# THE CANCER LETTER

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

#### The Duke Scandal

#### Potti Reprimanded By N.C. Licensure Board; Duke Settles 11 Medical Malpractice Cases

By Paul Goldberg

Anil Potti, formerly a Duke University cancer researcher whose papers have been retracted by the world's leading medical journals, was reprimanded by the North Carolina Medical Board on Nov. 22.

The action was made public last week.

Separately, the board reported on its website that Duke settled a cluster of 11 medical malpractice cases in mid-September.

State law requires institutions to notify the licensing board every time a payment exceeding \$75,000 is made in a malpractice case.

After such reports are submitted, the board determines whether to launch an investigation.

Though the two actions involving Potti were announced within days of each other, they are very different:

- The reprimand—a consent order in which Potti promises to obey all laws, rules and regulations pertaining to the practice of medicine—was focused on misconduct and represents a negotiated agreement between Potti and the board. However, after learning about the document from The Cancer Letter, Duke officials challenged the document's accuracy, arguing that it mischaracterized the conclusions of an internal investigation.
- And the settlement of malpractice cases—because Duke or its insurers have paid at least \$825,000 to participants in these clinical trials—while university officials maintain that no one was harmed in the three phase II studies, where over 100 patients were assigned to therapy based on faulty predictors developed by Potti and his associates.

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#### In Brief

### Barbara Rimer, Owen Witte to be Named Members of the President's Cancer Panel

The White House said it intends to name two members of the President's Cancer Panel.

**BARBARA RIMER**, dean and alumni distinguished professor at the Gillings School of Global Public Health at the University of North Carolina at Chapel Hill, will serve as chair of the panel. **OWEN WITTE**, founding director of the Eli and Edythe Broad Center of Regenerative Medicine and Stem Cell Research at the University of California, Los Angeles, will serve

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### **Duke: Potti's Consent Order Contains Inaccuracies**

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Potti currently practices in South Carolina. His application for a license in that state includes glowing recommendations from former Duke colleagues.

However, one doctor who submitted an enthusiastic letter of recommendation—Jeffrey Crawford, the George Barth Geller Professor for Research in Cancer and chief of medical oncology at Duke—said to The Cancer Letter that he now regrets having done so.

"In retrospect, I realize that it was a mistake to send this letter without understanding the situation as I do today," Crawford said in an email.

According to documents released by the North Carolina medical board, the 11 malpractice claims stemmed from treatment provided to Duke cancer patients from 2007 to 2009, and the payments settling the claims were made on various dates between Sept. 6 and Sept. 26, 2011. Duke spokesman Doug Stokke said to The Cancer Letter that the university continues to contend that no one was harmed in the clinical experiments. This has been the university's position from the outset of the controversy.

The state medical board said it's reviewing the malpractice settlements.

"We received this information from risk management or some similar organization at Duke, regarding the payments that they made," said Scott Kirby, the board's medical director. "It's a state



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requirement that payments that are made in the name of, or on behalf of, or related to a physician's care that occurs at that institution need to be reported to the medical board.

"Those are reviewed and determination is made about whether additional investigation needs to be undertaken, or whether some possibility of further public discipline needs to be engaged in," Kirby said to The Cancer Letter.

The board reported the reprimand and the settlements as part of "licensee information" on Potti, which can be found here: <a href="http://bit.ly/t5evng">http://bit.ly/t5evng</a>.

The scientific hypotheses on which the Duke clinical trials were based have been retracted by several medical journals, including Nature Medicine, The Lancet Oncology and The Journal of Clinical Oncology. Other papers have been retracted by The New England Journal of Medicine, Blood, PNAS and PLoS One. Altogether, about 13 full retractions and 13 partial retractions are expected.

The university has said that Potti's contributions had caused the retractions.

Moreover, Duke faces two lawsuits from patients, claiming that the university and its researchers had "knowingly engaged in a plan to generate billions of dollars in revenue; and that rather than actively protecting the safety and rights of patients in proper clinical trials, they chose a path of conduct that was evasive, deceptive, misleading and fraudulent by falsely representing that the delivery of chemotherapy agents to human subjects was based on valid science, when in fact they either knew or should have known that it was not."

