THE CANCER LETTER

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After ODAC: Questions On ESA Claims, Advertising, Reimbursement Gain Urgency

By Paul Goldberg

Getting ready for their May 10 date with the FDA Oncologic Drugs Advisory Committee, Amgen officials tried to convince Wall Street analysts that all is well with the erythropoiesis stimulating agents, the company's multibillion-dollar franchise.

At one such conference, George Morrow, Amgen's executive vice president for global commercial operations, said that "oncologists are very comfortable with the safety of ESAs" and that they continue to "believe in the quality of life benefits that they provide."

Morrow's comments, made May 3 at the Deutsche Bank Annual Health Care Conference, represented nothing less than defiance of the agency, which on March 9 purged all quality of life claims from the ESA labels, stating that these agents were approved as nothing more than an alternative to blood transfusions and that quality of life claims were not supported by science. *See story, page 2.*

A week after trying to reassure investors, Morrow and his Amgen colleagues faced ODAC, a group of cancer experts and one vocal patient advocate, who demonstrated that they were anything but comfortable with the quality of data on the safety of ESAs and even less comfortable with direct

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In the Cancer Centers:

ACS, NPCRC Award $1.5 Million In Grants For Palliative Care Research To 10 Institutions

AMERICAN CANCER SOCIETY and the National Palliative Care Research Center are awarding $1.5 million in research grants to 10 institutions for studies in palliative care. "These grants will bring much-needed research dollars to a field that has become an increasingly important part of patient care, but for which federal funding is inadequate, said **Jerome Yates**, ACS vice president of research. NPCRC Pilot Project Support Grant recipients include: University of Pittsburgh School Medicine, **Robert Arnold**, professor of medicine and director of the Palliative Care Fellowship Training Program; City of Hope National Medical Center, **Marcia Grant**, professor and director of research; University of North Carolina at Chapel Hill, **Sheryl Zimmerman**, professor of social work and senior research scientist and co-director for the Program on Aging, Disability and Long-Term Care of the Cecil G. Sheps Center for Health Services Research. ACS Pilot Project Support Grant recipients include: University of Colorado at Denver Health Sciences Center,

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Despite Weak Data, ESA Sales Grew To $4.9 Billion In U.S.

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to consumer marketing of these agents.

The committee's recommendations gave FDA broad authority to regulate what critics describe as dangerous overuse of these agents. *See story, page 3.*

At the ODAC meeting, Richard Pazdur, director of the FDA Office of Oncology Drug Products, said the agency is trying to determine how the ESA labels came to include the quality of life claims and how the agency regulated the direct to consumer advertising campaigns built around these claims.

Pazdur's comments prompted patient advocates to question the agency's ability to conduct a proper investigation of itself, arguing that, at a minimum, patients and scientists should be involved. Several advocates called for Congressional oversight.

The Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce is investigating the ESA controversy, but pending the outcome of the ODAC meeting, the committee hadn't focused its attention on FDA. *See story, page 4.*

The most significant blow to Amgen and Johnson & Johnson came on May 14, as the Centers for Medicare and Medicaid Services published a proposed plan that would severely restrict the use of ESAs in oncology.

The draft of the "national coverage decision" would restrict ESA reimbursement beyond the levels specified by ODAC. *See story, page 6.*

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Amgen Claimed QOL Benefit Despite FDA Label Change

By Paul Goldberg

At a series of Wall Street investors' conferences that preceded the May 10 meeting of the FDA Oncologic Drugs Advisory Committee, Amgen officials said repeatedly that their agent Aranesp improves the patients' "quality of life."

In March, FDA eliminated all references to quality of life from the labels of all ESAs, including Aranesp, and is now investigating how these claims got there in the first place. Earlier versions of the ESA labels included references to tiredness, lack energy, shortness of breath, chest pain, and feeling cold much of the time.

According to the agency, the ESAs were approved only as a substitute for blood transfusion and should be used in "the lowest dose… that will gradually increase the hemoglobin concentration to the lowest level sufficient to avoid the need for red blood cell transfusion."

Disregarding the new label, Amgen officials continued to refer to improvement in quality of life at analysts' conferences May 3 and May 4.

