THE CANCER LETTER

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A Streak Of Bad News For EPO Products Brings FDA Scrutiny, Payment Curbs

By Paul Goldberg

Following last week's revelations of a negative result of a Danish study of Aranesp in head and neck cancer, FDA said it would schedule a meeting of the Oncologic Drugs Advisory Committee to consider the data in the context of earlier negative signals.

Also last week, the agency issued a "clinical alert" based on a previously reported study that demonstrated that Aranesp didn't reduce the need for blood transfusions while causing an excess of deaths on a study of anemia due to cancer.

The FDA alert contained a reminder of the agency's earlier decision to treat all forms of EPO as a single class of biologics. "The findings in this

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In the Cancer Centers:

CTRC's Plan To Name New PI Of U01 Grant Met NCI Opposition, Temporary Accrual Halt

By Kirsten Boyd Goldberg

NCI told the Cancer Therapy and Research Center in San Antonio earlier this month to temporarily close patient accrual to certain clinical trials following a change in the leadership of a U01 grant.

CTRC officials removed Anthony Tolcher as the principal investigator of the U01 grant after he announced his decision to resign as director of the CTRC Institute for Drug Development.

Initially, CTRC Director Karen Fields was named PI on the grant. However, in a letter to CTRC dated Feb. 8, NCI's Cancer Therapy Evaluation Program opposed the appointment of Fields as PI on the $600,000-per-year grant and ordered the center to temporarily close to further accrual the phase I trials being conducted under the grant, as of Feb. 12.

Fields "does not appear to have experience performing first in human studies with investigational agents where only a limited amount of information is known about toxicity and dose determination has not been established," the letter, signed by S. Percy Ivy, associate chief for developmental chemotherapy in NCI's Investigational Drug Branch, said. "Consequently, she does not appear to be sufficiently prepared to be the principal investigator on the U01."

Fields declined to comment, but a CTRC spokesman submitted the following statement to The Cancer Letter: "The Cancer Therapy & Research

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Compendium Drops Listing Of Aranesp For Cancer Anemia

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study of Aranesp may apply to other [erythropoiesis-stimulating agents]," the agency said.

To make certain that everyone in oncology learns about the safety and efficacy concerns swirling around EPO, FDA has issued a letter to all members of the American Society of Clinical Oncology and the Oncology Nursing Society.

"FDA has previously noted that increased mortality, possible tumor promotion and thromboembolic events have been observed in patients receiving ESAs when dosing has targeted hemoglobin levels >12 g/dL," states an email signed by Richard Pazdur, director of the FDA Office of Oncology Drug Products, and sent out on Feb. 21. "The recommended labeled target hemoglobin in current product labeling is 12 g/dL. FDA is planning to review and discuss the safety and efficacy of ESAs at an upcoming meeting of the ODAC."

The committee's next meeting is tentatively scheduled for March 28-29. It is unlear when the EPO question would be considered.

Whatever the outcome of that meeting, it appears that the days when EPO agents could be easily prescribed off-label have come to an end.

Earlier this month, the US Pharmacopeia dropped its listing of Aranesp's use for anemia of cancer. The delisting occurred less than a week after a "Dear-Doctor" letter was posted on the FDA MedWatch adverse events reporting system. So far, the compendium's action doesn't appear to apply to Procrit.

The United States Pharmacopeia is one of the two compendia recognized by the Centers for Medicare and Medicaid Services in making payment decisions. If one of the compendia lists a drug's indication, the agency is obligated to provide reimbursement. Private insurers usually follow the CMS reimbursement policies.

Another compendium, AHFS Drug Information Compendium, doesn't list an off-label use of Aranesp for cancer-induced anemia. However, Procrit is listed for this use. The compendium is operated by the American Society of Health-System Pharmacists.

A third compendium, which is seeking recognition by CMS, the National Comprehensive Cancer Network, is in the process of revising its guidelines to caution against using EPO products—both Aranesp and Procrit—for the treatment of some patients with cancer-induced anemia. The organization will warn doctors against using the agents in patients who are similar to those enrolled in the Aranesp study.