In addition to alleging that patients had been harmed, the two suits focus on two companies owned by Duke and the researchers involved in developing the genomic technology and testing it in the clinic.

One company in question was CancerGuide Diagnostics (The Cancer Letter, Sept. 9, 2011). The lawsuits, filed in the Durham County Superior Court in September, are posted at <a href="http://www.cancerletter.com/categories/documents">http://www.cancerletter.com/categories/documents</a>.

The text of Potti's consent order points to complexity of the severance of his relationship with the university, which is still conducting a scientific misconduct investigation stemming from his case. Potti suspended clinical work at Duke on July 16, 2010, and resigned on Dec. 1, 2010.

#### "Careless and Honest Errors"

The medical board's consent order states that "Duke Medical Center has investigated Dr. Potti's

curriculum vitae and Duke Medical Center biographical sketch concerns and concluded that, while there were some inaccuracies on the biographical sketch and curriculum vitae, they were largely the result of

carelessness

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5.	Have you ever resigned from any hospital, institution or health care facility in lieu of disciplinary action?	YES □ NO	N N

**Excerpt from Potti's application for South Carolina Medical License** 

and honest errors with no clear intention to mislead."

The consent order was dated Nov. 22, and Duke officials said they first saw the consent order when it was reported—and posted—by The Cancer Letter on Dec. 4.

On Dec. 5, Duke officials responded by challenging the language of the consent order.

The document inaccurately characterizes Duke's finding, university officials said in a letter to the medical board.

The language appears to be "taken from the research misconduct inquiry report, which was evaluating these errors solely in the context of determining whether or not federal research misconduct had occurred and should be the subject of further investigation," Ann Bradley, Duke associate counsel, wrote in a letter to the board.

Such reports are the second step in standard misconduct investigations.

First, misconduct allegations are reviewed by a research integrity officer. Then, an inquiry committee looks at the case. The committee acts as an equivalent of a grand jury, interviewing witnesses and weighing the evidence.

Ultimately, the committee produces a report, which is shared with the respondent.

"The respondent may have shared portions of the initial inquiry report," Bradley said to The Cancer Letter. "Those words are in there, but nowhere will you see these words put together in the way they are in the consent order. That's what I believe may have occurred."

Bradley said she has been in contact with Potti's counsel and the medical board. "If the medical board agrees, there will be an amended consent order," Bradley said.

Potti's attorney, James Maxwell, of the Durham firm Maxwell, Freeman & Bowman, didn't respond to

a call from The Cancer Letter.

The Rhodes Scholarship—one of the honors Potti claimed in his CV, biographies and grant applications—is not a medical credential, which means that the medical board could pursue the case only on the grounds of unprofessional conduct.

The statute cited in the consent order applies to unprofessional conduct, which includes "committing of any act contrary to honesty, justice, or good morals, whether the same is committed in the course of the licensee's practice or otherwise, and whether committed within or without North Carolina."

Potti claimed that he had been a Rhodes Scholar, adding, parenthetically, (Australia). Rhodes is not an Australian scholarship.

Challenged by The Cancer Letter at the time, Potti claimed that he as a finalist rather than an actual Rhodes Scholar.

Also, Potti claimed to have been a research fellow at Queensland Medical Research Institute, which has no record of his having been there. His purported mentor for that fellowship—Gordon McLaren—said Potti had never been his fellow in Australia.

McLaren, who had spent a sabbatical at QMRI, had met Potti at the University of North Dakota, where Potti was a resident, but the two never worked together in Australia. The story of irregularities in Potti's biography first appeared in this publication in July 2010 (The Cancer Letter, July 16, 2010). The consent order states that Potti voluntarily suspended all clinical activities at Duke immediately after the allegations surfaced.

On Aug. 27, 2010, Peter Lange, Duke University provost, stated that "issues of substantial concern" were identified in Potti's biography and resulted in sanctions against the doctor. The Duke committee that reviewed

Potti's credentials noted that "the sheer number of errors" was a serious concern.

#### "Moving to Private Practice"

Potti is currently practicing at Coastal Cancer Center in Myrtle Beach, South Carolina.

He holds a temporary license that was issued on March 3 and is set to expire on June

30, 2013. (Last February, Potti also obtained a one-year license in Missouri, records in that state show.)

