THE CANCER LETTER

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House Committee Investigates ESA Safety, Urges Amgen, J&J, To Stop Promotions

By Paul Goldberg

The Democratic leadership of the House Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations began an investigation of the safety of erythropoiesis stimulating agents and their promotion by drug companies.

In letters addressed to the top executives of Amgen Inc. and competitor Johnson & Johnson, Rep. John Dingell (D-Mich.), chairman of the full committee, and Bart Stupak (D-Mich.), chairman of the subcommittee, urge the companies to discontinue incentives to physicians to prescribe ESAs to their patients.

The letters, dated March 20, also present a series of questions to the companies and instruct them to preserve records related to ESA products.

Dingell and Stupak sent no official communication to FDA, apparently

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In the Cancer Centers:

Fox Chase Board Selects Michael Seiden As New President, Succeeding Robert Young

MICHAEL SEIDEN was selected president and chief executive officer of Fox Chase Cancer Center effective June 1, board chairman **William Avery** announced March 22. Seiden leads the gynecologic cancer program at Dana-Farber/Harvard Cancer Center and is chief of the clinical research unit in Massachusetts General Hospital's Division of Cancer Medicine.

Seiden will succeed **Robert Young** as head of the NCI-designated comprehensive cancer center, which treats about 6,500 new patients a year and employs more than 2,500 people. Last fall, Young announced his intention to step down after serving 18 years as Fox Chase president. The board elected Seiden following a national search.

Seiden is principal investigator for the ovarian cancer tumor biology laboratory at Massachusetts General and co-principal investigator of DF/HCC's NCI grant for a Specialized Program of Research Excellence in ovarian cancer. His laboratory has also begun studies to identify and characterize the ovarian-cancer stem cell through the SPORE and support through the Harvard Stem Cell Institute at Harvard Medical School.

Born in Queens, N.Y., Seiden received his undergraduate degree magna cum laude at Oberlin College in 1980. In 1986, he simultaneously earned his M.D. and Ph.D. through the Medical Science Training Program

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Oversight Committee Seeks Information On ESA Promotion

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refraining from influencing the May 10 meeting of the Oncologic Drugs Advisory Committee, which was announced after The Cancer Letter reported that Amgen had failed to publicly disclose negative results of a Danish study of Aranesp in head and neck cancer (The Cancer Letter, Feb. 16).

The report of the Danish study also triggered an informal inquiry into Amgen's conduct by the Securities and Exchange Commission (The Cancer Letter, March 2). Amgen officials initially said that that they were under no obligation to disclose results of studies by cooperative groups, but ultimately the company top executive Kevin Sharer acknowledged that failure to disclose the result was a "miss."

On March 9, FDA placed a "black box" warning on the ESAs, and, citing multiple studies, suggested that physicians dramatically lower the doses of these agents (The Cancer Letter, March 16).

In a statement that accompanied the release of the letters, Dingell praised the agency's response.

"The FDA acted properly to demand a black label warning on these EPO products and to convene an advisory committee to determine the safety of these anemia drugs," Dingell said. "[ESA] products are being prescribed off-label with the result being increased deaths, tumor growth and blood clots, and we are very concerned that direct-to-consumer advertising may be driving the improper use of these drugs."

The letters give notice to all participants in the ESA controversy that Oversight and Investigations intends to monitor these events and collect information that could lead to a more intensive look.

Dingell and Stupak ask Amgen and Johnson & Johnson disclose when they learned about suspensions of any ESA clinical trials that may have been halted out of concern for the study participants.

"Hundreds of millions of dollars are spent by patients each year on off-label uses of EPO drugs that actually increase the risk of premature death," Stupak said in a statement. "Patients are placed in danger when drug company advertising and incentives to physicians highlight the benefits but not the deadly risks associated with EPO drugs."

The market for EPO agents in oncology was created largely by direct to consumer ads placed by J&J for its agent Procrit, which the company licenses from Amgen.

"We request that you cease all direct to consumer advertising and physician incentives until ODAC has met and FDA has had time to determine what, if any, additional measures need to be taken to protect the public from unnecessary risks to human life from these products," the Dingell and Stupak letter states.

