clinical goals with laboratory research areas.

This PA envisions funding new therapeutic clinical trials that move new treatment strategies more rapidly from the laboratory into the clinic. These clinical studies must involve human subjects, be designed to ultimately improve cancer treatment, and be based on a strong rationale. Furthermore, the underlying hypothesis should be supported by preclinical data. The proposed clinical protocol should be included in the Appendix of the application.

This PA has a second research goal of funding new correlative laboratory studies that are relevant to therapeutic clinical studies. The clinical correlates must have a future clinical application such as development of new treatment strategies or identification of patient subsets for specific treatment therapies.

Inquiries: Diane Bronzert or Dr. Roy Wu, DCTD, NCI, 6130 Executive Blvd Rm 734 MSC 7432, Bethesda, MD 20892-7432, tel: 301-496-8866, fax: 301-480-4663, email: BRONZERTD@CTEP.NCI.NIH.GOV or WUR@CTEP.NCI.NIH.GOV

*In Brief:*

## Ramsey Promoted At Tulane

(Continued from page 1)

the Human Genetics Program at the Tulane School of Medicine. Deininger is the former director of the Laboratory of Molecular Genetics at Ochsner Medical Foundation, and professor of biochemistry and molecular biology at Louisiana State University Medical Center. . . . **MARGUERITE RAMSEY** was named executive director of the Tulane Cancer Center. Ramsey is the former interim clinic manager of the Tulane Cancer Center Comprehensive Clinic. . . . **GAIL KUHN WEISSMAN** was named executive director of nursing at Memorial Sloan-Kettering Cancer Center. Weissman, former vice president of patient care services at Partners Healthcare System Inc., was named to the Enid A. Haupt Chair in Nursing at MSKCC. . . . **ROBERT BLOOM** was named chief of oncology for the Detroit Medical Center's Northwest Region. The region includes Grace Hospital, Sinai Hospital, and the DMC Health Care Centers. Bloom is the former chief of oncology at Sinai Hospital. . . . **DEADLINE** to submit abstracts for the 1998 meeting of the American Association of Cancer Education was extended to April 15. Contact Ginger Krawiec, tel: 404/329-7612, email: gkrawiec@cancer.org.