"For the most part, oncologists are very comfortable with the safety of ESAs. They believe in the quality of life benefits that they provide, even though we don't promote it, necessarily," George Morrow, Amgen's executive vice president for global commercial operations, said at the Deutsche Bank Annual Health Care Conference May 3.

A day later, Morrow lamented the fact that patients were being taken off treatment.

"A lot of patients are being pulled off treatment, unfortunately," Morrow said at the Morgan Stanley Global Healthcare Unplugged Conference May 4. "They are feeling pretty bad. I mean, these products that raise hemoglobin actually do have a profound effect on quality of life for patients, and so when you yank their treatment midstream, it is felt more than a patient who wasn't started and so they never really knew what they were missing, so to speak."

Morrow acknowledged that FDA doesn't recognize these claims, and said that the company hoped that physicians would urge the agency to reevaluate its stance.

"We are getting a lot of push-back from doctors, [who would] hopefully get that message to the FDA, which right now does not believe, because the companies haven't used validated patient reports of outcome measures, that there is a real quality of life

issue here," Morrow said. "So I think that will find its own equilibrium over time."

Morrow predicted that oncologists will find a way to bill Medicare for Aranesp for anemia of cancer no matter what FDA or Centers for Medicare and Medicaid Services require.

"I think, over time, since anemia of cancer is such a heterogeneous category, they will find some codes to work some of those patients back into the fold," he said at the Morgan Stanley conference. "For example, many of those patients have kidney disease, where their GFRs qualify them for being treated. I suspect that over time some doctors will code them differently as a relocation as opposed to a patient that has ongoing anemia, related somewhat to their cancer."

Morrow said that the CMS "National Coverage Decision" that would dictate coverage of on and off-label uses of ESAs wouldn't necessarily mirror the FDA label and may be less restrictive.

"We have encouraged them that whatever the FDA does shouldn't dictate exactly what you do," Morrow said at the Morgan Stanley conference. "Because you want to give doctors enough flexibility to treat their patients, and the last thing CMS wants is a bunch of patients who really should be receiving ESA therapy not getting it or complaining. I think they're going to have to look at transfusions, and what would happen to transfusions if you really choked off utilization of ESAs and what the risks are of transfusion. That will also be discussed at ODAC next week, I'm sure. So there's a lot that needs to be considered, and it's a pretty complex issue right now."

Putting a positive interpretation on the results of a Danish study of Aranesp in head and neck cancer, Roger Perlmutter, Amgen executive vice president for research and development, said that the trial was stopped for futility.

"And we received in fact an e-mail from Jens Overgaard [the principal investigator of the DAHANCA study], telling us not to overinterpret their results, that they—their posting on the website was exactly what they meant to say, that it was stopped for futility, and that's all they want to say about the study at the study at this point," Perlmutter said at the company's earnings call April 23.

Indeed, DAHANCA was stopped because the data and safety monitoring committee found that the study would be unlikely to prove its hypothesis. The study also found an increase in locoregional failure on the Aranesp arm, and its results are yet to be analyzed and presented. The document is posted at www.rejacms.au.dk/dahanca/get_media_file.php?mediaid=125.

Morrow said Amgen's marketing stance hasn't been aggressive in recent months, but vowed that this would change after ODAC.

"I guess, during the pre-ODAC, from the label change to ODAC, we have been very conservative, very focused on the label, more defensive than offensive," Morrow said May 4. "I think, once ODAC hits and we get through that, and we have a clear indication of where the FDA is coming from, then I think we'll be back on offense and going out there talking about studies and new use areas and so forth, new patient types."

FDA has the authority to regulate health claims in advertising, but not statements made to investors.

Amgen has acknowledged that it's facing an inquiry by the Securities and Exchange Commission stemming from the company's failure to disclose the DAHANCA study results until they were reported in The Cancer Letter. Also, the company is facing shareholders' suits stemming from its failure to report the Danish study.

"Miracle-Gro?" ODAC Vents At Amgen, J&J Over ESAs

By Paul Goldberg

For nearly 15 years, the ESA industry flourished in the absence of hard data.

No one knew the agents' impact on survival or time to progression. Scientists can't even point to dose-response curves for these widely used agents.

And with no one asking questions, an argument can be made that the absence of data has been the companies' principal asset.

At the ODAC meeting May 10, the absence of data became a major liability, as the companies that created the EPO market, were left without substantive means for defending their claims under rigorous scientific questioning.

