Duke Comprehensive Cancer Center
notes
A Comprehensive Cancer Center Designated by the National Cancer Institute
FALL 2010

Cycling Across America . . .
All in the Name of Cancer

On August 30, Martin "Marty" Smith completed a 3,000-mile bicycle ride across America to raise money for cancer research at Duke by dipping his bicycle's wheels in the Pacific Ocean. Smith's remarkable journey began on June 29 at Duke's Morris Cancer Clinic, where supporters cheered him on as he began the first leg of his trip. He biked the first 55 miles with Duke Comprehensive Cancer Center (DCCC) director H. Kim Lyerly, MD, and Duke cancer researcher Lee Jones, PhD. Smith has chronic lymphocytic leukemia (CLL), a rare cancer of the lymph nodes and bone marrow, and also has multiple sclerosis.

The 52-year-old Smith dreamt of cycling across the United States for almost 30 years, but kept delaying the trip for health and job reasons. Then, in early 2010, he made up his mind to live his dream. "I knew the time was now," explains Smith. "If I didn't do it soon, I never would."

The trip took him through 10 states, with daily temperatures often in the high 90s. Along the way, he encountered kind strangers, one of whom in Tennessee gave him money to help defray the expenses of the trip. A number of restaurants donated meals to Smith and his team, which comprised two interns who followed him in an RV. Perhaps most meaningful were the numerous survivors who greeted Smith throughout his journey, sharing stories of their own fights with cancer.

In addition to raising money for cancer research, Smith's goal was to spread the good news about the progress being made in cancer research, especially at Duke. "There is great momentum, and I believe cancer can be cured in our lifetime. Duke is leading the way," says Smith.

Duke Cancer patient Martin Smith began his nine-week journey, "Martin's Ride," from Durham to Los Angeles, to raise money for Duke on June 29. For the first leg of the trip to Greensboro, he biked with H. Kim Lyerly, MD, Director of Duke Comprehensive Cancer Center, and Lee Jones, PhD, a Duke researcher studying exercise and cancer treatment.

Today, Smith is doing well. While treatments he has received have been successful, Smith knows that CLL is a chronic condition. Smith's oncologist at Duke, Louis Diehl, MD, says there are a number of drugs and combination of drugs that are successful with many CLL patients.

In addition, there are additional promising drugs in clinical trials now, and research is being conducted to better understand the disease. Diehl, who has been a medical oncologist treating blood cancers including CLL for 30 years, says that experts originally thought there was no genetic aspect to CLL. However, research is starting to show that genetics may play a role in some patients. Duke physician-researcher Mark Lanasa, MD, PhD, is studying CLL in families to determine if genes play a role in its development. This research is especially exciting to Smith, whose father also has CLL. Smith's family is part of Lanasa's study.

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A Publication for Friends of Duke Comprehensive Cancer Center

To make an appointment, call 888-ASK-DUKE.

New Project Seeks to Connect Community Oncologists with Specialists Across U.S.

Duke radiation oncologist Carol Hahn, MD, has partnered with radiation oncologist Patricia Hardenbergh, MD, from Shaw Regional Cancer Center in Edwards, Colorado, to develop an innovative new program that would allow radiation oncologists not affiliated with major medical centers to consult with some of the country's leading radiation oncologists to determine the most effective treatment plans for their patients. This type of consultation among radiation oncologists already exists at many large medical centers like Duke, where radiation oncologists meet regularly to discuss and review cases to determine the best course of treatment for each patient.

Hahn, Butler-Harris Assistant Professor of Radiation Oncology and medical director of radiation oncology at Duke Raleigh Hospital, and Hardenbergh, director of radiation oncology at Shaw and a former Duke physician, have received a three-year $1.35 million grant from ASCO (American Society of Clinical Oncology) Cancer Foundation's Improving Cancer Care Grants Program (funded by Susan G. Komen for the Cure) to develop this new Web-based program.

Radiation oncologists outside major medical centers often practice without the benefit of colleagues nearby with whom they can consult. With this new program, those radiation oncologists can virtually collaborate and consult with leading radiation oncologists from around the country using a secure Internet connection to review patient records and images.

