THE CANCER LETTER

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Data On CT Screening For Lung Cancer Raises Questions About DOD Program

By Paul Goldberg

Data emerging from clinical trials of computed tomography screening for lung cancer are yet to produce answers on efficacy, but are already pointing to a high risk of false positive results.

The most recent cautioning results—a randomized trial which points to 33 percent risk of false-positive results after two screens and 7 percent risk of an invasive procedure—were published in the April 20 issue of the Annals of Internal Medicine.

The findings are based on the NCI-sponsored Lung Screening Study, a two-year trial that was a pilot for the ongoing National Lung Screening Trial. Both the pilot study and NLST compare CT screening with chest x-ray.

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<u>Foundations:</u> Komen Deal With KFC Yields Buckets Of Discord

By Kirsten Boyd Goldberg

Health advocacy organizations had a field day this week with an announcement from Susan G. Komen for the Cure that KFC would raise money for the foundation by selling pink buckets of chicken. The fundraising product is called "Buckets for the Cure."

"KFC has pledged 50 cents to Komen for every pink bucket ordered by its restaurant operators during the promotion period, with a minimum donation of \$1 million and a goal to raise more than \$8 million," according to the Komen website. "Twenty-five percent of the funds raised will be earmarked to Komen's 120-plus domestic affiliates for breast cancer programs in their communities. The remainder of the funds will support Komen's national research and community programs."

Also, the sides of the pink buckets would list names of "breast cancer survivors and those who have lost their battle with breast cancer," Komen said.

"Really, you can't make this stuff up," wrote Marion Nestle on her "Food Politics" blog. Nestle is a former chairman of the American Cancer Society's nutrition guidelines committee and the Paulette Goddard Professor in the Department of Nutrition, Food Studies, and Public Health at New York University.

"OK, scientists are still arguing about the dietary determinants of breast cancer and aren't too worried about fat, but they do worry about body weight,"

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Vol. 36 No. 15 April 23, 2010

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False Postive Rate In CT Higher Than In Mammograms, PSA

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However, the U.S. Congress has not been swayed by either earlier data on false positives or reports of ethical lapses and questionable science on the part of proponents of CT screening for lung cancer.

The House committee report accompanying the 2010 appropriations measure commits \$15 million to a lung cancer screening program that would be first implemented in the National Capital Region.

Congress also redirects some of the 2009 funds from peer-reviewed research in lung cancer to an early detection program in lung cancer. The program is designed in a way that can only use a specific brand of CT screening.

The DOD's outside advisors who have been guiding the creation of a peer-reviewed research program have objected to abandonment of research for the sake of unproven and possibly harmful screening, and are now pointing to growing evidence of harm.

"As chair of the Lung Cancer Research Program Integration Panel, I am very concerned by the drastic change in the language governing the program," said Regina Vidaver, executive director of the National Lung Cancer Partnership. "The research funded by the 2009 program has the potential to dramatically improve lung cancer prevention, and early-stage disease detection and treatment. This type of research will not be supported by the 2010 program. Given the most recent findings of



I he Cancer Letter is a registered tradema

Editor & Publisher: Kirsten Boyd Goldberg Editor: Paul Goldberg

Editorial, Subscriptions and Customer Service: 202-362-1809 Fax: 202-379-1787 PO Box 9905, Washington DC 20016 General Information: <u>www.cancerletter.com</u>

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No mainstream medical society recommends routine screening for lung cancer with CT, chest X-ray, or any other modality.

The report language was placed in the House appropriations bill by the late Rep. John Murtha (D-Penn.) and survived through the final version of the legislation. Since the mandate has not been rescinded by the Senate, it remains in force, Capitol Hill insiders say.

Insiders say that if no ethically acceptable screening program can be constructed, the \$15 million in DOD lung cancer research funds may have to be returned to the U.S. Treasury.

"You can continue to pursue policy disconnected from the data, but it puts you at grave risk of not only following a false path, but also putting people through all manner of procedures that they don't need, and raising costs," said Arthur Caplan, Director of Center for Bioethics at the University of Pennsylvania. "I attribute it to trying to do good, not harm, but sometimes your wish to do good, if it's not rooted firmly in evidence, is not going to take you where you want to go."