Targets of the investigation appear to include the practice of "bundling" of products, which has elevated Amgen to the dominant role in the ESA market in the U.S.

Spokesmen for the two companies said they are not using direct to consumer ads to promote ESAs. "We have not run DTC advertising since 2005," said Stephanie Fagan, a spokesman for Ortho Biotech, a unit of J&J. "When we did run consumer advertising, our ads did not promote off-label uses and were consistent with the product label at the time the claims were made."

Amgen spokesman David Polk said his company has never used direct to consumer ads to promote Aranesp.

The question of incentives to physicians to use ESAs leaves room for interpretation.

Aranesp is marketed in conjunction with the white blood cell growth factors Neupogen and Neulasta. In this bundle pricing schema, Amgen rewards the practices that sell greater amounts of Aranesp with discounts on Neupogen and Neulasta, products that aren't available from other sources.

"Discounting is a very standard practice in industry," Amgen's Polk said. "Amgen doesn't give financial incentives to physicians in order to increase

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their prescriptions of any of our products. We comply with all the laws and regulations and industry codes regarding interaction with healthcare professionals."

J&J, too, provides discounts to physicians who use their products, Fagan said. "We do not provide financial incentives for physicians to prescribe our products, including Procrit," she said. "Consistent with industry practice, we do provide discounts that comply with federal government regulations."

However, J&J is suing Amgen, claiming that its bundling practice violates antitrust laws. Also, J&J is petitioning CMS to change reimbursement for bundled products.

The Congressional letters to the two companies are nearly identical. The text of the letter to Amgen follows:

Pursuant to 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 conducting an inquiry into the ability of the Food and Drug Administration to protect the American public from excessive risks associated with prescription drugs. As part of that inquiry we note with increasing alarm reports indicating the Erythropoiesis-Stimulating Agents (ESAs), commonly known as EPO products, when used at higher than recommended doses, appear to cause increases in blood clots, grow tumors and are associated with significantly higher mortality rates than placebos.

Amgen markets these agents under the trade names Aranesp and Epogen to treat chemotherapy-related anemia in cancer patients and anemia in patients with chronic renal failure. By some estimates, perhaps as much as $700 million in annual sales of EPO products comes from uses that do not conform to the label. Appropriately, FDA has announced that it will convene on May 10, 2007, an Oncology Drugs Advisory Committee (ODAC) to consider overall safety of these products.

Amgen has agreed at the behest of the FDA to place black box warnings on the packaging indicating the severe consequences of off-label use. There has been, however, no indication that Amgen will forego its direct to consumer advertising which drives off-label uses of prescription drugs. Nor has there been any public announcement of a cessation of financial incentives to physicians to increase the prescription of Aranesp or Epogen to their patients.

Accordingly, we request that you cease all direct to consumer advertising and physician incentives until the ODAC has met and FDA has had time to determine what, if any, additional measures need be taken to protect the public from unnecessary risks to human life from these products.

We further request that you preserve all records relating to the promotion of these products from October 1, 2006, forward. We also request that you preserve the records relating to all communications with the FDA since last September, including, but not limited to, any internal documents that discuss such communications or proposed communications. The words "records" and "relating to" are defined in the attachment to this letter.

Finally, we ask that you supply us with answers to these specific questions (and preserve all records relating to the answers):

1. When did Amgen or any of its employees or consultants learn of the suspension of any EPO study (Phase II-IV) that was halted out of concern for the subjects in the study?

2. When did Amgen notify the FDA of such suspensions and who in the Agency was notified?

3. Please describe all discussions Amgen has had with the FDA or the Department of Health and Human Services (HHS) regarding direct to consumer advertising of Aranesp or Epogen since advising the Agency of any of the adverse events that are cautioned against in the black box warning announced last week.

4. Please describe all promotions that Amgen undertakes that have the effect of relating the prescription of EPO products to the income of physicians or their practices.

Please provide your response by close of business, two weeks from the date of this letter.

