



A publication of the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins Office of Public Affairs

Issue No. 1 • Spring 2011

# Getting Personal about Breast Cancer

newly appointed Co-Director of the Breast Cancer Program at the Johns Hopkins Kimmel Cancer Center, discusses her clinical and research focus, her vision for the program, and her impressions on how personalized cancer medicine will translate into individualized care for every breast cancer patient.

Vered Stearns is an internationally recognized breast cancer researcher. She has earned widespread recognition through work, using biomarkers to guide breast cancer prevention and treatment strategies, and deciphering genetically determined variations in patients' responses to the breast cancer drug tamoxifen. Her work has also led to improved therapeutic options for women who suffer from hot flashes.

A team of scientists working with Stearns has shown that certain women who take the commonly used breast cancer drug tamoxifen experience lower than normal levels of a byproduct of tamoxifen, called endoxifen. These are women who have a specific genetic mutation or who take certain drugs, such as paroxetine, used to treat depression or hot flashes. Low endoxifen levels indicate that tamoxifen is not being fully metabolized, thereby possibly limiting its effectiveness. Stearns is leading national studies designed to test the impact of genetic variability on tamoxifen effectiveness in individual women.



### Personalized Medicine:

## Matching Breast Cancer Patients with the Right Drug An Interview with Antonio Wolff, M.D.

ANCER IS VERY COMPLEX. It is a disease of many broken parts and in order to fix the broken parts, researchers need to understand them in detail. Groundbreaking discoveries led by scientists at the Johns Hopkins Kimmel Cancer Center determined in the 1990s that cancer occurs as a result of a cascading series of cellular alterations. This has dramatically changed the way we look at cancer therapies. Most recently with advanced technologies, we are able to pinpoint different types of cancers within a disease group. Breast cancer was among the first to be studied and in fact breast cancer is no longer considered just one disease.

"We've learned that breast cancer is made up of an umbrella of diseases," says Antonio Wolff, M.D., associate professor of oncology and breast cancer expert. "They often may look quite alike under the microscope, but genetically, they are very different," he adds.

Wolff explained that this is the reason why two women with seemingly similar breast cancers will respond very differently to treatment.

### **Targeted Therapies for Breast** Cancer—The Story of HER2

"We hear a lot today about personalized therapies for cancer and cancer treatment, but the truth is, in breast cancer, our researchers have been using personalized approaches to determine the kind of therapy that would be most effective. A major treatment breakthrough came in the late 1980s with the identification of the HER2 gene. Women with increased levels of HER2 detected by tests that measure the number of copies of the HER2 gene or the amount of its protein in breast cancer cells often have more aggressive tumors."

Since oncologists began screening for HER2 status (positive or negative) about 15 years ago, we have realized there is more to the cellular story of breast cancer, and new molecular markers to further specify breast cancer subtypes are now being tested. But central to that story is an old friend, the receptors for estrogen,



and progesterone that are found in twothirds of all invasive breast cancers and identify tumors that depend on hormone pathways to grow, and that can be used as targets for endocrine (or anti-estrogen)

"There is clearly a need to accurately identify breast cancer subtypes as they are critical to help doctors and their patients truly individualize treatment decisions. The most common breast cancer subtypes are the hormone receptor-positive (tumors that express the estrogen and/or progesterone receptor), the HER2-positive (~ 20% of invasive tumors), and the triplenegative subtype that lacks expression of all three markers (~ 15% of all)" says Wolff.

### **New Molecular Information Leads** to New Guidelines

As chair of the American Society of Clinical Oncology's (ASCO) Health Services Committee in the late 2000s, he oversaw the development, dissemination, and implementation of practice guidelines that call for regular testing in newly diagnosed invasive breast cancers, and uniform testing procedures, and helped establish the first formal collaboration between ASCO and the College of American Pathologists (CAP).

"The main goal of the ASCO/CAP guidelines on HER2 and on hormone receptor testing in breast cancer is to improve the accuracy of predictive biomarker testing in everyday practice and ensure that patients receive the right treatment for their specific breast cancer subtypes to maximize their chances of surviving breast cancer. Widespread access to highquality routine pathology assessment and accurate testing for ER, PR, and HER2 testing is a critical issue worldwide. Breast cancer is the most common cause of cancer death in women not just in high-income but also in low- and middleincome countries and most of them have ER and/or PR-positive disease," he says.

