THE CANCER LETTER

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Study Finds More Deaths On Aranesp Arm In Cancer Anemia Study, No Benefit Seen

By Paul Goldberg

Preliminary results from a large randomized study announced last week reported that patients with cancer-induced anemia who were not receiving chemotherapy or radiation were more likely to die if they received Aranesp (darbepoetin alfa) rather than placebo.

Also, in the nearly 1,000-patient trial, Aranesp failed to reduce the need for blood transfusions.

The difference in death rates, which was statistically significant, was cited in Amgen's "Dear-Doctor" letter that FDA posted on its MedWatch adverse events reporting system Jan. 27. The agency is also considering adding a "black box" warning to the Aranesp label, Amgen officials disclosed.

However, based on snippets of information released in the Dear-Doctor letter, oncologists and drug safety experts said they were unable to assess the clinical implications of the findings. The document didn't contain the name

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In the Cancer Centers:

William Hait To Step Down As CINJ Director, Joseph Bertino Named Interim Director

JOSEPH BERTINO was named interim director of Robert Wood Johnson Medical School's Cancer Institute of New Jersey, **Peter Amenta**, interim dean of UMDNJ-Robert Wood Johnson Medical School said. **William Hait**, who has served as CINJ director since 1993, will step down. Under his leadership, the center obtained cancer center designation from NCI in 1997. In 2002, NCI designated CINJ as a comprehensive cancer center. Bertino has served as associate director of CINJ and University Professor of Medicine and Pharmacology at UMDNJ-Robert Wood Johnson Medical School since 2002. He was appointed chief scientific officer of CINJ in 2004. Prior to joining CINJ and UMDNJ, Bertino served as chairman of the Molecular Pharmacology and Therapeutics Program, and member and co-leader of the Program in Developmental Therapy and Clinical Investigation at Memorial Sloan-Kettering Institute for Cancer Research. From 1973 to 1986, Bertino was director of the Yale Comprehensive Cancer Center. . . . **VANDERBILT-INGRAM** Cancer Center received a $6.5 million grant from NCI to study the microenvironment of tumors. One of the angiogenesis drugs that will be examined will be Avastin, recently approved by FDA for advanced, non-squamous, non-small cell lung cancer, said **Lynn Matrisian**, chairman of

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Amgen Sends Dear-Doctor Letter, Black Box Possible

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of the study and said little about the characteristics of patients enrolled.

"This Dear-Doctor letter, like most, raises more questions than it offers answers," said Charles Bennett, an oncologist at Northwestern University and an expert on adverse reactions to cancer drugs. "Here we go, we put this out to the community to interpret and alter practice, and we don't even know what the message is."

The trial in question was conducted in an apparent effort to expand the market for Aranesp to supportive care for cancer-associated anemia that is not secondary to chemotherapy. This is an off-label use for the biologic approved as a treatment for patients with non-myeloid malignancies receiving chemotherapy.

According to the company, this off-label use accounts for 10 to 12 percent of Aranesp's worldwide sales. Since the aggressively-marketed biologic generated worldwide sales of $4.121 billion last year, this could add up to as much as $495 million.

Amgen officials said the vast majority of this use occurs in the U.S., but were unable to estimate what proportion of patients in this country receive the agent as treatment for cancer-related anemia. The calculation could be even more complicated, because Aranesp is also used in nephrology.

If the findings of the recently reported study hold up, more than one in 10 Americans getting Aranesp without chemotherapy has no chance of benefiting from the agent and could be harmed or killed by it, experts say.

"What I would like to know is what were the actual causes of death in the Aranesp and placebo arms of the study," said Bennett, who is also the principal investigator of Northwestern's Research on Adverse Drug events And Reports (RADAR) program, a participant of the Cochrane Collaboration reviews of EPO and a member of a team of researchers that drafted the American Society of Clinical Oncology and the American Society of Hematology clinical practice guidelines for EPO six years ago. Bennett has also consulted for Amgen.

In 2003 and 2004, Amgen and Johnson & Johnson, the sponsor for Procrit, another version of EPO, updated their package inserts to include warnings that administration of their products to cancer patients has been associated with increased risk of thromboembolic events. Clinical trials have shown this to be the case when patients receiving cancer therapy also received Proctit in an effort to raise their hemoglobin levels beyond the correction of anemia and into the normal range (The Cancer Letter, Oct. 24, 2003).

