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PO Box 9905 Washington DC 20016 Telephone 202-362-1809

# IOM Review Of Duke Genomics Trials To Focus On Validation, Scientific Criteria

*By Paul Goldberg*

The Institute of Medicine has defined the scope of an investigation stemming from the Duke genomics scandal.

In a move that appears to be unprecedented, the institute, which usually confronts broader scientific and policy issues, will focus on the scientific underpinnings of three single-institution clinical trials in which Duke was testing the genomic technology developed by researchers Anil Potti and Joseph Nevins.

The accuracy of the work of the Duke genomics group has been challenged for years, but the controversy became explosive after The Cancer Letter found that Potti had misstated his credentials, claiming, among other things, to have been a Rhodes scholar (The Cancer Letter, July 16, July 23,

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*In the Cancer Centers:*

## NCI Awards First STRAP Grant Of $2 Million To MSKCC For Genetically Modified T Cells

**MEMORIAL SLOAN-KETTERING** Cancer Center researchers **Renier Brentjens, Michel Sadelain, and Isabelle Rivière** were granted a $2 million Special Translational Research Acceleration Project (STRAP) award from NCI. The award will support research into a novel cancer therapy whereby immune cells, or T cells, are manipulated to recognize and kill cancer cells.

Currently, MSKCC researchers are conducting two phase I clinical trials to assess the use of genetically modified T cells in treating cancer patients. One trial is evaluating the use of this therapy in treating advanced chronic lymphocytic leukemia in patients who have not responded to treatment or whose disease has returned after treatment, and the second trial evaluates this therapy in B cell acute lymphoblastic leukemia that has returned, stopped responding to therapy, or is in first remission and at risk of returning. The STRAP award will support a first-of-its-kind, multi-institutional consortium to conduct these trials in cooperation with investigators **Carl June**, at the University of Pennsylvania, and **Stephen Grupp**, at the Children's Hospital of Philadelphia.

Also at MSKCC, **Gerald Soff** has been appointed chief of the Hematology Service within the Department of Medicine's Division of Hematologic Oncology. Under Soff's leadership, the Hematology Service will

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## Duke Investigation Unusually Narrow In Scope For IOM

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and July 30).

As a consequence, Potti has been placed on suspension by Duke, but the decision whether he would retain his job would be determined by the outcome of review of his science, university officials said.

The controversy affects a large number of the Duke group's publications. The Lancet has issued an expression of concern over a Duke paper. Several other journals, including the Journal of Clinical Oncology, are examining articles they published.

Also, statisticians and genomic scientists have been using the Duke case to frame the question of reproducibility in scientific publications.

*Earlier this week, the IOM released the following description of the "consensus study" of the Duke scandal:*

"An IOM committee will review the published literature to identify appropriate evaluation criteria for tests based on 'omics' technologies (e.g. genomics, epigenomics, proteomics, metabolomics) that are used as predictors of clinical outcomes. The committee will recommend an evaluation process for determining when predictive tests based on omics technologies are fit for use as a basis for clinical trial design, including stratification of patients and response to therapy in clinical trials. The committee will identify criteria important for the analytical validation, qualification, and utilization components of test evaluation.

"The committee will apply these evaluation criteria to predictive tests used in three cancer clinical trials conducted by Duke University investigators (NCT00509366, NCT00545948, NCT00636441). For example, the committee may assess the analytical methods used to generate and validate the predictive models, examine how the source data that were used to develop and test the predictive models were generated or acquired, assess the quality of the source data, and evaluate the appropriateness of the use of the predictive models in clinical trials.

"The committee will issue a report with recommendations regarding criteria for using models that predict clinical outcomes from genomic expression profiles and other omics profiles in future clinical trials, as well as recommendations on appropriate actions to ensure adoption and adherence to the recommended evaluation process. The report will also include the committee's findings regarding the three trials in question."

Sources said the committee members have been selected, but their names will be released after they formally agree to serve.

"It looks pretty positive to me," said Keith Baggerly, a biostatistician at M.D. Anderson Cancer Center who first questioned the Duke group's science. "They do indeed want to make a statement about how trials should be done, and not just look at the ones in question, which fits my impression of why they might want to get involved."

