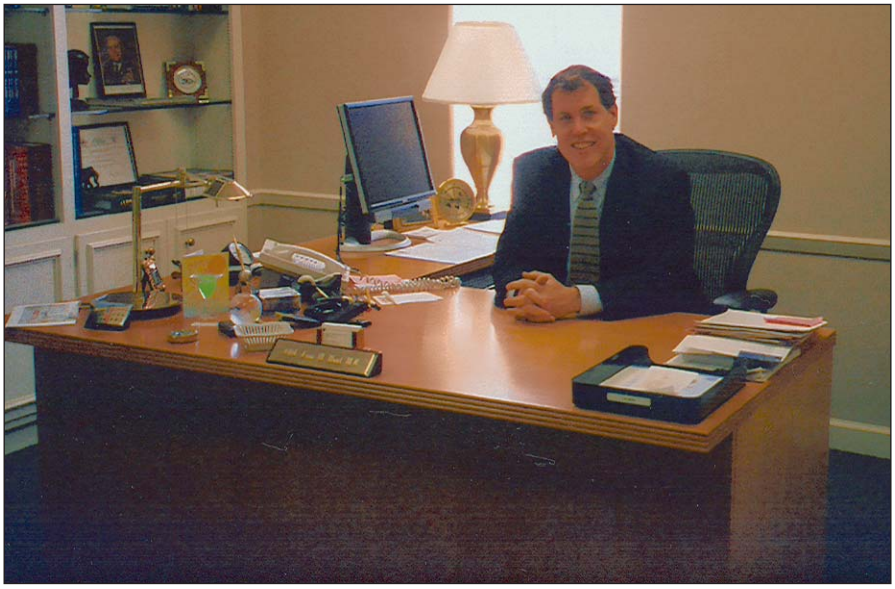
DUKE
UROLOGY Today
Summer 2005

A MESSAGE FROM THE CHIEF

Dear Friends, DYSURICS, and Colleagues,



I have now been a part of Duke Urology for one year and am continuing to enjoy the experience very, very much. Every day I see further examples of the drive, commitment, and passion for this program demonstrated in individuals at every level of the health care team. Medicine is complex today and it takes a team approach more than ever. Let me give you some specific examples of what has happened at Duke Urology since I last wrote to you in the Fall 2004 issue.

In the patient care arena, we have made a commitment to see patients who desire an appointment within 7 working days. This "7-Day-Access" policy has been adopted by a number of services at Duke, including Duke Urology, and has been a big hit. While we cannot guarantee a specific provider, patients will be able to be seen by one of our urologists in this time frame if they desire. If you are a patient or referring physician and feel we have not lived up to this promise, let me know at any time. I want to thank Craig Donatucci, M.D., our Vice Chief for Practice Affairs, for making this program a reality.

Also in the patient care area, I would like to introduce and welcome Kelly Maloney, MD to our Duke Urology faculty. Dr. Maloney is an outstanding doctor and person and is a wonderful addition to our program. She will be focusing on bladder cancer, benign prostate conditions, and general urology and is seeing patients at our North Duke Street office and main Urology clinic in 1-G of Duke South. Kelly is our first faculty member who hails from Canada as well as our first female senior staff member.

Regarding other new faculty members, we are excited to welcome back John Wiener, MD as the Chief of our Pediatric Urology Section. John left Duke a couple of years ago to become the Chief of Urology at the University of Mississippi. He has now completed that "Tour of Duty" and rejoined our faculty August 15, 2005. There will be more to follow in the next issue, but welcome back John! Also, Steve Freedland, MD will be joining our faculty in the Fall of 2005. Steve is a "rising star" in prostate cancer research, particularly in outcomes research, biomarkers, and databasing. I have tasked him with helping us

(Continued on next page)

A MESSAGE FROM THE CHIEF continued

continue to build this area of research at Duke and working with us on the Duke Prostate Center and Duke Outcomes Database. For the first several years, Steve will be primarily doing research both at Duke and at the Durham VA Medical Center.

Regarding the Duke Prostate Center (DPC), we are moving this forward to reality since the last issue. Space in Duke South Clinics has been set aside for an approximately 5,000 square foot stand-alone center for state-of-the-art care for men and their families with prostate cancer and disease. Our current prostate cancer multidisciplinary clinics with Medical Oncology and the Department of Radiation Oncology will be enhanced and expanded by the opening of this center in mid 2006. Special thanks to Drs. Dan George (Medical Urologic Oncology), Mitch Anscher (Radiation Oncology), Cary Robertson, Tom Polascik, Johannes Vieweg, Phil Walther, Phil Dahm and our administrative staff for their support in planning this new initiative. Our first Duke Prostate Center education symposium was held at the Durham Hilton in early April 2005 and was a great success with over 100 attendees. The 2nd DPC Symposium will be held on June 10, 2006 here in Durham and all friends of Duke Urology are welcome to join us!

Other very successful educational events since the last issue include the Winter Urologic Forum held in Telluride, Colorado in January. Special thanks to Dr. George Webster for serving as Course Director and to Ms. Jonna Clark for being the Course Administrator. The 39th annual Duke Urologic Assembly (DUA) was held in the beautiful island of Curacao in March and was well attended. Special thanks to Ms. Linda Mace and Ms. Joan McAlexander for administering the course and to our Guest Visiting Professor, Dr Anthony D'Amico from Harvard for a great series of talks on prostate cancer. The 40th annual DUA will be held from March 29th to April 2nd 2006 at the very beautiful and upscale Grand Floridian in Orlando, Florida. We look forward to seeing you there. Finally, we are proud to continue the longstanding Duke Tuesday in Urology series with outstanding visiting professors including my old boss, Dave Mcleod from Walter Reed.