In the current issue of the journal Blood, Franklin Bunn, a hematologist at Brigham and Women's Hospital, cited animal studies to assert that "rhEpo may pose a thrombotic risk independent of its effect on the red-cell mass."

"Administration of rhEpo to dogs resulted in a decline in platelet count but enhanced platelet reactivity, and promoted development of thrombus in those with an arteriovenous shunt," Bunn wrote. "In healthy human volunteers, intravenous administration of rhEpo (100 U/kg or 500 U/kg) resulted in a 10% to 20% increase in platelet count as well as activation of both platelets and the endothelium. However, the rise in platelets may be due in part to induction of iron deficiency owing to the increase in red-cell mass. Cancer patients are inherently predisposed to thrombosis. This complication may be enhanced in those treated with rhEpo."

Amgen officials have disappointing news for those clamoring to learn the causes of death on the company's recent study. "Remember, this study was not designed as a survival study," Roy Baynes, vice president for oncology supportive care, said to The Cancer Letter. "When you do a study for survival, you tend to adjudicate every death. This study had as its primary goal to assess the effect of the erythropoietic agent on reducing blood transfusion.

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"In the safety reporting, patients who die or have serious adverse events are reported as safety reports" and are attributed to cancer, he said. "Getting to cause of death in that type of analysis is extraordinarily difficult. The only definitive way to know what someone dies of is an autopsy, but the vast majority of cancer patients who die don't undergo autopsies."

Baynes said the company plans to publish the results, which may explain what happened. "We know this is a very sick population," he said. "We also know that there are imbalances in terms of baseline prognostic variables. Could it be that this is accounted for by imbalances? We have essentially reported the rates that we saw as accrued rates, that is to say, so many patients died on this arm; so many died on that arm. We have not adjusted this analysis for baseline imbalances, and we do know that there are some baseline imbalances."

Baynes said that there is no major difference between reported cardiovascular and thromboembolic events on the two arms of the study.

"Doctors Will Make Their Own Judgments"

The Dear-Doctor letter didn't include the name of the trial in question, which would have at least allowed the physicians, patients, and investment community to weigh the implications from the study.

The company's earnings press release Jan. 25 states that the trial's criteria "identify a subset of patients with an especially grave prognosis." Asked by The Cancer Letter, the company provided the link to a summary of the trial protocol: www.clinicaltrials.gov/ct/show/NCT00098696?order=11.

The trial is called "Darbepoetin Alfa in Treating Anemia in Patients With Non-Myeloid Cancer Who Are Not Receiving Chemotherapy."

The protocol's entry criteria state that patients had to have completed therapy at least four weeks earlier and limited the participants' performance status to ECOG 0-2. This includes patients ranging from asymptomatic to those who have symptoms, but are able to take care of themselves.

Based on information posted on the government website, patients whose disease was in complete remission couldn't enter the trial. On enrollment, the patients' hemoglobin level had to be under 11 g per deciliter, and the goal in the treatment group was to increase hemoglobin level to 12 g per deciliter.

The analysis of the initial 16-week treatment period didn't show a statistically significant effect on the primary efficacy endpoint, reduction in the number of transfusions (hazard ratio 0.89; 95% confidence interval: 0.65, 1.22), with an incidence of RBC transfusions of 24% in the placebo vs. 18% in the Aranesp group, p=0.15.

However, more deaths were reported in the Aranesp treatment group (26% (136/515)) than the placebo group (20% (94/470)). With median survival follow-up of 4.3 months the absolute number of deaths was greater in the Aranesp treatment group (216/470=46% and 250/515=49% for the placebo and the Aranesp arms, respectively, hazard ratio 1.25; 95% confidence interval: 1.04, 1.51).

At the very least, the findings mean that physicians should use Aranesp in accordance with the guidelines developed by the American Society of Clinical Oncology and the American Society of Hematology, said Jeffrey Crawford, chief of the division of medical oncology at Duke University Medical Center.

"I don't treat patients outside the guidelines," said Crawford. "I don't think oncologists are going to just dismiss this. If there truly is 12 percent of use, which is outside of those boundaries, I think that's going to change. I think Amgen will find out and they will make it public knowledge. They want to know what this is about, so the 90 percent of people who are getting it appropriately will keep getting it, so people wouldn't walk away from this drug altogether."

Crawford has consulted for Amgen and has received research funds from the company.