In his application for a medical license in South Carolina, Potti cited his reason for leaving Duke as "moving to private practice."

The application was obtained by Duke Chronicle reporter Taylor Doherty under the South Carolina Freedom of Information Act. Doherty made the documents available to The Cancer Letter.

In his "personal history information," Potti appears to have initially checked off "no" in response to the question of whether he was at the time under investigation or the subject of pending disciplinary action by a licensing board or an institution. Then he crossed out the "no" and marked "yes."

Potti's description of the proceedings—which is required—was not a part of the record made available by the South Carolina authorities under FOIA. Therefore, it's not publicly known whether the description was provided.

Asked to state his reasons for choosing to practice in South Carolina, Potti wrote:

"I was born to poor parents in a underserved community in India. When I was transitioning from my academic position into private practice, I was very attracted to the community in Loris, S.C., and their healthcare system. There appeared an opportunity for me and my family to return to a community that we would enjoy and hopefully help serve. Thanks."

Some Duke colleagues continued to support Potti after he departed from the university, writing letters on his behalf and submitting recommendations to the South Carolina medical licensure board.

		Name ANIL POTTI	
List all related employment (not training or residence			
1. Company Name  Duke University  Medical County	Company Address (Street, City, State, Zi BOX 3841, Div	ision of Oncology, DUMC, Dunha	NC, m 27
ASSISTMAL Professor	Type of Employment	Date of Employment   From: 01   01   20   0   To: 12   1   20   0	
Abbreviated Description of Duties Performed Imparticult on Outport out Climis Teaching, Research	Hours Worked per Week  60 - 80   Week	Reason for leaving Moving to Private Practice	
2. Company Name Duke University Medical Certifi	Company Address (Street, City, State, Z Box 3841, Division	m of Ducology, DUMC, Durham, N.	6
Job Title Assistant Professor	Type of Employment  Full-time Part-time	Prom: 05/01/2004 To: 01/01/2010	
Abbreviated Description of Duties Performed Impt 18 Outpatient Climes Tenching, Research	Hours Worked per Week 60 ~ 80   Week	Reason for leaving — N/A ~	

In his application, Potti states that he left Duke to move to private practice

"I am happy to write a letter for Dr. Anil Potti in support of his appointment to your group and for his hospital privileges," Crawford, chief of medical oncology at Duke, wrote in a letter to Coastal Cancer Center.

"His clinical skills are excellent," Crawford's letter, dated Jan. 7, 2011, continued. "During his tenure at Duke, Anil developed an impressive research program and helped the careers of a number of our fellows and junior faculty. He was always willing to help others around him and was an ideal model 'team player.' Despite a very active research program, Anil maintained his dedication to patient care and this always came first for him.

"The last several months have been difficult for him and for us as his colleagues. Throughout this time, Anil has conducted himself as he has throughout his time at Duke, with honesty, integrity and humility. I was hopeful that he would remain at Duke on our faculty in a clinical position, but his decision to resign his position at Duke in the end was probably best for him and his family.

"During this time period, there was a review of his clinical practice, and no issues were raised. Personally, I would be delighted to have Dr. Potti as a faculty member in our physician practice, or as an oncologist taking care of one of my family members."

Crawford's letter, addressed to the Myrtle Beach practice, ended up in Potti's file at the South Carolina Board of Medical Examiners.

Contacted by The Cancer Letter earlier this week, Crawford said he didn't have full understanding of the problem when he wrote the letter. "In retrospect, I realize that it was a mistake to send this letter without understanding the situation as I do today," he said in an email.

"It was based on my professional interactions with Dr. Potti and supported by

PART XI: Handwriting									
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Potti's reasons for wishing to practice in South Carolina

comments from his patients. While I was certainly aware of the controversy that was growing, I didn't have first-hand knowledge regarding the extent of the issues involved. Without that understanding, it was premature for me to write the letter of recommendation that I did."

Apparently, other Duke colleagues were equally saddened to see Potti leave.

David Rizzieri, an associate professor of medicine, wrote to the South Carolina board that he, too, would refer a family member to Potti.

"I would be pleased, if my own family had unfortunately contracted cancer, if Dr. Potti was their treating physician feeling comfortable in his knowledge base approach to care of sick patients and the ability to optimize their care."