On the research side of the house, Dr Johannes Vieweg, our Vice Chief for Research continues to do stellar immunology and vaccine work as well as helping the entire division work more closely on clinical trials. Dr Vieweg is helping to position us for a future GU or Prostate SPORE grant from the NCI and/or other major program project grants.

On the education side, Dr Glenn Preminger continues to excel as our Residency Program Director and Vice Chief for Education. Glenn worked very hard with our residency administrative coordinator, Ms. Gladys Walker to restructure our urology residency program to allow us to restore the research year of the residency. In addition to three stellar new PG1 residents who were picked in the match, we have selected three additional residents who have now started at the PG2 level to restore the research year and the 6-year program. Our new residents are listed elsewhere in this issue and we welcome them all to Duke Urology.

On a personal note, my wife, Ellen, joined me in Durham in the late Fall of 2004. Ellen is a senior government administrative officer with the federal government and was able to transfer from the National Cancer Institute (NCI) to the National Institute of Environmental Health Sciences (NIEHS). I am delighted that she was able to transfer here and for us to be together. Although I love my job, it would not be meaningful without her here to share the experience.

Until next time, I remain

Very respectfully,

Judd

RESIDENCY TRAINING PROGRAM

2005 Duke Urology Graduates

(standing from left) Alon Z. Weizer, MD, Fernando C. Delvecchio, MD, Ari D. Silverstein, MD with Residency Program Director, Glenn M. Preminger, MD (seated)

Current Residents

Chief Residents: (PG-6)

Brian R. Evans, M.D.
Matthew D. Young, M.D.
Charles W. Yowell, M.D.

Laboratory Residents: (PG-3)

Kristy M. Borawski, M.D.
Nicholas J. Fitzsimons, M.D.
Timothy Y. Tseng, M.D.

Senior Residents: (PG-5)

Drew A. Dylewski, M.D.
Charles G. Marguet, M.D.
Jeremy B. Wiygul, M.D.
Benjamin K. Yang, M.D.

New Junior Residents: (PG-2) *

W. Cooper Buschemeyer, III, M.D.
Ed Rampersaud, M.D.
Marnie R. Robinson, M.D.

Senior Residents: (PG-4)

Quintin V. Cancel, M.D.
Bassem M. Eldaif, M.D.
Regina D. Norris, M.D.

New 2005-2006 Residents: (PG-1)

Joseph Klink, M.D.
Charles D. Scales, Jr., M.D.
Florian R. Schroeck, M.D.

***The Residency was restored to 6 years and three PG-2 Residents started July 1, 2005 in addition to the three PG-1 Residents**

CURRENT FELLOWS

	Specialty	Mentor(s)
Elizabeth J. Anoia, MD	Female Urology and Urogynecology	George D. Webster, MB, FRCS
George E. Haleblian, MD	Endourology	Glenn M. Preminger, MD
Roger L. Sur, MD	Endourology	David M. Albala, MD
Vladimir Mouraviev, MD, PhD	Oncology Research	Thomas J. Polascik, MD Judd W. Moul, MD

New Faculty

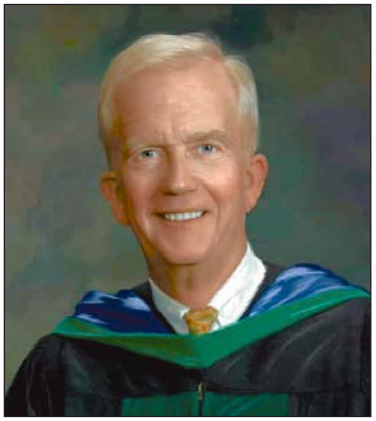
Kelly E. Maloney, MD
Assistant Professor

John S. Wiener, MD
Professor

Dr. Maloney received her undergraduate degree from the University of Guelph, Ontario, Canada and her medical degree, internship, and surgical residency from Dalhousie University in Halifax, Nova Scotia, Canada. In 1996, she received her urology residency at Duke University, and afterwards worked for a private urology practice in Pennsylvania. She joined our faculty on March 1, 2005. Her clinical interests are in bladder cancer and general urology.

Dr. Wiener received his undergraduate and urology residency degrees from Duke University, followed by a pediatric urology fellowship with Dr. Edmond Gonzales at Baylor. John returned to Duke in 1997 to lead the pediatric urology program at Duke. In 2003, he accepted a position as Chief of Urology at the University of Mississippi. He returned to Duke on August 15, 2005 as Professor and Director of Duke Pediatric Urology.

David F. Paulson, MD Retires



February 25th and 26th marked a very special occasion for Duke Urology. After 24 years of service as our Division Chief and a total of 38 years at Duke, Dr. David Paulson retired from full-time service. The retirement event started with a reception held in the Searle Center where local friends and associates greeted David and his wife, Ellen. On behalf of the entire Division and Urology Clinic, Dr. Moul presented Dr. Paulson with an engraved crystal caduceus.

On Saturday morning, February 26th, visiting guests were invited to a brunch celebration at the Durham Hilton. The finale was a black-tie dinner and tribute at Hope Valley Country Club, where David and Ellen were joined by their children and extended families, and over 130 friends and associates. Guest Professor and David's dear friend, Dr. Ralph deVere White, and many others paid tribute to his remarkable career at Duke. The event culminated with the unveiling of Dr. Paulson's portrait as seen above. The senior faculty also presented David with a bound volume of reprints from all his peer-reviewed publications.

Kudo's ...