Duke officials invited IOM to review the problem and pledged to provide all information the panel may seek. "We're pleased that the IOM has taken on this project and we look forward to the committee's analysis of the very serious issues and questions regarding the Nevins/Potti science, as well as their assessment of this field of research," Duke spokesman Doug Stokke said in an email.

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**Editor & Publisher**: Kirsten Boyd Goldberg
**Editor**: Paul Goldberg

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*Drug Development:*

## NCI Sends Second Letter On Carboplatin Dosing Issue

*By Paul Goldberg*

Confronting uncertainty about the dosing of carboplatin, NCI last week sent a second letter instructing clinical trials cooperative groups to amend protocols for all clinical trials that use the 21-year-old drug.

Altogether, 98 NCI-sponsored studies and as many as 175 industry-sponsored studies are affected

by the controversy that has emerged as a result of the standardization of assays that measure serum creatinine.

Since the new assay cannot be correlated with the old, there is no way to know whether patients are being underdosed or overdosed in treatment. Uncertainty also surrounds methods for estimation of creatinine clearance and methods for measuring the glomerular filtration rate.

Nobody knows how the change is affecting community practice.

The NCI approach so far has been to cap the dose received by patients with small body mass to protect them from overdosing. However, patients who are obese may be underdosed, some observers say (The Cancer Letter, Oct. 8, Oct. 15). NCI is developing a plan for addressing these problems in clinical trials, which may take at least two years to complete.

The latest CTEP "action letter," dated Oct. 15, expands on an earlier document, which was sent to the cooperative groups on Oct. 1.

The follow-up responds to queries regarding the original letter and includes additional information CTEP received in recent weeks.

Investigators would have till Nov. 12 to complete the revision of protocols.

"Physicians should use the instructions for carboplatin dose determination described below ONLY for patients initiating treatment," the revised letter states. "Patients already on study who have tolerated their carboplatin dose should not have their dose modified (unless they are experiencing toxicity that requires dose modification per protocol). As this is a change to enhance patient safety (by providing maximal allowed carboplatin doses), physicians should use the new instructions described below even if the treatment starts before the study amendment is approved."

The letter emphasizes the point that the new serum creatinine test, called Isotope Dilution Mass Spectrometry, cannot be correlated with previously used assays. "Due to this variability, the use of a single correction factor to convert IDMS creatinine values to 'non-IDMS' creatinine values will not work across all labs and institutions," the letter states.

The IDMS method usually generates a lower creatinine value than older methods in patients with normal renal function. In addition, the IDMS method is more likely to generate creatinine levels that are below the lower limit of normal.

When serum creatinine is used to estimate glomerular filtration rate, measurement of serum creatinine by the IDMS method could result in an overestimation of GFR in some patients with normal renal function. If the total carboplatin dose is calculated based on an estimated GFR using an IDMS-measured serum creatinine and a dosing formula, called the Calvert formula, carboplatin dosing could be higher than desired and could result in increased toxicity.

In recent months, as doctors started to notice that the IDMS test generally seemed to produce lower values than previously used tests, some adapted conversion formulas. One such formula was derived by Johnson & Johnson. Now, NCI is telling investigators to abandon such conversion formulas:

"Remove any language in protocols indicating that conversion of IDMS creatinine levels to 'non-IDMS' values should be performed," the latest CTEP letter states. "No standard correction factor has been adequately validated. Amend the protocol to assure that a correction factor is NOT used to calculate carboplatin doses based on modifications of IDMS serum creatinine measurement."

The letter suggests that oncologists actually measure the patients' GFR, as stated on the drug's label

However, measuring creatinine clearance is cumbersome and expensive and may not correlate with the methods used to derive the Calvert formula, which is used to calculate the drug's dose, clinical pharmacologists say. Also, in measuring GFR, Hilary Calvert, the author of the formula, used an isotope not approved in the U.S.

The new CTEP letter states:

"The current label for carboplatin provides safe dosing instructions that are based on measured GFR. Provided that direct GFR measurements are made to assess renal function, carboplatin can be safely dosed according to the instructions described in the label."