In a letter to the state board, another Duke physician, Arati Rao, assistant professor of medicine at the Division of Cellular Therapy and BMT, wrote:

"From a clinical standpoint, I know of only few physicians who are as bright, dedicated, conscientious and caring as Dr. Potti. His patients absolutely love him, and he is well respected by his colleagues."

The letters of recommendation and excerpts from Potti's application are posted at <a href="http://www.cancerletter.com/categories/documents">http://www.cancerletter.com/categories/documents</a>.

Taylor Doherty contributed to this story.

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#### Prostate Cancer

# NIH Panel Recommends New Active Surveillance Standards

An independent state-of-the-science panel convened by NIH said many men with localized, low-risk prostate cancer should be closely monitored, delaying treatment until the disease progresses.

The panel recommended standardizing definitions and conducting additional studies to help develop clear follow-up protocols for monitoring strategies such as active surveillance.

"It's clear that many men would benefit from delaying treatment, but there is no consensus on what constitutes observational strategies and what criteria should be used to determine when treatment might ultimately be needed among closely-monitored men," said Patricia Ganz, conference panel chairperson and director of the Division of Cancer Prevention and Control Research at the Jonsson Comprehensive Cancer Center at the University of California in Los Angeles.

Active surveillance differs from watchful waiting and passive approaches—it can include blood samples, digital rectal exams, and repeat biopsies on a regular schedule. The panel found that protocols to manage active monitoring still vary widely, hampering the evaluation and comparison of research findings.

The panel also identified emerging consensus in the medical community on a definition for low-risk prostate cancer: a prostate-specific antigen level less than 10 ng/mL and a Gleason score of 6 or less. Using this definition, the panel estimated that more than 100,000 men diagnosed with prostate cancer each year would be candidates for active monitoring rather than immediate treatment.

Due to the favorable prognosis of PSA-detected, low-risk prostate cancer, the panel also recommended

removing the anxiety-provoking term "cancer" for this condition.

The panel's draft statement, which incorporates public comments received in an open conference session, is posted at <a href="http://consensus.nih.gov">http://consensus.nih.gov</a>.

# Breast Cancer IOM Report Links Breast Cancer To Environmental Risk Factors

A new report from the Institute of Medicine says that women can lower their chances of developing breast cancer by reducing or eliminating certain environmental risk factors.

The report recommended avoiding unnecessary medical radiation, forgoing use of combination estrogen-progestin menopausal hormone therapy if possible, limiting alcohol consumption, maintaining a healthy weight, exercising regularly and avoiding tobacco use.

The committee based its recommendations on consistent scientific evidence of an association with breast cancer.

The report also noted possible, but less clear, links to exposure to benzene, 1,3-butadiene, and ethylene oxide—chemicals found in gasoline fumes, vehicle exhaust, tobacco smoke, and some workplace settings.

Meanwhile, the report said that multiple studies have found no impact in breast cancer risk from avoiding hair dyes or the radiation emitted by mobile devices.

Insufficient or contradictory evidence has delayed conclusions regarding many chemicals of concern, including bisphenol A, pesticides, cosmetic ingredients, dietary supplements, and other substances, said the report.

The committee cautioned that the evidence on exactly how much a woman's risk would be reduced by following these steps is inconclusive, and can vary considerably because of the innumerous complex factors that can influence the chances of disease.

The committee recommended research into certain risk factors that have provocative but inconclusive

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evidence, including: overnight shift work and accompanying disruptions of the sleep cycle; chemicals that mutate genes, alter gene expression, or affect hormones such as estrogen; and gene-environment interactions.

Most research has focused on adults and on exposures occurring within a few years prior to a diagnosis, but recent studies have shown the importance of exposures at various life stages, such as childhood, adolescence, pregnancy, and menopause.

"Breast cancer develops over many years, so we need better ways to study exposures throughout women's lives, including when they are very young," said committee chair Irva Hertz-Picciotto, professor in the department of public health sciences and chief of the division of environmental and occupational health at the School of Medicine at University of California, Davis. "We also need improved methods to test for agents that may be contributing to breast cancer risk and to explore the effects of combined exposures."