Waiting for the final results of NLST, which are likely to be reported in the next two years, would be the sensible and ethical thing to do, Caplan said.

False Positives Higher Than Mammography, PSA

The false positive rates reported in the Annals paper appear to be substantially higher than false positives for mammography and prostate-specific antigen screening.

This doesn't necessarily mean that CT screening would be found not efficacious. However, it does mean that efficacy—in this case, lung cancer-specific mortality—would have to be more dramatic if it is to outweigh the known harm.

According to the Annals paper, after the first scan, the risk for a false-positive was at 21 percent and 33 percent at second scan. In the comparator group patients who got chest x-rays—the false positive rate was at 9 percent for the initial screen and 15 percent for the second screen.

In earlier studies, the false positive rate for PSA was 5.4 percent during the first screen and 7.9 percent during second (J. Croswell et al, Annals of Family Medicine, May/June 2009).

At year two, the risk of a false positive from

mammography is around 13 percent (J. Elmore et al, NEJM, April 16, 1998).

"It looks like CT is going to have higher false positives than either PSA or mammography," said Jennifer Croswell, acting director of the NIH Office of Medical Applications of Research and the lead author of the recently published study. However, the significance of these false positives will not be clear until efficacy data become available, she said.

"At the end of the day, just having a higher false positive rate is not enough to say we shouldn't do this, because what you are looking for is the net benefit to a person," Croswell said. "If it turned out that it had a very large mortality reduction, you might say that it's worth it to an individual or a population to be screened. But the problem is right now, we don't even know it works. So having a higher false-positive rate reduces the chances of a net benefit and makes you more reluctant to want to take that gamble in the interim, but there is still a chance of a net benefit. We need to know how big the mortality reduction is."

In an interview, Croswell discussed the implication of her study and did not comment specifically on the DOD screening program.

This is not the case where additional trials are needed to answer an important public health questions. The trials that are expected to produce the answers— NLST and the Scandinavian study called NELSON have been conducted and are in follow-up stage.

"If you are a smoker, the first thing you might do is stop smoking," Crosswell said. "The second thing you do is maybe say, 'I will wait and see what the results of these trials are.""

Harm to a patient who receives an abnormal finding can be substantial. There is no single protocol for follow-up, which means that the specter of an indeterminate diagnosis of a fatal disease can haunt the patient for months or years.

"If you look at previous studies and if you look at expert guidelines, there is a lot of variability in terms of what happens to you after you have an indeterminate test," Croswell said. "It doesn't seem like there is universal agreement on that. Most of the time, that person would be brought back and be rescanned. The question is, at what point and how many more times before we finally say, 'Okay, they don't have cancer.' That can range from one month after the screening test to up to two years afterwards."

Reliance on invasive procedures to rule out lung cancer is even more troubling. "There were certainly a few people in our study and in other studies who wound up having major surgery—taking out the nodule or a part of the lung—to then find out that it was not cancer," Croswell said. "It's a pretty big procedure for a benign finding."

The surgeries carry a risk of complications and may result in partial loss of lung function.

"If they are smokers, you would rather not reduce their lung function if you can get away with that," Croswell said. "What are the psychological burdens to being put in that indeterminate state, where you are being followed up with repeat scans over time? What are the radiation risks of being followed up with repeat scans over time? And what are the economic costs, both to individuals and to the healthcare system?"

Language Points To CT Screening, I-ELCAP

The House report language doesn't name any screening modality, but the language clearly points to CT screening, which implies reliance on the program of the controversial group called the International Early Lung Cancer Action Program.

The report language states:

"The Committee has included \$15,000,000 for peer-reviewed lung cancer research. Lung cancer, continues to be the most lethal of all cancers, taking more lives annually than all other major cancers combined. The five year survival rate is only 15 percent and a major contributor is that 70 percent of the diagnoses are late stage. Furthermore, military personnel have increased exposure to lung cancer carcinogens and are thus more susceptible to lung cancer than the general population. These funds, in conjunction with the funds provided in fiscal year 2009, are primarily for an early detection program for military beneficiaries. It is expected that this early detection regimen will be initially implemented in Military Medical Treatment facilities in the National Capital Region."

