THE CANCER LETTER

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NCI R01 Payline Falls To 12th Percentile In Fifth Year Of No-Growth Budgets

By Kirsten Boyd Goldberg

NCI's payline for R01 investigator-initiated grants will drop to the 12th percentile this fiscal year, from the 15th percentile in fiscal 2007, as the institute plans to fund fewer grants with a budget that has remained flat for the past five years.

"Something has to give," NCI Director John Niederhuber said to the NCI Board of Scientific Advisors at its March 3 meeting. "We need to inject a little bit of reality into this process. We can't continue to increase the grant pool with a flat budget."

NCI plans to award 1,283 research project grants this year, 30 fewer

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ESA Controversy:

Dingell, Stupak Urge FDA To "Act With Due Haste To Avoid Endangering Patients" Steered To ESAs

The House Committee on Energy and Commerce urged FDA to "seriously reconsider the overall safety" of erythropoiesis-stimulating agents at a meeting of the Oncologic Drugs Advisory Committee on March 13.

"Most importantly, we encourage FDA to act with due haste to avoid further endangering patients who may have been steered toward these drugs by aggressive marketing practices, including the use of direct-to-consumer advertisements and recommendations from physicians who personally profit from the sale of these drugs," states the letter, dated March 6 and signed by Committee Chairman John Dingell (D-Mich.) and Rep. Bart Stupak (D-Mich.), chairman of the Subcommittee on Oversight and Investigations.

The text of the letter follows:

Under Rules X and XI of the Rules of the United States House of Representatives, the Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations are investigating the ability of the Food and Drug Administration to protect the American public from excessive risk associated with prescription drugs.

Early last year, the Committee became aware of troubling signs of safety problems in connection with a class of drugs known as Erythropoiesis-Stimulating Agents (ESAs), which are designed to prevent the need for blood transfusions in cancer and dialysis patients suffering from anemia. Since then, we have been increasingly alarmed by clinical study reports that indicate ESAs, also known as erythropoietin (EPO) products, cause increased

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NCI Cuts Grants, Trial Accrual, Long-Term Commitments

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than the 1,312 grants funded in FY07. The R01 payline could move up to the 14th percentile toward the end of the fiscal year with funds NCI sets aside for exceptions and emergencies, Niederhuber said.

"Star" R01s for first-time investigators will be funded to the 19th percentile. Large R01s over $700,000 will be funded at the 14th percentile for the first and second rounds; the payline for the third round will be determined later.

This year, NIH has given the institutes greater flexibility to determine specific grant funding policies, including cost-of-living increases (if any) and budget cuts (The Cancer Letter, Feb. 8).

Rather than imposing across-the-board cuts to funded grants, NCI will provide small increases to certain types of grants. Last year, some grants were cut so severely that they were in danger of becoming meaningless, Niederhuber said to the BSA.

NCI will provide a 1 percent inflationary increase to non-competing grants, and will make no cuts to modular non-competing grants. Type 2 (competing continuing) grants will receive a 3 percent increase. Type 2 modular grants recommended for seven modules or fewer will receive a 5 percent increase. Type 1 (new competing) grants will be cut by about 17 percent; in the past, NCI cut about 25 percent from these grants, Niederhuber said.

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Editor & Publisher: Kirsten Boyd Goldberg
Editor: Paul Goldberg
Editorial Assistant: Shelley Whitmore Wolfe

Editorial: 202-362-1809 Fax: 202-318-4030
PO Box 9905, Washington DC 20016
Letters to the Editor may be sent to the above address.

Subscriptions/Customer Service: 800-513-7042
PO Box 40724, Nashville TN 37204-0724
General Information: www.cancerletter.com

"Cutting Significant Muscle, If Not Bone"

BSA Chairman Robert Young, chancellor of Fox Chase Cancer Center, said the consistently flat budget is causing NCI to dismantle well-regarded research programs.

"The financial environment is so disturbing that it's difficult to know where to start," Young said. "It seems pretty clear that we are now engaged in cutting some significant muscle, if not some bone, from out of our program."

Young noted NCI's decision to not renew a Request for Applications for the Transdisciplinary Tobacco Use Research Centers, a P50 grant program funded at $7.2 million this year. NCI will contribute about $2 million to $4 million for a TTURC program supported under a Program Announcement jointly with the National Institute on Drug Abuse (The Cancer Letter, Feb. 8).