The document, which is slated to be posted next week, states:

"The results of a large, mutlicenter, randomized, placebo-controlled study showed that darbepoetin [Aranesp] was ineffective in reducing red blood cell transfusions or fatigue in patients with cancer who have anemia that is not due to concurrent chemotherapy. The study also showed higher mortality in patients receiving darbepoetin. Until new research evidence changes current benefit-risk restimates, physicians should be advised not to administer erythropoietin to patients similar to those enrolled in the Amgen trial."

The document is not a delisting, and it's unclear how CMS—or, for that matter, clinicians—would interpret it, since the details of that study are yet to be released.

For Aranesp, this off-label use brings in around $400 million, with most of this use occurring in the U.S., Amgen said. Johnson & Johnson spokesman Stephanie Fagan said the company doesn't comment on the sales of its products for off-label use.

The fate of erythropoietin—by far the single largest product in oncology—now hinges on a handful of clinical trials designed to determine whether the anemia agent is, in fact, helping cancer patients.

Observers who believe in EPO's usefulness and its future as a commercial product say that the first firm answer about its safety and efficacy would emerge from an Amgen-sponsored trial of Aranesp in small-cell lung cancer.

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The results of that study—trial 20010145—are expected by the end of the year, company officials said. Wall Street analysts who have watched Amgen stock slip in recent weeks are now describing that trial as a cliffhanger that will determine the product's viability.

The financial stakes in this cliffhanger are easy to quantify: $4.9 billion worth of Amgen's Aranesp and Johnson & Johnson's Proctit are used by oncologists in the U.S. Another $2.4 billion worth of these products is used in cancer care outside the U.S. Also, Roche sells $1.811 billion worth of its EPO outside the U.S., with some of its product used in oncology.

Some implications of the new findings seem unthinkable: it could turn out that for nearly 15 years, oncologists have been giving cancer patients a biologic that was making their tumors grow.

More Bad News From The Clinic

Meanwhile, the Journal of Clinical Oncology Feb. 20 published the results of an obscure Canadian study demonstrating that Procrit was associated with shorter median survival in patients with advanced non-small-cell lung cancer.

The study is significant primarily because it represents a fourth study suggesting a negative impact of EPO agents, oncologists say.

Questions about EPO products were first raised four years ago, as studies showed increases in mortality in two randomized trials in head and neck cancer, and breast cancer (The Cancer Letter, Oct. 24, 2003).

Last month, Amgen reported a drop in survival in a study that tested Aranesp in cancer-related anemia (The Cancer Letter, Feb. 2).

Then, last week, this publication reported that Amgen had failed to disclose that a long-awaited Danish randomized study found an increase in disease progression among head and neck cancer patients receiving Aranesp (The Cancer Letter, Feb. 16).

The latest bit of bad news, published by JCO online, shows just how jittery clinical researchers have become about using EPO, an agent that used to be dispensed with little reflection.

The trial began in 2001, but stopped for an unplanned analysis two years later as other studies reported an increased incidence of thromboembolic events. This was particularly evident on trials that used EPO to elevate hemoglobin above 12 g/dL, and closer to the normal range. The hemoglobin target in the Canadian trial was between 12 and 14 g/dL.

At the time of the interim analysis, only 70 of the required 300 patients had been enrolled. Though the groups were unequally distributed in favor of placebo—33 of the 70 patients received EPO and 37 got placebo—the patients' median survival favored the placebo arm (63 v. 129 days; hazard ratio, 1.84; P=.04). The decrease in survival couldn't be linked to thromboembolic events.

The study raises questions about the importance of hemoglobin targets in the debate about EPO. J&J officials said the result validates maintaining the hemoglobin targets at 12 g/d/L, the level recommended in the joint guidelines of the American Society of Clinical Oncology and the American Society of Hematology.

"When patients are treated beyond the target hemoglobin levels that are in the label today, that can be problematic," said Craig Tendler, vice president, clinical affairs, at Ortho Biotech, a unit of J&J. "This was a study that was beyond correction of anemia, where hemoglobin levels were allowed to go to 14 g/dL before the dose was held. We now know that that's not beneficial to patients."

Both J&J and Amgen describe recent failures in the clinic as off-label uses that haven't panned out.