Benjamin K. Yang, MD received the Montague L. Boyd essay competition award for his paper entitled "A Cross-Sectional Survey of Long-Term QOL Following RPP" at the annual meeting of the Southeastern Section of the American Urological Association held in Charleston, South Carolina, March 3-6, 2005.

Dr. Yang (right) receives Montague L. Boyd Essay award.

Charles D. Scales, Jr., MD was featured during a live webcast for his abstract on "Co-prescription of phosphodiesterase-5 inhibitors and nitrates"at the annual meeting of the American Urological Association in San Antonio, Texas, May 21-26, 2005.

Philipp Dahm, MD was awarded the Society of Urologic Surgery Junior Faculty Award.

Drs. Shiv Srivastava, Vasantha Srikantan, Zhiqiang Zou, and **Judd W. Moul, MD** were granted a patent for their invention of "Prostate-Specific Gene, PCGEM1, and the Methods of Using PCGEM1 to Detect, Treat, and Prevent Prostate Cancer."

(l to r): Dr. Norman M. Rich, Dr. David G. McLeod, Dr. Moul, and Dr. David G. Burris

Judd W. Moul, MD was invited plenary speaker at the First Annual Multidisciplinary Prostate Cancer Symposium held in Orlando, Florida, February 17-19, 2005.

Judd W. Moul, MD presented the first annual David G. McLeod Distinguished Surgical Lecture at the Uniformed Services University of the Health Sciences in Bethesda, Maryland on March 10, 2005.

Philipp Dahm, MD received the Wyeth-Society University Surgeons Foundation Clinical Scholar Award for his project, "Active Immnotherapy with Human LAMP Telomerase RNA-Transfected Immature, Autologous Dendritic Cells Primed in Situ using Escalating Doses of the Topical Immunostimulant Imiquimod (Aldara TM) in Patients with Metastatic Prostate Cancer."

Judd W. Moul, MD was listed as one of "America's Top Doctors for Cancer" in Castle Connolly's acclaimed guide to the top medical specialists in the nation.

The American Association of Genitourinary Surgeons (AAGUS) is the most prestigious society for Urologists in the United States. Limited to only 75 active members at any one time by original charter more than 100 years ago, it is considered the top professional society for academic urologists. With the election of **Judd W. Moul, MD** in the spring of 2005, Duke Urology now has four active members (**Glenn M. Preminger, MD, George D. Webster, MB, FRCS**, and **David F. Paulson, MD**). No other urology program in the country currently has four active AAGUS members, which gives Duke Urology a very distinct honor.

(Urology Clinic Clerical Staff from left) Tammy Matthews, Ernestine Charles, Jobnicia McNeil, Margaret Holland, and Cynthia Bridges

Urology Clinic Staff attended their 5th Annual Team Building Retreat at the Aqueduct Conference Center in Chapel Hill, NC on May 25, 2005. The theme was "Managing Your Stress Contributes to Team Success", facilitated by Ruth E. Quillian-Wolever, Ph.D. of Duke's Department of Psychiatry and Behavioral Sciences.

Urology Clinic Clerical Staff were awarded the First Quarter Service Champion Award at a ceremony in their honor on July 12, 2005.

HIGHLIGHTS OF THE FIRST ANNUAL DUKE PROSTATE CENTER SYMPOSIUM:

"Carolina Prostate Cancer Clinical Trials and Care Update"

Hilton Hotel • Durham, North Carolina • April 9, 2005

Dr. Moul opens the program and provides an overview of the challanges we face in treating prostate cancer.

Keynote speaker: Christopher L. Amling, MD discusses the link between obesity and prostate cancer.

Doris Coleman, RN represents Duke Urology's Clinical Trials Program.

PROSTATE SPECIFIC ANTIGEN TESTING IN MEN OVER 75

At the 2004 Society of Urologic Oncology Winter Meeting, Dr. Chuck Scales, a research associate in the Division of Urology, presented results from an investigation of prostate-specific antigen (PSA) testing among men over 75 years of age. This age group is of particular interest, as guidelines recommend screening men over 50 with at least a 10-year life expectancy, yet the average life expectancy for men over 75 is less than 10 years. Working with Drs. Dahm, Albala, Norris and Moul in the Division of Urology, Dr. Scales used data from the National Ambulatory Medical Care Survey (NAMCS) to estimate PSA test use at outpatient visits in the United States.

During the 4-year period 1999-2002, over 40 million PSA tests were performed, excluding tests to monitor prostate cancer recurrence or progression. Approximately 14% of these tests were performed in men over 75 years of age. Among these men, more than one third were screened for prostate cancer in 2002, based on US population estimates. This may represent over-utilization of PSA testing, given that on average men over 75 are unlikely to develop clinically significant prostate cancer.

"While the average man over 75 may have less than a ten year life expectancy, clearly some men will live longer than ten years, and may benefit from prostate cancer detection and treatment," said Dr. Scales. To address this issue, Dr. Scales recommends development of guidelines to identify elderly men with a 10-year life expectancy, and studies to determine if detection and treatment of prostate cancer is beneficial in this age group.

Dr. Charles D. Scales, Jr.