Capitol Hill:

NIH Director Urges Lifting Ban On Embryonic Stem Cell Work

By Kirsten Boyd Goldberg

NIH Director Elias Zerhouni said federal restrictions on use of government funds to conduct research on embryonic stem cells should be lifted so that U.S. scientists can remain competitive.

"It is clear today that American science will be better served, and the nation will be better served, if we let our scientists have access to more cell lines," Zerhouni said at a March 19 hearing of the Senate Labor, HHS, Education Appropriations Subcommittee, in response to questioning by Sen. Tom Harkin (D-IA), the subcommittee chairman.

Federal funds can be used to study only certain cell

lines that were available in 2001, but they are of poor quality and it's unlikely that any of them would be used for human interventions, Harkin said.

"We now know that there are much better ways of deriving and growing stem cells than we knew in 2001," Harkin said in his question to Zerhouni. "However, the lines derived from these new methods are not eligible for federal funding…. [W]ould scientists have a better chance of finding these new cures, new interventions for diseases, if the current restrictions on embryonic stem cell research were lifted?"

ZERHOUNI: "I think the answer is yes. My experience has been this: In 2001, the policy that was put in place was the first one to fund embryonic stem cell research. I think NIH has done a great job in the first three years of that in establishing infrastructure, funding new scientists which weren't fundable before. Since 2004, I think it's very clear from the point of view of science and what I have overseen, that these cell lines will not be sufficient to do all the research we need to do, for the reasons that you mentioned, but the most important one is that these cell lines have exhibited instability from the genetic standpoint, and it's not possible for me to see how we could continue the momentum of science in stem cell research with the cell lines that we have currently at NIH that can be funded. So, from my standpoint, it is clear today that American science will be better served, and the nation will be better served, if we let our scientists have access to more cell lines that they can study with the different methods that have emerged since 2001, the different strategies that we now understand, underlie the fundamental issue which is nuclear programming, DNA programming, or reprogramming. So the answer is yes."

HARKIN: "Dr. Zerhouni, let me ask you to comment on two things, then. One is, what we are hearing a lot in the popular press, not the scientific journals, that we don't have to do this, that adult stem cells can take care of it all. Then we have amniotic stem cells and we have umbilical cord stem cells, and we don't need embryonic stem cells…. Secondly, just on the issue of stem cell research itself, why is it so important that NIH do this? Already, California is doing it, Missouri just passed a constitutional amendment on it. Iowa, my own state, the legislature just voted and the governor signed into law lifting the ban. Wisconsin, of course. People say if the states are doing it, there's no reason for NIH to. So, why is it important for NIH and what about all these other stem cells?"

ZERHOUNI: "Let me give you my point of view and the scientific point of view. Again, my statement, as I made five years ago, is that I will always stick to the scientific truth and disease knows no politics. The presentations about adult stem cells having as much or more potential than embryonic stem cells, in my view, do not hold scientific water, if you will. I think they are overstated. I think we do not know at this point where the breakthroughs will come from. I think scientists who work in adult stem cells themselves will tell you we need to pursue as vigorously embryonic stem cells.

"My point of view is that all angles in stem cell research should be pursued. I think people sometimes misunderstand what the fundamental challenge is in stem cell research. It's not solely to use it to replace things like in adult stem cell transplantation. It's to really understand, for the first time in the history of mankind, how DNA is programmed and reprogrammed. To do that, you need to have copies of cells that have been programmed, adult stem cells, but also copies of cells that have never been programmed, embryonic stem cells. The key thing here is that the nation that understands that will be in a stronger position, as we were in the 20th century for the information revolution, for computers. It's basically the software of life we are talking about. So from my standpoint as NIH director, it is in the best interests of our scientists, our science, our country, that we find ways, that the nation finds a way, to allow this science to go full speed across adult and embryonic stem cells equally.

"Why is it important for NIH? As NIH director, I can tell you that the role NIH has played in this country over the years has been second to none. There is no state that can really provide the depth and oversight, and stimulation of this research over the long run. This is not a one-mile race; this may be a marathon, and it is important, I think, for NIH to play a historical role. I think that we have done that.