Members and staff of IOM's Committee on Breast Cancer and the Environment are:

- Irva Hertz-Picciotto (chair), professor and chief of the Division of Environmental and Occupational Health; Department of Public Health Sciences, University of California, Davis
- Lucile Adams-Campbell, professor of Oncology and associate director for Minority Health and Health Disparities Research; Lombardi Comprehensive Cancer Center, Georgetown University Medical Center
- Peggy Devine, founder and president of the Cancer Information and Support Network
- David Eaton, associate vice provost for research, and professor and director of the Center for Ecogenetics and Environmental Health; School of Public Health and Community Medicine, University of Washington
- S. Katharine Hammond, professor in the Division of Environmental Health Sciences; School of Public Health, University of California, Berkeley
- Kathy Helzlsouer, director of the Prevention and Research Center at Mercy Medical Center, and adjunct professor of epidemiology at Johns Hopkins University
- Robert Hiatt, professor and chair of the department of epidemiology and Biostatistics and director of Population Sciences at Helen Diller Family Comprehensive Cancer Center, University of California, San Francisco
- Chanita Hughes Halbert, director of the Community and Minority Cancer Control Program, and associate professor in the Department of Psychiatry,

University of Pennsylvania, Philadelphia

- David Hunter, dean for academic affairs, and Vincent L. Gregory Professor of Cancer Prevention, Departments of Epidemiology and Nutrition, Harvard School of Public Health
- Barry Kramer, editor in chief of JNCI, and director of the NCI Division of Cancer Prevention
- Peggy Reynolds, senior research scientist, Cancer Prevention Institute of California
- Joyce Tsuji, principal scientist at the Center for Toxicology and Mechanistic Biology, Health Science Group, Exponent Inc.
- Cheryl Lyn Walker, director of the Institute of Biosciences and Technology at the Center for Translational Cancer Research, at Texas A&M Health Science Center
- Lauren Zeise, chief of Reproductive and Cancer Hazard Assessment Branch, Office of Environmental Health Hazard Assessment, California Environmental Protection Agency
  - Lois Joellenbeck, study director

#### In Brief

## White House Names Two Members To The President's Cancer Panel

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as panel member.

Rimer has 35 years of experience in cancer control. She was elected to the Institute of Medicine in 2008, and has received the NIH Director's Award and distinguished service awards from both the Secretary of Health and Human Services and the American Cancer Society.

Witte, an investigator in the Howard Hughes Medical Institute, is also Distinguished Professor of Microbiology, Immunology, and Molecular Genetics at UCLA and a member of the National Academy of Sciences, the American Academy of Arts and Sciences, and the Institute of Medicine. He has received the Rosenthal Award from the American Association of Cancer Research and the Leukemia and Lymphoma Society's de Villiers International Achievement Award.

They will replace **LaSalle Leffall**, **Jr.**, the Charles R. Drew Professor of Surgery at Howard University, and **Margaret Kripke**, the Vivian L. Smith Chair and professor emerita at MD Anderson Cancer Center at the University of Texas.

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# THE UNIVERSITY OF ARIZONA Cancer Center and ST. JOSEPH'S HOSPITAL and Medical Center will collaborate to deliver cancer care, work with community-based oncologists, participate in clinical and translational research, and establish a center for ambulatory and inpatient oncology.

"We envision our operations in Phoenix—at St. Joseph's and at our future outpatient facility—as a national and international model of integrated healthcare to fight cancer," said David Alberts, director of the university's NCI-designated comprehensive cancer center.

St. Joseph's would serve as the primary inpatient clinical site. It will also provide outpatient clinical facilities at its central Phoenix medical center campus, eventually expanding activities to a new outpatient center to be constructed in downtown Phoenix. Construction is planned to begin in 2012.

# CEDARS-SINAI MEDICAL CENTER in Los Angeles was named a Roche Molecular Center of Excellence by the pharmaceutical company.

The center's molecular pathology laboratory focuses on new prognostic and diagnostic tools for individualized molecular testing for personalized treatments in such key areas as cancer, infectious diseases, genetic and familial disorders, and cardiovascular diseases.

The center joins an alliance network of non-competing regional laboratories nationwide to collaborate and share scientific knowledge in molecular testing and help advance new test methods and technology.

The center's laboratory will offer the latest Roche molecular technologies, including the cobas 4800 BRAF V600 Mutation Test, a companion diagnostic test to identify patients eligible for treatment with Zelboraf (vemurafenib) for inoperable or metastatic melanoma.