"This is exciting for the physicians but also for the patients," says Hahn. Eighty-five percent of patients who receive radiation treatment do so in a community practice, not a large medical center, according to Hahn.

Whereas radiation oncologists at Duke specialize in a particular type of cancer (Hahn's expertise is with breast cancer patients), many community radiation oncologists are generalists. "It can be difficult to be a generalist in oncology," says Hahn. "There may be cases that community physicians rarely see while those at Duke deliver care to regularly."

Hahn and Hardenbergh are recruiting 300 community radiation oncologists from across the country to participate in the study. "Nothing exists like this currently," she says. "This is an opportunity to help bridge the gap between small radiation oncology rural practices and the rapidly advancing technology utilized in larger group practices. We hope it will allow physicians to come together to learn from one another."

"We have two main goals of this project," says Hahn. "First and foremost, we want the patients to receive the best possible treatment. Another goal is to determine how quality of care can be improved." The physicians also want to see if patients were offered additional services that they would not have been given otherwise, such as participating in a clinical trial or meeting with a genetic counselor.

According to Hahn, the program's concept and technology and model for collaboration could potentially be translated into other fields of oncology including medical oncology and surgical oncology and also enhance collaboration among the different fields of practice.

To learn more about this program, e-mail info@chartrounds.com or call toll free 877-645-8760.

Carol Hahn, MD

"This is an opportunity to help bridge the gap between small radiation oncology rural practices and the rapidly advancing technology utilized in larger group practices. We hope it will allow physicians to come together to learn from one another."

— Carol Hahn, MD

CYCLING ACROSS AMERICA

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"I'm confident new treatments for CLL and many other cancers are on the horizon," says Smith.

To learn more about CLL research at Duke, go to http://centerforcll.duhs.duke.edu. To learn more about Smith and how you can show your support, visit www.martinsride.com.

Top: Smith and intern, Jeremy Sadler, at the Continental Divide on top of Monarch Pass in Colorado.

Bottom: Smith takes a break from his ride in the Capitol Reef National Park in Utah.

Photos were taken by Smith's intern, Brian Russo.

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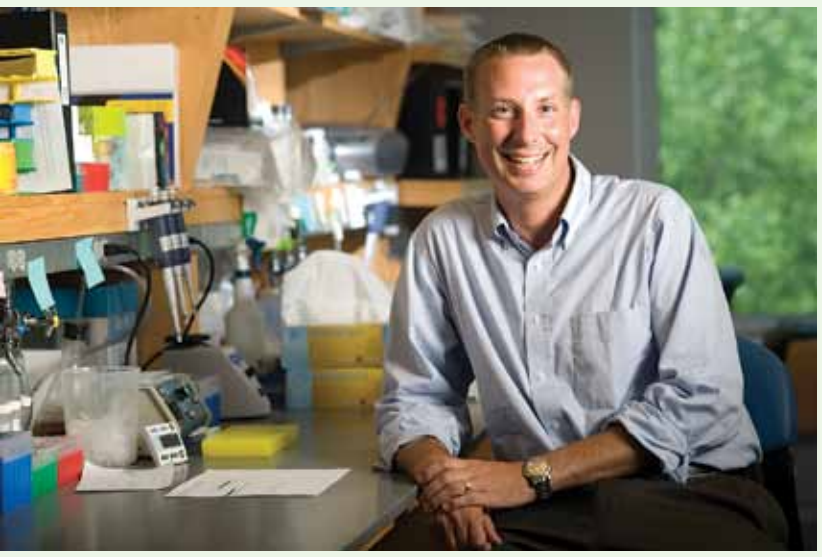
Duke Researcher Probes Deeper to Understand Cell Death

Although there are many different types of cancers, they all share one fundamental characteristic: unchecked cell growth that progresses toward limitless expansion. In normal healthy tissues, the rates of new cell growth and old cell death are kept in balance. In cancer, this balance is disrupted. This disruption can result from uncontrolled cell growth or the loss of an old or damaged cell's ability to self-destruct.

"In order to understand how to kill cancer, we need to understand why cancer cells grow rapidly without dying," says Jeffrey Rathmell, PhD, associate professor of pharmacology and cancer biology and member of the Duke Comprehensive Cancer Center.