"We can do this with appropriate oversight, with a lot of safeguards to make sure that this research is not misused—ethical guidelines. You know, Senator, we have done this with the Recombinant Advisory Committee in 1976, '77, '78. At that time, as you know, genetic engineering came on the scene. There was a huge question about both the safety and the ethics of using genetic engineering. NIH took the lead and set up a committee called the Recombinant Advisory Committee.

"We have been probably the most successful country in biotechnology. We have created a completely new industry, and I think this is the kind of role NIH could play. If you have a patchwork of policies, a patchwork of approaches, you may not have the same

standards. It will be very difficult for our country to muster its strength unless we have some move forward in this area. We cannot be second-best in this area. I think it is important for us not to fight with one hand tied behind our back here. "

HARKIN: "California is in a bidding war to get scientists to come there…. It seems to me that by providing NIH with this authority… I think it would reduce this bidding war between states. NIH could reach out to other countries also."

ZERHOUNI: "My view is that I think it's time to move forward in this area. It's time for the nation's policymakers to find common ground to make sure that NIH does not lose its historical leadership. I think we maintained that leadership through 2004-2005, but as we discovered, the lines that we have are less viable than we would have liked them to be, because these lines are older. I think it's important to realize that we need to move forward here and NIH needs to continue its historical role as the leader of biomedical research in the world. To sideline NIH on such an issue of importance, in my view, is shortsighted. I think it would serve the nation well in the long run. We need to find a way to move forward. Obviously, there is more than science that is involved here, but I hope that we can find that, soon."

HARKIN: "Dr. Zerhouni, let me thank you for that very profound and courageous statement that you made here today."

Funding: "We Will Not Allow Those Cuts"

Harkin and ranking subcommittee member Arlen Specter (R-Pa.) said they would work to increase NIH funding and avoid the $529 million cut in the institutes' $29 billion budget as proposed by President Bush (The Cancer Letter, Feb. 9). They have introduced an amendment that would increase funding for health-related programs by $2.2 billion over the proposed budget resolution.

NIH funding has failed to keep pace with inflation for four consecutive years, since its budget was doubled between 1999-2003, Harkin said. "That cut threatens to squander our nation's investment in biomedical research, delay new cures and treatments, and discourage the next generation of young investigators from entering the field," Harkin said. "We will not allow those cuts to take place."

"It is simply unacceptable to have a $500-million plus cut in NIH funding as proposed by the administration this year," Specter said. "When you have a federal budget of $2.9 trillion… to have an allocation of less than $30 billion [for NIH], candidly, is scandalous."

Specter said political pressure could change the budget outlook for NIH. "You have two strong allies in Sen. Harkin and myself, Dr. Zerhouni, and you have the potential to have 533 more if there is sufficient political pressure brought to bear on Washington, D.C.," he said.

"I've talked about a million-person march on the Mall—a million people could be heard from the living quarters of the White House," Specter said. "Attitudes are changed in Washington with political pressure, and with 110 million people affected directly or indirectly, that group of public opinion could write its own ticket. Sen. Harkin and I want to be the scriveners."

NIH has historically funded about 30 percent of the grant applications submitted by scientists, but in recent years, that "success rate" has fallen to about 20 percent, Zerhouni said. However, the number of scientists who want to do research has doubled. To maintain the success rate at 20 percent for the past two years, NIH has favored investigator-initiated research at the expense of clinical trials, he said.

"We are giving up the ability to do clinical trials," Zerhouni said.

Advocates for biomedical science are seeking a 6.7 percent increase for NIH, or about $1.9 billion. For that increase, NIH could sustain research and "recover our ability to fund clinical trials," Zerhouni said.

Also testifying at the hearing were scientists representing a consortium that is seeking increased funding for NIH. Cancer researcher Joan Brugge, chairman of the Department of Cell Biology at Harvard Medical School, said four years of flat funding is damaging the research capacity in the U.S.

Brugge said that while the overall success rate for grant funding is 20 percent, the success rate for a new investigator submitting his or her first grant is about 5 percent in the first round. Zerhouni said that figure was correct.