For an entire day, committee members pounded the sponsors with questions they surely knew couldn't be answered and resorting to gallows humor to vent their frustration.

Could these widely used drugs be "Miracle-Gro for cancer?" asked Otis Brawley, professor of hematology and oncology at the Winship Cancer Institute.

Could safety warnings in anemia of cancer be modeled on warning labels on cigarettes, "where it's kind of scary?" asked Gail Eckhardt, acting chairman of ODAC and director of the division of Medical Oncology GI malignancies Program at the University of Colorado

Health Sciences Center.

"Yes, we have burning questions," said Silvana Martino, director of the breast cancer program at The Angeles Clinic and Research Institute. "The burning question is, does this thing actually kill people? What are the doses that are reasonable and appropriate?"

"Many of us have been confused about the quality of life and fatigue, and some of the patient reported outcomes data and exactly why this is part of the label," said Eckhardt, opening discussion at the ODAC meeting. "We understand that that was not sufficient at the time of registration.

"I think it's very interesting that these data have not been available, at least to the level to reach those kind of conclusions, because many of us see marketing to be revolving around patient-reported data," Eckhardt said.

"The other thing is that there is very little known about the dosing with regards to this agent, and I really didn't hear a lot of discussion about why the doses utilized were quite a bit higher than those utilized on the label," Eckhardt said. "We are not talking about a regimen that actually prolongs life. This is supportive care, so need to be thinking about the risks and benefits within this context."

The paucity of data is all the more frustrating because the ESAs are useful in some settings, Eckhardt said. "Certainly, there are appropriate times for transfusions, but I think the idea of going to the Dark Ages with regards to supportive care is just backwards," she said. "I think what we should be doing about that is find ways to manage the risks that we've heard about with regards to this very useful supportive care agent."

The committee gave FDA the mandate to reel in the overuse of the drug, voting that "further marketing restrictions" would be warranted for ESAs.

The group also recommended that:

—Labeling should "specifically state that ESAs are not indicated for use in the specific tumor types studied in trials that showed adverse safety signals."

—The product labels should "define a hemoglobin level in asymptomatic patients at which ESAs should be initiated." However, the committee voted against lowering the hemoglobin target for suspending ESAs. The current target is 12 g/dL.

—ESAs should be discontinued after "completion of a chemotherapy regimen and re-evaluation of the degree of anemia with subsequent chemotherapy regimen."

Overall, the committee was in agreement with the FDA assessment of the controversy. The FDA document is posted at http://www.fda.gov/ohrms/dockets/ac/cder07.htm#OncologicDrugs.

"I still don't understand why it's been approved that it is safe under 12 g/dL, especially if it has been found that there is not an increase in [thromboembolic events] as the hemoglobin rises," asked Helen Schiff, a member of SHARE, a New York-based advocacy group. "So that means it's the same under 12 g/dL as it is above 12 g/dL if there is no difference. So, why are we assuming that under 12 g/dL is safe at this point? I haven't seen the data for that."

Kathy Albain, professor of medicine at Loyola University Medical Center, agreed. "I guess in situations like adjuvant breast cancer therapy, I am not yet reassured," she said. "I have no proof that a well designed non-inferiority study that it will not adversely impact survival. I would like to see that on the label."

The rationale for using these drugs has nothing to do with evidence, said Brawley. "I think one of the most important issues here is most doctors and most patients think that this drug has been approved because it improved quality of life," he said. "I don't see that in the FDA presentation. I see it on television. There is a lot of sleight of hand here with how this drug is used, what the drug is used for. I think that's a real problem. I was struck by one of the comments earlier today, 'Let the doctors decide who gets the drug.' The problem is, the doctors get $1,200 for every dose they give patients. The doctors don't have to sign the same conflict of interest statement that people who spoke here had to do today."

FDA Examines Its Own Role In Allowing Misleading Ads

By Paul Goldberg

As ODAC members focused on how much is unknown about ESAs, Eckhardt asked FDA's Pazdur to explain the agency's role in regulating the advertising campaigns for these products.

"We have all been struggling today with the advertising that we see versus the body of data that was presented to actually support the indication," Eckhardt said.

