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ESAs Increase Risk Of Death By 11%, Blood Clots By 59%, Meta-Analysis Finds

By Paul Goldberg

A recently updated meta-analysis of studies of erythropoiesis stimulating agents shows a statistically significant drop in survival and a rise in venous thromboembolism associated with the use of these agents in oncology.

The findings, which update and reinterpret the Cochrane Collaboration reports on ESAs, were presented May 22 at a meeting of the Society for Clinical Trials, and will be presented in an updated form at a poster session June 3 at the annual meeting of the American Society of Clinical Oncology.

"The fact is that these drugs are being used in a very big way, and we have two safety signals here," said Charles Bennett, a hematologist-

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ASCO Annual Meeting:

NCI Cooperative Groups Recognized By ASCO For 50+ Years Of Clinical Trials, New Therapies

The American Society of Clinical Oncology will present its Distinguished Service Award for Scientific Leadership to the **National Cancer Institute Cancer Cooperative Groups** at the society's annual meeting in Chicago June 1-5.

Representatives from each of the 12 groups will receive the awards, in recognition of more than 50 years of contributions to programs that support the design of clinical trials, many of which have led to the development of new cancer treatments.

Sen. Arlen Specter (R-PA), will receive the 2007 Public Service Award for introducing cancer-specific legislation on Capitol Hill. A Hodgkin's lymphoma survivor, he has served as a vocal supporter of increased biomedical research, which has directly benefited millions of cancer survivors throughout the nation. Specter will receive his award at a ceremony in Washington, D.C., following the annual meeting.

Evelyn Lauder, senior vice president of The Estee Lauder Companies, will be recognized with the Partners in Progress Award for her career-long commitment to ending breast cancer. Lauder has advocated for the development of education and awareness campaigns about this disease since the late 1980s. She formed the Breast Cancer Research Foundation devoted to generating crucial funding for breast cancer research.

Martin Abeloff, of the Sidney Kimmel Comprehensive Cancer Center

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Trials After 2003 Tip Balance Against ESAs, Study Finds

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oncologist at Northwestern University's Robert H. Lurie Comprehensive Cancer Center and principal investigator of the NCI-funded Research on Adverse Drug Events and Reports project.

According to Bennett's analysis of data from randomized trials reported since 2003, patients taking these agents face a 59 percent greater risk of VTE and an 11 percent increase in the risk of death, compared to patients who don't take ESAs.

The new meta-analysis—the first such study to show an increase in mortality and the second to show an increase in VTE—is unveiled at a time when FDA is considering further restricting the use of these agents and when the Centers for Medicare and Medicaid Services are finalizing restrictions on reimbursement.

"We have a safety signal on deep vein thrombosis, and we now have a safety signal that we see on survival," Bennett said to The Cancer Letter. "How much more do we need to show you to stop overuse of these drugs? How many safety signals do we need before we get to the idea that we have to reconsider what we are doing here?"

Bennett is also a participant in the Cochrane Collaboration of meta-analysis experts and one of the authors of the ASCO and the American Society of Hematology guidelines on ESA use, and the Buehler Professor of Geriatrics and Economics at the Kellogg Business School and Northwestern Medical School.

Bennett used the year 2003 as a cut-point, separating the early ESA studies that were typically small and didn't address harder endpoints from the larger studies that were first reported that year. The later studies, which reported survival and time to progression, first raised concern about the adverse effects of ESAs.

"I was impressed with the general approach [of Bennett's study,]" said Stephen George a biostatistician at Duke University and a former member of the FDA Oncologic Drugs Advisory Committee, who heard Bennett's plenary session presentation at the SCT meeting in Montreal earlier this month.

George agreed that a prospective approach for selection of trials that would be included in a meta-analysis is an appropriate approach to interpretation of the data. "These kinds of analyses can make a major contribution when there are clinical trials with clearly specified primary endpoints," he said. "I think I would probably do the same type of thing: I would tend to focus on the big new studies. That's a reasonable thought, to pick some time frame and see what happened since then."