On a Jan. 25 conference call with security analysts, George Morrow, Amgen's executive vice president of global commercial operations, said doctors may elect to prescribe the drug in this setting.

"We'll share this information with doctors, and they will make judgments," he said. "They want to help their patients. These are patients who in many cases in this study—they've tried everything else and they are on the way out, unfortunately, and doctors will make judgments about what kind of benefits they feel EPO has been providing them.

"And I think in a lot of cases they will say, 'You know what? I want to make these people feel as good as they possibly can, the last few months of life,' and probably err on that side. But we'll make sure there's total transparency on the data, and doctors will make their own judgments, and I think that will determine what impact it has."

Aranesp doesn't have FDA approval for improving quality of life.

In an interview, Baynes said the number of patients receiving Aranesp off-label for cancer-related anemia is difficult to estimate. "This is a very difficult population

to really get a good handle on," he said. "If you look at coding around anemia of cancer, there are something like 20 or 30 codes that potentially describe this entity. It's a very heterogeneous group. It's very, very difficult to triangulate on what that number is."

Baynes said the company doesn't recommend off-label use of its drugs, "but if you put yourself in the position of a practicing oncologist, you have a lot of bad options." Though the study excluded patients who had complete responses to therapy, another off-label use is called "chemo hangover" where patients who may well have been cured receive EPO for complications from therapy.

"I am sure there is some use in that setting," Baynes said.

Howard Ozer, chief of hematology and oncology and Eson chair and professor of medicine at the University of Oklahoma Cancer Center, has a suggestion for physicians who may be trying to make that decision:

"My response to that is, '*Primum non nocere.*'" First, do no harm.

"That's something we live by," said Ozer, who has consulted for Amgen, is a member of the company's speakers' bureau. "It's giving chemotherapy where you get all the toxicity and none of the benefit. If you give something, you don't want to shorten survival."

Different Populations?

The EPO products in oncology were approved based on their ability to reduce the need for transfusions, and their effect on survival hasn't been addressed definitively.

The ASCO and ASH guidelines support using EPO to treat chemotherapy-associated anemia in patients with solid tumors and hemoglobin levels of less than 10 g per deciliter. Use of these agents in patients with less severe anemia, less than 12 g per deciliter, "should be determined by clinical circumstances," the guidelines say. The consensus guidelines from the National Comprehensive Cancer Network support a trigger point of 11 g per deciliter.

However, whenever patients get to higher levels, such as 13 g per deciliter, they are believed to enter a danger zone.

"In the on-label setting there is about a 1.67 odds ratio increase risk of venous thromboembolism when EPO is given to cancer patients," said Bennett, who has consulted for Amgen. "When the drug was used off-label in two clinical trials in an effort to raise hemoglobin levels above 13, the odds ratio went up to 3.0"

Patients with cancer-related anemia could well be different from patients with chemotherapy-related anemia, said Jerome Seidenfeld, an associate director at the Blue Cross/Blue Shield Association Technology Evaluation Center, a member of the Cochrane Collaboration and one of the authors of the ASCO and ASH guidelines.

"The target may be different for patients who are continuing to get chemotherapy vs. those who are not," Seidenfeld said. "I don't think there is good evidence to support generalizing from one of those populations to the other, not only how to treat them, but also what the target should be. I think the target issue should be studied differently."

Also, Aranesp, a biologic that has the advantage of requiring less frequent administrations than other forms of EPO, may not be as easy to maintain at safer levels, Seidenfeld said.

"You can't titrate it that closely, particularly with Aranesp," he said. "Aranesp takes longer to get rid of from the body, which is why EPO first started out as a three-time a week regimen, and then a once a week regimen, and an even longer than once-a-week regimen by just jacking out the amount that you give," he said.

"It's clearly a longer-lasting molecule in the human than epoetin is. But even with the regimens with epoetin that are designed to reduce the frequency of administration, it lasts longer. That's Point One. Point Two: the effect lasts beyond when the drug gets in.

"What the drug does is start these progenitor cells down a pathway of differentiation and development that turns them into full-blown red cells. That pathway takes some time, so even when you turn off the spigot by stopping administration of the drug, first of all you have the problem that some of the drug is still in there and has to be cleared from the body, but you also have those cells that have gotten past a certain point in their maturation pathway are still going to continue marching down to become full-blown red cells."