"In the labeled indication for Procrit in chemo-induced anemia, I feel we have over the last two decades established a comprehensive database demonstrating its safety and efficacy," Tendler said to The Cancer Letter. "That has been incorporated into evidence-based guidelines in chemo-induced anemia. Those are representative of how the drug should be used, and these new results don't call that into question, especially those in which the drugs are being used for correction beyond anemia.

"Many of these other studies that are coming to light are outside the labeled indications. They were appropriate research questions to ask, but we now see the results of those, and unfortunately, in some settings, this drug may not be benefiting patients. But it doesn't take away from the fact that in chemo-induced anemia, the safety and efficacy is still there," Tendler said.

While J&J has stopped all studies with hemoglobin levels above 12 g/dL, Amgen is pushing forward with five trials that will address the survival and disease progression questions.

The Magic At 12 g/dL?

ODAC members would likely have to address the question of the importance of hemoglobin levels in determining safety and efficacy of EPO agents.

"It's amazing how these data are coming together at the same time," said Howard Ozer, chief of hematology and oncology and Eson chair and professor of medicine

at the University of Oklahoma Cancer Center. "I think we are now talking about true signal. This isn't noise anymore."

The "signal" in this case could be coming from a biological effect of EPO, which suggests that scientists should focus on the patients' exposures to these agents, Ozer said.

"Number one, all of the studies that have shown a negative effect have different hemoglobin endpoints," Ozer said. "So it's hard to make a comparison. And, number two, there is immense variability from patient to patient of the hemoglobin at which they start and the endpoint at which they reach it. If your target hemoglobin is 12 g/dL, some patients might get there at three months, some patients might get there at six months. It's a little hard for me to imagine that the target hemoglobin is that crucial. Rather, I would speculate that something else is involved."

Michael Henke, an oncologist at Klinik fuer Strahlenheilkunde in Freiburg, Germany, whose study four years ago first implicated EPO as a suspect in disease progression, said that hemoglobin levels may be appropriate for discussion of thromboembolic events, but are irrelevant in discussion of tumor growth.

"I do not think that the arguments about hemoglobin targets are valid for the ongoing discussion," Henke said. "My impression is that they are used to allow one criticism—thomboembolic disease—to be discussed. Meanwhile, these arguments detract from the even more serious discussion of ESA stimmulating tumor growth."

Ortho's Tendler agrees that questions of exposure should be on the table, but said that the dose effect should be considered as well.

"I think dose is very much related to exposure to the agent," Tendler said. "If there is a dose effect here, and typically, if there is some stimulation of the tumor, we may expect to see an effect at higher doses or longer exposures."

Tendler pointed out that Henke's 2003 study and the Danish study, called DAHANCA 10, first disclosed in this publication last week, were pushing hemoglobin beyond correction of anemia, to test the hypothesis that high hemoglobin reverses tissue hypoxia.

"In both those studies, the goal was to really drive the hemoglobin up beyond the labeled target levels to reverse tissue hypoxia, so perhaps the locoregional failure results were not unexpected," Tendler said. "I agree that it raises an issue about exposure, but you can't talk about exposure without talking about dose delivered. They are interrelated."

Still More Bad News

The onslaught of bad signals continued on Feb. 23, as Roche announced that it had suspended recruitment into a phase II dose-finding study (NH19960) with its version of EPO, called CERA, in anemic patients with advanced non-small-cell lung cancer receiving first-line chemotherapy.

The company said that a data safety monitoring board recomended suspension of the trial "because of a numerical imbalance in the number of deaths across the four arms of the study (three arms with CERA and one arm with darbepoetin alfa) driven in part by deaths reported to be due to the progression of the underlying cancer."

The trial enrolled 153 stage IIIb and IV non-small-cell lung cancer patients receiving first line chemotherapy. According to Roche, "the investigators reported all deaths to be unrelated to the study drugs."

The company said that "there appears to be no association of these events to excessive hemoglobin levels or the administered doses based on the current review of the data." According to Roche, review of the patient data showed imbalances upon entry into the trial between the different arms in categories, including the severity of tumor spread, presence of liver metastases and incidence of chronic obstructive pulmonary disease.

The study assessed the optimal starting dose of CERA in the treatment of anaemia in patients with non-small cell lung cancer receiving first line chemotherapy.