In addition to his work on international guidelines, Wolff is collaborating with Sara Sukumar Ph.D., on a test that uses epigenetic biomarkers to detect and improve treatment decisions in early-stage breast cancer, and he leads a multidisciplinary group of experts at Johns Hopkins to address the unique needs of cancer survivors.

### **Did You Know?**

- Dr. Wolff is fluent in four languages: English, Portuguese, French, and Spanish
- Dr. Wolff sees patients at two Johns Hopkins locations: Downtown Baltimore (Weinberg Building on the main medical campus and at Green Spring Station in suburban Lutherville, Maryland
- · Dr. Wolff is a member of the Komen Scientific Advisory Council



You can follow Dr. Wolff on Twitter at: http://twitter.com/awolff

### **Getting Personal about Breast Cancer**

Stearns leads an active research team at the Kimmel Cancer Center. She is particularly interested in studying new agents that target epigenetic alterations, including abnormal methylation patterns, in breast cancer. Unlike genetic alterations that directly mutate genes, epigenetic alterations modify the chemical environment of genes and silence key tumor suppressor genes.

In her new role as co-director of the Breast Cancer Program, Stearns says she will focus on the emerging era of cancer management in which treatment is tailored to the unique genetic alterations contained within each individual patient's cancer. "We are using new technologies and collaborating with molecular biologists to further decipher the complex genetic code of cancer cells so that we can make personalized medicine—therapies that target the unique genetic and epigenetic characteristics of each individual's cancer-a reality." Her goal is to also acquire patient-specific information concerning the risks and benefits of specific treatments, allowing women and their physicians to make improved decisions regarding the choice of treatment and follow-up care.

With the genetic and epigenetic discoveries made at the Kimmel Cancer Center over the last several years, including the mapping of the breast cancer genome, Stearns and her collaborators are not just focused on developing new prevention and therapeutic strategies for patients, but also on personalizing these approaches to each individual's cancer. In the past, experts have referred to cancer as a general name for a group of hundreds of diseases. Based on the new genetic understanding of cancer—pioneered at our Center—it may actually be closer to 500 diseases. Breast cancer alone is currently recognized as six distinct diseases, and as research continues, it is likely that more subtypes will emerge.

"These new discoveries are changing the way our investigators think about clinical trials," she says. Within the next few years, all cancer patients at the Kimmel Cancer Center will have their tumors analyzed to reveal a unique "fingerprint." The fingerprint represents the combination of genetic and epigenetic alterations specific to each person's cancer. The availability of individual genomic and epigenomic information will change the way we study new drugs and use old ones. "Instead of trying them on all patients with breast cancer, we can direct them to the patients whose cancers contain the specific gene change that is targeted by the drugs—these are the patients who are likely to benefit," says Stearns. This shift

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in how we do drug screening will not only ensure that the best treatments get to the right patients, but also speed the pace and slash the cost of drug research.

The breast cancer drug bevacizumab (Avastin) is a good example of the need for this approach. Currently, its use in breast cancer is controversial because the data developed in women with several types of the disease indicate it is largely ineffective. Still, investigators know that some women derive notable benefits from the drug. Stearns believes that a closer look at the women who showed a response could uncover the cancer signature it targets. Giving the drug only to those with this signature would not merely strengthen the data concerning the effectiveness of a controversial drug, but more importantly, it would improve the quality of care for the target group of women receiving it. "This is really what personalized medicine is about," says Stearns.

Stearns has been instrumental in

building a translational research team and the infrastructure for implementing innovative early clinical trials. "Our program is home for experts in the fields of hormone resistance, epigenetic regulation and biomarkers, metastasis, and immunotherapy. For example, we are developing clinical trials including a treatment vaccine that boosts the patient's own immune system to fight cancer cells that evade chemotherapy," she says.

The Kimmel Cancer Center, she says, is one of the few cancer centers in the country setting the standard of care for breast cancer therapy and for survivors following treatment. "We excel in giving patients the best possible care from the very beginning of and throughout their cancer journey," says Stearns. As continued research leads to improved treatments, there will be a greater number of breast cancer survivors. With this in mind, Stearns is interested in expanding the clinical management of side effects, including those that affect women longterm, such as premature menopause, toxicities related to prior chemotherapy use, or symptoms associated with ongoing hormonal treatments.