The fact that the mandated \$15 million program is labeled both "research" and "early detection regimen" indicates that only a CT screening regimen advanced by I-ELCAP could be used.

With NLST no longer accruing, there are no other research regimens available. Many features of the I-ELCAP regimen are covered by issued patents and pending patents, which could limit the chances that anyone could set up a similar program without permission from the group.

Proponents of the I-ELCAP protocol argue that the results of a study published in the Oct. 26, 2006, issue of The New England Journal of Medicine support changing health policy to include annual CT screening of current and former smokers.

A Washington group called the Lung Cancer Alliance has been lobbying Congress to institute such programs. Also, physicians affiliated with I-ELCAP have been testifying in court cases to include medical monitoring as part of penalties against tobacco companies.

However, mainstream cancer experts reserve judgment on this form of screening, and not a single NCI-designated comprehensive cancer center is involved in I-ELCAP.

Moreover, I-ELCAP's credibility is not helped by the fact that it received \$3.6 million from a fund that owns Liggett Tobacco Co. and that this contribution was not disclosed in publications. Patents held by I-ELCAP leadership (and royalties paid on those patents) were similarly not disclosed.

After these ethical lapses were revealed in coverage by The Cancer Letter, major medical journals published corrections on papers by I-ELCAP. Such corrections ran in The New England Journal of Medicine, The Journal of the American Medical Association, The Lancet, Cancer, and Nature Clinical Practice Oncology. NEJM was sanctioned by the Accreditation Council for Continuing Medical Education for offering CME credit for a paper where relevant conflicts were not properly disclosed.

More significantly, NEJM was forced to correct one of the central claims made in the paper—the number of patients who died of lung cancer after refusing care based on I-ELCAP protocol.

Though the claim, which speaks to clinical relevance of the findings, was acknowledged as incorrect, the paper has not been retracted by the journal.

I-ELCAP, led by radiologist Claudia Henschke, recently moved its operations from Weill Cornell Medical Center to the Arizona State University's Biodesign Institute in Tempe.

<u>Foundations:</u> Critics Allege "Pinkwashing" In Komen-KFC Campaign

(Continued from page 1)

Nestle wrote. "Maintaining a healthy body weight is still the first recommendation of the American Cancer Society, for example. Isn't this campaign an incentive to buy as many buckets of KFC as you can?"

"What the cluck?" Barbara Brenner, president of Breast Cancer Action, wrote in an email to supporters.

"KFC and Susan G. Komen for the Cure are telling us to buy buckets of unhealthy food to cure a disease that kills women," Brenner wrote. "KFC's 'Buckets for the Cure' campaign is an especially tasteless example of pinkwashing—when a company purports to care about breast cancer by promoting a pink ribbonned product, but manufactures products that are linked to the disease."

Brenner's organization posted a letter of protest to KFC and Komen asking the organizations to "rethink this partnership."

In press interviews, Komen officials said that in addition to fried food, KFC offers grilled chicken and sides orders of vegetables

<u>FDA News:</u> Agency To Expand Disclosure For Advisory Committees

FDA announced draft guidance that would expand transparency and disclosure when the agency grants a conflict of interest waiver to permit an individual's participation at an FDA advisory committee meeting.

The draft guidance would expand the information disclosed about waivers prior to committee meetings. FDA proposes to post online the name of the company or institution associated with the financial interest along with the type of conflict of interest.

Scientific advisory committees provide expert advice on significant scientific, technical, and policy matters including specific regulatory decisions, such as product approvals, and general policy matters, including regulations and guidance. The agency said that at times, it believes it is appropriate to seek advice from experts who are top authorities in specific areas and who may have conflicts of interest.

"In my view, it is clearly better for the agency in fulfilling its public health mission when advisors have no conflicts of interest," FDA Commissioner Margaret Hamburg said in a letter to senior agency officials. "FDA staff should search far and wide for experts who have the requisite knowledge without conflicts of interest. At the same time, however, I recognize the fact that many of the top authorities in specific areas may have conflicts of interest."