"Obviously, there is a great deal of concern that I have and that most of the clinical review staff have about these advertisements that were made," Pazdur said. However, the review division has no enforcement authority, he said. Separate units at the Center for Drugs and the Center for Biologics make decisions on

enforcement.

"The FDA Chief Counsel's office, obviously, sets the tone for enforcement," Pazdur said at the meeting. "We are looking into this whole issue of why these ads were allowed to go on, and I think that the FDA is responsible for giving the American public as well as the review staff that sits here the reasons why these ads were allowed to go on. And I really would like to thank the advocate community for bringing this up, because FDA really does need to address this issue.

"Obviously, there is a fine line between the First Amendment free speech and the protection of the American population from false and misleading advertisement."

Pazdur's comments followed public hearing testimony, where several breast cancer patients challenged the agency's role in allowing the aggressive direct to consumer marketing of ESAs. FDA officials said that the agency is holding meetings to discuss how decisions were made regarding the advertising of EPO products.

The agency will have to explain how the following claims made their way into the patient information section of the Procrit label:

"Procrit is used to treat anemia (a lower than normal number of oxygen-carrying red blood cells). People with anemia may feel tired or may feel a lack of energy. They may also experience weakness, dizziness, difficulty with concentration, shortness of breath, chest pain, and feeling cold all of the time. Your doctor has prescribed Procrit to treat your anemia. If your body responds to Procrit, your symptoms may improve."

The Aranesp package insert describes the same symptoms and claims that "an increase in the number of red blood cells may relieve the symptoms of anemia." "Your doctor will know when Aranesp is working because your blood tests will show an increase in the number of red blood cell," the Aranesp label stated.

Though Procrit and Aranesp were approved only for their ability to reduce the need for blood transfusions, the quality of life claims laid out in the patient information section of the label paved the way for direct to consumer ads that created the diagnosis of cancer fatigue, and with it the most valuable franchise in oncology. Altogether, $4.854 billion worth of ESAs were sold for use in oncology in the U.S. last year.

How did this unsubstantiated claim remain in the label until March 9? Why didn't the agency confront this problem at the May 4, 2004, ODAC, when it weighed the questions of safety of these agents?

Early in the Bush administration, the agency required that the FDA Office of Chief Counsel sign off on all warning letters. This policy is still in force. The agency's Chief Counsel is a political appointee.

Patient advocacy groups agreed that the agency should examine its role in the ESA controversy. However, several advocates and scientists requested that at the very least the agency should include outsiders in this review process. Others said that ideally, the investigation should be conducted by Congress.

"The question that I have been asking myself again and again is how this could have happened?" patient advocate Schiff said in an interview.

"The ESA ads clearly violated the FDA label," Schiff said. "Why didn't the FDA pull it? It is clear to me that an investigation of the FDA is called for and patient advocates need to be at the table to make sure there is complete transparency and no cover up. I also think the harm done to cancer patients by the overselling of ESAs and the kickbacks given to doctors demands a Congressional investigation. And certainly, for starters, any company that does false advertising should be made to run corrective ads in both print and TV to inform the public that they were misinformed by previous ads."

Eckhardt agreed that an investigation is warranted. "Should the disconnect between the scientific evidence and advertising be explored?" she said. "Absolutely."

Any investigation should include outside experts. "For any investigation, there should be neutral parties involved that are familiar with the medical evidence and without conflicts of interest," Eckhardt said to The Cancer Letter.

Fran Visco, president of the National Breast Cancer Coalition, said FDA owes an answer to American women.

"I would prefer for it to be done in a non-political way, but if the investigation of what happened at the FDA is not a transparent process that involves the outside community and the patient advocacy community, then I think there should be Congressional oversight of this," Visco said in an interview. "They have to assure the public, the patients that they are acting in the best interest of patients and not in self-interest."

The examination shouldn't be limited to the FDA, Visco said. "It's just not about this particular drug or this particular class of drugs," she said. "They need to look more broadly, at the whole process, everything that allowed it to get to this point. Why did the FDA step in now? Did something specific happen that precipitated their deciding to look at this? There have been indications of this for a long time. Why didn't this happen a long time ago?

"The FDA needs to be investigated, but I think the medical community needs to also. We just can't afford to allow anything like this to happen again."

A lot can be learned from an investigation of the ESA advertising campaign, said Robert Erwin, president of the Marti Nelson Foundation.