The initial dose of carboplatin may be calculated using an estimated GFR or a measured GFR, the letter states.

However, "if the initial carboplatin dose is based on an estimated GFR, amend the protocol to assure that your protocol uses a dose not to exceed the maximum dose for carboplatin based on the target [area under the curve]," the letter states. "Once the initial dose of carboplatin is calculated, it does not need to be recalculated for subsequent cycles unless the patient is experiencing toxicity and requires dose modification to a lower dose of carboplatin."

In another clarification, NCI suggests that it may be preferable to use GFR measurement in patients with

low muscle mass.

"For specific patients, e.g. those with low muscle mass, direct measurement of GFR may be preferable to an estimation of GFR," the letter states. "In patients with an abnormally low serum creatinine, estimate GFR using a minimum creatinine level of 0.6 mg/dL, or cap the estimated GFR at 125 mL/minute."

The .06 mg/dL minimum was not cited in the previous version of the letter.

Carboplatin is the only drug dosed based on the patient's kidney function. However, a variety of other drugs in oncology and other areas are dose-adjusted based on nephrotoxicity. The impact of the introduction of IDMS on these drugs is unknown.

The revised CTEP action letter is posted at http://cancerletter.com/categories/documents.

*FDA News:*

## Agency Asks GnRH Sponsors To Add Warnings On Labels

*By Paul Goldberg*

FDA has asked the sponsors of gonadotropin-releasing hormone agonists to add warnings to the labels of this class of drugs used in the treatment of prostate cancer.

The label change, announced Oct. 20, warns about increased risk of diabetes and cardiovascular diseases including heart attack, sudden cardiac death and stroke.

The action concludes safety review of this class of drugs, announced May. At that time, the agency issued a MedWatch warning and said that its preliminary and ongoing analysis found that patients receiving GnRH agonists were at a small increased risk for diabetes, heart attack, stroke, and sudden death (The Cancer Letter, May 7).

Under the worst-case public health scenario, widespread use of these agents is causing men to die of cardiovascular disease and diabetes before they would ordinarily die of prostate cancer, some epidemiologist warn.

The agency stops short of issuing a "black box" warning or mandating that sponsors institute Risk Evaluation and Mitigation Strategies for these drugs. The new labels will include updates in the Warnings and Precautions section about these potential risks. The agency's action affects the following drugs: Eligard, Lupron, Synarel, Trelstar, Vantas, Viadur, and Zoladex. Several generic products are also affected.

The text of the agency's safety communication is posted at http://www.fda.gov/Drugs/DrugSafety/ucm229986.htm. These actions follow a "science advisory" issued by the American Cancer Society, the American Urological Association, the American Heart Association, and the American Society for Radiation Oncology (The Cancer Letter, Feb. 5).

GnRH agonists are approved for palliative care of advanced prostate cancer, and randomized trial data show that they slightly improve survival for clinically advanced localized disease when combined with radiation therapy. There are no randomized trials that would point to improvement in survival in any other setting.

Pattern of care studies show that now about one in three men treated for prostate cancer receives GnRH agonists at least at one point in their disease. This adds up to 60,000 to 70,000 new patients per year. Altogether, at least 250,000 men are receiving GnRH agonists drugs, paying about $800 a month, often for the rest of their lives, epidemiologists estimate.

Frequently, GnRH agonists are prescribed to men with asymptomatic early disease after it is detected via screening with prostate-specific antigen assays. No one knows exactly how many of these men receive GnRH agonists for early disease, but epidemiologists say that the proportion of such use is likely to be substantial.

There is no ongoing trial that would answer the scientific questions of toxicity of these drugs. To address these questions, researchers would need to compare the consequences of using these drugs early after diagnosis with using them after disease progression.

In the absence of efforts to expand the GnRH agonists franchise, the negative data are being generated in observational studies. Three papers that triggered the FDA review and the earlier joint statement by ACS, AUA and ADA include:

• Nancy L. Keating, A. James O'Malley, Stephen J. Freedland, and Matthew R. Smith. Diabetes and Cardiovascular Disease During Androgen Deprivation Therapy: Observational Study of Veterans With Prostate Cancer. J Natl Cancer Inst, 6 January 2010; 102: 39 - 46.