Patients are randomized to receive CERA 6.3µg/kg, 9µg/kg or 12µg/kg s.c. every 3 weeks or darbepoetin alfa according to the approved local label (either 6.75µg/kg s.c. every 3 weeks, or 2.25µg/kg every week).

The company is seeking U.S. approval for the agent in the renal indication.

Tilting At Hard Endpoints

Many physicians and financial analysts have focused on Amgen's lung cancer trial as a predictor of EPO's future as a commercial product.

In a conference call with financial analysts last week, Roger Perlmutter, Amgen's executive vice president for research and development, said the trial was designed to test whether the treatment of anemia would improve survival.

"The logic of it was, if you could improve tumor oxygenation, you might sensitize patients to chemotherapy or radiation," Perlmutter said in a company conference call Feb. 16.

The company-sponsored 600-patient trial started in 2001 and appears to be fully enrolled.

One of Amgen's five efficacy trials, DAHANCA 10, was stopped early in December, after showing an increase in disease progression. Another study, in non-Hodgkins lymphoma, showed comparable survival and progression-free survival between the two groups on interim analysis. That study is ongoing, the company said.

J&J, too, is conducting an efficacy trial, albeit one that is unlikely to figure in the current discussion. That trial, conducted to measure progression-free survival in metastatic breast cancer, has accrued about 100 patients, and the company expects to complete accrual in mid-2009 and finish the study in late 2010, said Alexander Zukiwski, head of the oncology therapeutic area and acting head of oncology research and development at Pharmaceutical Research and Development, a unit of J&J.

"This is a very tough trial to accrue to, because we are looking for patients who are going to be maintaining a standard chemotherapy regimen, who are anemic, who would go on the trial and would be followed in a longtitudinal fashion," Zukiwski said to The Cancer Letter. "I would estimate that for every patient that gets randomized to this trial, there are nine or 10 patients who have to be screened. And remember the challenges for Epoetin, where it is viewed as a standard of care for the treatment of this patient population, to go into a placebo arm is also a challenge for investigators and for the patients."

The Small Cell Study

The question asked in Amgen's small-cell lung cancer trial doesn't seem as provocative in late February 2007 as it did when the study was originally designed, said Fadlo Khuri, Blomeyer chair in translational cancer research at Emory University Winship Cancer Institute.

"In theory, it's true that improving tissue oxygenation could improve the efficacy of treatment, particularly for radiation therapy," said Khuri, an expert in lung and head and neck cancers. "In practice, what we've seen so far, in head and neck cancer, has been the opposite. These growth factors have appeared to show a deleterious effect."

Still, Khuri regards the lung cancer trial as a make-or-break event for EPO. "If that study is negative, and the head and neck study was closed early because of disease progression on Aranesp, it's going to be very difficult to give this agent in solid tumors," he said.

However, if the trial is positive, EPO isn't home free, Khuri said. "If that trial is positive, and there are two trials that show harm, then physicians will use it in small-cell, which is 15 percent of all lung cancers in the U.S.," he said.

Survival is too big a question to be answered with any one study, especially for a drug that hasn't been rigorously evaluated for survival and disease progression during its 15-year history, said Charles Bennett, an oncologist at Northwestern University.

"It's only one study, and survival is a huge issue," said Bennett, who participates in reviews of EPO by Cochrane Collaboration, a meta-analysis group, and who took part in formulating the ASCO and ASH guidelines for using the product. "It's too much of a leap scientifically to say that we can use this $10-billion drug and save people's lives based on this one study."

Bennett said that the Cochrane Collaboration plans to meet in the next few months and update the meta-analysis with some of the new data. "I think that now, with clinical trials coming out this week and over the past month, we finally have enough data to start getting some answers," Bennett said. "In the next, three, four, or five months, we will be able to address whether, in fact, there is a negative signal."

Previous reports of the Cochrane Collaboration are widely used by Amgen and J&J to argue that there is no firm evidence of harm stemming from the use of EPO.

Amgen Pledges To Disclose Future Results

On Feb. 16, after The Cancer Letter reported that that Amgen had known about the discontinuation of the Danish study, but didn't disclose this outcome publicly, the company's stock dropped by more than two percentage points.