Also, only 10 percent of investigators secure renewal funding on their first round, meaning that 90 percent of investigators then need to resubmit their grants and become consumed with securing funding rather than working on their science. Grants also are cut by 20 to 30 percent, she said.

"Young scientists are looking elsewhere," Brugge said. "We can't afford to stand still, because the demographics are against us…. There is going to be a virtual tsunami of cancer. Investment now could have profound savings later."

FDA News:

FDA Tightens Eligibility For Advisory Committees

FDA announced new draft guidance March 21 that would implement a more stringent approach for considering potential conflicts of interest for its advisory committee members and for recommending eligibility for meeting participation.

The agency is accepting public comments on the proposal for the next 60 days.

"FDA is committed to making the advisory committee process more rigorous and transparent so that the public has confidence in the integrity of the recommendations made by its advisory committees," said Randall Lutter, FDA acting deputy commissioner for policy. "Today's draft guidance document should provide more consistency in the consideration of who is eligible to participate in advisory committee meetings and would simplify the process."

FDA currently screens all prospective advisory committee participants before each meeting to determine whether the potential for a financial conflict of interest exists. Under law, FDA may grant a waiver when certain criteria are met, such as when the need for an individual's expertise outweighs the potential for a conflict of interest.

The draft guidance document would replace guidance issued in 2000 on FDA Waiver Criteria, www.fda.gov/oc/advisory/conflictofinterest/intro.html. Because of its complexity, FDA officials said they found it difficult to achieve consistent results that the public could readily understand.

The new guidance, www.fda.gov/oc/advisory/waiver/coiguidedft.html, would reduce the likelihood that the process for recommending waivers would vary from meeting to meeting, FDA officials said.

In addition to a more streamlined approach for considering who may participate in meetings, FDA would tighten its policy for considering eligibility for participation.

If an individual has disqualifying financial interests whose combined value exceeds $50,000, after applying certain exemptions, the person would generally not be considered for participation in the meeting, regardless of the need for his or her expertise.

If the financial interests are $50,000 or less, after applying certain exemptions, the individual might be recommended to participate as a non-voting member.

Only individuals with no potential conflicts would be eligible to fully participate in meetings as voting members, the agency said.

Financial interest means the potential for gain or loss to a person (or their family and outside affiliations) as a result of the government's action on a particular topic. Financial interests screened include, but are not limited to, stock ownership, related research and consulting arrangements.

To submit electronic comments on the draft guidance, see www.fda.gov/dockets/ecomments. Written comments may be sent to: Division of Dockets Management (HFA-305), U.S. Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD, 20852. Comments must include the docket number 2007D-0101.

FDA said it also has opened a Web page dedicated to improving recruitment of advisory committee members and enhancing public participation in the process: www.fda.gov/oc/advisory/.

Professional Societies:

Shortage Of Oncologists Projected By ASCO Study

A study commissioned by the American Society of Clinical Oncology projects a significant shortage of medical and gynecologic oncologists in the U.S. by 2020.

The study found that an aging and growing population, increasing numbers of cancer survivors, and slower growth in the supply of oncologists will result in a shortage of 2,550 to 4,080 oncologists by 2020. At that time, the total supply of oncologists is projected to be roughly 12,500.

The study conducted for ASCO by the Association of American Medical Colleges' Center for Workforce Studies is a comprehensive analysis of future supply and demand for oncologist services.

ASCO formed a special working group to develop recommendations to address the projected shortfall, and expects to issue the recommendations later this year.

"The last several decades have been a time of extraordinary progress in cancer research and patient care," said Michael Goldstein, chairman of the ASCO Workforce in Oncology Task Force and an oncologist at Beth Israel Deaconess Medical Center in Boston. "But unless we address the coming shortage of oncologists now, we will face a major challenge in ensuring that all patients receive high-quality care, and benefit from recent advances."

It is estimated that nearly 1.4 million people in the

U.S. will be diagnosed with cancer this year, and more than 560,000 will die of the disease.