"I've never heard anything other than tremendous support for the concept of interdisciplinary research around the issues of tobacco," Young said. "I'm sure it was a painful procedure to decide that the finances available simply wouldn't allow the Cancer Institute to continue a program like this. It's pretty self-evident that taking 600 patients out of clinical trials or 500 patients out of prevention trials is certainly cutting the speed with which we are trying to advance the cancer program."

Given the FY09 President's budget request for NCI of $4.8 billion, a 0.1 percent increase over the current year, it would appear that no relief is in sight and the institute will need to continue to make additional cuts to its "substance," Young said.

"We are looking at programs that have been around a long time, and whether there are other ways to support those programs—whether other people can step up to the plate and support those activities—so that we can be working a little more on the short term, so that we don't have long-term entitlements," Niederhuber said.

One example is a blood and marrow transplant registry that NCI funded for $600,000 a year. This will be cut to about $130,000 a year. "We have to look hard at these long-term commitments and we need to push these organizations to find other resources," Niederhuber said.

The TTURC program "has been a very successful program," funded in conjunction with NIDA and the Robert Wood Johnson Foundation, said Robert Croyle, director of the NCI Division of Cancer Control and Population Sciences. "This was something we evaluated very positively, but decided to change the mechanism. In a climate of money going up, not down, [cutting it] is probably not something we would have liked to do."

The TTURCs are "very strong" P50 centers and some of them probably could apply for P01 grants through the standing NCI process, Croyle said. Those centers that work exclusively in basic neuroscience of tobacco addiction could work through NIDA and give that program a focus that would be similar to an RFA, he said.

"We are going through a lot of changes," said BSA member Hoda Anton-Culver, chairman of the Department of Epidemiology at University of California, Irvine. "Are we going to lose something we will regret five or six years later?"

"The way I look at it is the train simply moves slower," Niederhuber said. NCI's "bypass budget," or professional judgment budget, which seeks $6 billion, outlines "what we could use to make it move faster."

ASCO, NCCS Urge 6.6 Percent Increase for NIH, Greater Support For Cancer Clinical Trials

Cancer professional societies and patient advocacy groups have urged Congress to increase funding for biomedical research. At a press briefing March 6, the American Society of Clinical Oncology and the National Coalition of Cancer Survivorship said they support a 6.6 percent increase in the NIH budget in FY09.

"The NIH and NCI budgets have been basically frozen for the past five years," said Allen Lichter, ASCO executive vice president and CEO. "We have been saying for a long time that this is going to hurt a great deal, and nowhere is this more evident than in the clinical trials mechanism—the cooperative group system. Cancer is the only major disease that has a standing infrastructure for doing clinical trials. It was brilliantly created, and it has been the bedrock of cancer clinical investigation in this country for the past 50 years."

As a result of the flat funding, patient enrollment in cooperative group trials decreased by 3,000 in 2007, and the number of trials has consistently decreased since FY04. Also, in FY08, NCI plans to cut the number of patients on trials in the Community Clinical Oncology Program. The number of patients on these community-based studies will drop from 6,400 to 6,100.

"The problem was always that we needed more patients to go on clinical trials," Lichter said. "No one is saying that the pace of advance in cancer is just fine, thank you. The entire thrust of this is how do we make progress faster."

Another, "even more chilling" statistic is the decline in number of new clinical trial concepts developed by the cooperative groups, Lichter said. Only 20 new clinical trial concepts were proposed and 67 new protocols approved last year, down from a high of 51 concepts and 128 protocols in FY04.

"Tomorrow, we are going to be looking around and wondering where did all this stuff go?" Lichter said. "We are in the process of slowly unraveling a system that has been the engine of clinical cancer research for the past 50 years. The damage will take years and years to put back together. This must be turned around."

ASCO also is concerned that the increasingly competitive grant process discourages young investigators from a research career, Lichter said. The average age of a tenure track appointment for a life scientist is 38, while the average age for winning the first independent grant award from NIH is 40. The chance of being funded on the first try was 21 percent in 1998. In 2006, the chance of being funded was 9 percent for new investigators and 7 percent for established investigators.