However, George said that another approach would be to censor studies that don't meet specific quality criteria. "It's more standard to try to identify all trials that meet certain quality criteria—such as existence of a data and safety monitoring board—independent of the time period," he said. "But you could do both; there is no reason why you couldn't."

Bennett and collaborator Benjamin Djulbegovic, an oncologist at the H. Lee Moffitt Cancer Center and a co-author of the Cochrane Reviews, said they planned to run such an analysis before their ASCO presentation. The analysis would exclude the small and mostly positive soft-endpoint studies reported since 2003, and therefore would likely produce a higher risk of thromboembolic events and mortality.

"It's a reasonable approach," said Djulbegovic, a member of the NCCN and ASCO/ASH guidelines panels on ESAs. "We'll try to get it done in the next few days."

Responding to government regulators and skeptics in the academia and on Wall Street, the sponsors of ESAs have been pointing to results from five previously published meta-analyses that fail to show harm from these agents. If Bennett's methodology stands up to academic scrutiny, this defense will vanish.

Though FDA hasn't recognized meta-analyses as a methodology for demonstrating efficacy for drug approval or a change of label, the agency can rely on

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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.

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such data to determine whether drugs are sufficiently safe.

"Some argue that you get the most reliable answers from meta-analysis, because you are putting together all of the information from randomized studies," said Susan Ellenberg, a former FDA biostatistician who is now a professor of biostatistics and associate dean for clinical research at the University of Pennsylvania.

"But you never quite know how people selected the studies that went into meta-analyses" and therefore it's not easy to detect bias, said Ellenberg, who heard Bennett's presentation, but hasn't reviewed his data and methodology in-depth. If a reliable meta-analysis points to a safety problem, FDA might be more likely to use it as grounds for a regulatory action, Ellenberg said.

"A meta-analysis that shows efficacy might not be accepted, but a meta-analysis that suggests a safety problem is a different kettle of fish," she said. "You are willing to take a little more of a chance on being wrong when you are letting people know about safety issues. You have a lower threshold. You might warn people that something might be a problem with less confidence about the reliability of that than you would about saying, 'Okay, this really works, and we are going to make it available to everybody.'"

Bennett's findings will be presented in the relative obscurity of a poster session Sunday morning at the McCormick Center. Bennett said he submitted his abstract in December. At that time, he thought that he was seeing a safety signal related to deep-vein thrombosis, he said. After the news of the negative studies of Amgen's Aranesp in anemia of cancer, Bennett, decided to test whether survival has been affected, too.

Bennett and his RADAR team updated the second Cochrane analysis with results of new studies that were presented at the May 10 meeting of the FDA Oncologic Drugs Advisory Committee. The updates are still ongoing.

Mulling over these results, Bennett and collaborators realized that they were staring at two different generations of studies: those concluded before and after 2003.

Before 2003, studies were smaller—the median size was 87 patients per trial—and the endpoints were soft, usually reduction of risk of blood transfusions in heterogenous populations.

Studies reported in 2003 and later were much larger—median accrual was 215 patients per trial. The endpoints were harder, too: survival and time to progression. Also, the populations weren't as heterogenous. Newer studies focused on specific sites: breast cancer, head and neck cancer, and lung cancer.

Bennett said that last month, he decided to see what would happen if he were to define 2003 as a cut-point and analyze 53 trials using random-effects models. Would this new way of looking at the data still show no harm for ESAs?

"The cut-point of 2003 was chosen based on the year of the first safety signals," he said. "While a different cut-point might have been selected, this year coincided with a change in clinical trials from small studies focusing on transfusions versus larger studies focusing on potential benefits of ESAs on tumor responses or survival."

The balance of evidence on ESAs has been shifting slowly.