Jeff Rathmell, PhD, in his Levine Science Research Center laboratory.

Rathmell is most interested in the role metabolism plays in cell death. "When cells undergo stress, metabolism shuts down and the cells stop taking in nutrients. The cells essentially starve themselves. But cancerous cells are able to sustain a high rate of metabolism, and consequentially, do not die." While this fact has been known for 90 years, it is only within the last decade that scientists like Rathmell have probed deeper in an effort to understand this phenomenon.

Rathmell's goal is to find ways to manipulate metabolism to cause the cancerous cells to die. Much like genetic profiling, which is used to determine the most effective treatment for patients based on their DNA, Rathmell is studying the metabolic profiling of cancer cells. Currently, he is using mice that have been injected with leukemia cells to make a metabolic profile of cancerous cells. He is paying particularly close attention to two types of proteins in these cells, MCL1 and Puma, because of their importance in regulating cell death.

"Dr. Rathmell is a tremendously innovative scientist and a terrific colleague and collaborator," says Anthony R. Means, PhD, Nanaline H. Duke Professor, chairman of the Department of Pharmacology & Cancer Biology, and deputy director of Duke Comprehensive Cancer Center. "He is a pioneer in relating how metabolism affects cell death, and his findings to date regarding the relationship between these two cellular events in cancer are exciting and bode well for the future. We are very fortunate to have recruited Dr. Rathmell to Duke together with Duke's Sarah W. Stedman Nutrition and Metabolism Center."

Eventually, Rathmell hopes that physicians may be able to target treatments based on an individual patient's own metabolic profile. While he currently is studying leukemia, he believes his research may be applicable to other cancers in the future.

$10 Million Gift to Fund Innovative Cell Therapy Research

Joanne Kurtzberg, MD, director of Duke's Pediatric Blood and Marrow Transplant Program, has received a $10.26 million commitment from the Robertson Foundation to create a state-of-the-art Translational Cell Therapy Center to help fight a variety of diseases—from cancer to cerebral palsy.

"Dr. Kurtzberg's research reflects the kind of transformational science that has the potential to change the lives of thousands of people throughout the country and around the world," says Julian Robertson on behalf of the Robertson Foundation. "The Foundation has enormous respect for the research conducted at Duke over the course of our longstanding relationship, and we are pleased to support it through this gift."

A portion of the Robertson Foundation gift will be used to construct a special laboratory where therapeutic cells will be manipulated and stored so Kurtzberg's team can conduct clinical trials using cell therapy.

Cell therapy is used to replace old or diseased cells with healthy cells, whether from a relative, stranger, or sometimes the patient. Bone marrow transplant, for example, is a type of cell therapy used to treat patients with cancers such as certain types of leukemia. After receiving large doses of chemotherapy that kill much of the patient's cells—both cancerous and healthy—stem cells from the bone marrow of a healthy person are transplanted into the patient.

Joanne Kurtzberg, MD

Kurtzberg also is internationally recognized for her leadership in umbilical cord blood transplants, another type of cell therapy that uses the stem cells found in a newborn's umbilical cord blood to treat a variety of diseases including cancer in children and adults.

The Robertson gift will initially fund five different research studies. In one of the studies, Kurtzberg will use cell therapy to treat patients with glioblastoma multiforme (GBM), a type of brain tumor.

According to Kurtzberg, when radiation is administered to cancer patients, radiation oncologists work to ensure that the tumor is targeted and as little as possible of the healthy surrounding tissue is impacted. Even when done carefully, however, healthy cells are usually destroyed. If healthy tissue is radiated, patients can experience side effects. These side effects are especially harmful for patients with brain tumors because radiation that reaches healthy brain tissue can cause serious problems with memory.

Kurtzberg plans to work with GBM patients after they have had surgery and radiation but before chemotherapy. Patients will receive an injection of their own, healthy brain cells that were removed prior to treatment, to replace those that may have been destroyed by radiation. Since the patient will receive their own cells, Kurtzberg thinks that there is a high chance of success with fewer possible side effects.