"If we want to improve the pace of progress, it comes from funding," Lichter said. "The cancer clinical trials process is like a funnel. The width of the mouth of the funnel is the speed at which progress flows through the system. We are narrowing and constricting that funnel by killing these trials.

"We are going backwards, not because patients are unwilling to go on trials, or physicians are unwilling to participate in trials, or that we have nothing to test," he said.

The NCI cooperative group program costs only $140 million a year and runs about 400 trials. "We can always do things more productively, but the public is getting an enormous benefit from this system," Lichter said. "The involvement of academic researchers who don't work for companies and whose careers are not dependent on the outcome of a study is important. Preserving and enhancing the clinical trials infrastructure in this country is a wise investment."

Office of Centers, Training, and Resources

Niederhuber announced that Toby Tucker Hecht was named acting director of the NCI SPORE program during the search for a new director.

She replaces Jorge Gomez, who is leading a new NCI initiative to enhance global research and clinical trials participation in Central and South America. NCI Director John Niederhuber and Division of Cancer Treatment and Diagnosis Director James Doroshow will oversee the program, which has moved out of the Office of Centers, Training and Resources, and into DCTD.

NCI officials plan to review the SPORE grant guidelines and plan to "fine-tune" the program "to make

it more real for today," Niederhuber said.

The Cancer Centers Program will remain in the Office of the Director. Linda Weiss is the director of the program. "The reality for any director of the NCI is that the centers program is an integral part of NCI and needs to be close to the director," Niederhuber said.

The Training Branch will move its grants portfolio to match up with research programs within the NCI divisions. An internal committee will provide operational advice on training activities.

NIH Clinical Center

Niederhuber said he is working on ways to improve various aspects of oncology training, research, and care at the NIH Clinical Center. He takes part in a committee that is developing recommendations for the center.

Also, NCI is leading the development of an Oncology Imaging Center in the center's radiology department and is recruiting a new head of the department. The new department head would be based in NCI and conduct research, as well as leading the clinical radiology service, Niederhuber said.

Niederhuber is working with the military to try to gain approval for an oncology ambulatory care facility at the National Naval Medical Center across Wisconsin Avenue from NIH. NCI leases 25,000 square feet at the center for laboratories, but the space needs renovation or replacement, Niederhuber said.

This would be in conjunction with the planned move of Walter Reed Army Medical Center to the Naval center. "I've said that if you see having a major tertiary care facility for the Eastern seaboard, you are going to need research and training," Niderhuber said..

NCI also is exploring the possibility of establishing a satellite center at nearby Suburban Hospital.

Cancer Screening:
Professional Groups Agree On Colon Screening Options

By Paul Goldberg

Earlier this week, professional groups involved in screening for colon cancer signed on to consensus guidelines that systematically review the screening options for the disease.

"An overriding goal of this update is to provide a practical guideline for physicians to assist with informed decision making related to CRC screening," states the paper published online by the American Cancer Society's CA: A Cancer Journal for Clinicians.

The joint guidelines were issued March 6 and signed by ACS, the American College of Radiology, and the U.S. Multi-Society Task Force on Colorectal Cancer. The latter group includes the American College of Gastroenterology, the American Gastroenterological Association, and the American Society for Gastrointestinal Endoscopy.

While several groups have issued guidelines for colon cancer in the past, their recommendations differed, often favoring their own specialty.

"Only half of Americans over 50 have been screened for colon cancer," said Otis Brawley, ACS medical director. "The guidelines basically say, 'All these modalities work—get something. Big national problem.' That is it."

The guidelines, posted at http://caonline.amcancersoc.org/, recommend two screening modalities that haven't been recommended in previous guidelines. These are virtual colonoscopy and stool DNA.

"The important thing about these guidelines is that they stress the prevention rather than detection; prevention by finding polyps that can be removed," said Bernard Levin, the lead author of the guidelines and emeritus professor at M.D. Anderson Cancer Center. "It's a shift in emphasis."

Levin said the guidelines demonstrate that medical specialties can set aside their parochial interests. "I believe the colon franchise doesn't exist," he said. "The patient, the primary care physician, and the specialist should make the decisions."

The guidelines, which are intended for individuals at average risk, give preference to screening tests that can not only detect cancer early, but also detect precancerous polyps.