In her personal work, Stearns also allocates a significant amount of time to investigating new treatments and approaches to ameliorate hot flashes and musculoskeletal and other symptoms that women with breast cancer commonly experience. Incorporating basic, clinical, and population science, her research and that of her team has answered fundamental questions about the mechanisms of breast cancer at the molecular level. It has also led to new interventions that not only help women who have or have had breast cancer, but also many other individuals who never faced this disease.

"It's a very exciting time to be part of cancer medicine," says Stearns. Most breast cancer patients survive their cancer, and, for me, some of the most rewarding and happiest experiences in the clinic involve watching women who have endured demanding and often painful treatments come to enjoy and regain control of their lives."

# From the petri dish to the patient

Researcher Sara Sukumar is Developing New Ways to Prevent, Detect and Treat Breast Cancer

THE DEVELOPMENT of a treatment that destroys cancer without destroying the breast and a screening test that can detect breast cancer from a tiny drop of breast fluid are among the research projects of Saraswati Sukumar, Ph.D., Co-Director of the Breast Cancer Program at the Kimmel Cancer Center and Barbara B. Rubenstein Professor of Oncology.

"In about the time it takes someone to read this article, at least three women will be diagnosed with breast cancer," says Sukumar. "I ask myself, if I were one of these women, what would I want out of treatment." On Sukumar's patientinspired wish list is treatment without mastectomy, reducing or eliminating side effects to treatment, and very high cure rates. Working with colleague Vered Stearns, M.D., the other Co-director of the Breast Cancer Program, she is researching a new therapy that may fit the bill.

#### Destroying Cancer, Not the Breast

Up to 95 percent of breast cancers, says Sukumar, begin in the breast epithelial cells that line the breast ducts. While epithelial cells are often at the root of the cancer, they make up a very small amount of the breast tissue, accounting for just five to ten percent of total breast cells. "If you get rid of the epithelial cells," she says, "you get rid of the cancer-causing cells while leaving the breast itself intact."

Sukumar and Stearns are testing a technique to deliver anticancer drugs directly to the epithelial cells using a tiny catheter inserted through the nipple and into the breast ducts. In animal models, the technique worked better than traditional intravenous drug therapy. Early

trials in patients, proved her concept, demonstrating that the technique successfully delivers drugs to the breast ducts and cleans out cells that are thinking about becoming tumors—and without causing any adverse effects.

### Finding Cancer from a Single Drop of Breast Fluid

Sukumar's work on a breast cancer screening test is making it possible to



"IN ABOUT THE TIME IT TAKES SOMEONE TO READ THIS ARTICLE, AT LEAST THREE WOMEN WILL BE DIAGNOSED WITH BREAST CANCER,"

detect breast cancer from a tiny drop of breast fluid. The test, called QM-MSP, is based on new findings in the emerging field of cancer epigenetics. The test simultaneously analyzes methylation patterns, a chemical process linked to the silencing of tumor suppressor genes, in five known breast cancer genes. Using the test on a tiny amount of breast fluid, about the size of a pinhead, Sukumar and collaborator Antonio Wolff, M.D., recently evaluated the test in a small clinical study of 64 women and were able to detect six of seven cancers using QM-MSP. By comparison, just two cancers were detected by cytology, the current standard of care where a microscope is used to look for abnormal cells in breast fluid.

"This preliminary study proves that detecting breast cancer with QM-MSP is feasible," says Sukumar. She plans to confirm these preliminary findings in a larger study of 500 women.

### Positive or Negative? That is the Question

Current testing fails to correctly identify two key groups of patients--those who are at risk for cancer recurrence and could be helped by chemotherapy, and those who are bound to have a recurrence of the breast cancer despite standard adjuvant chemotherapy. As a result, all patients end up receiving the same kind of chemotherapy, even those who don't need it.

Patients with early stage breast cancers that express the estrogen receptor (ER-positive tumors), will likely receive adjuvant therapy with antiestrogens like tamoxifen or an aromatase inhibitor, but experts know that this treatment is probably not necessary for all patients.

The problem has been in figuring out what patients will benefit and those who will not. New assays, such as Oncotype DX, that examine the molecular and genetic signature of an individual tumor are now commercially available and can help identify those patients at higher risk of breast cancer recurrence who should have adjuvant chemotherapy.

However, Sukumar points out that 30 percent of all breast cancers are triplenegative cancers, or cancers that are not fueled by hormone receptors (estrogen, progesterone, and epidermal growth factor or HER2) within the cells. Sukumar laments that, all too often, the only treatment option offered these patients is "chemotherapy and more chemotherapy."