"Treatments for brain tumors are getting more successful and people are living longer," says Kurtzberg. "Our goal is to rescue their brain cells, lessen the radiation effects and improve their quality-of-life in the future."

Duke Breast Oncologist and Director of Duke's Women's Wellness Clinic Dr. Victoria Seewaldt is seated beside Dr. Sharon Elliott-Bynum, co-founder and clinical director of CAARE, and Stephanie Robertson, patient navigator and coordinator of Patient Navigator Program in the Duke's Women's Wellness Clinic.

Duke Research Team Partners with Community

Focus: Health Care Disparities in Women with Breast Cancer

Durham County, North Carolina, has one of the highest rates of breast cancer deaths for African American women in the state (47.2 deaths per 100,000). This rate is considerably higher than the national average of 38.4 deaths per 100,000 for African American women and more than double the national rate of 23 deaths per 100,000 for Caucasian women.

According to Duke Oncologist Victoria Seewaldt, MD, the causes of these disparities are complex, but include lack of access to care, cultural norms regarding preventive screening, and the high frequency of clinically aggressive triple-negative breast cancer in African American women.

Seewaldt and her team are conducting studies which provide evidence that one key to reducing breast cancer death is to identify high-risk women before, rather than after, they are diagnosed with breast cancer. In addition to gender, a woman is considered at higher risk when she is in one or more of the following categories: previous history of breast cancer, family history of breast cancer, BRCA 1/2 mutation gene carrier, and/or has had previous abnormal screenings.

"There are many barriers to identifying breast cancer risk, especially in African American women, including cultural barriers, education, mistrust, and hesitancy to participate in clinical trials, says Seewaldt. "Our goals are to work with women in the community to develop clinical trials together to address community concerns and to be a trusted community partner."

"In our studies, we are examining the incidence of breast changes that occur before breast cancer is detected as well as invasive breast cancer, family history of breast cancer, and mammographic screening," explains Seewaldt. "We are finding that many young African American women undergo mammography only when they have symptoms that indicate something might be wrong."

Unique Collaboration Aims to Improve Cancer Clinical Trials

Statisticians and oncologists from Duke University, the University of North Carolina at Chapel Hill, and North Carolina State University have received $12.5 million in grant funding over five years from the National Cancer Institute and will partner to investigate new ways to speed up the cancer clinical trial process—thus getting new drugs to patients faster—while still ensuring that the drugs are safe and effective.

On average, it takes more than eight years to conduct a series of clinical trials testing a new drug before it is submitted to the U.S. Food and Drug Administration to be considered for approval. That is in addition to the six years or more of laboratory research often required before clinical trials begin.

Stephen George, PhD, leader of the Duke Comprehensive Cancer Center's (DCCC) Biostatistics Shared Resource and an internationally recognized leader in cancer biostatistics is Duke's principal investigator on the grant.

"Typically, statistical work is done independently," says George. "It is an exciting challenge to get experts from the three universities to work together on this grant. The ultimate goal is to help the individual patient."

The work of the statistician begins in the planning stages, as he or she collaborates with the researcher to determine the precise objectives of the clinical trial. For example, with almost any new drug being tested, the drug will benefit some, but not others. Similarly, some patients will experience side effects, while others will not. Statisticians work to determine how many patients must be enrolled in the study in order to be statistically accurate; too few and the researchers may miss side effects that only occur in a small number of patients. The more patients enrolled in the study, the more reliable the results; however, the more patients required for a study also extends the length of the trial because it takes longer to

Stephen George, PhD

Left: Dr. Sharon Elliott-Bynum and Stephanie Robertson talk with LaToya Lenoir about being at increased risk for developing breast cancer, the importance of early detection, and available screening resources in her community.

Right: Dr. Sharon Elliott-Bynum discusses funding and grant opportunities with Dr. Victoria Seewaldt.

In one of Seewaldt's current clinical trials, her team's central objective is to use geospatial analysis tools (to use data which is tied to geographic coordinates) to guide the development and evaluate the effectiveness of tailored screening interventions—including patient navigation, community-partnered research, and advanced imaging technologies when appropriate—in pre-menopausal African American women.