Cochrane's first meta-analysis, completed in 2004 and published in JNCI in 2006, showed a trend towards a survival advantage for ESAs, but an updated analysis published in the same journal showed the opposite trend. Survival was poorer among cancer patients who received ESAs, with a p-value that narrowly missed statistical significance.

Now, Bennett suggests that results from more comprehensive longer-term studies reported after 2003 have tilted the meta-analysis against ESAs, and this seems to occur both in on-label and off-label settings.

"The signal on VTE is a very clear signal that's independent of whether you measure on-label or off-label usage," Bennett said.

According to Bennett's presentation at the SCT meeting, in 20 trials with 2,917 patients reported prior to 2003, compared to control patients, cancer patients who received ESAs had a trend toward increased VTE risk (relative risk, 1.49; 95% confidence interval 0.95 to 2.35), but improved survival (hazard ratio, 0.83; 95% CI, 0.71 to 0.97).

This changed in 2003, as analyses of results for 33 trials with 9,093 cancer patients identified a 59 percent increase in VTE risk increased VTE risk (RR 1.59; 95% CI 1.28, 1.97) and an 11 percent increase in the risk of death with ESAs (HR 1.11 (95% CI 1.08, 1.20).

The data don't make it possible to ascertain the causes of death or separate out the deaths from VTEs.

The distinction between associating ESAs with improved survival in early trials versus decreased survival in recent trials mirrors findings reported in the first Cochrane Review (HR of 0.8; 95% CI 0.7,1.0 for trials reported prior to 2002), indicating a trend to improved survival with ESAs, compared to the second Cochrane Review (HR 1.08, 95% CI 0.99, 1.18) for trials reported prior to 2006, indicating trend to

decreased survival with ESAs.

It is unclear why the smaller studies have tended to be positive for ESAs. Duke's George suggests that publication bias could be one problem.

"There have been studies showing a relationship between the size of the study and the likelihood of a positive result, at least in the published literature," George said. "It probably is the publishing that's the issue. Small trials that are negative get hammered when you try to publish them. So the only small trials that squeak through have positive results. The big trials have to wait until they reach their specified endpoints, so they trend to be more realistic."

Another form of bias is driven by the design of the smaller studies that compared ESAs with blood transfusion. "When the timing of a meta-analyses or summary of studies is not pre-specified, the results will be biased toward the event that triggers the timing of the analysis," said Vinni Junega, an FDA medical reviewer, at the ODAC meeting May 10.

Bennett said his findings are consistent with the second Cochrane analysis.

"We did exactly what Cochrane would do in the level of trial-based meta-analysis, which is take all the trials together for a comprehensive look, and then review it," Bennett said. "We reviewed the actual trials that were reported in prior Cochrane reports and we updated them by going through literature and going through the ODAC presentations.

"The reason ours is different i.e. with a $p<0.05$ and the second Cochrane analysis has a p-value of 0.052, is because we have the benefit of having data for several studies that were reported between April 30, 2005, when the Cochrane Review closed its database, and when ODAC met on May 10, 2007," Bennett said.

The Cancer Letter has not been given the final version of Bennett's dataset, which is being updated for presentation at ASCO and is under an embargo.

Cancer Control:

Stronger Measures Needed To Cut U.S. Smoking Rate, IOM Committee Says In Report

A combination of increased excise taxes, nationwide indoor smoking bans, and other measures would significantly lower the U.S. smoking rate, which now hovers at around 21 percent of the adult population, according to a report from the Institute of Medicine.

To achieve faster, more certain reductions, FDA should be given broad regulatory authority over tobacco marketing, packaging, and distribution, and other revisions to current tobacco policy should be enacted, the report said.

Although smoking in the U.S. has declined by more than 50 percent since 1964, tobacco use still claims about 440,000 lives every year, and secondhand smoke causes another 50,000 deaths annually. Smoking-related health costs are estimated to be $89 billion a year.