In her letter, Hamburg listed three steps, consistent with existing agency policy, to minimize concerns when needed experts may have a conflict of interest:

• Consideration of the nature of the conflict of interest, recognizing that not all conflicts are created equal. For example, an academic researcher whose institution receives grants from an affected company but who does not personally participate in the studies

has a more tangential relationship to the conflict than the researcher who conducts studies for the company directly.

• Consideration of the type of advice to be provided by the advisory committee. A waiver may be more appropriate for a meeting about a policy issue affecting a class of entities or products than for a meeting focusing on approval of a specific product.

• Justification of waiver recommendations with a description of the search for equally expert advisors without conflicts and an explanation of why the individual's participation is needed to afford the advisory committee essential expertise.

Draft Revised Guidance on Transparency and Advisory Committees: <u>http://www.fda.gov/</u> <u>RegulatoryInformation/Guidances/ucm122045.htm</u>.

Hamburg's letter: <u>http://www.fda.gov/</u> <u>AdvisoryCommittees/AboutAdvisoryCommittees/</u> <u>ucm209001.htm</u>.

<u>Professional Societies:</u> Guideline Aims To Improve Hormone Receptor Testing

The American Society of Clinical Oncology and the College of American Pathologists issued a joint guideline aimed at improving the accuracy of immunohistochemistry testing for the expression status of estrogen and progesterone receptors in breast cancer.

The two groups conducted a systematic review of medical research literature in partnership with Cancer Care Ontario to develop the recommendations. The guideline is being published in the April 19 issues of ASCO's Journal of Clinical Oncology and CAP's Archives of Pathology & Laboratory Medicine.

As many as two-thirds of breast cancers are ER and/or PgR-positive with their growth influenced by activation of the estrogen receptor pathway. The purpose of ER/PgR testing is to identify breast cancer patients whose tumors express ER and/or PgR (hormone receptorpositive), and who should therefore be considered candidates for treatment with endocrine therapies, which may include options like tamoxifen, an aromatase inhibitor, and/or suppression of ovarian function, as appropriate. These treatments can substantially improve survival in patients with hormone receptor-positive invasive breast cancer. Immunohistochemistry is an established assay to determine the ER/PgR status of a tumor by measuring protein amounts of ER and PgR in breast cancer cells. However, up to 10-20 percent of IHC test results throughout the world may be inaccurate (false-positive or false-negative).

"There is clearly a need to accurately identify breast cancer subtypes as ER and/or PgR-positive to help us identify those patients most likely to benefit from endocrine therapy and minimize the risk of potentially denying effective and life-saving therapy to patients incorrectly labeled as having ER/PgR-negative invasive disease, while allowing patients with true ER/PgRnegative disease to be considered for other therapies." said Antonio Wolff, co-chair of the ASCO/CAP Hormone Receptor Testing in Breast Cancer Panel and associate professor of oncology at the Johns Hopkins Kimmel Comprehensive Cancer Center. "Widespread access to accurate ER/PgR testing is also critical because breast cancer is the most common cause of cancer death in women in low and middle-income countries, and most of them have ER and/or PgR-positive disease."

The guideline recommends the following:

• Testing ER and PgR status on all newly diagnosed invasive breast cancers (primary site and/or metastatic site), and whenever appropriate, repeat testing in patients with a known breast cancer diagnosis who now present with a local or distant recurrence.

• Establishing uniform testing measures that focus on proven, reliable and reproducible assays and procedures.

• Having testing laboratories validate their assays against existing and clinically validated tests. Results should agree at least 90 percent of the time with those of the clinically validated assays for positive receptor status and at least 95 percent for negative receptor status.

• Transporting breast tissue specimens from the operating room to the pathology laboratory as soon as they are available for gross assessment. The time from tumor removal to initiation of fixation should be kept to one hour or less. Fixation of the sample in neutral buffered formalin must extend for at least six hours and no longer than 72 hours.

• Performing ER and PgR testing in a CAPaccredited laboratory or in a laboratory that meets the accreditation requirements spelled out in the guideline. CAP will require that every accredited lab performing testing participate in a mandatory proficiency testing program.