Responding to the story, the company put together a 4 p.m. conference call to state that as a matter of policy it doesn't disclose the results of investigator-initiated studies and that it was under no obligation to do so. However, Kevin Sharer, Amgen president, chairman and CEO, acknowledged that "in retrospect, it would have been ideal" to disclose the Danish result and pledged to disclose such events in the future.

An excerpt from Sharer's statement follows:

"Today The Cancer Letter reported on a study, the DAHANCA 10 trial that is part of the FDA-approved Aranesp pharmaco vigilance program. This report has raised questions we want to answer…

"Our policy is to fully disclose the results of our studies as the data are available. We do not disclose investigator-initiated study data, the investigators are in

control of the data and disclose the results themselves.

"Of course, we will comment on investigator data as we become aware of it and find significant to investors and regulatory authorities. The DAHANCA 10 trial involved a head and neck cancer trial in which the treatment arm had a hemoglobin target level of 14.6 g/dL.

"Our label in this indication is 12 g/dL. The trial was stopped in December but full data will not be available until later this year. While we didn't have access to the data, we did advise FDA and European authorities of the study termination. We have not seen the data. The investigator is compiling it now. He has asked for our support in this effort, and we will help. We strongly believe, as we have consistently stated, that Aranesp and Epogen are safe and effective medicines when used in accordance with label indications.

"In retrospect, it would have been ideal to mention that the DAHANCA 10 study was stopped as well as the status of the other FDA-approved pharmaco-vigilance trials. We will do that, going forward."

Tobacco Control:
Bills Introduced Allowing FDA To Regulate Tobacco Products

By Kirsten Boyd Goldberg

A bipartisan group of Senate and House members on Feb. 15 introduced a bill that would allow FDA to regulate tobacco products.

Bill sponsors include Senate Health, Education, Labor and Pensions Committee Chair Edward Kennedy (D-Mass.), Sen. John Cornyn (R-Texas), House Committee on Oversight and Government Reform Chair Henry Waxman (D-Calif.) and Rep. Tom Davis (R-Va.).

The bill would not allow FDA to ban tobacco or tobacco products that contain nicotine, but it would allow FDA to:

—Require tobacco companies to disclose the contents of their products and tobacco smoke.

—Issue regulations to prevent youth smoking and reduce the number of individuals addicted to tobacco products.

—Regulate the sale, distribution and promotion of tobacco products.

—Eliminate the use of cigarette vending machines.

—Require larger warning labels on tobacco products.

—Prohibit claims about the health effects of tobacco products that are not scientifically verified.

—Prohibit the use of promotional terms such as "light," "ultralight," and "low tar" on tobacco products.

—Require tobacco companies to remove toxic ingredients or reduce nicotine levels in their products.

The Senate version of the bill has 29 co-sponsors, and the House version has 100 co-sponsors. The Bush administration previously opposed similar bills.

The text of the bill is available at http://www.house.gov/waxman/issues/health/tobacco_110th.htm.

NCAB Drafting Statement

The National Cancer Advisory Board is in the process of drafting a resolution in support of federal and state interventions to control tobacco use. Among the measures that the board is considering for support in its statement are legislation giving FDA authority to regulate tobacco products, sources said, as well as Senate ratification of the World Health Organization's Framework Convention on Tobacco Control, a treaty that was adopted by WHO's 192 member states in 2003 and has since been ratified by 143 nations.

At the board's Feb. 6 meeting, two members debated what to put in a resolution on tobacco control.

"We need to express the will of this board in support of efforts to control tobacco in the United States," said board member Bruce Chabner, clinical director, Massachusetts General Hospital Cancer Center. "To recognize that this is a massive threat to health of our country, and that it's of growing importance as a threat to people all over the world."

Board member Donald Coffey, professor of urology, Johns Hopkins University, said he didn't support NIH spending money on studies of tobacco control in other countries. "I think we need to find out what policies work," Coffey said. "I think everyone would say smoke-free policies work. Raising taxes should work."

Chabner and Coffey debated how to move forward on a statement by the board.

CHABNER: "I don't think it's our job to write out a policy, to tell them to increase taxes 20 percent. I think we need to take a stand. How do you feel about smoking?"