The guideline development process was divided into two phases. The first focused on the stool tests, including guaiac-based fecal occult blood test, fecal immunochemical test, and sDNA. The second focused on the structural exams, including flexible sigmoidoscopy, colonoscopy, double contrast barium enema, and CT colonography (virtual colonoscopy).

The panel acknowledged that some patients are resistant to undergoing an invasive test that requires preparation, or may not have the option to do so. However, the panel said doctors and patients should understand that those tests are less likely to prevent cancer, compared with the invasive tests; they must be repeated at regular intervals to be effective; and if the test is abnormal, colonoscopy will still be needed.

The addition of sDNA and virtual colonoscopy may encourage more people to be screened, said Arl Van Moore, chair of the American College of Radiology

Board of Chancellors. "This could result in early detection of the disease for more patients, increasing the chance of successful treatment, and potentially reduce colorectal cancer deaths nationwide," Van Moore said in a statement.

The stool DNA test is under FDA review, but is commercially available as a "home brew," a regulatory category exempt from approval requirement. The test is marketed by Exact Sciences Corp. of Marlborough, Mass. The guidelines note that the cost of the new test "is much higher than the other stool tests." The frequency with which the stool DNA test should be performed is uncertain, too, the guidelines state.

The American Society for Gastrointestinal Endoscopy said the guidelines overstated perforation rates from colonoscopy and failed to "emphasize that this is the current gold standard."

"During the guideline development and review process, ASGE leadership recommended several important changes," the group said in a statement. "While not all of ASGE's concerns were fully addressed in the final document, ultimately, leadership decided that it was important for the society to support this broad-scale initiative aimed at increasing colorectal cancer screening."

Professional Societies:

Douglas Blayney Elected ASCO President for 2009-10

Douglas Blayney, an expert in oncology quality and informatics, and hematologic malignancy, has been elected to become president of the American Society of Clinical Oncology for a one-year term beginning in June 2009.

He will take office as president-elect during the ASCO annual meeting in Chicago this June. Four new members were elected to the ASCO Board of Directors and two new members to the ASCO Nominating Committee, all for three-year terms beginning in June 2008.

Blayney serves as professor of internal medicine at the University of Michigan Medical School and medical director of the university's Comprehensive Cancer Center. He joined the University of Michigan in 2003 from the Wilshire Oncology Medical Group, a private oncology practice in Pasadena, Calif., where he practiced for 17 years. He also served as an associate professor of clinical medicine at the University of Southern California, as well as a voluntary attending physician at the Los Angeles County General Hospital.

"It will be my privilege and pleasure to work with the newly elected leadership, in particular, the newly elected President-Elect, Dr. Douglas Blayney," said Allen Lichter, chief executive officer of ASCO. "For over a decade, Dr. Blayney has committed his time and dedication to the Society through various volunteer and leadership positions. ASCO is fortunate to have such a highly qualified oncologist and dedicated ASCO member lead the Society's efforts to improve cancer care and prevention."

"I am honored to have been elected to serve as ASCO president, following in the very large footsteps of those who have served before me," Blayney said. "ASCO is an exceptional organization and I look forward to working alongside my esteemed colleagues on the Board of Directors to continue improving the care and treatment of those living with cancer."

Blayney joined ASCO in 1983. He served on the Board of Directors from 1996 to 1999 and has been a member of the ASCO Cancer Foundation Board of Directors since 1999. He has also been a member of the editorial boards of the Journal of Clinical Oncology and the Journal of Oncology Practice, and serves as editor in chief of JOP.

He also has served on the Clinical Practice Committee, the Cancer Education Committee, the Information Technology Committee, and the Strategic Planning Committee.

Blayney is a member of the American Society of Hematology and the Southwest Oncology Group. He serves on the Board of Directors of the National Comprehensive Cancer Network.

Newly Elected ASCO Board Members

The following physicians will begin three-year terms as members of ASCO's Board of Directors on June 3:

Monica Bertagnolli has been elected to a Surgical Oncology seat. Bertagnolli is associate professor of surgery at Harvard Medical School and an associate surgeon at Brigham and Women's Hospital and the Dana-Farber Cancer Institute.