The report proposes a two-pronged approach to further reduce tobacco use. The first element focuses on strengthening existing tobacco control measures to preserve and enhance the gains already made. The committee's recommendations include:

—Increasing the federal excise tax on cigarettes substantially, and boosting taxes in states with lower rates to achieve greater parity in prices nationwide and thwart interstate smuggling.

—Dedicating $15 to $20 per capita annually of the proceeds from higher taxes or other resources to fund tobacco control efforts in each state.

—Imposing smoking bans in all nonresidential indoor settings nationwide, including restaurants, bars, malls, prisons, and health care facilities.

—Requiring all public and private health insurance plans to make coverage of smoking cessation programs a lifetime benefit.

—Licensing retail outlets that sell tobacco products.

—Launching additional efforts aimed at curbing youth interest in smoking and access to tobacco, including bans on online sales of tobacco products and direct-to-consumer shipments.

These measures focus on reducing demand for cigarettes, but do not address the addictive aspects of tobacco or constrain manufacturers' incentives to attract more smokers. The committee expressed concern that overall smoking rates may not drop significantly below 15 percent and that youth smoking rates may not fall permanently below 20 percent unless the basic legal framework of the tobacco market is changed. Therefore, it proposed a second set of further-reaching recommendations. The committee called for:

—Changing federal law to give FDA authority to regulate tobacco products, including powers to restrict how they can be marketed.

—Removing federal restrictions on state laws so that states are free to supplement federal regulations with more stringent measures to suppress smoking.

—Limiting tobacco advertising and promotional displays to text-only, black-and-white formats.

—Prohibiting tobacco companies from using

misleading terms such as "mild" and "light."

—Requiring new, large pictorial warnings on the harmful effects of smoking—similar to those required in Canada—on all cigarette packs and cartons.

—Requiring manufacturers to correct false or misleading information on products and at the point of sale.

—Restricting the type or number of outlets that can sell tobacco products, and requiring them to display warnings and give a proportional amount of space to cessation aids.

—Prohibiting tobacco companies from targeting youth for any purpose and urging them to redirect money they now spend on prevention to independent public health organizations.

—Developing a plan for gradually reducing the allowable nicotine content of cigarettes.

Cigarettes are a unique consumer product in that they contain carcinogens and other dangerous toxins and would be banned under federal public health statutes if these statutes did not expressly exempt tobacco, the report states. Tobacco is the only legal product for which the government's stated goal is to suppress use altogether rather than to promote safe or responsible use. Moreover, recent revelations of the industry's efforts to manipulate nicotine levels to encourage addiction have eroded the supposition that all smokers have freely assumed the risks of smoking and are solely responsible for the consequences, the committee noted.

"Smoking is a habit with potentially deadly consequences that is often taken up by adolescents before they can truly appreciate the risk of addiction," said Richard Bonnie, committee chairman and the John S. Battle Professor of Law and director, Institute of Law, Psychiatry, and Public Policy, University of Virginia. "We propose aggressive steps to end the tobacco problem—that is, to reduce tobacco use so substantially that it is no longer a significant public health problem. This report offers a blueprint for putting the nation on a course for achieving that goal over the next two decades."

The desire to educate youth and limit their access to tobacco underlies many of the committee's recommendations because of the high rate at which teens start smoking. Most smokers start before they turn 18, and the rate of daily smoking among high school seniors has hovered around 20 percent for most of the past two decades. Adolescents generally recognize the harmful effects of smoking, but typically overestimate their ability to escape addiction and fail to appreciate fully the personal impact of the long-term health consequences, the report said.

The committee believes that federal regulation is an essential element of a comprehensive approach to tobacco control. Therefore, it urges Congress and the president to give FDA the authority to enforce standards for nicotine reduction and to regulate companies' claims that their products reduce exposure or risk. The agency should have the authority to restrict the kind or number of outlets that can sell tobacco products and limit how the industry promotes its products.