COFFEY: "Everybody in this room realizes that smoking causes cancer. I would love to see a world-wide ban."

CHABNER: "Then that's what we should say."

COFFEY: "I'm not sure I want to spend a lot of money funding something about labeling in countries

overseas."

CHABNER: "That's the NCI's decision to figure out what to fund."

COFFEY: "Ban NIH money going to any university that takes money from tobacco companies to do research. Would you be for that?"

CHABNER: "Yes. Even my own."

CAROLYN RUNOWICZ, NCAB chairman, of University of Connecticut: "Don, is that a motion on the table that you want us to put forward?"

COFFEY: "No, I just don't want to spend a lot of money on research that I don't think is going to be effective, but to focus on the policies that have been shown to work, and let's do the research to back those that prove policies that work here, and then try to spread them out across the world."

CHABNER: "We don't know how to fight terrorism either. There are more people dying every day of smoking than died in 9/11. Not to say that 9/11 wasn't a catastrophe. We should do everything possible to stop smoking. Maybe we have incomplete knowledge about what works; let's support the research. But at the same time, let's take a stand on this. Our country should be leading the fight against smoking, rather than sitting in the back and watching the others ratify this treaty. We should declare our position about this."

NCI Programs:

caBIG Developers Release New Software, caGrid 1.0

An team of researchers led by Ohio State University Medical Center released the second distribution of a computer project—caGrid 1.0—a suite of tools, resources and computer software that will enable researchers to tap into libraries of data and genetic information that, until now, have been largely inaccessible.

"What we've needed is a common language and an agreed-upon set of standards that will enable systems and datasets to 'talk' to each other, and that's what caGrid 1.0 provides," said Joel Saltz, chairman of the department of biomedical informatics and a member of the Ohio State University Comprehensive Cancer Center.

Saltz's department serves as the lead developer site for caGrid 1.0, part of cancer Biomedical Informatics Grid (caBIG) project funded by NCI.

caGrid 1.0 is the unifying architecture and operating environment for systems and applications in caBIG. The caGrid 1.0 release contains several new features, such as a tool that provides for rapidly developing caBIG-compatible data and analytical grid services; tools for managing and administering a security infrastructure; and a portal, which provides a dynamic view of services running on caGrid, along with information about research institutions and service providers participating in the caBIG program. Other collaborators include the National Cancer Institute Center for Bioinformatics; University of Chicago/Argonne National Laboratory; Duke Comprehensive Cancer Center; ScenPro Inc.; SemanticBits, LLC; Science Application International Corp. and Booz Allen Hamilton.

In the Cancer Centers:

CTRC Reappoints Tolcher As PI On U01 For Phase I Trials

(Continued from page 1)

Center continues to offer its entire spectrum of care for patients with cancer, including all of its phase I studies, and is working with its new director of the Institute for Drug Development, Francis Giles, to expand its services and fulfill its mission."

The studies were closed to accrual until CTRC officials approached Tolcher on Feb. 13 and asked him to continue as PI on the grant, sources said. Several patients who had made the decision to enroll in the phase I trials and arrived expecting treatment had to wait about four hours in the chemotherapy room during the hiatus, sources said.

Tolcher and seven other staff members announced their intention to leave CTRC, and some are reportedly planning to join a private practice in San Antonio (The Cancer Letter, Jan. 26).

Tolcher could not be reached for comment.

Sources at CTRC said center officials confiscated the computers of several of the staff members who planned to leave. The staff members whose employment contracts allowed them to leave immediately were escorted out the door, sources said.

Sources familiar with the situation said Tolcher plans to leave in early April. Another researcher, Chris Takimoto, director of pharmacology at IDD, has been told that he cannot leave the center until the end of August, as stipulated in his employment contract, sources said.

CTRC reported a deficit of $2.45 million and total revenues of $70.49 million, including $30 million in government grants, for the fiscal year ending Sept. 30, 2005. Fields earned compensation of $336,538 and benefits of $112,180, according to the center's 2005 Form 990 tax document.