Triple-negative cancers are typically aggressive cancers and have the lowest survival rates of all types of breast cancers, but Sukumar and Wolff are using new information gained by the analysis of the cancer epigenome, including methylation markers, to uncover

biomarkers for patients with these kinds of tumors to not only detect cancer but also to predict how they will respond to treatment.

Among the promising new approaches being investigated is a combined approach using new targeted agents known as HDAC inhibitors and aromatase inhibitors. Many of the heralded targeted treatments for breast cancer, such as tamoxifen and Herceptin therapy, only work in patients whose cancers are sensitive to hormones—ER, PR and HER2 positive. Working with Angela Hartley Brodie, Ph.D., professor of pharmacology and experimental therapeutics at the University of Maryland Greenebaum Cancer Center, Sukumar found that HDAC or histone deacetylase inhibitors can reactivate estrogen receptors and also makes breast cancer cells sensitive to treatment with another class of targeted drugs known as aromatase inhibitors. Studies of this new approach are offering new hope to patients with triple-negative breast cancers.

### **Team Science**

Sukumar, who is also a professor of pathology, a preceptor in human genetics, cell, and molecular medicine, and the pathobiology graduate program, credits the Breast Cancer Program's success to the Johns Hopkins Kimmel Cancer Center model of translational research. With clinical programs that are as strong as the basic science research and collaborations that extend to all departments and experts involved in the treatment of breast cancer, Sukumar says this team approach fosters new discoveries. "From the birth of a concept in the laboratory, all the way to the clinical trial, our researchers engage the medical oncologist, the pathologist, surgeons, and other experts to make sure we ask the critical questions and figure out the best way to use our laboratory science to benefit the clinical care of breast cancer patients."



### Did you know....

- Dr. Sukumar is the Principal Investigator for the Kimmel Cancer Center's NCIsponsored Breast Cancer SPORE (Specialized Program of Research Excellence) which focuses on advancing discoveries in prevention, detection, and treatment for breast with the goal of rapidly translating them into clinical applications.
- Dr. Sukumar has mentored over 40 postdoctoral fellows and researchers and has helped them establish careers in academic and other research arenas.
- · She serves on the Scientific Advisory Council of the Susan G. Komen for the Cure and was a scientific advisory board member.

### Research Notes

These are some of the abstracts presented at the international San Antonio Breast Cancer Symposium in December 2010. For details about these and other studies being conducted at the Johns Hopkins Kimmel Cancer Center, go to www.hopkinskimmelcancercenter.org

### **HOXB7** Gene Promotes Tamoxifen Resistance

Many postmenopausal women with early-stage breast cancers who initially respond well to tamoxifen become resistant to the drug over time and develop recurrent tumors. Johns Hopkins Kimmel Cancer Center researchers have found that a gene called HOXB7 may be the culprit in tamoxifen resistance.

### **Trio Of Drugs May Combat** "Triple Negative" Breast Cancer

Working with cell cultures and mouse models, researchers at the Johns Hopkins Kimmel Cancer Center have tested a cocktail of three drugs that holds promise for treating so-called triple negative breast cancers.

Women with such cancers lack all three hormone receptors - estrogen, progesterone and human epidermal growth factor 2 (HER2). Currently, treatments for triple negative breast cancers are limited and prognosis is poor.

According to the scientists, each of the three drugs used alone may have some effect on killing tumors cells, but combining them tips the scale in favor of killing more cells.

The researchers are discussing potential clinical trials of the combo therapy, which they hope to start in the next year.

### Simple Fingertip Test May Identify **Breast Cancer Patients At Risk For** Carpal Tunnel Syndrome

As many as half of postmenopausal women taking aromatase inhibitor drugs for breast cancer complain of bothersome musculoskeletal symptoms, including carpal tunnel syndrome (CTS). Now, a new study by Johns Hopkins Kimmel Cancer Center researchers shows that a simple test that measures a woman's ability to feel two metal points pressed against her fingertips may help evaluate the risk for developing CTS.



#### On the Web:

www.hopkinskimmelcancercenter.org

San Antonio Breast Cancer Symposium: http://www.sabcs.org/

Beyond Breast Cancer

# Surviving and Thriving

REMEMBER BEING SO scared when my oncologist said he did not need to see me on a regular basis anymore. There was no warning and no preparation—like a Band-aid being ripped off. I realized I'd grown to depend on the very appointments I originally loathed," said Elissa Bantug, two-time breast cancer survivor and program coordinator of the Johns Hopkins Breast Cancer Survivorship Program.