The study projects a significant increase in patients who will require oncologist services by 2020. The study draws upon NCI analyses of Medicare data to estimate future demand and utilization of oncologist services. The incidence of cancer rises rapidly with age, especially after the age of 65. The projected rise in demand is driven by the doubling of the number of Americans over age 65, as well as growth in the number of cancer survivors due to improvements in screening and treatment. The study predicts a 48 percent increase in cancer incidence and an 81 percent increase in people living with or surviving cancer between 2000 and 2020.

At the same time, the supply of oncologists available to provide services is not expected to increase fast enough to meet this additional demand. This limited growth is due to the disproportionate number of oncologists near retirement today and the limited number of oncology fellowship training slots.

As a result, while visits to oncologists are expected to increase by 48 percent by 2020, the number of visits provided by the projected supply of oncologists is expected to rise by only 14 percent, leaving a shortfall of 9.4 to 15.1 million visits.

"This study uses the most current information on the supply, use and demand for oncologist services, said Edward Salsberg, director of the AAMC Center for Workforce Studies. "While there are many uncertainties in forecasting supply and demand more than 10 years out, almost all future scenarios that we evaluated indicate a significant shortage of oncologists is likely."

The study drew from both original and existing data. AAMC Center for Workforce Studies and ASCO surveyed oncology fellows, oncology fellowship program directors, and 4,000 practicing oncologists from across the country about current practice activities, work hours, visit rates, practice setting, use of nurse practitioners and physician assistants, and options for addressing future workforce shortages. Survey respondents were also asked for their views on potential ways to address the shortage and focused on a number of strategies to increase the efficiency of oncologists' practices, including: the reduction of paperwork, increased use of electronic medical records, and increased use of nurse practitioners and physician assistants.

The study, "Future Supply and Demand for Oncologists: Challenges to Assuring Access to Oncology Services," was published online in ASCO's Journal of Oncology Practice and is available at www.asco.org/workforce.

In the Cancer Centers:

Swain Named Medical Director, Washington Cancer Institute

(Continued from page 1)

in Immunology at Washington University in St. Louis. Seiden completed his internship and residency in medicine at Massachusetts General, serving as chief resident in 1991.

He was a fellow in medicine at Harvard, held a three-year clinical fellowship in medical oncology at Dana-Farber, and completed a one-year bone-marrow transplant fellowship there. He completed a postdoctoral fellowship in molecular pathology at Harvard's Brigham and Women's Hospital. Seiden joined the Harvard medical faculty as an instructor in 1991 and became an assistant professor in 1994 before becoming associate professor in 2003.

* * *

SANDRA SWAIN was appointed medical director of the cancer program at the Washington Cancer Institute, Washington Hospital Center. Swain, an inflammatory breast cancer researcher, was head of the Breast Cancer Section, Medical Oncology Branch, and chief of the Cancer Therapeutic Branch in the NCI Center for Cancer Research. She also is professor of medicine at the Uniformed Services University of Health Sciences in Bethesda. Swain serves as vice chairman of the breast committee of the National Surgical Adjuvant Breast and Bowel Project. An investigator in more than 20 breast cancer trials, she recently led the intramural clinical breast cancer clinical research effort at the NCI Center for Cancer Research. She also serves as chairman of the education committee of the American Society of Clinical Oncology. She succeeds **Lawrence Lessin**, who had been medical director since 1992. WCI received 3,000 new patients and 80,000 patient visits last year. . . . **WEBSTER CAVENEE** was awarded the Albert Szent-Györgyi Prize for Progress in Cancer Research by the National Foundation for Cancer Research. Cavanee, director of the Ludwig Institute for Cancer Research and professor of medicine at the Moores Cancer Center at University of California, San Diego, is known for his research in tumor suppressor genes. . . . **THOMAS BROWN** was named chief operating officer for the Arizona Cancer Center and appointed professor in the College of Medicine, said **David Alberts**, director of the Arizona Cancer Center. He was professor of gastrointestinal medical oncology at M.D. Anderson Cancer Center, where he also served as vice president from 2001 to 2005. . . . **CARL MORRISON**

was appointed director of the Division of Molecular Pathology, Department of Pathology and Laboratory Medicine at Roswell Park Cancer Institute. Morrison also will direct the Pathology Resource Network, which includes the Tissue Procurement Service, Tissue Archives Service and Pathology Core. He was director of Pathology Core Facility, and principal investigator for Cooperative Human Tissue Network at Ohio State.