Amgen and independent investigators are conducting at least five trials with survival as a primary endpoint. These trials test hemoglobin targets that go beyond the FDA-labeled target of 13 g per deciliter, and even beyond the European hemoglobin target of 14 g per deciliter.

The trials are in non-Hodgkin's lymphoma (FR-2003-3005), breast cancer (DE-2001-0033 and DE-2002-0015), head and neck cancer (SE-2002-9001) and small cell lung cancer (20010145).

On Nov. 16, the New England Journal of Medicine published the results of two randomized trials that

sought to find the optimal hemoglobin levels in patients with chronic renal disease. Neither of the studies showed a benefit in bringing hemoglobin closer to normal range, and one of the studies showed higher cardiac toxicity on the treatment arm.

The text of the Dear-Doctor letter follows:

Dear Health Care Professional:

Amgen wishes to inform you of the results of a large, multicenter, randomized, placebo-controlled study showing that Aranesp was ineffective in reducing RBC transfusions in patients with cancer who have anemia that is not due to concurrent chemotherapy. In addition, this study showed higher mortality in patients receiving Aranesp. In the study, Aranes (darbepoetin alfa) was compared to placebo in patients with active malignant disease not receiving or expected to receive chemotherapy or radiation therapy. This study was designed to establish the effectiveness of Aranesp in this new indication and failed to meet its primary endpoint of reducing RBC transfusions in the Aranesp treatment group. This study was not optimal in design to establish the effect on survival, a safety endpoint, however more deaths occurred in the Aranesp treatment group when compared to the placebo group.

Aranesp is not approved for use in this population. Aranesp is approved for the treatment of patients with anemia, which is caused by chemotherapy treatment of their malignant disease, rather than the underlying malignant disease itself. Aranesp should be used only in accordance with its approved product labeling for the treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitantly administered chemotherapy.

Study Description. This Amgen-sponsored study was a Phase 3, double-blind, randomized, placebo controlled clinical study, monitored by an independent Data Safety Monitoring Board. The treatment period was 16 weeks; additional information on safety and effectiveness will be obtained from a 16 week extension study in which randomized treatment with Aranesp or placebo was continued. All patients have completed this extension study. Survival follow up will continue on patients for a minimum of 2 years. The target hemoglobin in the Aranesp treatment group was 12 g per deciliter. A total of 989 patients with hemoglobin (Hgb) < 11 g per deciliter, with active cancer, and who were not receiving myelosuppressive chemotherapy or radiotherapy were enrolled. Approximately 60% of patients enrolled had advanced (stage IV) disease.

The final analysis of the initial 16-week treatment period did not show a statistically significant effect on the primary efficacy endpoint (Hazard ratio 0.89; 95% Confidence Interval: 0.65, 1.22), with an incidence of RBC transfusions of 24% in the placebo vs. 18% in the Aranesp group, p=0.15.

In the 16-week treatment phase of the study, more deaths were reported in the Aranesp treatment group (26% (136/515)) than the placebo group (20% (94/470)). With median survival follow-up of 4.3 months the absolute number of deaths was greater in the Aranesp treatment group (216/470=46% and 250/515=49% for the placebo and the Aranesp arms, respectively, Hazard Ratio 1.25; 95% Confidence Interval: 1.04, 1.51). Follow-up of surviving patients continues. Details of this study will be presented and published in a peer-reviewed setting as soon as possible.

A copy of the prescribing information for Aranesp is enclosed. Should you have any questions or require further information regarding the use of Aranesp, please contact Amgen's Medical Information Connection at 1-800-77AMGEN or online at http://www.amgenmedinfo.com.

FDA News:

FDA Plans Safety Reviews Of Newly Approved Drugs

By Kirsten Boyd Goldberg

FDA announced plans to strengthen its oversight of drug safety, including comprehensive safety reviews 18 months after new drugs are approved for marketing.

The agency said the initiatives are a response to recommendations by the Institute of Medicine in a 2006 report that criticized FDA's handling of drug safety. However, that report called for broad changes, some requiring legislation, that would exceed the steps the agency announced Jan. 30.

FDA's plan isn't strong enough, members of Congress said this week. "Only legislation can give FDA the tools it needs to ensure that the agency is the gold standard for safety," Sen. Edward Kennedy (D-Mass.) said in a statement.

Kennedy and Sen. Michael Enzi (R-Wyo.) introduced legislation that would give FDA authority to impose safety requirements on marketed drugs, and require registration of clinical trials and results in public databases.