"At some point during my treatment, without me even being conscious of it, those appointments had become my security blanket," she said.

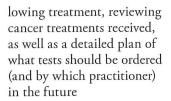
For many breast cancer patients like Bantug, living through treatment is only half the story. Regaining a sense of balance and normalcy afterward can be as challenging as the disease itself. The reality for a majority of patients is, there are a number of short- and long-term physical and psychological effects to cope with following medical treatment for breast cancer. To complicate things further, there currently is no organized system in place

to ensure communication between a woman's cancer specialist and her primary care provider, once she's completed treatment.

### **Bridging the Gap**

Recognizing this need, Johns Hopkins launched its Breast Cancer Survivorship Program last year with support from the Maryland affiliate of Susan G. Komen for the Cure. Under the leadership of principal investigator Antonio Wolff, M.D., a multidisciplinary team of specialists, including internists, oncologists, nurses, survivors, scientists, and social workers, are working together to improve long-term care and address the specific needs of breast cancer survivors at Johns Hopkins and elsewhere. A new consultation service for women who have finished treatment began in December 2010 with Bantug coordinating the various services a woman will see during her visit. In the new clinic, a breast cancer survivor will:

· Receive an individualized survivorship care plan fol-



- Discuss how to manage current or potential late side effects of treatment
- Find out about new research being conducted at the Johns Hopkins Kimmel Cancer Center
- Learn about reducing the risk of recurrence
- Suggestions for wellness activities, psychosocial support
- Coordination of medical care

### **Not Just Surviving** but Thriving

For Bantug, life after cancer has developed into more than a series of medical milestones. "As I move further from treatment, having cancer no longer is the singular most important piece about my identity. That's not to say that I, nor even most patients, don't occasionally think about it; but it no longer dictates every avenue of my life as it once did. Cancer has earned a piece of me just as has being a wife, daughter, and mother."



### **FIND OUT SURVIVORSHIPISSUES**

ON OUR WEB SITE

Bantug and colleagues have created a survivorship Web site with a variety of post-treatment topics being discussed. She also felt strongly that breast cancer survivors hear from other survivors regarding their experiences with survivorship care. There are currently 20 survivor videos clips taken from focus groups available on the Web site. Some of the topics include finding a "new" normal, survivorship care planning, sexuality, body image, and fear of recurrence. More videos are being planned for early 2011. hopkinsmedicine.org/breast\_

cancer survivor care

Read Elissa Bantug's blog posts on the Kimmel Cancer Center's blog: Cancer Matters

hopkinskimmelcancercenter. org

## Philanthropy

# Helping Us Beat Breast Cancer

The generosity of many people and groups allows us to take new ideas to the clinic. All of our donors play a part in making us a leader in research and promising new therapies for patients. In this issue, we highlight some of the foundations, corporations and individuals committed to beating breast cancer.



Johns Hopkins is grateful for the support of Susan G. Komen for the Cure, both nationally and through the Maryland chapter. Komen provides essential support through grants for research and innovative patient cancer and survivorship projects.



Sunset Hills Vineyard, located in Virginia, supports Ben Park, M.D., Ph.D., and his research team. Among the team's discoveries was pioneering research on mapping the breast cancer genome.



Kimmel Cancer Center Director William Nelson, M.D., Ph.D., and breast cancer program co-director Sara Sukumar, Ph.D., helped Baltimore Safeway customers with their groceries to raise awareness about breast cancer in October as part of Safeway's annual fundraising campaign benefitting breast cancer research at Johns Hopkins.





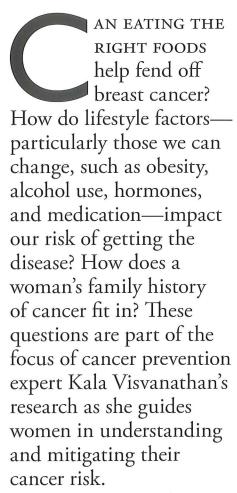
Sidney Kimmel (left), recipient of the 2010 FFANY Jodi Fisher Humanitarian Award, and Dr. Vered Stearns.