• Considering an ER and PgR test performed by an IHC assay as positive if at least one percent of the tumor in the sample tests positive, which helps predict whether a patient is likely to benefit with endocrine treatment. The panel recognized that it is reasonable for oncologists to discuss the pros and cons of endocrine therapy with

patients whose tumors contain low levels of ER by IHC (one percent to ten percent weakly positive cells) and to make an informed decision based on available information.

"Increased attention to simple measures such as the handling of tissue specimens from the moment they are taken from the patient to when they reach the pathologist, the uniform fixation of specimens, the standardization and validation of lab assays, rigorous reporting procedures, and greater access to treatment interventions have the potential to significantly improve breast cancer outcomes around the world," said Elizabeth Hammond, co-chair of the ASCO/CAP Hormone Receptor Testing in Breast Cancer Panel, pathologist at Intermountain Healthcare, and professor of pathology at the University of Utah School of Medicine.

Classifying subtypes of breast cancer by a tumor's biological characteristics (tumor phenotype) can include whether or not it is hormone (estrogen or progesterone) receptor positive, human epidermal growth factor receptor 2 (HER2) positive, or "triple negative," lacking receptors for estrogen, progesterone, and HER2. The latter, HER2, plays a role in cancer cell growth and spread and identifies patients that may be considered candidates for treatment with anti-HER2 drugs in the adjuvant or metastatic settings. In 2007, ASCO and CAP issued clinical practice guideline recommendations to improve HER2 testing accuracy.

About 20 percent of all women with invasive breast cancer are HER2-positive, meaning they overexpress HER2, and about 15 percent of breast cancers do not express HER2, ER, or PgR receptors (triple-negative). Accurate determination of tumor phenotype is critical to properly select therapy options and individualize treatments.

The ASCO/CAP Panel also expects that the new ER/PgR guideline will foster improved communications among cancer specialists and also between patients and their doctors. Because of the availability of effective therapies for patients with hormone-receptor positive disease, the panel chairs encourage women who are told to have an ER/PgR-negative breast cancer to discuss the test result with their cancer specialists, including their oncologist and pathologist. This conversation would touch on questions like whether the hormone receptor test result is consistent with the overall pathology assessment of the tumor and whether the ER/PgR testing was done in a manner that is consistent with the new ASCO/CAP guideline.

In conjunction with the publishing of the guideline, ASCO and CAP have developed clinical tools and

resources for oncologists and pathologists that summarize the findings and recommendations. These resources include a slide presentation on ASCO's website and a guideline summary in the Journal of Oncology Practice. In addition, CAP has developed a Breast Predictive Factors Testing Certificate Program and associated Continuing Medical Education, which will also allow pathologists to gain special expertise in the development and implementation of these tests.

AACR Presents Awards At Annual Meeting In D.C.

The American Association for Cancer Research presented awards at its annual meeting in Washington, DC, earlier this week.

Janet Rowley, AACR Award for Lifetime Achievement in Cancer Research.

Phillip Sharp, Margaret Foti Award.

Joseph Schlessinger, Pezcoller Foundation-AACR International Award for Cancer Research.

Titia de Lange, G.H.A. Clowes Memorial Award.

Distinguished Public Service Awards: John Niederhuber, Julie Fleshman, and Jon Huntsman.

Elaine Fuchsia, AACR-Women in Cancer Research Charlotte Friend Memorial Lectureship.

Pasi Jinnee, AACR Richard and Hinda Rosenthal Memorial Award.

Mary-Claire King, AACR-Princess Takamatsu Memorial Lectureship.

Henry Lynch, AACR Joseph H. Burchenal Memorial Award for Outstanding Achievement in Clinical Cancer Research.

Joshua Mendell, AACR Award for Outstanding Achievement in Cancer Research.

Amelie Ramirez, AACR Minorities in Cancer Research-Jane Cooke Wright Lectureship.

Stuart Schreiber, AACR Award for Outstanding Achievement in Chemistry in Cancer Research.

Michael Thun, AACR-American Cancer Society Award for Research Excellence in Cancer Epidemiology and Prevention.