"Currently, breast cancer screening recommendations for African American women are based on studies undertaken in primarily Caucasian populations," says Seewaldt. "Since the breast cancer death rate in young African American women is higher than in Caucasian women, the timing and recommendations for breast cancer screening may benefit from increased attention to identifying the highest risk women, reaching them effectively, and getting them screened earlier using better technology."

To implement the study, a multidisciplinary team has been assembled consisting of African American community leaders, patient navigators, outcomes researchers (researchers who focus on quality-of-life outcomes by considering human functionality and health care experience, particularly in individuals facing chronic illnesses), minority breast cancer biologists, physicians including Seewaldt, and geospatial scientists. Together, the team aims to identify African American women who are highest risk for breast cancer, eliminate barriers to early detection, develop community-partnered clinical trials to provide access to state-of-the-art breast imaging, and track the success of this intervention using novel geospatial mapping tools.

Seewaldt and her team have already established community relationships that enable them to research their targeted group. They have strong ties with CAARE (a free public health clinic in Durham) and the Triangle Sisters Network, an African American breast cancer survivorship organization.

"We are committed to working collaboratively, placing knowledge in service of society, and fostering strong interdisciplinary community research programs focused on improving early breast cancer detection and consequently breast cancer survival," says Seewaldt.

accrue larger numbers of patients.

With funding from the grant, the statisticians and oncologists will also work to determine if it is possible for data from clinical trials to be analyzed and conclusions drawn sooner than the time needed using the current statistical methods.

George and his colleagues also will investigate the best way to handle missing data from studies and determine how that impacts the outcome of trials. For example, explains George, participants in a clinical trial may be asked to fill out forms, but a participant may not complete the forms sufficiently. Thus, there is missing data from that patient. This has the potential to greatly impact the results of a study.

"The increasing emphasis on the development of molecularly targeted therapies in cancer necessitates a simultaneous change in the way clinical trials are designed," says Neil Spector, MD, director of Translational Research in Oncology at Duke and an investigator on the grant. "For example, clinical specimens are increasingly being collected as a part of therapeutic trials. The value of this biological information in providing insight into the mechanisms by which targeted therapies exert their effects in patients, which will enable optimization of their use in the clinic, is directly dependent upon the robustness of the statistical analysis. To meet these demands, we need to develop new strategies to analyze the complex data sets that are associated with clinical trials."

Neil Spector, MD

"Statisticians are important in the development, conduct, and analysis of clinical trials," says George. "By understanding how to improve the statistical processes associated with the conduct of clinical trials, we can improve the entire process."

In addition to George, other statisticians from Duke participating in the study are Sin-Ho Jung, PhD; Kouros Owzar, PhD; Herbert Pang, PhD; and Xiaofei Wang, PhD. Oncologists are Kimberly Blackwell, MD; Jeffrey Crawford, MD; David Harpole, MD; and Spector.

Cancer Patient Support Program Teaches Intern Life Lesson

Charisse Coleman is anything but a typical patient counselor . . . if there is such a thing. She recently acquired her Master's of Science degree in Clinical Mental Health Counseling from the University of North Carolina at Greensboro. She holds a Bachelor's of Fine Arts degree in Acting, a Master's of Fine Arts degree in Writing and Literature, and spent 15 years as a professional stage actress. She is currently seeking publication for her first book.

She brought this wealth of experiences to her role as counselor intern with the Duke Cancer Patient Support Program (DCPSP) during the last year.

"I could not have had a richer or more diverse experience working anywhere else," Coleman says of her time at Duke.

For nine months, Coleman spent approximately 25 hours per week working with the DCPSP. She began by shadowing the program's four licensed counselors. As time passed and she grew more knowledgeable and comfortable, Coleman gradually took on more responsibility. She began assisting the counselors during their sessions, and eventually served as the sole facilitator of counseling sessions, under the direct supervision of one of the licensed counselors.

Her internship allowed Coleman to interact with many patients, all of whom made a significant impact on her. She was able to grow from each experience and use her experiences to help other patients she encountered.

"One thing I saw in common among almost all of the patients I worked with, was the painful distress that accompanied the loss of control most of them felt upon receiving their diagnosis," recalls Coleman. "They taught me that part of a counselor's work is to help patients regain a sense of control within their lives wherever it is possible, even though they couldn't control their cancer journey."