The Breast Cancer Research Foundation provides support to Kimmel Cancer Center physician-scientists Ben Park, M.D., Ph.D., Vered Stearns, M.D., Kala Visvanathan M.B.B.S., Antonio Wolff, M.D., and Richard Zellars, M.D., for innovative translational research studies.

Focus on Prevention

# What Causes Breast Cancer



"We need to do a better job ensuring that all women have their breast cancer risk assessed and are informed about preventive options available to them," says Visvanathan, M.B.B.S., M.H.S., who co-directs a Johns Hopkins clinic for women at high risk of developing breast and ovarian cancer. "Women who have a family history of breast cancer or have

family members who developed breast cancer at a young age may benefit from genetic testing, more tailored screening and prevention plans, and chemoprevention (medications used to help prevent cancer development).

Most breast cancers, however, are caused by cellular alterations that are acquired over time, and identifying ways to interfere with these cancer-causing alterations is the focus of much of her work. She is a leading expert in the study of biomarkers or cellular red flags that can warn of a person's predisposition for developing cancer and serve as a target for prevention and therapy.

### A Cancer Fighter from your **Grocer's Produce Aisle**

Visvanathan is examining the protective effects of sulforaphane, a cancerpreventing compound found in high concentrations in broccoli sprouts that helps mobilize the body's cancer-fighting resources. "We need less toxic approaches to prevent breast cancer than are available now with drugs, and ones that are cheap and safe," says Visvanathan. "Broccoli sprouts are natural, inexpensive and high in this cell-detoxifying agent and can be used even in young women."

In animal models, sulforaphane has been shown to prevent breast cancer by turning on enzymes that protect cells. Now, she is looking for the same evidence in people. In two ongoing clinical trials, Visvanathan and team are examining whether women taking a broccoli sprouts preparation have increased expression



of a known cell-detoxifying gene when compared with those taking a placebo. The researchers also are evaluating a broad panel of gene and protein markers related to breast cancers and known to be modified by sulforaphane.

In other studies, Visvanathan is evaluating the short- and long-term risks,

"WE NEED LESS TOXIC APPROACHES TO PREVENT BREAST CANCER, AND ONES THAT ARE CHEAP AND SAFE. BROCCOLI SPROUTS ARE NATURAL, INEXPENSIVE AND HIGH IN THIS CELL-**DETOXIFYING AGENT."** 

including metabolic changes, cardiac disease, bone density, and cancer development, for women who have had their ovaries removed for breast and ovarian cancer prevention. Another follows women and men at high risk of breast cancer. Ultimately, she hopes to determine how the way we live relates to the way we develop cancer.



#### Did You Know?

Dr. Visvnathan co-chaired the American Society of Clinical Oncology (ASCO) guidelines that updated recommendations for breast cancer prevention

### Our Breast Program Faculty

Vered Stearns, M.D., Co-Director Sara Sukumar, Ph.D., Co-Director

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### Radiology

David Eisner, M.D. Nagi Khouri, M.D.

Learn more about the many specialists including pathologists, gynecologist and nutritionalist, who work together as part of the Johns Hopkins Avon Foundation Breast Center at: www.hopkinsbreastcenter.org

### Co-Directors







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### **Plastic** Surgeons



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Ariel Rad



Gedge Rosson



Justin Sacks

### Radiology



David Eisner



Nagi Khouri



Breast Cancer Program co-director Sara Sukumar, Ph.D. (in black and pink), stands with some of the 30-member team from Johns Hopkins that participated in the annual Avon Walk for Breast Cancer in Washington, D.C. Each year, Avon awards grants to organizations, including the Kimmel Cancer Center, to advance access to care and breast cancer research with funds raised from the D.C. walk and others around the country.

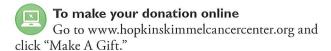
### KIMMEL CANCER CENTER

## **Help Us**Make A Difference

Each contribution to the Breast Cancer Program at the Johns Hopkins Kimmel Cancer Center makes a difference in the lives for cancer patients here at Johns Hopkins and around the world.

Our physician-scientists are leading the way on many of the scientific breakthroughs in breast cancer and your donation will support patient care and innovative research that is translated to better, more effective treatments. We are also focusing on ways to prevent breast cancer and support survivors.

You may designate a gift to a specific faculty member.





### To mail your donation, send to:

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A publication of The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins Office of Public Affairs 901 South Bond Street / Suite 573 Baltimore, MD 21231 410-955-1287