The committee acknowledged that its recommendations to impose greater restrictions on tobacco advertising may not survive a challenge on First Amendment grounds. However, the report argues that restricting companies' ability to encourage smoking while still enabling them to relay information about the characteristics of their products to consumers satisfies the constitutional rights of the industry and consumers.

As a long-term strategy, the report also recommends that FDA look into developing a plan to gradually reduce the nicotine content of cigarettes and thereby decrease their addictive power. The committee noted that this proposal requires further investigation and careful assessment before it is implemented, but said it offers a reasonable prospect of making it easier for smokers to quit and to decrease the likelihood that youthful or casual smokers would progress to regular smoking.

The study was sponsored by the American Legacy Foundation.

Copies of the report, "Ending the Tobacco Problem: A Blueprint for the Nation," are available at www.nap.edu. A podcast of the public briefing held to release the report is available at http://national-academies.org/podcast.

In the Cancer Centers:

DFCI's Winer Named Komen's Chief Scientific Advisor

ERIC WINER was named chief scientific advisor for Susan G. Komen for the Cure. Winer will maintain his positions as director of the Breast Oncology Center at Dana-Farber Cancer Institute and associate professor of medicine at Harvard Medical School. He will advise the organization on its grants strategy and help plan public policy efforts. He will also advise the organization on the development of new educational messages, assist in responding to emerging breast cancer news and serve as a global spokesman for Komen. Winer also will help create a small group of top-level scientific and

medical advisors that will guide Komen over the years ahead. Winer also serves as co-chairman of the breast cancer committee in the Cancer and Leukemia Group B. "The breast cancer world listens to Eric," Komen founder **Nancy Brinker** said. "He is a leader, a brilliant idea person and a gifted clinician, recognized as a role model and guide for coming generations of doctors and researchers. Most importantly, he is deeply devoted to new and better treatments for breast cancer patients." . . . **NCI Public Affairs and Marketing Network**, an association of communications professionals working in cancer research and clinical organizations, announced its leadership at its 2007 annual meeting, hosted at the UCSF Comprehensive Cancer Center. Newly elected to the organization's steering committee are: **Pamela Perry**, director of public and media relations, Indiana University School of Medicine; **Bill Schaller**, director of media relations, Dana-Farber Cancer Institute; and **Jon Weiner**, executive director of public relations, University of Southern California Norris Comprehensive Cancer Center. **Karen Mallet**, senior director of public affairs at Fox Chase Cancer Center, was elected to serve as vice chair. **Cynthia Manley**, associate director of communications at Vanderbilt-Ingram Cancer Center, is chairman of the steering committee. Other members of the PAN steering and planning committee are: **Amy Mone**, director of public affairs, Johns Hopkins Kimmel Cancer Center; **Don Clayton**, associate vice chancellor for medical public affairs, Washington University Siteman Cancer Center; **Dan Fischer**, senior marketing specialist, Holden Comprehensive Cancer Center/ University of Iowa; **Mary Hawkins**, communications director, Norris Cotton Cancer Center at Dartmouth; **Nancy Jensen**, chair, division of public affairs, Mayo Clinic Jacksonville; **Kevin Koga**, associate vice president for marketing and communications, City of Hope Comprehensive Cancer Center; **John Mugge**, communications manager, University of California at San Francisco Comprehensive Cancer Center; **Dianne Shaw**, director of communications, UNC Lineberger Comprehensive Cancer Center; and **Arlinda Warren**, director of marketing, PR and physician services, Washington University Siteman Cancer Center. . . . **SAMUEL OSCHIN** Comprehensive Cancer Institute at Cedars-Sinai Medical Center will open a new sarcoma center on June 12. The Cedars-Sinai Sarcoma Center will offer a multidisciplinary team in surgery, oncology, pain management, radiation oncology, nursing, social work and orthopedic oncology. The sarcoma center also will offer clinical trials for medical and surgical treatments, including therapeutic drug trials, and provide second opinions to newly diagnosed patients, said **Charles Forscher**, oncologist and medical director of the new sarcoma center. Patients will have access to Cedars-Sinai's outpatient infusion center for chemotherapy and other services.