Evidence Based Medicine: A Duke Survey of the Members of the American Urological Association

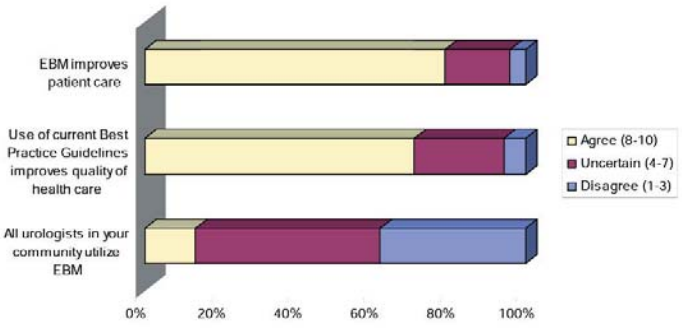
In April of 2005, a team of researchers from Duke Urology represented by Drs. Roger L. Sur, Charles D. Scales Jr., Glenn M. Preminger and Philipp Dahm were provided with the unique opportunity to survey members of the American Urological Association (AUA) about their understanding of and attitudes towards evidence-based medicine. The web-based survey instrument that was developed at Duke attracted the attention of leaders of the AUA that offered to send out the survey from its own website together with an introductory letter by Dr. Joseph Segura, Chairman of the AUA Guidelines Committee.

The efforts that led to the development of the survey resulted from the recognition that evidence-based medicine is having an increasing effect on the practice of urology. This trend can be witnessed on several fronts: First, supported by the power of the Internet, our patients are becoming increasingly educated about their choice of treatment options, i.e. for the management of localized prostate cancer, and are demanding to see hard data not only on modality-specific, but also institution- and surgeon-specific outcomes. Second, in a setting of ballooning health care costs, third party payers are becoming more and more reluctant to pay for new medications, procedures and devices that have yet to demonstrate superior results as assessed by rigorous scientific methodology. Finally, there is awareness in the urology community that the level of evidence provided by a majority of studies in the urology literature is suboptimal, and that efforts to improve the methodological standards of clinical research are indicated.

This entirely web-based survey that was sent to all members of the AUA began by introducing the survey participant to the paradigm of evidence-based medicine as the "integration of best research evidence, clinical skills, and patient values to optimize medical outcomes." Subsequent questions were then grouped into three categories: 1) Questions about the current role of evidence-based medicine in urology and its perceived potential for improving the quality of patient care, 2) A survey of urologists' self perceived understanding of common statistical and evidence-based medicine-related terms such as publication bias, relative risk and standard deviation, and 3) The knowledge and actual use of evidence-based medicine -related resources such as the AUA Practice Guidelines, PUBMED or the Cochrane Database of Systematic Review.

The survey was completed by over 700 AUA members. One of the main findings was that an overwhelming endorsement of evidence-based medicine as a method to improve patient care, and strong support of the Best Practice Guidelines (i.e. as put forth by the AUA Panel on the Management of Renal and Ureteral Calculus Panel led by Dr. Glenn Preminger) to promote evidence-based care (Figure 1). The participants however also expressed skepticism as to whether evidence-based medicine has yet been broadly endorsed in the greater urology community.

Figure 1. Survey responses to three statements related to the role and importance of evidence-based medicine (EBM) in urology. Participants (n=714) were asked to respond on a scale of 1 (completely disagree) to 10 (completely agree), which were grouped into three categories "disagree" (1-3), "uncertain" (4-7) and "agree" (8-10) for this analysis.



This survey has also helped to identify shortcomings among urologists in the understanding of key terms relating to evidence-based medicine. The AUA has begun to address this issue by offering the first course on Evidence-Based Medicine and Statistics for urologists at the recent AUA meeting in San Antonio. This course, which was directed by Dr. Philipp Dahm, was very well received and is expected to be offered again next year, particularly, since 76% of urologists that responded to this survey indicated that they would be interested in learning more about evidence-based medicine in the future. Meanwhile, a comprehensive report of the results of this first evidence-based medicine survey of the urology community is in preparation and expected to be published by Dr. Sur and colleagues from Duke Urology in the *Journal of Urology* in the near future.

FUTURE CONFERENCES & WORKSHOPS

11/8/05 1:00–6:00 pm	Duke Tuesday in Urology Searle Conference Center	Guest Lecturer: Jack W. McAninch, MD, FACS Professor and Chief of Urology San Francisco General Hospital
3/29/06 thru 4/2/06	Duke Urologic Assembly	Grand Floridian Orlando, Florida
6/10/06	Duke Prostate Center Symposium	Hilton Hotel Durham, North Carolina

For more information, please call us at (919) 684-2033
or visit our website at www.dukeurology.com.

11/4/05 and 12/16/05	Prostate and Renal Cryotherapy Clinical Applications Workshop	Duke University Medical Center Durham, North Carolina Course Director: Thomas J. Polascik, MD, FACS

Register on-line at www.oncura.com/cryo-registration.html

NAFC
DUKE UNIVERSITY HEALTH SYSTEM

The National Association for Continence
and Duke University Health System

Host

An Educational Forum:
LIFELONG BLADDER HEALTH AND PELVIC SUPPORT

Saturday – November 12, 2005
8:45 a.m. – 4:00 p.m.
Washington Duke Inn
Durham, North Carolina

Forum speakers include Arthur Frommer, noted travel authority and author,
Judd W. Moul, MD, Professor and Chief of Duke Urologic Surgery,
George D. Webster, MB, FRCS, Professor of Urology and Cindy L. Amundsen, MD,
Associate Professor of Urogynecology at Duke as well as
other nationally recognized experts from UNC-Chapel Hill, Emory, Cornell,
Mayo Clinic, and the University of Virginia.

To register, call 1-800-BLADDER or visit www.nafc.org.

SOME OF OUR NOTEWORTHY PUBLICATIONS...