Robert Tjian, AACR-Irving Weinstein Foundation Distinguished Lectureship.

Team Honored for Discovering Genomic Changes Affecting Treatment of Lung Cancer: Dana-Farber/ Harvard Cancer Center Thoracic Oncology Research Team: Michael Eck, Jeffrey Engelman, Nathanael Gray, Daniel Haber, Pasi Jänne, Bruce Johnson, Susumu Kobayashi, Eunice Kwak, Neal Lindeman, Thomas Lynch, Shyamala Maheswaran, Matthew Meyerson, Lecia Sequist, Jeffrey Settleman, Daniel Tenen, Mehmet Toner, and Kwok-Kin Wong.

Landon Foundation-AACR INNOVATOR Award for Research in Personalized Cancer Medicine: W. Kimryn Wrathful.

2010 Landon Foundation-AACR INNOVATOR Award for Cancer Prevention Research: Samuel French.

Landon Foundation-AACR INNOVATOR Award for International Collaboration in Cancer Research: Ralph Hruban.

The Pancreatic Cancer Action Network-AACR Innovative Grants: Frank McCormick, Diane Simeone, Gloria Su, Amy Tang.

The Pancreatic Cancer Action Network-AACR Career Development Award: Jonathan Brody, Alec Kimmelman, Michael venison.

The Pancreatic Cancer Action Network-AACR Pathway to Leadership Grant: Zeshaan Rasheed.

The Pancreatic Cancer Action Network-AACR Fellowship: Vikram Bhattacharjee.

ACCC To Begin Program On Small-Population Cancers

Association of Community Cancer Centers has launched a program to provide community-based cancer care providers the tools they need to improve the quality of care for patients with small-population cancers, such as chronic myeloid leukemia.

"Caring for patients with less common cancers presents unique challenges for community-based cancer care providers," said ACCC President Al B. Benson III. "Physicians treating small-population cancers have limited time and resources to incorporate emerging clinical data into practice. Other health professionals, including nurses, social workers, and pharmacists, see these diseases less frequently and need information to better support the physician and the patient."

ACCC surveys revealed that many communitybased cancer care providers see a relatively high number of patients with breast, lung, colon, or prostate cancer. Practice patterns are relatively well-established for these cancers and resources are available for both providers and patients. Patients with a small-population cancer, however, usually are underserved or elderly and may not have the resources or desire to be treated far away from their homes.

ACCC's first objective will be to raise awareness

among the public and healthcare providers about the challenges presented by small-population cancers and the need to assess barriers to treatment and best practices within the community setting. Barriers include limited physician and cancer team knowledge of emerging data, difficulties in incorporating new clinical information into practice, and inadequate managerial and administrative processes in treating small-population cancers like CML.

The project is funded by an educational grant from Novartis Pharmaceuticals and will take about two years to complete.

ACCC will launch a comprehensive online resource that will include community-provider-specific information about how to design a program to best serve patients with small-population cancers, as well as clinical news and non-clinical resources for specific small-population cancers.

In the Cancer Centers: M.D. Anderson Wins Grant For Study of Yoga In Cancer

M.D. ANDERSON CANCER CENTER received a \$4.5 million NCI grant to study the efficacy of incorporating yoga into the treatment program of women with breast cancer.

The grant, the largest ever awarded by NCI for the study of yoga in cancer, will allow researchers to conduct a phase III trial in women with breast cancer to determine the improvement in physical function and quality-of-life during and after radiation treatment. It will also investigate if such stress reduction programs result in economic and/or work productivity benefit.

Lorenzo Cohen, professor and director of M. D. Anderson's integrative medicine program and the study's principal investigator, received the funding.

The research is being done in collaboration with the Vivekananda Yoga Anusandhana Samsthana, a yoga research foundation and university in Bangalore, India. M.D. Anderson has been collaboration with VYASA for more than six years.

Two previous studies led by Cohen investigating yoga in similar populations of breast cancer patients have shown benefits in physical function, compared to women who did simple stretching or those who did not participate in any such program. Patients who participated in the yoga program reported that their ability to engage in everyday activities—walking a flight of stairs or around the block, carrying a bag of groceries—all improved. The study also found an indication of improved sleep and reduced fatigue levels, and preliminary analysis suggests lowered stress hormone levels in the yoga group.