In Brief:

Scientists, Hedge Fund, Form $1M Prize For Cancer Research

GOTHAM PRIZE for Cancer Research, a $1 million personal use award to encourage new and innovative approaches to cancer research by promoting collaboration among top thinkers in the field, has been established by a group of scientists and hedge fund managers. A panel of scientists from Harvard, Johns Hopkins, and New York University will select the winner of the prize, as well as an additional prize, the $250,000 Ira Sohn Conference Foundation Prize in Pediatric Oncology. A Gotham Prize Web site will provide a mechanism to match cancer researchers with each other and with interested foundations and other sources of funding. The Gotham Prize was founded by **Gary Curhan**, of Harvard Medical School, and **Joel Greenblatt**, founder and managing partner of Gotham Capital, a private investment firm. The panel to select winners includes **Bert Vogelstein**, of Johns Hopkins School of Medicine. Selections will be made in February 2008. The Web site is www.gothamprize.com. . . . **JAMES HOLSINGER** was nominated 18th surgeon general by **President Bush**. A cardiologist, Holsinger was secretary for health and human services for the Kentucky and chancellor of the University of Kentucky Medical Center. His 26-year career with the U.S. Department of Veteran Affairs culminated in an appointment as under secretary for health in 1992. Holsinger served more than 30 years in the U.S. Army Reserve, retiring with the rank of Major General in 1992. . . . **MITCH BERGER** was elected to the board of directors of the American Association of Neurological Surgeons. He is the Kathleen M. Plant Distinguished Professor and chairman of neurosurgery and director of the Brain Tumor Research Center at the University of California, San Francisco. He also is principal investigator of the UCSF Brain Tumor SPORE Grant. . . . **INTEGRATIVE MEDICINE** Consult Service was established by the National Center for Complementary and Alternative Medicine at the NIH Clinical Center. The service will allow physicians, nurses, and other members of the Clinical Center health care team to discuss complementary and alternative medicine

therapies with medical staff from the consult service and learn how CAM practices might complement or interact with patient care. The service will establish a research program and provide CAM education for NIH staff, patients, and their families, said **Patrick Mansky**, clinical oncologist and researcher at NCCAM and director of the consult service. . . . **AMERICAN SOCIETY for Biochemistry and Molecular Biology** awarded researchers at its annual meeting in Washington, D.C., April 28-May 2. The ASBMB Opening Lecture and Herbert Tabor/Journal of Biological Chemistry Lectureship was presented by **Tony Hunter**, American Cancer Society Professor of Molecular and Cell Biology, Salk Institute for Biological Studies; ASBMB Opening Lecture and Herbert Tabor/Journal of Biological Chemistry Lectureship was given by **Tony Pawson**, senior investigator, Samuel Lunenfeld Research Institute of Mount Sinai Hospital, Toronto. Avanti Award in Lipids was presented by **Scott Emr**, investigator with the Howard Hughes Medical Institute and professor of cellular and molecular medicine, School of Medicine, University of California, San Diego. ASBMB Award for Exemplary Contributions to Education was given by **Sarah Elgin**, professor of biology, genetics and education at Washington University, St. Louis. ASBMB-Merck Award was delivered by **Judith Klinman**, professor of chemistry, University of California, Berkeley. Fritz Lipmann Lectureship was presented by **Ronald Evans**, professor of biology at the Salk Institute for Biological Studies, San Diego. Schering-Plough Research Institute Award was given by **Christopher Burge**, associate professor of biology at MIT. Howard K. Schachman Public Service Award was given by **Mary Woolley**, president and CEO of Research!America. ASBMB-Amgen Award was delivered by **Angelika Amon**, associate professor of biology at MIT. William C. Rose Award was given by **Susan Taylor**, professor of chemistry and biochemistry at the University of California, San Diego. . . . **AMERICAN SOCIETY for Therapeutic Radiology and Oncology** announced the addition of two staff members to its Health Policy Department. **Marsha Kaufman** was named assistant director of Health Policy. She was account executive in consumer directed health plans for WellPoint. **Jesleen Papneja** was appointed health policy analyst. Papneja completed an internship at VitalSpring Technologies, where she worked on in-depth cost and use analyses of benefits and financial payment data. . . . **ONCOLOGY NURSING** Certification Corp. announced its Board of Directors for 2007-2008. **Carol Brueggen** and **Julie Earle**, both of Rochester, Minn., were elected to the board in the 2007 ONCC election. Brueggen is an oncology clinical nurse specialist at St. Mary's Hospital in Rochester. Earle is a radiation oncology nursing supervisor at the Mayo Clinic, also in Rochester. Each will serve a three-year term. **Adele Hammermon**, of Baltimore, was appointed by the ONCC Board to serve a three-year term as the public member. **Bertie Ford**, of Genentech BioOncology, was appointed as the representative from the Oncology Nursing Society Board of Directors. In March, the ONCC Board elected officers for 2007–2008. They include: President, **Carlton Brown**, of Georgetown University; vice-president, **Josephine Visser**, of H. Lee Moffitt Cancer Center; secretary/treasurer, **Vicki Norton**, of Methodist Hospital, St. Louis Park, Minn. Other board members include **Kathleen Adlard**, of Children's Hospital of Orange County, Calif.; **Darla York**, of Kosair Children's Hospital in Louisville, Ky.; **Georgia Decker**, ex-officio, from Albany, N.Y., and **Paula Trahan Rieger**, ex-officio, chief executive officer of ONCC.