One patient, an older man, quiet and pensive with a dry sense of humor, showed Coleman that fear is not mandatory. Although not the goal for all therapy, he learned that he must look death square in the eye. "By accepting death as a part of life, he was able to bring himself clarity and comfort, and, despite his prognosis, lived his life with considerable poise," says Coleman.

To some, her job and that of the counselors may sound difficult and even depressing, but Coleman insists otherwise. "At times it was sad and painful, but never depressing. I felt privileged to be given the opportunity to work with people who are confronting some of the biggest challenges of their lives… It is a humbling and inspiring thing."

The DCPSP offers free services to patients with cancer and their family members including individual, couple and family counseling, support groups, self-image resources, and workshops. Founded by Rachel Schanberg in 1987, in honor of her daughter Linda who died at 26 from Hodgkin's disease, the program offers support from diagnosis through survival, for those facing the physical, emotional, relational or spiritual struggles that cancer brings into their lives.

Support is offered to special populations as well including the children of patients being treated for cancer. KidsCan! is a support group that gives these children the opportunity to discuss their feelings and to meet other children with similar experiences. As part of the KidsCan! program, parents participate in a parents' group and receive counseling in order to learn how to help their families cope.

The DCPSP has four licensed counselors and family therapists, masters and doctoral level interns, and hundreds of volunteers. "We simply could not serve our patients effectively without help from our volunteers and interns," says Phillip Shoe, coordinator for the DCPSP's Volunteer Services Program. "We have interns each year, many working on degrees in counseling, family therapy, or divinity, and they all bring their own unique perspectives and special skills to the job. We are grateful to have all of them and our volunteers working with us to fulfill our mission of service to our patients."

"It is important for medical centers to offer support services to patients and their families, as cancer reaches beyond the physical into the psychosocial and spiritual areas of their lives. So, we are happy to provide a training opportunity for future therapists to help them build the skills and knowledge-base they need to continue to help those dealing with medical illness," says Cheyenne Corbett, PhD, LMFT, Director, Duke Cancer Patient Support Program.

To learn more about the DCPSP, call 919-684-4497.

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>
> — Charisse Coleman

Coleman with Phillip Shoe, coordinator for the DCPSP's Volunteer Services Program

Duke Alumni Give $1M to New Cancer Building and Brain Tumor Center

George Beischer T'63 has a special place in his heart for Duke. It all started a few months after his first semester as an undergraduate student at Duke University in 1959 when he met his future wife, Susan WC'63, a fellow student. Over the years, Beischer has donated time and money to the university, funding scholarships for undergraduates and supporting research in the medical center.

This most recent gift may be his most personal. In 2010, the Beischers committed $1 million to the Duke Comprehensive Cancer Center to be equally divided to support brain tumor research and to help fund construction of a new 267,000-square-foot state-of-the-art facility dedicated solely to the care of patients with cancer, which is slated to open in 2012. Beischer, who was diagnosed with a brain tumor in 2008, has been treated at The Preston Robert Tisch Brain Tumor Center at Duke.

In recognition of this most recent gift, two conference rooms in the new Cancer Center will be named in honor of the family.

"From my first appointment at The Brain Tumor Center, I saw people from all across the country coming to Duke for treatment. I knew there had to be something amazing about this place," says Beischer. "The whole medical staff is superb. It's not just the doctors but the nurses and people helping with quality-of-life issues."

Beischer has been treated by surgeon Allan Friedman, MD; medical oncologist Henry Friedman, MD; and neurologist Katy Peters, MD, PhD.

George and Susan Beischer

"How do you get such amazing care and not feel obligated to help Duke?" he asks. "I know that this gift may not help me but I hope it can help the people after me. I do not expect to be cured but I hope it can happen for someone else down the road."

Half of his gift will support research at The Brain Tumor Center investigating the links between exercise and cancer prevention/treatment and how to improve quality-of-life for brain tumor patients.

"Duke is the heart and soul of brain tumor research and patient care," he says. "Even if we didn't live in Durham, we would have made the trip to Duke because it is the best place to be treated for a brain tumor."