Sens. Christopher Dodd (D-Conn.) and Charles Grassley (R-Iowa) introduced two bills—one that would set up a new center within FDA to monitor the safety of marketed drugs and another that would require drug

sponsors to publicize the results of all clinical trials.

The agency's plans are part of an "ongoing assessment of the drug and medical product safety system," FDA Commissioner Andrew von Eschenbach said in a statement.

The agency's plans include:

—Strengthening the science that supports the medical product safety system from pre-market testing and development through post-market surveillance and risk management. FDA plans to develop new scientific approaches to detecting, understanding, predicting, and preventing adverse events, develop and incorporate new quantitative tools in the assessment of benefit and risk, and conduct a pilot program to review the safety profiles of certain newly approved drugs on a regularly scheduled basis.

—Improving communication and information. FDA plans to form an advisory committee to improve the agency's risk communication policies, review its public communication tools, and develop a risk communication strategic plan.

—Improving operations and management to ensure implementation of the review, analysis, consultation, and communication processes needed to strengthen the U.S. drug safety system. FDA plans to hire external management consultants to help the Center for Drug Evaluation and Research develop a strategy for improving its "organizational culture," and make specific organizational and management changes to increase communication among review and safety staff.

Charles Bennett, an oncologist at Northwestern University and an expert on adverse reactions to cancer drugs, said post-marketing studies are important to cancer care. "Cancer is a very difficult area for drug safety to show up," he said. "It largely shows up off-label or after the drug is approved, because drugs get approved oftentimes with 300 or 400 people, and we don't really know much about the drug's safety. The fact that there is this commitment [at FDA] to doing these formal studies after a drug gets approved, within the first 18 months, is very important. It's the first 18 months when some important safety signals often show up."

An example of a post-marketing safety issue in oncology was Celgene's Revlimid, approved by FDA in 2005 for myelodysplastic syndrome. Only after the drug was approved for MDS did safety concerns about blood clots arise in clinical trials testing Revlimid for myeloma, Bennett said. (Revlimid was approved last year for use in combination with dexamethasone for myeloma.)

Companies are starting to build safety registries for some of their newer cancer drugs, Bennett said. FDA's support for registries "would be very helpful," he said.

Bennett said FDA should consider providing funding for academic research on safety issues. "We in academics can be a useful third tier, in addition to FDA and companies," he said. "There should be some support for academics to have some funds to do post-marketing safety assessment surveys."

FDA's response to the IOM report is available at www.fda.gov/oc/reports/iom013007.html.

Capitol Hill:

House Approves $28.9 Billion For NIH In FY07 Spending Bill

By Kirsten Boyd Goldberg

The House this week approved a $463.5 billion fiscal year 2007 spending bill that includes $28.9 billion for NIH, a $619.5 million increase.

The bill passed Jan. 31 on a vote of 286-140, with 57 Republicans breaking ranks to vote in favor. The White House criticized the bill, but indicated that President Bush doesn't plan to veto it. The President is expected to send his fiscal 2008 budget request to Congress next week.

The bill funds agencies through Sept. 30, filling in the gap left when the 109th Congress adjourned last year having completed only two of 11 appropriations bills. A continuing resolution has funded most agencies through Feb. 15.

Other increases include $4.7 billion for the National Science Foundation—a $335 million increase—and a $3.6 billion increase for medical care for veterans.

Up to $483 million of the FY07 NIH funding will be designated for the Common Fund, established in the NIH reauthorization bill that passed Congress in early December and signed by President Bush in January.

"It is a great day for science, for the country, and for the American people," Leo Furcht, president of the Federation of American Societies for Experimental Biology, said in a statement. "On behalf of the biomedical research community, FASEB is immensely grateful for this reaffirmation of Congressional support for scientific research and the potential it provides to improve the quality of our lives." FASEB represents 21 scientific societies comprising over 80,000 biomedical and life science researchers.

"It is a tremendous credit to congressional champions like Chairman David Obey, Sen. Arlen

Specter, and Sen. Tom Harkin that our policymakers have recognized and prioritized the vital role that science plays in advancing the needs of the nation," Furcht said. "As scientists, we are keenly aware of the privilege that allows us to spend public money in order to find treatments for our most insidious diseases, identify new energy resources, and develop the technologies that drive our economy. We cannot thank congressional leaders enough for investing in our country's future through research.