"The Effect of Botulinum-A Toxin on Patients with Severe Urge Urinary Incontinence"

Michael K. Flynn, George D. Webster and Cindy L. Amundsen

Subjects with severe urge urinary incontinence were recruited from female urology and urogynecology clinics at Duke Medical Center in this open label uncontrolled clinical trial. All subjects were administered 150 units of botulinum-A toxin (Botox, Allergan, Irvine, California) and reported remarkable subjective improvement in incontinence. Even though most of the women seemed to be incontinent again six months after treatment, the results strongly suggest that Botox is a safe, effective therapy for short-term management of severe urge incontinence. Further studies are needed to confirm these findings and to address other issues such as how often Botox should be given and at what dose. Results of this study were published in *The Journal of Urology* Vol 172, 2316-2320, December 2004.

"Telomerase mRNS-Transfected Dendritic Cells Stimulate Antigen-Specific CD8+ and CD4+ T Cell Responses in Patients with Metastatic Prostate Cancer"

Zhen Su, Jens Dannull, Benjamin K. Yang, Philipp Dahm, Doris Coleman, Donna Yancey, Sylvia Sichi, Donna Niedzwiecki, David Boczkowski, Eli Gilboa, and Johannes Vieweg

This exploratory phase I/II clinical trial showed that patients with metastatic prostate cancer who were vaccinated with Telomerase mRNA-transfected dendritic cells had stimulated antigen-specific cell responses at frequencies comparable to those seen after vaccination for infectious diseases that result in clearance of the infection. In addition, these patients had a reduction in serum PSA velocity and a clearance of circulating tumor cells. Results of this trial were published in the March 15, 2005 issue of *The Journal of Immunology*.

"Supplement Use Among Men With Prostate Cancer"

Jeremy B. Wiygul, Brian R. Evans, Bercedis L. Peterson, Thomas J. Polascik, Philip J. Walther, Cary N. Robertson, David M. Albala, and Wendy Demark-Wahnefried

Based on a survey of men diagnosed with prostate cancer at Duke Medical Center, data revealed a high percentage of men take supplements such as multivitamins, vitamin E, vitamin C, and calcium. In addition, supplement use increased significantly after diagnosis and in men who were white, highly educated, exercise regularly, and who consume five or more daily servings of fruits and vegetables. These data are essential to understanding the potential benefits of supplements on disease outcome since no current data exist. Results of this study were published in *Urology* 66(1): 161-166, 2005.

DUKE UROLOGY CLINICAL TRIALS CURRENTLY OPEN TO ENROLLMENT:

Cancer Prevention

CALGB 70004/S9917 L-Selenium-Based Chemoprevention of Prostate Cancer Among Men With High Grade Prostatic Intraepithelial Neoplasia

Overview: To compare the effects of oral l-selenomethionine vs. placebo administered under randomized, double-blind conditions upon the three-year incidence rate of prostate cancer among men diagnosed with high-grade prostatic intraepithelial neoplasia (HGPIN) and who have not been found to have prostate cancer on prostatic biopsy

Eligibility Criteria: Men at least 40 years of age with prostate biopsy documenting HGPIN with no evidence of cancer and PSA <= 10 ng/mL within 3 months not currently taking finasteride or other androgen suppressor

Principal Investigator: Philip Walther, MD

Contact: Ann Walker (919)684-2223

Prostate Cancer — Long-Term Survivorship

RENEW: Reach-out to ENhancE Wellness

Overview: A randomized, controlled study to test whether a home-based diet and exercise program (through mailed materials and telephone counseling) can improve the physical function of long-term cancer survivors

Eligibility Criteria: Patients at least 65 years of age and diagnosed with prostate, breast, or colorectal cancer at least 5 years ago currently without progressive disease or second cancers

Principal Investigator: Wendy Demark-Wahnefried, PhD

Contact: Denise Snyder (919)660-7580

Prostate Cancer — Local, Untreated

Prostate Cancer: Impact of Fat & Flaxseed Modified Diets

Overview: To determine the effects of flaxseed supplementation (30 g/day) and/or a low fat diet (<20% of total energy) on markers associated with prostatic neoplasia among 160 men with prostate cancer who are scheduled for prostatectomy

Eligibility Criteria: Patients at least 3 weeks before scheduled radical prostatectomy who have not received prior hormonal therapy and have not started any new dietary supplements in past 3 months (except multi-vitamins)

Principal Investigator: Wendy Demark-Wahnefried, PhD

Contact: Denise Snyder (919)660-7580

A Prospective Study of Health Related Quality of Life Following Radical Prostatectomy

Overview: To longitudinally measure Quality of Life issues in patients with prostate cancer undergoing radical prostatectomy

Eligibility Criteria: Men diagnosed with adenocarcinoma of the prostate scheduled to undergo radical prostatectomy who are willing and able to complete self-report questionnaires

Principal Investigator: Philipp Dahm, MD

Contact: Doris Coleman (919)668-2555

A Research Study to Determine the Efficacy of Prostascint with CT Coregistration Imaging to Locate Prostate Cancer Within the Prostate Gland When Compared to Pathological Findings After Prostatectomy

Overview: To compare the results of ProstaScint with CT coregistration imaging to results of the surgically removed prostate to determine the efficacy of the combined scan to detect areas of prostate cancer within the prostate gland

Eligibility Criteria: Diagnosed with clinically localized prostate scheduled to undergo radical prostatectomy and have not received prior radiation, chemotherapy, or hormone therapy

Principal Investigator: Thomas Polascik, MD

Contact: Jill S. Smith (919)668-3613

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A Research Study to Determine the Efficacy of Prostascint (111In-Capromab Pendetide) with CT Coregistration Imaging to Stage Clinically Advanced Prostate Cancer Prior to Surgical Lymph Node Dissection