Beischer has always exercised and believes that if he hadn't, he might not be alive; he thinks that it has helped fight the cancer. That's why he wants more research to be done on the subject.

Lee Jones, PhD, one of the country's leading experts on exercise and cancer (and the first to publish on brain tumors and exercise) will use the gift to support several projects, including his research investigating the effects of exercise in patients with brain tumors. Similarly, he will use the funds to conduct research studies on the effects of exercise on patients with other types of cancer including lung, breast, and prostate. But arguably most importantly, Jones is using the gift to support translational studies that will clarify the mechanisms underpinning the exercise–cancer relationship.

"I have spent time with Mr. and Mrs. Beischer, and they are a wonderful family," says Jones. "Without their generous gift, I likely would not be able to perform the critical preclinical studies that complement my ongoing clinical trials to discover how exercise may impact tumor biology and response to therapy."

The Beischers' gift will also support the work of Peters, who is studying quality-of-life issues as they relate to patients with brain tumors. One project is a collaboration with Jones to study patients who have received the drug Avastin for treatment of their brain tumors and the side effects associated with the drug such as joint pain and cognitive issues.

Peters is also conducting a long-term study of patients with glioma, a type of brain tumor, to better understand neuro-cognitive issues of these patients. She will also study sleep issues that affect brain tumor patients and the effect of sleep agents and antidepressants.

"I am so grateful for the Beischers' gift," Peters says. "As a young researcher it is difficult to get support for studies. In addition, quality-of-life studies in particular often don't receive federal funding. I would not be able to do much of this research without their generosity."

STRIKE OUT CANCER

Working Together to Fight Cancer

UBS · VALEANT Pharmaceuticals International · Womble Carlyle Our Lawyers Mean Business

For breast cancer survivor Donna Ray, knowing that her employer, law firm Womble Carlyle, wanted to partner with the Duke Comprehensive Cancer Center (DCCC) to raise money for cancer research left a warm feeling in her heart.

"I was so pleased to hear that my own company was supporting this great initiative with the Duke Comprehensive Cancer Center," Ray says. "I have received great care at Duke but I know more research needs to be done to fight this deadly disease." Ray's medical oncologist is Gretchen Kimmick, MD, and her radiation oncologist is Janet Horton, MD.

Womble Carlyle, along with Valeant Pharmaceuticals and UBS, have teamed with Duke this season to support the Strike Out Cancer program.

Strike Out Cancer is a partnership created in 2009 between the DCCC and the 2009 AAA National Champion Durham Bulls minor league baseball team to raise money to fund innovative cancer research. Every time a Bulls pitcher records a strikeout during a home game, the DCCC will receive a donation from Womble Carlyle, Valeant Pharmaceuticals, and UBS, as well as from individuals. During the 2009 season, Durham Bulls pitchers struck out 557 batters during home games. As a result, the DCCC received more than $55,000.

"As a neighbor of the Duke Comprehensive Cancer Center, we wanted to support their innovative research by taking part in this unique initiative," says J. Michael Pearson of Valeant Pharmaceuticals, which has an office in Durham, adjacent to the Bulls' stadium. "We understand the importance Duke is making in the fight against cancer." Valeant Pharmaceuticals develops many different types of drugs, including a drug used to relieve nausea associated with chemotherapy.

"UBS is an international company, but our company believes it is important to support the organizations that make a difference in the communities in which we serve," says Mark Kean, a UBS financial advisor in the Raleigh office. "It is our privilege to be a part of this program."

Ray at the Durham Bulls Athletic Park

"The funds raised through Strike Out Cancer will allow Duke to continue to do great research and to offer the best care to their patients," says Jon Bishop, assistant general manager of the Durham Bulls. "We love being able to help raise funds for such important work and are so pleased about the support this program has received from Womble Carlyle, Valeant Pharmaceuticals and UBS."

Individuals can make donations to the Strike Out Cancer program as well by going to www.cancer.duke.edu/strikeoutcancer

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ask the expert

CANCER DRUG DEVELOPMENT AND APPROVAL

Gary Lyman, MD, MPH, FRCP (Edin), is professor of medicine and director of Comparative Effectiveness and Outcomes Research at Duke University School of Medicine and the Duke Comprehensive Cancer Center. He is also a senior fellow in the Duke Center for Clinical Health Policy Research. Lyman has served on the Food and Drug Administration's (FDA) Oncologic Drugs Advisory Committee for four years and has just been reappointed to serve an additional four years.