• Tsai HK, D'Amico AV, Sadetsky N, Chen M-H, Carroll PR. Androgen deprivation therapy for localized prostate cancer and the risk of cardiovascular mortality. J Natl Cancer Inst 2007;99:1516-1524.

• Keating NL, O'Malley AJ, Smith MR. Diabetes and cardiovascular disease during androgen deprivation therapy for prostate cancer. J Clin Oncol. 2006 ; 24 ( 27 ): 4448 – 4456.

The review of GnRH agonists involved the FDA

Office of Oncology Drug Products and the Office of Surveillance and Epidemiology.

*Clinical Trials:*

## Beth Israel Suspends Trials After Audit Finds Problems

*By Paul Goldberg*

The Beth Israel Deaconess Medical Center suspended enrollment in cancer clinical trials after an audit by FDA and an internal audit found problems with handling data. These problems included delays in reporting of adverse events to the institutional review board.

"These issues primarily have to do with documentation and reporting compliance," Randy Mason, vice president, research operations, wrote in an email to the hospital's leadership Oct. 15. "It is important to note that there have been no issues of patient harm identified to date in any of the approximately 285 clinical trials that are involved in this action."

The Boston Globe Oct. 21 reported that the problems first surfaced when FDA discovered problems in the trial of the metastatic melanoma drug candidate ipilimumab under development by Bristol-Myers Squibb.

Separate problems, which involved two other trials, were detected through spot-checking by the Protocol Review and Monitoring System operated by the Harvard institutions, sources said.

Now that enrollment has been suspended, the institution will conduct comprehensive auditing and institute further safeguards.

The text of Mason's email follows:

"BIDMC has temporarily paused enrollment on most active cancer clinical trials. BIDMC patients who are currently enrolled in ongoing cancer clinical trials will continue to be treated without disruption.

"This voluntary action is being taken after a routine internal audit revealed procedural issues that brought us to the conclusion that some of our clinical trials were not running with the high standards that we expect. These issues primarily have to do with documentation and reporting compliance. It is important to note that there have been no issues of patient harm identified to date in any of the approximately 285 clinical trials that are involved in this action.

"Notifications of this voluntary action are being made to the appropriate government agencies, including the FDA, NCI and the Office for Human Research Protections.

"BIDMC has pledged to do whatever it takes to address any issues. Mandatory education and training programs are already in place for the investigators involved in these clinical trials. We expect to have many of the clinical trials re-opened for enrollment of our patients very soon.

"Our plan is to first address the immediate issues and fix them, and then do a deeper analysis to learn from the event and make any systemic changes necessary. We are grateful for the support of the Dana-Farber/Harvard Cancer Center during this reassessment."

The Boston Globe story is posted at http://www.boston.com/news/local/massachusetts/articles/2010/10/21/cancer_trials_suspended_for_new_patients/.

*Compendia:*

## NCCN Guidelines Retain Avastin For Breast Cancer

The drug Avastin continues to be listed in the guidelines published by the National Comprehensive Cancer Network.

In 2008, Avastin (bevacizumab) received an accelerated approval for previously untreated advanced HER2-negative breast cancer treatment of metastatic breast cancer, but confirmatory studies failed to produce a sufficient improvement in delay of progression to convince an FDA advisory committee that the drug should retain its breast cancer indication. (The Cancer Letter, July 23, Sept. 3).

FDA was expected to reach a final decision on Sept. 17, but didn't, citing new data that had been submitted by the sponsor, and will now make the decision on Dec. 17.

Breast cancer experts said that there are no known phase III data on Avastin. However, the drug's approval has apparently become a political issue and the agency reportedly delayed its final decision until after next month's elections (The Cancer Letter, Sept. 24).

"Genentech is pleased this independent panel of breast cancer experts continues to believe Avastin should be part of the NCCN guidelines for the treatment of metastatic breast cancer," said Charlotte Arnold, a spokesman for Genentech, a subsidiary of Roche, the drug's sponsor.