Bruce Johnson has been elected to an Undesignated Specialty, Oncology, or Hematology/Oncology seat. Johnson is director of the Lowe Center of Thoracic Oncology at the Dana-Farber Cancer Institute and Brigham and Women's Hospital and a professor of medicine at Harvard Medical School.

Robert Langdon Jr. has been elected to a Community Oncology seat. Langdon works in private oncology practice and is president of Oncology Hematology West,

P.C. in Omaha, Neb.

Sandra Swain has been elected to an Undesignated Specialty, Oncology, or Hematology/Oncology seat. Swain is the medical director of the Washington Cancer Institute at Washington Hospital Center and a professor of medicine at Georgetown University and the F. Edward Hébert School of Medicine of the Uniformed Services University of the Health Sciences.

New Members of ASCO Nominating Committee

Two newly elected ASCO Nominating Committee members will serve three-year terms beginning in June:

Theodore Lawrence, the Isadore Lampe Professor and Chair in the Department of Radiation Oncology at the University of Michigan Medical School, will serve as the Nominating Committee Chair in 2010-2011.

Julie Gralow, director of breast medical oncology at the University of Washington School of Medicine and Fred Hutchinson Cancer Research Center.

NIH News:

Advisors Urge Overhaul Of NIH Peer Review System

Advisors to NIH proposed a major overhaul of the Institutes' peer review system last week.

The Advisory Committee to the Director Working Group, co-chaired by Keith Yamamoto, executive vice dean, School of Medicine, UCSF, and Lawrence Tabak, director of the National Institute of Dental and Craniofacial Research, issued the final draft of a report to NIH outlining six major recommendations for reform:

—Mark some applications "not recommended for resubmission."

—Amended applicaitons considered as new, omitting rebuttals of criticism.

—Rate all applications by specific criteria and rank to reduce ambiguity.

—Shorter application with focus on impact and innovation, less on methods and preliminary data.

—Require at least 20 percent of effort, to limit principle investigators with multiple grants.

—Consider a separate review for new investigators.

Last June, NIH Director Elias Zerhouni called upon leaders from across the scientific community and NIH to join a trans-NIH effort to examine peer review with the goal of optimizing efficiency and effectiveness.

During the summer and fall of 2007, the working groups collected ideas for enhancing the peer review system from all stakeholder communities (i.e. extramural community, advocacy groups, professional society groups, and NIH staff). This process included an online Request for Information, an NIH internal survey, an interactive website for liaisons, analyses of previous and existing peer review experiments and practices at the NIH and other agencies (international and domestic), direct communication with stakeholders through teleconferences with deans, emails, letters, and a series of internal and external consultation meetings and regional meetings across the nation.

Zerhouni said he would work with the Steering Committee Peer Review Implementation Group to develop an implementation plan. NIH will formally announce the new initiatives it plans to implement in the spring of 2008.

NIH is accepting comments on the report until March 17. Comments may be sent to PeerReviewRFI@mail.nih.gov or by mail to Penny Wung Burgoon, Senior Assistant to the Deputy Director, Office of the Director, NIH, One Center Drive, Building 1, Room 114, Bethesda, MD 20892-0183

The report is posted at http://enhancing-peer-review.nih.gov.

Open-Access Publication Policy

Peer-reviewed journal articles based on NIH-funded research will soon become available to the public at no cost through the PubMed Central 2 online database, which is administered by the NIH National Library of Medicine.

This policy goes into effect on April 7 and will affect all intramural and extramural research funded in fiscal year 2008 and beyond.

The policy is outlined at http://publicaccess.nih.gov and is legislated by the Consolidated Appropriations Act of 2008.

Previously, study authors were asked to voluntarily submit their published manuscripts.

To enforce the policy, NIH has instituted a condition in all grants and cooperative agreements such that, in accepting funds, researchers agree to submit their manuscripts to PubMed Central upon acceptance of publication. Articles can be embargoed for up to 12 months. After the embargo, the article will be made publicly available in PubMed Central.

More than 300 journals have an agreement with NLM where they automatically submit articles to PubMed Central, and the authors who want to publish in these journals need not do anything more. But if an author wishes to publish in another journal, they

must submit the article themselves on the Manuscript Submission System at www.nihms.nih.gov.