The phase III study will enroll 600 women with stage 0-3 breast cancer, all undergoing radiation at M. D. Anderson. The women will be randomized to one of three groups: yoga, stretching/relaxation or those who receive the standard of care and do not enroll in any exercise program. Participants in both the yoga and stretching groups will attend sessions three days a week throughout their six weeks of radiation.

Participants will self-report quality-of-life aspects, including physical function, mental health and fatigue levels. In addition to reporting their sleep quality, patients also will wear an activity watch monitor that objectively monitors the restfulness of their sleep. Cortisol levels will also be collected and studied, as blunted cortisol slopes have been linked to worse outcomes in breast cancer, said Cohen. A secondary aim of the trial is assessing cost efficiency analysis for the hospital, and health care utilization costs in general, as well as examining work productivity of patients.

AL B. BENSON III was named president of the Association of Community Cancer Centers. Benson is a professor of medicine in the Division of Hematology/ Oncology at the Feinberg School of Medicine and associate director for clinical investigations at the Robert H. Lurie Comprehensive Cancer Center of Northwestern University. Benson has served on ACCC's board of directors since 2003 and has been active on ACCC's Strategic Planning Committee, Editorial Committee, New Technology Committee, Corporate Development Committee, Awards Committee, Bylaws Committee, Program Committee, and Membership Committee.

DREXEL UNIVERSITY College of Medicine, in collaboration with University of Pennsylvania School of Medicine, Cheyney University, and Inovio Biomedical Corp., will receive \$2.8 million over four years from the Commonwealth Universal Research Enhancement (CURE) competitive grant program funded through Pennsylvania's share of the 2009-2010 national tobacco settlement.

Funds will be used to conduct pre-clinical studies to test the safety and effect on the immune system of a DNA-based vaccine that is designed to treat persons who are chronically infected with the hepatitis C virus and have not responded to currently available therapies. People with chronic HCV infection face an increased risk of developing hepatocellular cancer. To create a diverse applicant pool for high-level research positions, a research training program for students and faculty from Cheyney University will also be established through this grant.

Jeffrey Jacobson will serve as the principal investigator. Jacobson is professor of medicine in the Division of Microbiology & Immunology, and the chief of the Division of Infectious Diseases & HIV Medicine, at Drexel University College of Medicine. Michele Kutzler will serve as co-investigator. Kutzler is an assistant professor of medicine in the Division of Microbiology & Immunology at Drexel University.

WINSHIP CANCER INSTITUTE of Emory University executive director Walter Curran Jr. announced the recipients of the inaugural Kennedy Seed Grant Research Awards. The five Winship faculty members who earned the awards will each receive \$50,000 for up to two years to support high-impact cancer research projects.

The grants are made possible through a generous gift of \$4.7 million from James Kennedy, CEO of Cox Enterprises, and his wife, Sarah.

A review panel of Winship senior-level faculty members reviewed 39 proposals submitted by faculty members who are early in their careers. The five grant recipients are based in five different academic departments in two schools at Emory and represent membership in all four Winship scientific programs.

The Kennedy Seed Grant winners are: **Daqing Wu**, assistant professor, Department of Urology; **Xingming Deng**, associate professor, Department of Radiation Oncology; **Brian Pollack**, assistant professor, Department of Pathology and Laboratory Medicine; **Suresh Ramalingam**, associate professor, Department of Hematology and Medical Oncology; **Carla Berg**, assistant professor, Department of Behavioral Sciences and Health Education.

CHARLES BENNETT has been recruited as the endowed chair of the Center for Economic Excellence in Medication Safety and Efficacy and the Josie M. Fletcher Professor of Pharmacy at the University of South Carolina campus of the South Carolina College of Pharmacy. His appointment is supported in part by Health Sciences South Carolina, the Centers of Economic Excellence and the Frank P. and Josie M. Fletcher Endowment. He will hold full faculty appointments at both SCCP founding institutions the University of South Carolina and the Medical University of South Carolina.