Overview: To compare the results of ProstaScint with CT coregistration imaging of the pelvic lymph nodes to the pathology results of the surgically removed lymph nodes to determine the efficacy of the combined scan to detect areas of prostate cancer within the lymph nodes

Eligibility Criteria: Diagnosed with high-risk prostate cancer and scheduled to undergo radical prostatectomy and have not received prior radiation, chemotherapy, or hormone therapy

Principal Investigator: Thomas Polascik, MD

Contact: Jill S. Smith (919)668-3613

Lidocaine Patch (Lidoderm®) for Analgesia Following Radical Retropubic Prostatectomy

Overview: To determine if application of the Lidoderm® patch (a patch containing lidocaine, a local anesthetic) close to the surgical incision will result in less morphine use and better pain relief after surgery compared to using morphine alone

Eligibility Criteria: Patients scheduled to undergo radical retropubic prostatectomy

Principal Investigator and Contact: Thomas Polascik, MD (919)660-2238

A Pivotal Study Of *In Vivo* Dosimetry During External Beam Radiotherapy Utilizing An Implantable Telemetric and Dosimetric Device

Overview: To evaluate safety of the implant procedure and *in vivo* use of the Dose Verification System (DVS) device, an implantable telemetric dosimeter to monitor, in real time, the dose of radiation delivered at the site of the intended target, and to gather information on the *in vivo* measured dose

Eligibility Criteria: Patients with biopsy-proven prostate cancer or breast cancer being considered for pre-operative or post-operative external beam radiation therapy

Principal Investigator and Contact: Mitchell Anscher, MD (919)668-5637

Monitoring TGF-Beta Levels During and After Radiation Therapy

Overview: To measure serum levels of TGF-ß in patients undergoing radiation therapy in order to determine whether TGF-ß may be a marker for late radiation-induced fibrotic injury

Eligibility Criteria: Patients undergoing radiation therapy

Principal Investigator and Contact: Mitchell Anscher, MD (919)668-5637

Prostate Cancer — Local, Treated

CALGB 9687 The Role of Salvage Prostatectomy for Radiation Failure in Prostate Carcinoma: A Phase II Trial

Overview: To assess survival and quality of life for patients treated with salvage prostatectomy for recurrence or persistent disease after treatment with radiation therapy for localized prostate cancer.

Eligibility Criteria: Patients with persistent or recurrent prostate cancer, PSA ≤ 20 ng/ml, and no evidence of metastatic disease who have received prior radiation or brachytherapy treatment for localized prostate cancer

Principal Investigator: Philip Walther, MD

Contact: Ann Walker (919)684-2223

Prospective, Observational Registry of the Management of Men with Prostate Cancer and a Rising PSA Following Definitive Surgical or Radiological Treatment of the Primary Tumor: PCA Registry (COMPARE)

Overview: An observational study to collect data on the treatment decisions, management practices, and patient outcomes of men presenting to their physician for the treatment of a rising PSA following primary treatment.

Eligibility Criteria: Prostate cancer patients who present during follow-up with rising PSA post-prostatectomy ((0.2 ng/ml on repeated testing) or post-radiation (2 rises above nadir, (50% above nadir, most recent (0.2 ng/ml over nadir)

Principal Investigator: Judd W. Moul, MD

Contact: Jill S. Smith (919)668-3613

(Continued on next page)

Duke Urology Clinical Trials CONTINUED

Prostate Cancer — Hormone-Naïve/Hormone-Responsive

CALGB 99904/SWOG 9921 Adjuvant Androgen Deprivation Versus Mitoxantrone Plus Prednisone Plus Androgen Deprivation in Selected High Risk Prostate Cancer Patients Following Radical Prostatectomy, Phase III

Overview: To evaluate overall survival and toxicity using Casodex + Zoladex vs. mitoxantrone + prednisone w/ Casodex + Zoladex in high-risk localized prostate cancer patients following radical prostatectomy.

Eligibility Criteria: Men with early-stage (clinical T1-2) prostate cancer prior to radical prostatectomy and PSA ≤ 0.2 post-surgery, as well as any of the following: pre-op PSA>15 or PSA>10 and biopsy Gleason score>6; GS>7; GS=7 and positive margin; positive lymph nodes; pT3b or T4 or N1.

Principal Investigator: Judd W. Moul, MD

Contact: Jill S. Smith (919)668-3613

A Randomized, Active Controlled Study of AMG-162 in Subjects with Advanced Cancer Currently Being Treated with Intravenous Bisphosphonates

Overview: To determine the effectiveness of AMG-162, a fully human monoclonal antibody, in reducing bone loss in advanced cancer patients with bone metastases. AMG-162 blocks a growth signal for osteoclast activation and is being tested in patients with evidence of ongoing osteoclast activity despite Zometa.

Eligibility Criteria: Patients currently receiving intravenous bisphosphates (Zometa) for treatment of bone metastases in prostate, bladder, and kidney cancer with radiographic evidence of 1 or more bone metastases.

Principal Investigator: Daniel George, MD

Contact: Trish Creel (919)668-7531

Prostate Cancer — Hormone-Refractory/Chemotherapy

A Phase I/II Dose-Escalation Study of Combination Chemotherapy Using Docetaxel and Atrasentan for Men with Metastatic, Hormone-Refractory Prostate Cancer

Overview: The primary objectives of this study are: Phase 1 — To determine the maximal tolerated dose (MTD)/recommended Phase 2 dose of combination therapy using docetaxel and atrasentan in male subjects diagnosed with metastatic, hormone-refractory prostate cancer. Phase 2 — To determine the percentage of subjects with a reduction of (50% in PSA.