The NCCN guidelines panel for breast cancer affirmed its existing recommendation of bevacizumab in combination with paclitaxel as an appropriate therapeutic option for metastatic breast cancer, with the evidence designation 2A, meaning that it is based

on lower level evidence.

The panel revised the related footnote, which now states: "Randomized clinical trials in metastatic breast cancer document that the addition of bevacizumab to some first-or second-line chemotherapy agents modestly improves time to progression and response rates but does not improve overall survival. The time to progression impact may vary among cytotoxic agents and appears greatest with bevacizumab in combination with weekly paclitaxel."

The NCCN Guidelines and the NCCN Drugs & Biologics Compendium are posted at NCCN.org.

*FDA Approvals:*

## Herceptin Approved For HER2+ Metastatic Stomach Cancers

FDA earlier this week approved Herceptin (trastuzumab) for HER2-positive metastatic cancer of the stomach or gastroesophageal junction, in men and women who have not received prior medicines for their metastatic disease.

Herceptin was approved for use in combination with cisplatin plus either capecitabine or 5-fluorouracil.

The patients' HER2 status should be assessed with FDA-approved diagnostic tests, the company and the agency said.

"Since Herceptin's approval in HER2-positive advanced breast cancer more than a decade ago, we have continued to study how the HER2 pathway contributes to the growth and spread of other cancers, such as stomach cancer," Hal Barron, Genentech executive vice president, product development and chief medical officer, said in a statement. "Approval of Herceptin in combination with chemotherapy provides an important new, personalized medicine for people with this life-threatening disease who have few treatment options."

Last January, the European Commission approved Herceptin in combination with chemotherapy for people with metastatic stomach (gastric) cancer with tumors exhibiting high levels of HER2.

The FDA approval is based on positive results from an international phase III study, known as ToGA, which demonstrated a survival advantage for Herceptin plus chemo, compared to chemo alone.

ToGA enrolled 594 people with locally advanced or metastatic, HER2-positive stomach cancer who were randomized to receive Herceptin plus chemotherapy (cisplatin plus either capecitabine or 5-FU) or chemotherapy alone. Results from the final overall survival (OS) analysis demonstrated Herceptin plus chemotherapy improved OS by 37 percent compared to chemotherapy alone (based on HR=0.73, 95 percent CI 0.60-0.91, p=0.0038; median OS 13.5 vs. 11 months). An updated OS analysis based on an additional year of follow-up showed a 25 percent improvement in OS (based on HR=0.80, 95 percent CI 0.67-0.97, p=0.02; median OS 13.1 vs. 11.7 months).

The company said that in ToGA, the safety profile of Herceptin was consistent with previous studies in HER2-positive breast cancer and no new or unexpected adverse events were seen in the Herceptin plus chemotherapy group (one person in the Herceptin group and two people in the chemotherapy alone group experienced heart failure). Five percent of people in the Herceptin plus chemotherapy group compared to 1.1 percent of people in the chemotherapy alone group had Left Ventricular Ejection Fraction (LVEF) values below 50 percent with a 10 percent absolute decrease in LVEF from pretreatment values. The most common adverse events that were increased with Herceptin and chemotherapy compared to chemotherapy alone were low white blood cell count (78 percent), diarrhea (37 percent) and fatigue (35 percent).

All patients in the were tested for HER2 status using two companion diagnostics developed by Dako. Based on HER2 screening results (using both HER2 IHC and FISH diagnostic tests) in ToGA, approximately 22 percent of people with advanced stomach cancer were found to have HER2-positive tumors. A positive result for HER2 overexpression with either test was required for study entry.

*In the Media:*

## ProPublica Compiles Database Of Pharma "Dollars For Docs"

ProPublica, an independent non-profit news organization, has compiled a database that contains the payments pharmaceutical companies make to doctors.

The "Dollars for Docs" database accounts for $258 million in payments to 17,700 health professionals, including many oncologists. It was intended to enable patients to look up their doctors.

Much of the information was obtained as a result of the companies' settlements with the federal government. The database isn't comprehensive. It compiles 2009 and 2010 payments from AstraZeneca, Cephalon, GlaxoSmithKline, Eli Lilly, Johnson & Johnson, Merck and Pfizer.