Funding Opportunities:

RFA-CA-07-048: Community Clinical Oncology Program. U10. Letters of Intent Receipt Date: June 18; Application Receipt Date: July 18. Full text: http://www.grants.nih.gov/grants/guide/rfa-files/RFA-CA-07-048.html. Inquiries: Lori Minasian, 301-496-8541; minasilo@mail.nih.gov.

RFA-CA-07-049: Minority-Based Community Clinical Oncology Program. U10. Letters of Intent Receipt Date: June 18; Application Receipt Date: July 18. Full text: http://www.grants.nih.gov/grants/guide/rfa-files/RFA-CA-07-049.html. Inquiries: Worta McCaskill-Stevens, 301-496-8541; mccaskiw@mail.nih.gov.

RFA-CA-07-506: A Data Resource for Analyzing Blood and Marrow Transplants. Limited Competition U24. Letters of Intent Receipt Date: June 25; Application Receipt Date: July 25. Full text: http://www.grants.nih.gov/grants/guide/rfa-files/RFA-CA-07-506.html. Inquiries: Roy Wu, 301-496-8866; wur@ctep.nci.nih.gov.

RFA-CA-07-047: Biology of Breast Pre-Malignancies. R01. Letters of Intent Receipt Date: Oct. 14; Application Submission/Receipt Date: Nov. 14. Full text: http://www.grants.nih.gov/grants/guide/rfa-files/RFA-CA-07-047.html. Inquiries: Anne Tatem, 301-594-5371; tatema@mail.nih.gov.

RFA-MD-07-003: NCMHD Community-Based Participatory Research Initiative in Reducing and Eliminating Health Disparities: Intervention Research Phase. R24. Letters of Intent Receipt Date: July 31; Application Receipt Date: Aug. 31. Full text: http://www.grants.nih.gov/grants/guide/rfa-files/RFA-MD-07-003.html. Inquiries: Francisco Sy, 301-402-1366; SyF@mail.nih.gov.

ASCO Annual Meeting:

Moffitt's Balducci To Receive First B.J. Kennedy Award

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at Johns Hopkins, will receive the Distinguished Service Award for Scientific Achievement for his leadership in the field of translational breast cancer research.