Gary Lyman, MD

What is the Oncologic Drugs Advisory Committee?

LYMAN: The Oncologic Drugs Advisory Committee or "ODAC" reviews and evaluates data concerning the safety and effectiveness of drugs used to treat cancer. The committee makes recommendations to the FDA about whether or not to approve a drug for use by patients. This includes new drugs as well as drugs already approved by the FDA for treating other conditions.

Can you explain the process for a new drug to be developed and then approved by the FDA for patients?

LYMAN: By the time a pharmaceutical company submits a drug application for approval from the FDA, it has often spent 10 years or more and millions of dollars to develop and test the drug. During that time, the company has conducted clinical trials and also has often met with the FDA, sometimes numerous times, to discuss the drug and the data.

Once submitted to the FDA, the drug application is reviewed. At that point, the FDA has the authority to make the final decision to approve a drug or not. The FDA can do so without asking for review and recommendation by ODAC. However, the FDA can choose to send the information about the drug to ODAC for its additional review, and it often does.

If a drug application is sent to ODAC, then members of that committee review the data. A hearing is then held, during which the FDA and the company make presentations and members of the public can ask questions. After extensive review and discussion, members of ODAC vote on recommendations to the FDA anonymously to avoid any perceived influence. The FDA usually follows the advice of ODAC on new drug approval, any change in approved indications and any requirement for further safety monitoring.

Who serves on ODAC?

LYMAN: The committee consists of 13 voting members including the chair. Members and the chair are selected by the commissioner of the FDA and are considered authorities knowledgeable in the fields of general oncology, pediatric oncology, hematologic oncology, immunologic oncology, biostatistics, and other related professions. The committee includes a patient advocate and also a non-voting member associated with the pharmaceutical industry.

How long does it normally take a drug to go through this final approval process with the FDA and ODAC?

LYMAN: It usually takes a minimum of six months, but it can be closer to nine to 12 months for some drugs to go through the review process once a final application is sent to the FDA.

Why does it take so long for a new drug to be approved by the FDA?

LYMAN: The drug approval process is lengthy and the rules and regulations change frequently. The FDA not only reviews hundreds of pages of documents but also conducts their own independent analysis of the data. Many members of the public believe the drug approval process takes too long while others argue that there is not enough attention to safety. The FDA is committed to ensuring that the science behind the development of the drug is solid both in terms of efficacy and safety.

What types of things are considered when reviewing a drug for approval?

LYMAN: As a member of ODAC, I consider many things. For example, I consider side effects of the drug. I review the study design to make sure it is methodologically sound. Considerations include whether there are currently available alternatives to the drug under consideration. ODAC members are specifically instructed not to consider the cost of the drug in our recommendations. This is different from many other countries, where the cost of the drug is considered part of the approval process.

The role of an ODAC member is difficult because you don't want to hold drugs from any patient who may benefit, but you also don't want to recommend approval of an unsafe drug. It's a balancing act–need and benefit versus safety and harm.

What is accelerated approval of a drug and when does that occur?

LYMAN: This is a conditional approval. Essentially, accelerated approval can occur when there is enough evidence to approve the drug; however more information is desired to be certain of the level of benefit and safety. This often occurs when clinical trials show very good results for the patients, and there are few alternatives for that patient population that might benefit from the drug. The pharmaceutical company is required to provide additional information to the FDA even after the drug is approved and prior to granting the agent full approval.

Do you see more drugs being approved faster in the future? Why or why not?

LYMAN: Since we want and need to ensure the safety and effectiveness of all drugs, we can only shorten the process so much. Certainly, we will continue to see more and more cancer treatments submitted to the FDA for approval. Many of these drugs will be targeted therapies which have potential advantages but also present additional challenges. Nonetheless, the ultimate goal of the FDA and ODAC is to get safe and effective drugs to patients with cancer as quickly as possible.

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