In Brief:

ONS Receives Contributions For Endowment Campaign

ONCOLOGY NURSING SOCIETY FOUNDATION received $1.5 million from Amgen, $1 million from GlaxoSmithKline, and $1 million from Sanofi Aventis for the future development of oncology nursing. The contributions were made to the foundation's Silver Anniversary endowment campaign emphasizing its 25 years of funding nursing research, education, and leadership programs in oncology nursing, said **Kevin Sowers**, president of the ONS Foundation. . . . **TURNER & GOSS LLP**, a new law firm representing non-profit organizations in health care and public policy matters, has been formed by **Sam Turner** and **Elizabeth Goss**, both formerly of Ropes & Gray. Recent clients have included the American Society of Clinical Oncology, the National Coalition for Cancer Survivorship, the Leukemia & Lymphoma Society, the Lymphoma Research Foundation, the North American Brain Tumor Coalition, the Cystic Fibrosis Foundation, and the Cancer Leadership Council. The firm is located in Washington, D.C. . . . **LOUIS MUNOZ** was named 2007 president of the American College of Radiation Oncology. He is medical director of the Division of Radiation Oncology and chairman of the radiation research committee within Texas Oncology, a member of the US Oncology network. His sub-specialty is pediatric radiation oncology and adult radiation oncology. He served as ACRO president-elect in 2006. . . . **AMERICAN SOCIETY** for Therapeutic Radiology and Oncology hired two analysts for its government relations and research departments. **Richard Martin** was named legislative and regulatory analyst, and **Anil Vaish** was named research health analyst. Martin was editor and writer for labor and tax law publications at BNA Inc. He will work on radiation oncology regulations and legislation. Vaish was breast cancer research coordinator at George Washington University Medical Center in Washington. He will work on the research and grant awards program.

Funding Opportunities:

NIH Offers New Investigators Grants For Innovative Projects

NIH has begun a program to fund new investigators who propose highly innovative research projects in biomedical or behavioral science.

The NIH Director's New Innovator Award offers grants of up to $1.5 million in direct costs over five years.

"New investigators are the future of science, and innovative ideas are its lifeblood," NIH Director Elias Zerhouni said. "This flagship program underscores NIH's commitment to supporting these two critical elements of the research enterprise. The New Innovator Award, funded through the NIH Roadmap Common Fund, complements longstanding activities in both areas at the NIH level and at its institutes and centers."

The application period opens on April 25 and closes on May 22. NIH expects to make at least 14 awards in September

New investigators who have not yet obtained an NIH R01 or similar grant are eligible to apply. Applicants must hold an independent research position at an institution in the United States and must have received a doctoral degree or completed a medical internship and residency in 1997 or later.

"We want proposals in a broad range of scientific areas relevant to the NIH mission and from a diverse pool of applicants," Zerhouni said. "We're shortening the application and emphasizing the significance of the research, what makes the approach exceptionally innovative, how the applicant will address challenges and risks, and the applicant's qualifications for the grant. We aren't requiring applicants to present preliminary data, although we'll allow it if they choose to do so," he added.

Application instructions: http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-07-009.html. Further information: http://grants.nih.gov/grants/new_investigators/innovator_award/.

Other Funding Notices

NOT-HG-07-011: Administrative Supplements for Making Knockout Mice. Full text: http://www.grants.nih.gov/grants/guide/notice-files/NOT-HG-07-011.html. Inquiries: Cheryl Marks, 301-594-8778; marksc@mail.nih.gov.

NOT-OD-07-056: Announcing the NIH Director's Bridge Awards. Full text: http://www.grants.nih.gov/grants/guide/notice-files/NOT-OD-07-056.html. Inquiries: Office of Extramural Research, NIH, 6705 Rockledge Dr., Rm 350, Bethesda , MD, 20892–7963.

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