The 2007 Special Recognition Award will be presented to **Charles Balch**, also of Hopkins and former ASCO executive vice president, for his contributions to the fields of melanoma and breast cancer research. He also will be recognized for his extensive service to ASCO and for his influence as a leader in the oncology community.

The inaugural B. J. Kennedy Award and Lecture for Scientific Excellence in Geriatric Oncology will be given to **Lodovico Balducci**, who for 35 years has treated older patients with cancer, provided follow-up care for survivors, and actively pursued scientific investigation of topics relevant to the management of cancer in the older population at the H. Lee Moffitt Cancer Center & Research Institute.

The 2007 Pediatric Oncology Award and Lecture will be presented to **Sarah Donaldson**, from the Stanford Comprehensive Cancer Center, for her work to cure childhood cancers. She is an internationally renowned radiation oncologist whose research has led to a greater understanding of the long-term effects of treatment for pediatric cancers and the development of safer treatment regimens for children. Her work has been instrumental in the development of innovative treatment approaches for Hodgkin's disease and rhabdomyosarcoma.

The 2007 Science of Oncology Award and Lecture will be presented to **Napoleone Ferrara**, from Genentech, for his groundbreaking research. He was the first to identify the vascular endothelial growth factor protein, and he subsequently spearheaded the development of the anti-angiogeneic drug bevacizumab.

Robert Kyle, from the Mayo Clinic, is the recipient of the 2007 David A. Karnofsky Memorial Award for his pioneering research in hematology. Kyle's discovery of two significant hematologic entities, monoclonal gammopathy of undetermined significance and smoldering multiple myeloma, are considered fundamental to the understanding and practice of modern hematology.

Scott Lippman, of M.D. Anderson Cancer Center, will receive the American Cancer Society Award in recognition of his pioneering work in cancer prevention. His translational research has greatly expanded the understanding of the risk, biology and chemoprevention of carcinogenesis in various organ sites with a particular focus on oral premalignancies.

ASCO also will present more than 100 new Statesman Awards, which recognize members who have made significant contributions to the society and the practice of clinical oncology. This year, the award will pay special recognition to outstanding past achievement. More than 100 recipients representing ASCO founders, past presidents and past members of the board of directors will be honored.

Clinical Trials Participation Recognized By ASCO

American Society of Clinical Oncology will present Clinical Trials Participation Awards to 10 community oncology practices for improving cancer care by increasing participation in clinical trials. The presentation will take place June 2 at the society's annual meeting in Chicago.

Awardees include Cancer Centers of Carolinas, Greenville, S.C.; Duluth Clinic Cancer Center, Minn.; Kaiser Permanente, Northern California, Oakland, Calif.; New Hampshire Hematology-Oncology, P.A., Hooksett, N.H.; Northwest Cancer Specialists, Vancouver, Wash.; Oncology Hematology Associates of Central Illinois, Peoria; Oncology Hematology Care Inc., Cincinnati; Scottsdale Medical Imaging; Summa Health System Hospitals, Akron; and University of Texas Health Science Center at San Antonio.

"Clinical trial research is the necessary step to translate laboratory discoveries into treatments that improve the lives and health of cancer patients," said Allen Lichter, ASCO executive vice president and CEO. "The Clinical Trials Participation Awards honor those practices that have demonstrated their commitment to improve cancer care through clinical research and demonstrated innovative ways to offer clinical trials to patients in the community setting."

Selection was based on factors including patient accrual to clinical trials over a three-year period, with special consideration given to practices that increased participation among underrepresented populations. Consideration also was given to practices that used innovative techniques to overcome barriers to enrollment, said ASCO.

The Coalition of Cancer Cooperative Groups funds the program, which provides recipients with a travel grant to attend the ASCO annual meeting. Since 2003, 53 community-based practices have received the award.

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The Cancer Letter
PO Box 9905
Washington DC 20016
Tel: 202-362-1809
www.cancerletter.com