"Aggressive advertising of pharmaceutical products may exacerbate safety issues by driving consumer demand for the products beyond medical necessity," Erwin said in an interview. "Even though some of the worst ESA ads are no longer running, I think understanding what the FDA did, or did not do, with respect to these particular ads can help strengthen rules to insure that similar mistakes are not made in the future.

"I think there must be an investigation of what went wrong at FDA that allowed these products to be overprescribed and improperly advertised," Erwin said. "This investigation should not be behind closed doors, and preferably patient advocates would be at the table. If it is not possible or appropriate for FDA to conduct this investigation of itself, then it may be necessary to seek help from Congress."

Johnson & Johnson started its direct to consumer ads for Procrit in 1998 and stopped them in July 2005. The ad campaign ended "for no other reason than making different choices with our marketing effort," said Stephanie Fagan, a spokesman for Ortho Biotech, a unit of J&J.

"Ortho Biotech has had ongoing dialogue with the FDA about our direct-to-consumer television advertising at the time it was running," Fagan said. "At times, the FDA did provide feedback, and the company believes it consistently addressed their comments to the agency's satisfaction."

"Amgen has never done broadcast radio or TV DTC for Aranesp," said Trish Hawkins, an Amgen spokesman.

However, the company sponsors direct to consumer ads for Neulasta, a white blood cell growth factor. These ads have educational value, Hawkins said. "While many cancer patients know about the more 'visible' side effects of chemotherapy like nausea, fatigue, and hair loss, few are aware that chemotherapy puts them at a higher risk for serious infections."

Neulasta and another drug, Neupogen, are sold to oncologists in a "bundle" with Aranesp. Under these contracts, oncology practices have to meet sales targets to qualify for the most lucrative rebates from the company.

"It's disingenuous of Amgen to say that it's not doing direct to consumer marketing of Aranesp," Brawley said in an interview. "The company uses direct to consumer ads to sell the patient on Neulasta, then uses the bundling contract to incentivize oncologists to push Aranesp. In a bundle, it doesn't matter which product you push and how you push it. It's all the same pile of cash."

CMS Proposal Restricting ESA Use Is Too Much, Too Fast, Critics Say

By Paul Goldberg

The Centers for Medicare and Medicaid Services proposes restricting the erythropoiesis stimulating agents beyond the levels recommended by ODAC.

The agency's proposed National Coverage Decision would require that no ESAs are prescribed to patients whose hemoglobin levels are above 9 g/dL. Patients with documented symptomatic ischemic disease that cannot be treated with blood transfusion would be able to start treatment at hemoglobin of less that 10 g/dL

Now, physicians can prescribe ESAs to patients whose hemoglobin drops below 12 g/dL.

ODAC concurred that lowering the threshold would be reasonable, but didn't propose a lower level. This change alone—if it becomes policy—would cut billions of dollars from the government's spending on ESAs. The companies are in a position to estimate the decrease, but are declining to do so. (Amgen officials didn't respond to this question even when asked directly by an ODAC member.)

Maximum covered treatment duration would be 12 weeks per year.

CMS said that its decision is based in part on the literature that points to existence of EPO receptors on some tumors. ODAC concurred with FDA that some diseases may respond to ESAs differently from others, but the committee made no attempt to resolve the scientific controversy over EPO receptors.

The CMS proposal to cut reimbursement for some hematologic malignancies also isn't based on any ODAC recommendation. The committee was told in testimony at the public hearing that reimbursement for MDS was becoming a problem, but wasn't asked to make any recommendations on the subject.

"These are really different situations, and they really need a supplemental NDA for the indication, and the sponsor really should work with us and with these groups to bring in these data and have a supplemental

indication on the books," FDA's Pazdur said at the ODAC meeting. "They are much different from the situation that we are talking about with general anemia of cancer, which we are usually talking about solid tumors."

These differences notwithstanding, CMS officials emphasized that they were working with FDA.

The process of reassessment of payments was initiated in response to FDA's decision to place a black box warning on the ESAs in March. Subsequently, the agency made it easier for its contractors to cut payment for using ESAs for anemia of cancer. The agency's National Coverage Analysis on the use of ESAs for conditions other than end-stage renal disease was started on March 14.