Beginning May 25, authors must include a PubMed Central reference number for each article that they cite in their grant applications and proposals.

Retroactive submission of articles that were published before the April 7 deadline is not mandatory, but authors are encouraged to submit these manuscripts if they have appropriate copyright permission.

NICHD Honors Shriver

National Institute of Child Health and Human Development was renamed the Eunice Kennedy Shriver National Institute of Child Health and Human Development in recognition of Shriver's advocacy in founding the institution.

Shriver, executive vice president of the Joseph P. Kennedy Jr. Foundation and founder and honorary chairman of Special Olympics, also was inducted into the NICHD Hall of Honor in Bethesda March 3.

In the early 1960s, Shriver urged her brother, President John F. Kennedy, to establish an institute that would conduct research on children's health and human development. She worked with House and Senate leaders to pass legislation that would make the institute a reality. NICHD was established in 1963.

"Forty-five years ago, Eunice Kennedy Shriver sought to create a research endeavor to understand human development throughout the life process, focusing on developmental disorders, including intellectual disabilities, and illuminating important events that occur during pregnancy and childhood," said NIH Director Elias Zerhouni.

In the Cancer Centers:

Emory Forms Hematology, Medical Oncology Department

EMORY UNIVERSITY School of Medicine has established the Department of Hematology and Medical Oncology and named **Fadlo Khuri** the department chairman. Khuri will hold the Roberto C. Goizueta Chair for Cancer Research. He was deputy director of clinical and translational research and section head of hematology and oncology.

"Our NCI funding base has increased three-fold over the last six years, and the majority of the new grants involve leadership from members of hematology and medical oncology," Khuri said.

Since joining Emory Winship in 2002, Khuri has recruited more than 25 faculty to the hematology and medical oncology section. He is principal investigator of a $7.9 million NCI P01 grant in lung cancer, co-led with **Haian Fu**, and co-principal investigator on the $12.5 million NCI Specialized Project of Research Excellence grant in head and neck cancer.

"The newly created Department of Hematology and Medical Oncology is vital to Emory Winship's development as a true comprehensive cancer center," said **Brian Leyland-Jones**, director of the Winship Cancer Institute. "And Dr. Khuri is the natural choice to serve in this important position. Dr. Khuri is internationally recognized as a leader for his work in improving therapies for tobacco-related cancers. In addition, he has earned tremendous respect among faculty, staff and our patients for his leadership, his devotion to patient care and his incredible work ethic."

In May, Emory Winship will submit a grant application to NCI for cancer center designation, Leyland-Jones said.

UNC LINEBERGER Comprehensive Cancer Center named **Stuart Gold** and **Thomas Shea** to new positions. Gold, professor of pediatrics and center member, was named chief of the Division of Pediatric Hematology and Oncology. He succeeds **Julie Blatt**. Gold is responsible for clinical care programs, translational research, and training of residents and fellows. He will continue running a monthly outreach clinic at New Hanover Regional Medical Center in Wilmington. He is known for establishing the late effects clinic at UNC for children off treatment but at risk for late occurring side effects of chemotherapy. Shea was named associate director of Clinical Outreach for LCCC. Shea, professor of medicine and director of the UNC Health Care Bone Marrow and Stem Cell Transplantation Program, will develop a collaboration in education, research, and clinical care with the North Carolina Area Health Education Centers, health systems, and oncology practices. "His role in developing the UNC Bone Marrow Transplant program has put him in touch with everyone across the state over the last 15 years," said **Shelton Earp**, Lineberger director. . . **MAYO CLINIC** Comprehensive Cancer Center and Translational Genomics Research Institute formalized a strategic alignment to collaborate on cancer research initiatives. TGen researchers will become members in the Mayo Clinic Cancer Center to facilitate and enhance collaboration among the faculty of both organizations in areas of mutual scientific interest. The alliance builds on a 2003 agreement between Mayo and TGen to broaden the scope of joint research. The TGen Pharmaceutical