"Thousands of researchers across the nation have spent the past week urging Congress to make NIH, NSF, and DOE priorities in FY 2007," Furcht said. "Now that our voices have clearly been heard, we hope the Senate will swiftly pass this crucial legislation and that it will be signed into law without delay."

FASEB this week released recommendations for science funding in fiscal 2008:

—Fund NIH at a level that will set the agency on a 3-year track to recoup the losses caused by biomedical research inflation.

—Appropriate $6.5 billion for the National Science Foundation.

—Fund the Department of Agriculture's National Research Initiative at $248 million and the Agriculture Research Service at $1.38 billion.

—Increase appropriations by $39.5 million for NASA's biological research.

—Fund the Department of Energy's Office of Science to at least $4.37 billion.

—Appropriate $480 million for the Veteran's Affairs Medical and Prosthetics Research Program.

In the Cancer Centers:

Vanderbilt Picks Pietenpol As Interim Center Director

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cancer biology at Vanderbilt-Ingram. The discovery research grant allows Vanderbilt-Ingram to become part of network of investigators that will meet twice a year to share discoveries. Other groups in the network include Harvard-MIT, Memorial Sloan-Kettering Cancer Center, Baylor College of Medicine, Columbia University, Lawrence Berkeley National Laboratory, Albert Einstein Cancer Center, and the Fred Hutchinson Cancer Research Center. Vanderbilt-Ingram also will collaborate with a group from Dana-Farber Cancer Institute. Researchers will work with **John Gore**, professor and director of the Vanderbilt University Institute of Imaging Science, to merge proteomics, oxygen and blood flow images into one picture of the tumor and its environment, said Matrisian. . . . **JENNIFER PIETENPOL** was named interim director of Vanderbilt-Ingram Cancer Center. Pietenpol, the Ingram Professor of Cancer Research and professor of biochemistry, will lead the center while a national search is under way for a successor to **Ray DuBois**. DuBois will leave Vanderbilt later in the year to become provost and executive vice president at M.D. Anderson Cancer Center. A successor should be identified by summer, said **Harry Jacobson**, vice chancellor for health affairs. . . . **UNIVERSITY OF COLORADO** Cancer Center, University of Colorado at Boulder, and University of Texas at Dallas were awarded a $1.1 million, four-year grant from the National Science Foundation. The grant supports the collaboration between electrical engineers, mechanical engineers and cancer researchers to improve diagnosis, treatment and follow-up for melanoma. The collaborators will develop a mechanical system the size of a wristwatch that will display the presence or absence of genetic signals of melanoma. "Better understanding the interaction of nanomaterials with various biomolecules will open doors to radically new ways to detect and intervene in disease processes," said **Won Park**, assistant professor at the University of Colorado at Boulder and principal investigator. . . . **DONNA BERRIER** was named administrator and associate director for administration and finance at the University of Colorado Cancer Center. She was administrator, Department of Preventive Medicine and Biometrics, University of Colorado at Denver and HSC. She replaces **Rae Ann Paden**, who is now administrator of the University of New Mexico Cancer Research and Treatment Center. . . . **LORENZO COHEN**, director of the integrative medicine program at M. D. Anderson Cancer Center and associate professor, Departments of Behavioral Science and Palliative Care and Rehabilitation Medicine, was named president-elect/vice president of the Society for Integrative Oncology. Cohen is known for his work in biobehavioral effects of psychosocial interventions in relieving side effects of cancer treatment and improving quality of life. **Peter Johnstone**, professor of radiation oncology at Emory University School of Medicine and director of the cancer survivorship program, Winship Cancer Institute, is president of the society. . . . **DIANE CASSELS** was named executive administrator for Winship Cancer Institute, said **Brian Leyland-Jones**, director of WCI. Cassels is administrator of the Department of Radiation Oncology and will continue in that capacity. . . . **BARUCH BLUMBERG** has joined the Hepatitis B Foundation as distinguished scholar. A