The public comment period on the proposed change is open until June 13. The final decision would be made no later than 60 days after the conclusion of the public comment period.

"We pay close attention to FDA black box warnings because the safety of our Medicare beneficiaries is paramount," said CMS Acting Administrator Leslie Norwalk said in a statement. "We have carefully examined the evidence surrounding these labeling changes and have issued this proposed decision to protect our beneficiaries."

"Because there is a preponderance of emerging data for ESA use in the oncology setting, we have narrowed the focus of the national coverage analysis to ESA use in cancer and related neoplastic conditions," Barry Straube, CMS chief medical officer and director of the Office of Clinical Standards and Quality, said in a statement. "Medicare beneficiaries with cancer and renal disease are among our most vulnerable patients, and we are dedicated to ensuring that they are receiving appropriate care."

The CMS proposal reaches beyond the ODAC recommendations, Eckhardt said.

"I was shocked to see how the CMS restrictions go way beyond the scientific evidence that indicates what's actually proven beneficial or non-beneficial. That's a huge list.

"I am concerned because of the collateral damage to the indications such as MDS that are not yet on the label and justified," Eckhardt said. "Clearly, a supplemental NDA needs to be filed. However, it hasn't been done yet, and yet CMS has clamped down."

Eckhardt said the CMS decision to base its actions on the hypothesis that response to EPO is regulated by EPO receptors is premature. "There is a huge amount of conflicting science on that issue, so I don't think that anybody can say definitively one way or the other, certainly not at ODAC."

In a statement, the American Society of Clinical Oncology said that CMS "has moved prematurely."

"Although CMS cites national practice guidelines, they do so selectively, ignoring language that is not supportive of their proposed policy," ASCO wrote. "ASCO is deeply concerned that this proposal would set a dangerous precedent in which evidence-based standards of high quality care are ignored in setting national policy. Implementation of these provisions has the potential to introduce serious harm to the many cancer patients who rely on ESAs in the course of receiving treatment for their disease. CMS should not be making scientific judgments about the appropriate use of ESAs prior to FDA decisions on the same issues."

The text of the proposed NCD is posted at: http://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=203.

In the Cancer Centers:

Iris Cantor Endows Chair In Digestive Cancer At MSKCC

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Kristin Kilbourn, research associate professor in the Department of Psychology; University of California, Davis, **Frederick Meyers**, professor and chairman of internal medicine; Mount Sinai School of Medicine, **Judith Nelson**, associate professor of medicine/pulmonary and critical care; Harvard Medical School, **Joanne Wolfe**, staff physician in the Department of Pediatric Oncology at the Dana-Farber Cancer Institute/Children's Hospital Boston; Brown University School of Medicine, **Joan Teno**, professor of community health and medicine and associate director of the Center for Gerontology and Health Care Research. NPCRC Junior Faculty Career Development Award recipients include: Duke University Medical Center, **Kimberly Johnson**, assistant professor of medicine, Division of Geriatrics; Harvard Medical School; and **Christina Ullrich**, fellow in Pediatric Palliative Care at the Dana-Farber Cancer Institute/Children's Hospital. . . . **IRIS CANTOR**, chairman and president of the Iris and B. Gerald Cantor Foundation, has committed $2.5 million to Memorial Sloan-Kettering Cancer Center to create an endowed chair for a senior researcher in the field of digestive cancers. The Iris Cantor Chair will be endowed in perpetuity in honor of **Sidney Winawer**, former chief of

the Gastroenterology and Nutrition Service at Memorial Sloan-Kettering and an internationally recognized leader in the prevention of digestive cancers. Winawer is credited with establishing national guidelines for colorectal screening in the U.S. The chair will be held by a distinguished translational researcher with a proven track record of bringing discoveries from the laboratory to the treatment of patients. . . . **VIRGINIA COMMONWEALTH UNIVERSITY** Massey Cancer Center received a five-year, $10.7 million grant from NCI to research safer radiation therapy administration for aggressive cancers. The NCI Project Program Grant, Image Guided Adaptive Radiation Therapy, was awarded to **Jeffrey Williamson**, professor of radiation oncology and chairman of the Division of Medical Physics. Other investigators include faculty members **Jeffrey Siebers**, **Martin Murphy**, and **Nesrin Dogan**, as well as **Paul Keall**, adjunct professor at VCU who is also director of radiation oncology physics at Stanford University.