The database is posted at http://projects.propublica.org/docdollars/.

*In the Cancer Centers:*

## Northwestern Wins $12 Million Nanotechnology Alliance Grant

(Continued from page 1)

focus on the management and study of non-neoplastic hematologic disorders, including thrombosis, blood coagulation, and disorders of red cells and platelets. This will include a particular focus on the hematologic disorders that occur in cancer patients.

Soff joined the center in 2009 as the director of the Benign Hematology Program. He succeeds **Stephen Nimer**, who served as chief of the service since its inception nearly 20 years ago. Nimer, incumbent of the Alfred P. Sloan Chair, now serves as the vice chair for faculty development in the Department of Medicine and is a member of the Sloan-Kettering Institute, as well as an attending physician on the Leukemia Service.

**NORTHWESTERN UNIVERSITY** received a five-year, $12 million grant from NCI to renew its participation in the NCI Alliance for Nanotechnology in Cancer program and continue work to develop nanomaterials and nanodevices primarily for application in brain, breast and pancreatic cancer diagnostics and therapeutics.

Another grant for $2.1 million from the Chicago Biomedical Consortium will establish a new facility enabling Northwestern's discoveries to be shared with CBC-affiliated biology laboratories at no cost.

The Northwestern University Center of Cancer Nanotechnology Excellence combines the resources of the Lurie Cancer Center and Northwestern's International Institute for Nanotechnology. Some of its affiliated researchers collaborate with the University of Chicago and the University of Illinois at Chicago.

**Steven Rosen** and **Chad Mirkin** are co-directors of the NU-CCNE. Rosen is director of the Robert H. Lurie Comprehensive Cancer Center of Northwestern University. Mirkin is the George B. Rathmann Professor of Chemistry.

Northwestern also has received a Cancer Nanotechnology Partnership Platform grant of $1.9 million over five years for a project on the treatment of metastatic breast and ovarian cancer. The project will be led by Thomas O'Halloran and Vincent Cryns, both of the Lurie center.

**OHIO STATE UNIVERSITY** Comprehensive Cancer Center – Arthur G. James Cancer Hospital and Richard J. Solove Research Institute named **John Byrd** director of the newly formed division of hematology. Byrd, a leukemia specialist, came to Ohio State in 2001, where he is a professor of medicine and medicinal chemistry. He also is the associate director for translational research at the cancer center, where he co-leads the innate immunity program and is a member of the experimental therapeutics program. He holds the D. Warren Brown Family Designated Professorship in Leukemia Research.

The hematology unit was previously part of the department of internal medicine's division of hematology and medical oncology. The two sections are now independent divisions within the department of internal medicine. **Miguel Villalona** directs the newly formed division of medical oncology.

**GEORGETOWN LOMBARDI** Comprehensive Cancer Center researcher Jeffrey Toretsky received a $4.37 million grant from NCI, issued under the American Recovery and Reinvestment Act, to help fund preclinical toxicology studies of a new agent identified by Toretsky and his team.

The studies of the agent are based on a 2009 discovery in which Toretsky and his colleagues found a novel way to block the activity of the fusion protein responsible for Ewing's sarcoma, a rare cancer found in children and young adults. Toretsky described the finding in the journal Nature Medicine.

**UNIVERSITY OF ARKANSAS FOR MEDICAL SCIENCES** researcher **Mayumi Nakagawa** was awarded a $3.3 million, five-year NIH grant to support a phase I clinical trial of an HPV therapeutic vaccine for those already infected with the HPV virus. Nakagawa is an associate professor of pathology. **William Greenfield**, associate professor in the UAMS Department of Obstetrics and Gynecology, will be involved in recruiting subjects for the trial.

Women with high-grade precancerous lesions will be enrolled, and the effectiveness of the vaccine will be assessed by monitoring the lesions. "The vaccine will consist of synthetically made peptides of the E6 protein of HPV since this protein has been shown to be important in clearing HPV infection," Nakagawa said. Her work will include studying how Candida, a naturally occurring yeast in the body, which will be used as a novel adjuvant, works to enhance immune response.