Sciences Division is located on the Scottsdale campus of Mayo Clinic. Results of the collaboration include a 30 percent success rate on the submission of joint grant applications. With the new agreement, the volume of joint cancer research grant applications will increase, said **Robert Diasio**, director of the Mayo Clinic Cancer Center. . . . **CITY OF HOPE** established a Division of Supportive Care Medicine, which puts psychosocial support and clinical palliative care programs under one umbrella. **Matthew Loscalzo**, administrative director of the Sheri and Les Biller Patient and Family Resource Center at City of Hope, will serve as co-chairman of the division alongside a physician chairman specializing in palliative medicine, said **Alexandra Levine**, chief medical officer. The division will incorporate departments and programs at City of Hope including Supportive and Palliative Care, Pain Management, Psychiatry, Psychology, Clinical Social Work, Spiritual Care, Patient Navigation, and Patient, Family and Community Education. The division will provide patient services in clinical nutrition, rehabilitation support and patient navigation, which assigns a personal navigator to the patient through the range of diagnosis, treatment and survivorship. . . . **CORRECTION:** In last week's issue of The Cancer Letter, the title of **Franklyn Prendergast** was incorrect. He is director of the Mayo Clinic Center for Individualized Medicine.

ESA Controversy:

House Committee Urges FDA To Reconsider ESA Safety

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blood clots and mortality, and may even enhance disease progression.

The Data Safety Monitoring Boards of a number of ESA clinical studies have recommended suspension of their studies because of heightened risk of harm to patients. In April 18, 2007, letters to this Committee, Johnson & Johnson, and Amgen listed 10 ESA clinical studies that were terminated or suspended because of unanticipated harm to patients: BEST Study; PR00-03-006; LEGACY Study; CHOIR Study; PR00-27-024; RP01-04-005; GOG 191; RTOG 99-20; EP-CAN-20; DAHANCA 10; and Roch's study NH19960.

As a result, FDA issued a "black box" label warning last yeare on all drugs in the ESA class, citing heart and cancer risks and urging their use in the lowest dose possible that still helped patients avoid blood transfusions. Nevertheless, these drugs continue to be prescribed for indicated as well as off-label use. Indeed, Johnson & Johnson and Amgen, the manufacturers of these drugs, continue to invest millions of dollars into lobbying and marketing campaigns that misrepresent the risks associated with ESAs.

Furthermore, the dramatic findings of a recent meta-analysis of ESA data published in the Journal of the American Medical Association (JAMA) raise serious concerns about the risk profile of the entire class of ESA products, including Aranesp and Procrit. In the February 27, 2008, issue of JAMA, Charles L. Bennett, M.D., Ph.D., et al. found that even when used as directed, ESAs put cancer patients at nearly 57 percent increased risk of blood clots. Study researchers also reported that ESAs increase the risk of death in cancer patients by about 10 percent. The meta-analysis also discusses results of experiments that indicate use of ESAs could actually *enhance* cancer growth at the same time that doctors are using other drugs to control the disease.

We applaud the past efforts of FDA officials who have insisted on science and evidence-based decisions respecting use of ESA drugs. The analysis published in JAMA, however, along with the 10 clinical studies halted by Data Safety Boards and other negative safety data, suggest a need for reconsideration of the risk/benefit profile of this potentially dangerous class of drugs.

We urge FDA to use the scheduled Oncologic Drugs Advisory Committee meeting on March 13, 2008, to seriously reconsider the overall safety of ESAs and address the question of whether any demonstrable benefits of these drugs offset the evidence of increased mortality, blood clots, and tumor promotion.

Most importantly, we encourage FDA to act with due haste to avoid further endangering patients who may have been steered toward these drugs by aggressive marketing practices, including the use of direct-to-consumer advertisements and recommendations from physicians who personally profit from the sale of these drugs.

Funding Opportunities:

RFA-CA-08-019: Tumor Stem Cells in Cancer Biology, Prevention, and Therapy. R01. Letters of Intent Receipt Date: April 12. Application Due Date: May 12. Full text: http://www.grants.nih.gov/grants/guide/rfa-files/RFA-CA-08-019.html. Inquiries: R. Allan Mufson, 301-496-7815; mufsonr@mail.nih.gov

NOT-HG-08-002: Administrative Supplements for Making Knockout Mice Submission dates: April 1; June 1. Full text: http://www.grants.nih.gov/grants/guide/notice-files/NOT-HG-08-002.html. Inquiries: Cheryl Marks, 301-594-8778; marksc@mail.nih.gov.

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