In Brief:

ONS Board Takes Office

ONCOLOGY NURSING SOCIETY announced the 2007–2008 board of directors at its 32nd Annual Congress in Las Vegas. **Georgia Decker**, nurse practitioner at Integrative Care and the Braverman-Panza Medical Group in Albany, continues in her second year as president. **Brenda Nevidjon** is president-elect. She is a clinical professor and chairman of the master's program in the School of Nursing at Duke University. The board secretary is **Amy Tranin**, medical science liaison for Cephalon Oncology. Newly elected ONS directors-at-large are **Barbara Gobel**, oncology clinical nurse specialist at Northwestern Memorial Hospital, Chicago, and **Joanne Itano**, associate professor of nursing and director of academic planning and policy at the University of Hawaii. Continuing as treasurer is **Gay Bailey**, director of nursing and ambulatory services at Memorial Sloan-Kettering Cancer Center. Board-appointed member **John Poister**, director of coverage and content at WPXI-TV in Pittsburgh, is continuing his two-year term. ONS directors-at-large continuing their three-year terms are **Lisa Schulmeister**, oncology nursing consultant in River Ridge, LA; **Bertha Ford**, clinical oncology specialist with Genentech BioOncology; **Ellyn Matthews**, assistant professor in the School of Nursing at the University of Colorado Health Sciences Center, Denver; and **Peg Esper**, nurse practitioner in medical oncology at the University of Michigan Comprehensive Cancer Center, Ann Arbor. Also at the Las Vegas congress, Oncology Nursing Certification Corp., an affiliated organization of ONS that administers and evaluates programs for certification in oncology nursing, presented three awards. **Michele Gaguski** was chosen Advanced Oncology Certified Nurse of the Year for her contributions to oncology nursing and oncology nursing service, education, and for supporting and promoting certification in oncology nursing. She is oncology clinical nurse specialist at Ocean Medical Center in Brick, N.J. **Kimberly George** was chosen OCN of the Year for contributions to oncology nursing and oncology nursing service, and for supporting and promoting certification in oncology nursing. She is oncology coordinator at United Regional Health Care System in Wichita Falls, TX. Hartford Hospital, of Hartford, Conn., received the Employer Recognition Award for sustained support of oncology nursing certification. . . . **NATIONAL COALITION for Cancer Survivorship** honored individuals in fashion and the arts at its Rays of Hope Awards Gala May 2 in Washington, D.C. The awardees included **Ann Hand**, jewelry designer, who received the Special Recognition Award for her philanthropic work; **Patti Balwanz**, **Kim Carlos**, **Jennifer Johnson** and **Jana Peters**, authors of the book "Nordie's at Noon," who were awarded the Natalie Davis Spingarn Writer's Award; **Carmen Marc Valvo**, fashion designer, who accepted the President's Award for fundraising as an Entertainment Industry Foundation Ambassador; **Pamela Bailey**, president and CEO of the Cosmetic, Toiletry, and Fragrance Association, who received the Private Sector Leadership Award; and **Daniel Lalonde**, president and CEO of Louis Vuitton North American, who accepted the Lilly Tartikoff Hope Award for raising research funds through the Louis Vuitton United Cancer Front Gala. The awards were presented by **Elizabeth Edwards**, **Alma Powell**, **Sen. Tom Harkin**, **Patrick Dempsey**, **Julia Rowland**, and **Lilly Tartikoff**.

Funding Opportunities:

RFA-TW-08-001: Framework Programs for Global Health. R25. Letters of Intent Receipt Date: Aug. 20; Application Submission/Receipt Date: Sept. 20. Full text: http://www.grants.nih.gov/grants/guide/rfa-files/RFA-TW-08-001.html. Inquiries: Flora Katz, 301-402-9591; katzf@mail.nih.gov.

NOT-NS-07-009: Announcement of the US-JAPAN Brain Research Cooperative Program-U.S. Component. Receipt date: Sept. 15, 2007, 2008, 2009. Full text: http://www.grants.nih.gov/grants/guide/notice-files/NOT-NS-07-009.html. Inquiries: Roy Wu, 301-496-8866; wur@mail.nih.gov.

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