1976 Nobel Laureate for his discovery of the hepatitis B virus and the invention of the first vaccine against hepatitis B, Blumberg will spend several days a month at the non-profit at the Pennsylvania Biotechnology Center in Bucks County. He has been on the medical and scientific advisory board of the foundation for the past 15 years. Currently a senior advisor to the president of Fox Chase Cancer Center, Blumberg has been director of the National Aeronautics and Space Administration Astrobiology Institute at NASA Ames Research Center and later a senior advisor to the administrator of Biology at NASA in Washington, D.C. . . . **KAREN RECKAMP** was named assistant professor of medicine, lung cancer and thoracic oncology program, City of Hope. She will design and conduct clinical trials for lung tumors. Reckamp was assistant professor of medicine at the David Geffen School of Medicine and Jonsson Comprehensive Cancer Center at UCLA. She was awarded a three-year Career Development Award from the Department of Veterans Affairs for lung cancer as well as a career grant from NCI. . . . **FRANK SMITH**, director, division of hematology and oncology at Cincinnati Children's Hospital Medical Center, was appointed vice chairman-elect of the Children's Oncology Group. Smith, who will begin serving in 2008, is known for his work in pediatric leukemia, blood and marrow transplantation, and clinical gene therapy trials. His research focuses on clinical and translational studies of normal and malignant hematopoietic stem cells. . . . **EDWARD CHU** was appointed deputy director of the Yale Cancer Center, center director **Richard Edelson** said. Chu succeeds **José Costa**, who completed 10 years as deputy director. Costa will remain an active member of the center in addition to his appointments as professor of pathology and internal medicine, vice chairman of the Department of Pathology at Yale School of Medicine, and director of anatomic pathology. Chu has held positions of increasing responsibility at Yale Cancer Center since 1996 and is professor of medicine and pharmacology and chief of medical oncology. In his new role, Chu will continue to lead the Section of Medical Oncology and will also direct the clinical research initiatives for the center. . . . **PHILIP AGOP PHILIP** was named team leader of the Gastrointestinal Multidisciplinary Team at Barbara Ann Karmanos Cancer Center. Philip is also a professor of medicine and oncology at KCC and Wayne State University School of Medicine. Philip will continue to head the Protocol Review and Monitoring Committee at Karmanos. He is involved at the national level in pancreas cancer research.

In Brief:

MMRF Awarded $9.5 Million In 2006 For Research Grants

MULTIPLE MYELOMA Research Foundation awarded more than $9.5 million in research grants and funding to academic centers, biotech companies and the Multiple Myeloma Research Consortium in 2006. In 2006, MMRF also offered research grants through four new research programs: Validation of Novel Combinations, Compound Validation, Cell Line Development and Leveraging Existing myeloma targets to Accelerate Drug discovery and development, or LEAD. Thirty-five research grants, totaling $6.6 million, were awarded to investigators from 20 institutions worldwide. Funding for the MMRC totaled $4 million supporting the Genomics Initiative, pre-clinical validation of potential therapeutics and several exciting clinical trials. . . . **ONCOLOGY NURSING** Certification Corp. Advanced Oncology Certified Nurse Practitioner and Advanced Oncology Certified Clinical Nurse Specialist programs have received accreditation by the National Commission for Certifying Agencies for four years. Also in ONCC news, Cynthia Murphy, executive director, was elected president-elect of the National Organization for Competency Assurance.

Funding Opportunities:

PA-07-303: Novel Approaches to Enhance Animal Stem Cell Research. R01. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PA-07-303.html. Inquiries: Donald Blair, 301-496-7028; blaird@mail.nih.gov.

PA-07-304: Novel Approaches to Enhance Animal Stem Cell Research. R21. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PA-07-304.html.

RFP N02CM67035-21: Development of Dosage Forms and Delivery Systems for Anti-Tumor Agents. Response Due Date: Feb. 7. Full text: http://www.fbodaily.com/archive/2007/01-January/26-Jan-2007/FBO-01218121.htm. Inquiries: Drake Russell, 301-228-4217; russeldr@mail.nih.gov.

RFP N02-CM-67036-65: Analysis of Anti-Cancer Chemicals and Pharmaceutical Formulations. Response Due Date: Feb. 13. Full text: http://www.fbodaily.com/archive/2006/12-December/28-Dec-2006/FBO-01202544. Inquiries: C. Timothy Crilley, Treatment and Support Branch, P.O. Box B, 244 Miller Dr., Rm 116A, Fort Detrick, Frederick, Md. 21702-1201.

RFQ-NCI-70003-NC: GMP Storage of Monoclonal Antibodies under GMP Conditions for Clinical Trials. Response Due: Feb. 14. Full text: http://www.fbodaily.com/archive/2007/01-January/20-Jan-2007/FBO-01214413.htm. Inquiries: Debbie Moore, 301-402-4509; dm170b@nih.gov.

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