"Roche is very pleased to welcome Cedars-Sinai Medical Center into the Molecular Center of Excellence alliance," said Whitney Green, senior vice president for molecular diagnostics at Roche Diagnostics Corporation. "We value their expertise in implementing molecular technologies in the advancement of personalized medicine."

The new relationship offers Cedars-Sinai a focal point to bring together many existing initiatives related to personalized diagnostics, as well as a newly created Advanced Biorepository and Morphology Translational Core. It also complements the center's Molecular Genetics Pathology fellowship program.

"With Roche's leadership in personalized healthcare and companion diagnostics, this agreement enhances our opportunities to collaborate in support of Cedars-Sinai's own personalized medicine initiatives," said Jean Lopategui, medical director of the laboratory.

THE CONQUER CANCER FOUNDATION of the American Society of Clinical Oncology will award 20 oncology trainees with Merit Awards at the 2012 Genitourinary Cancers Symposium in February 2012. The awardees will have the opportunity to present their research at the symposium.

*The awardees are:* 

- **Arjun Balar**, Memorial Sloan-Kettering Cancer Center; Alterations in the PI3K/Akt signaling pathway and association with outcome in invasive high-grade urothelial cancer
- Eugene Cha, Weill Cornell Medical College; Predicting clinical outcomes after radical nephroureterectomy for upper tract urothelial carcinoma
- **James Chen**, The University of Chicago; Role of homeobox pathway in prostate carcinogenesis
- Adrian Fairey, University of Southern California Keck School of Medicine; Association between cancer stem-like cell gene expression and clinical outcome in localized prostate cancer: A nested case-control study
- **Phillip Gray**, Brigham and Women's Hospital; Bowel and bladder toxicity patterns in patients with prostate cancer treated with proton beam versus intensity-modulated radiation therapy
- **Petros Grivas**, University of Michigan; Randomized phase II trial of maintenance sunitinib versus placebo following response to chemotherapy for patients with advanced urothelial carcinoma
- Christopher Hallemeier, Mayo Clinic; Longterm outcomes of radiotherapy for stage II testicular seminoma: The Mayo Clinic experience
- Thai Ho, The University of Texas MD Anderson Cancer Center; Regulation of SETD2, a histone methyltransferase, in advanced clear cell renal cell carcinoma
- Mark Jesus Magbanua, University of California, San Francisco; Physical activity and prostate gene expression in men with low-risk prostate cancer
- Xueying Mao, Queen Mary University of London; The different genetic alterations between Western and Chinese prostate cancers and the underlying mechanisms
  - David Margel, University of Toronto; Impact of

multiparametric endorectal coil prostate MRI on disease reclassification among active surveillance candidates: A prospective cohort study

- **Kenneth Nepple**, Washington University School of Medicine; Impact of different definitions of high-risk prostate cancer on survival after radical prostatectomy
- **Phillip Palmbos**, University of Michigan; ATDC as a novel oncogene in bladder cancer
- Erin Richman, University of California, San Francisco; Genetic variants in antioxidant genes, Gleason grade, and prostate cancer recurrence after radical prostatectomy
- Michael Rink, Weill Cornell Medical College; Influence of preoperatively detected circulating tumor cells on the outcome of patients with urothelial carcinoma of the bladder treated with radical cystectomy
- Nathan Sheets, University of North Carolina; Comparative effectiveness of intensity modulated radiation therapy, proton therapy, and conformal radiation therapy in the treatment of localized prostate cancer
- **Brian Shuch**, NCI; Metabolic evaluation of sporadic papillary kidney cancer
- Monica Shukla, Cleveland Clinic; Identifying patients with node-positive prostate cancer who may benefit from adjuvant pelvic radiation following prostatectomy
- **Ben Tran**, Princess Margaret Hospital; Impact of renal impairment and granulocyte colony stimulating factor on bleomycin-induced pneumonitis, febrile neutropenia, and survival in patients with germ cell tumor treated with chemotherapy
- Che-Kai Tsao, Tisch Cancer Institute, Mount Sinai Medical Center; Cytoreductive nephrectomy in the United States: Patterns of care and patient characteristics

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