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M.D. ANDERSON CANCER CENTER received a $9-million award from the Health Resources and Services Administration, part of the U. S. Department of Health and Human Services, for its cord blood bank. The three-year grant will fund the collection, processing and storage of umbilical cord blood at M. D. Anderson to be entered in the National Cord Blood Inventory. **Elizabeth Shpall**, professor in the Department of Blood and Marrow Transplantation, is director of M. D. Anderson's cord blood bank.

The bank has collected more than 1,900 cords to date through partnerships with the Woman's Hospital of Texas and Ben Taub General Hospital. The funding will allow M. D. Anderson to increase its staff at each site. There are also plans to add a third collection site in the Houston area.

HRSA funded five other cord blood banks, including the Carolinas Cord Blood Bank Program at Duke University Medical Center, the Milstein National Cord Blood Program at the New York Blood Center, StemCyte, the University of Colorado Cord Blood Bank and the Puget Sound Blood Center.

* * *

HEALTH DISPARITIES Education, Awareness, Research & Training Consortium, M.D. Anderson Cancer Center, and the Ministry of Health of the Federal Republic of Nigeria have signed a memorandum of understanding to collaborate on cancer research, education, and training programs in Nigeria. The consortium, whose director is **Nancy Dickey**, president of Texas A & M Health Science Center, brings together over 20 academic and health care institutions in the U.S. and Mexico to develop programs on health disparities. The agreement was the result of the first cancer conference held in Abuja, Nigeria, last October. . . . **OHIO STATE UNIVERSITY** cancer program received a $5 million pledge from the estate of entrepreneur and philanthropist **John Messmore**. The gift would support research in the cancer center and advanced clinical care at the James Cancer Hospital and Solove Research Institute. Ohio State has begun a campaign to raise $500 million for research, patient care, and medical education, said **David Schuller**, senior executive director of The James and medical director of the campaign. . . . **CANCER INSTITUTE OF NEW JERSEY** said earlier this week that **William Hait**, director of the center since 1993, will step down to lead Johnson & Johnson's Worldwide Hematology/ Oncology Research and Development organization. The center previously announced the appointment of **Joseph Bertino** as interim director (The Cancer Letter, Feb. 2). . . . **ROSWELL PARK Cancer Institute** announced two staff appointments. **Jonathan Adams** was named assistant vice president and chief of pharmacy services. Adams was assistant director for clinical research and director of clinical operations, Kentucky Lung Cancer Research Program, Clinical Trials Network, Markey Cancer Center, University of Kentucky Chandler Medical Center. He was head of the Clinical Research Pharmacy Section in NCI's Cancer Therapy Evaluation Program. **Edward Tirpak** was appointed associate director of technology and commercial development. He was manager of the intellectual property group in the Office of Science, Technology Transfer and Economic Outreach, University at Buffalo. . . . **UNIVERSITY OF LOUISVILLE** signed an agreement with the Institute for Advanced Cancer Therapeutics to accelerate cancer research from the lab to the marketplace, said **Jim Zanewicz**, technology transfer director at the university. The school would own 30 percent of the company, which would be housed in the Louisville area. The rest of the company would be held by private investors. The agreement allows researchers at the James Graham Brown Cancer Center to submit their findings to the company, which will evaluate their discoveries for commercial value and license them as appropriate. "This is an important step for the university," Zanewicz said.

Funding Opportunities:

PA-07-218: Diet Composition and Energy Balance. R01. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PA-07-218.html. Inquiries: Sharon Ross, 301-594-7547; sr75k@nih.gov.

PAR-07-214: Academic-Industrial Partnerships for Development and Validation of In Vivo Imaging Systems and Methods for Cancer Investigations. R01. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PAR-07-214.html. Inquiries: Guoying Liu, 301-496-9531; guoyingl@mail.nih.gov.

PA-07-279: Bioengineering Research Grants. R01. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PA-07-279.html. Inquiries: Houston Baker, 301-594-9117; bakerhou@mail.nih.gov.

N02-CP-71002-50: Interdisciplinary Studies of Occupational and Environmental Cancer. Response Due Date: April 2. Full text: http://www.fbodaily.com/archive/2007/02-February/08-Feb-2007/FBO-01226423.htm. Inquiries: http://rcb.cancer.gov/rcb-internet.

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