Eligibility Criteria: Metastatic prostate cancer on androgen deprivation therapy (ADT) for at least 3 months with documented evidence of disease progression on ADT, PSA ≥5.0 ng/mL, and no prior chemotherapy

Principal Investigator: Daniel George, MD

Contact: Trish Creel (919)668-7531

A Phase I Study of PTK787/ZK222584 and RAD001 for patients with advanced solid tumors

Overview: A Phase 1b study combining PTK787, an inhibitor of receptors for VEGF and PDGFR, and RAD001, an inhibitor for mTOR, to determine their tolerability in active dose ranges

Eligibility Criteria: Hormone-refractory prostate cancer patients with progression on chemotherapy and metastatic kidney cancer patients

Principal Investigator: Daniel George, MD

Contact: Trish Creel (919)668-7531

Prostate Cancer — Immunotherapy

Active Immunotherapy with Human LAMP Telomerase RNA-Transfected Immature, Autologous Dendritic Cells Primed in Situ Using Escalating Doses of the Topical Immunostimulant Imiquimod (Aldara™) in Patients with Prostate Cancer

(Continued on next page)

Overview: To evaluate the safety and toxicity of the administration of immature dendritic cells into pre-treated intracutaneous injection sites, and to assess the ability of *in situ* matured dendritic cells to stimulate potent antigen specific immune responses and potentially clinical responses

Eligibility Criteria: Metastatic prostate cancer, or rising serum PSA despite continued androgen ablation with LHRH agonists or after orchiectomy, not on concurrent chemotherapy, radiation therapy, or immunotherapy and without other serious illness

Principal Investigator: Philipp Dahm, MD

Contact: Doris Coleman (919)668-2555

Active Immunotherapy With Mature, Human Telomerase Reverse Transcriptase RNA-Transfected, Autologous Dendritic Cells with or without the IL-2 Diphtheria Toxin Conjugate, Denileukin Difitox (ONTAK®) in Subjects with Metastatic Prostate Cancer

Overview: To evaluate the safety of intradermal injections of mature dendritic cells with or without a single intravenous dose of denileukin difitox (ONTAK®), and to analyze the induction of tumor- specific T cells among subjects receiving mature dendritic cells enrolled in both treatment arms

Eligibility Criteria: Patients with metastatic prostate cancer and without other serious illness or infection

Principal Investigator: Philipp Dahm, MD

Contact: Doris Coleman (919)668-2555

Bladder Cancer

RTOG 0233— A Phase II Randomized Trial for Patients with Muscle-Invading Bladder Cancer Evaluating Transurethral Surgery and BID Irradiation Plus Either Paclitaxel and Cisplatin or 5-Fluorouracil and Cisplatin Followed by Selective Bladder Preservation and Gemcitabine/Paclitaxel/ Cisplatin Adjuvant Chemotherapy

Overview: To estimate the safety and tolerance of induction chemoradiotherapy including paclitaxel, cisplatin, and irradiation (TCI) or 5-Fluorouracil, cisplatin, and irradiation (FCI); chemoradiotherapy will be followed by radical cystectomy if the initial tumor response is incomplete or by consolidation chemoradiotherapy if the tumor has cleared.

Eligibility Criteria: Operable patients w/*muscularis propria* invasion carcinoma of the bladder, AJCC Stages T2-T4a, NX or N0, M0 who have undergone resection of bladder tumor within 8 weeks of start of treatment

Principal Investigator: Bridgett Koontz, MD

Contact: Chris Marino (919)668-3034

Renal Cell Carcinoma

A Phase 2 Study of SU011248 in the Treatment of Patients with Bevacizumab-Refractory Metastatic Renal Cell Carcinoma

Overview: To determine the antitumor efficacy of single-agent SU011248, an inhibitor of receptors for VEGF and PDGF, administered orally once daily for 4 consecutive weeks repeated every 6 weeks in patients with metastatic RCC who are refractory to prior bevacizumab-based treatment

Eligibility Criteria: Patients with metastatic renal cell carcinoma who have undergone prior radical or partial nephrectomy, received at least 4 doses of bevacizumab, and demonstrated disease progression on bevacizumab

Principal Investigator: Daniel George, MD

Contact: Trish Creel (919)668-7531

A Phase I Study of PTK787/ZK222584 and RAD001 for patients with advanced solid tumors

Overview: A Phase 1b study combining PTK787, an inhibitor of receptors for VEGF and PDGFR, and RAD001, an inhibitor for mTOR, to determine their tolerability in active dose ranges

Eligibility Criteria: Metastatic kidney cancer patients and hormone-refractory prostate cancer patients with progression on chemotherapy

Principal Investigator: Daniel George, MD

Contact: Trish Creel (919)668-7531

A Pilot Study of Active Immunotherapy Using Telomerase RNA-Transfected Dendritic Cells Following Depletion of Immature Myeloid Cells Using Tretinoin (Vesanoid®) in Subjects with Advanced or Metastatic Renal Cell Carcinoma

Overview: To evaluate the safety and efficacy of pretreatment of patients with metastatic renal cell carcinoma with Tretinoin (Vesanoid®) followed by intradermal administra-

(Continued on next page)

Duke Urology Clinical Trials CONTINUED

tion of LAMP hTERT mRNA-transfected dendritic cell vaccination.