**THOMAS JEFFERSON UNIVERSITY** has been awarded a four-year, $2.5 million grant from the NIH for a study of cancer gene activation in lung cancer.

The research team proposes to use imaging techniques to highlight a gene involved in solid tumors, thus helping to direct cancer therapy. The principal investigator is **Eric Wickstrom**, professor of biochemistry & molecular biology.

**DANA-FARBER CANCER INSTITUTE** breast cancer expert **Ann Partridge** will serve as chair of the Centers for Disease Control and Prevention's Advisory Committee Chair on Breast Cancer in Young Women, a federal advisory committee established by the Affordable Care Act.

The law charges CDC with the responsibility of developing initiatives to increase knowledge of breast health and breast cancer among women, particularly among those under the age of 40 and those at heightened risk for developing the disease.

Partridge is an assistant professor of medicine at Harvard Medical School and serves as the clinical director of the Breast Oncology Center at DFCI. She founded and directs the Program for Young Women with Breast Cancer at Dana-Farber/Brigham and Women's Cancer Center.

**UNIVERSITY OF MARYLAND** Marlene and Stewart Greenebaum Cancer Center researcher **Stuart Martin** received an Era of Hope Scholar Award from the U.S. Department of Defense.

The five-year, $3.5 million grant will be used to establish an international consortium to study tumor cells that break away from primary cancers and circulate in the bloodstream. The consortium will be made up of physicists, engineers, cell biologists and breast cancer doctors. The researchers hope to develop new therapies to target these cells and reduce the spread of cancer.

**MOUNT SINAI** Medical Center announced the appointment of **David Samadi** as vice chair of the Department of Urology.

"In his new role, Dr. Samadi will lead the effort to expand the scope of the Department of Urology," said **Simon Hall**, professor and chair of the Department of Urology. "He will provide a special emphasis on building relationships with outside physicians and other medical entities to increase our Department's market share and presence."

Samadi joined Mount Sinai in 2007 as director of the Division of Robotics and Minimally Invasive Surgery. Since his arrival, he has performed 1,500 radical da Vinci prostatectomies, representing one of the busiest robotic programs in the country. He is an advocate of frequent PSA screenings in men over 50, sometimes as early as age 40, based on risk factors.

**NYU LANGONE** Medical Center has established the Smilow Comprehensive Prostate Cancer Center with a $5 million gift from **Joel Smilow**, a member of the Board of Trustees at NYU Langone Medical Center and New York University.

The Smilow Center is dedicated to providing comprehensive, state-of-the-art personalized care for men with prostate cancer as well as educating men and their families about the disease and the wide range of treatment options.

"The goal of the Smilow Center team is to help each patient make an informed decision about their treatment options for prostate cancer and choose the treatment that is the best fit for them personally and medically," said **Herbert Lepor**, the Martin Spatz Chairman and Professor of Urology and director of the new center.

**JOHNS HOPKINS** Kimmel Cancer Center member **Vered Stearns** has been named co-director of the center's Breast Cancer Program. Stearns serves as co-director with **Sara Sukumar**, the Barbara B. Rubenstein Professor in Oncology.

Stearns joined the Johns Hopkins faculty in 2002 and is best known for her work on the pharmacogenetics of tamoxifen and the use of biomarkers to implement new interventions for breast cancer treatment and prevention. Her research focuses on agents that target epigenetic modifications in breast cancer and gene methylation as a prognostic and predictive marker in breast cancer. She is recognized for her research in improving therapeutic options for women who suffer vasomotor symptoms.

*Advocacy:*

## Kidney Cancer Association Presents Award To Vogelzang

**KIDNEY CANCER ASSOCIATION** presented **Nicholas Vogelzang** with its Eugene P. Schonfeld Award at the association's symposium earlier this month in Chicago. Vogelzang, an investigator at the Comprehensive Cancer Centers of Nevada, is a founding member of KCA and served on its board. He is also the chair of the Developmental Therapeutics Committee for US Oncology Research, a subsidiary of US Oncology Inc. Vogelzang also serves on the Research Executive Committee for US Oncology.