Eligibility Criteria: Metastatic renal cell carcinoma patients who have undergone nephrectomy; not on chemotherapy, radiation therapy, immunotherapy, or steroid or immunosuppressive agents within 4 weeks of treatment; and without other serious illness

Principal Investigator: Philipp Dahm, MD

Contact: Doris Coleman (919)668-2555

Erectile Dysfunction

A Randomized, Double-Blind, Parallel-Design, Placebo-Controlled Study to Evaluate the Effects of 5mg Tadalafil and 50mg Sildenafil Administered Once Daily for 6 Months on Visual Function in Healthy Subjects or Subjects with Mild Erectile Dysfunction

Overview: To evaluate the visual safety of daily tadalafil compared with placebo for 6 months in healthy male subjects or subjects with mild erectile dysfunction (ED). Visual safety will be assessed by extensive visual testing, including ERG, intraocular pressure, tests of visual function, and inspection of ocular anatomy.

Eligibility Criteria: Healthy male subjects or males with mild erectile dysfunction aged 30-65 without significant visual abnormality and vision correctable to 20/20, not currently prescribed or taking nitrates.

Principal Investigator: Craig F. Donatucci, MD

Contact: Jill S. Smith (919)668-3613

The AMS Tactile Pump Performance Study

Overview: To evaluate ease of use of the redesigned tactile pump in a three-piece inflatable penile prosthesis (IPP)

Eligibility Criteria: Men electing implantation of an IPP as treatment for erectile dysfunction

Principal Investigator: Craig F. Donatucci, MD

Contact: Jill S. Smith (919)668-3613

Safety and Effectiveness of the Mentor Two-Piece Inflatable Penile Prosthesis

Overview: To evaluate safety and effectiveness of a two-piece inflatable penile prosthesis (IPP) in men undergoing surgical treatment for erectile dysfunction

Eligibility Criteria: Men electing implantation of an IPP as treatment for erectile dysfunction

Principal Investigator: Craig F. Donatucci, MD

Contact: Jill S. Smith (919)668-3613

Benign Prostatic Hyperplasia (BPH)

A Phase II Randomized, Sham-Controlled, Double-Blind, Dose-Finding Study to Assess the Efficacy and Safety of Transurethral Photodynamic Therapy with Lemuteporfin in Subjects with Lower Urinary Tract Symptoms Due to Benign Prostatic Hyperplasia (PLUS)

Overview: To compare effect of minimally-invasive transurethral photodynamic therapy (PDT) vs. sham treatment in patients with LUTS due to BPH. Subjects receive lemuteporfin injected transurethrally into the prostate, are treated with transurethral application of one of 3 active light doses or sham control, then followed for 3-12 months to determine safety and efficacy.

Eligibility Criteria: Subjects with LUTS due to BPH, who have not previously undergone minimally invasive or surgical treatment for BPH. AUA score ≥13, 5≤ Qmax ≤15 ml/sec, PSA ≤15, and no evidence of prostate, testicular, or bladder cancer.

Principal Investigator: Cary N. Robertson, MD

Contact: Jill S. Smith (919)668-3613

IN REMEMBRANCE

DR. JAMES H. SEMANS
May 30, 1910 – April 21, 2005

Dr. James H. Semans was a Duke University surgeon and urologist who combined a career as a leading medical scientist and physician with a passion for the arts and charitable causes.

In addition to his leadership as a medical scholar, Dr. Semans, along with his wife of 52 years, Mary Duke Biddle Trent Semans, was involved in numerous arts and charitable causes. Dr. Semans helped lead the establishment of the North Carolina School of the Arts in Winston-Salem in the 1960s and served as chairman of the school's board of trustees for the first 17 years. He established and then accompanied for over three decades the North Carolina School of the Arts' International Music Program in Italy, Germany, and France.

He also served for 48 years on The Mary Duke Biddle Foundation and was chair until his retirement in 2004. The Biddle Foundation funds charitable activities at Duke and other institutions in North Carolina and New York. As leader of the Biddle Foundation, he was instrumental in the establishment of the Ciompi Quartet and the Institute of the Arts at Duke.

Born in 1910 in Uniontown, Pennsylvania, Dr. Semans graduated from the Lawrenceville School in 1928. He received his bachelor's degree from Princeton University in 1932. He earned his medical degree from the Johns Hopkins School of Medicine in 1936, where he also graduated Phi Beta Kappa. He did his residency at Johns Hopkins under the leadership and mentorship of the Chief of Urology, Dr. Hugh Hampton Young. On January 1, 1944, he entered the U.S. Army. After serving two-and-a-half years as a major in the Army's medical corps, where he developed a lifelong interest in spinal cord injury and rehabilitation, he eventually entered private practice for six years in Atlanta, and then joined the Duke medical staff as a surgeon and professor of urology.

In 1953, Dr. Semans married Mary Duke Biddle Trent, the great-granddaughter of Washington Duke, in whose honor Duke University was named. Together they focused their energies on charitable work, especially involving the arts.

In 1997, the Semanses were awarded the North Carolina Philanthropy Award. In recognition of their leadership in human relations, the Semanses received the first Humanitarian Freedom Award given by the Durham chapter of Hadassah in 1960. Nine years later, they received the National Brotherhood Award from the National Conference of Christians and Jews for distinguished service in human relations. Dr. Semans received honorary degrees from the North Carolina School of the Arts and Duke University, and also was honored by Duke University Hospital and the North Carolina Association of Arts Councils, among others.

In addition to his wife, Dr. Semans is survived by seven children: Mary Trent Jones of Abingdon, VA; Sally Trent Harris of Charlotte, NC; Dr. Rebecca Trent Kirkland of Houston, TX; Barbara Trent Kimbrell of Sullivan's Island, SC; Jenny Semans Koortbojian of Durham, NC; James Duke Biddle Trent Semans of Chapel Hill, NC; and Beth Semans Hubbard of Los Angeles, CA; as well as 16 grandchildren, 22 great-grandchildren; and four nephews and one niece.

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