

JUDGES & LAWYERS BREAST CANCER ALERT

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Summer 2021

UPCOMING PROGRAM – CANCER: IT’S NOT JUST PHYSICAL

Please save the date to join JALBCA for “Cancer: It’s Not Just Physical,” the third in our series of “Treatment Beyond the Tumor” programs, on Tuesday, October 12, 2021 at 6 p.m. (by Zoom and in person at location TBD). Author Cynthia Hayes, *The Big Ordeal: Understanding and*

Managing the Psychological Turmoil of Cancer, will be joined by Alyson Moadel, PhD, Founding Director, BOLD Cancer Wellness Program at Montefiore Einstein Cancer Center, to discuss the emotional ramifications of a cancer diagnosis, helping patients and their loving caregivers learn about

the typical sequence of emotions experienced at diagnosis, treatment and beyond, understand the science behind those emotions as well as how the disease and its treatment contribute to the psychological experience, and discover how to cope with it all.

JALBCA’s ANNUAL AWARDS PRESENTATION GALA

On May 25, 2021, JALBCA went virtual for the second time with its Awards Presentation Gala. Richard Edlin and Maura Miller co-chaired the Gala as in recent years and Faith Miller joined them as an emcee. A huge thank you to all our sponsors and contributors, whose generous support allowed JALBCA to raise \$1.2 million through the Gala. (A video of the Gala can be viewed at <https://vimeo.com/554769116> and a listing of our many sponsors can be viewed at <https://jalbca.org/donors/>.)

Hon. Saliann Scarpulla, JALBCA’s outgoing Co-President, delivered a beautiful tribute to the late Court of Appeals Judge Paul Feinman, who was a friend of Judge Scarpulla and of JALBCA, had sworn her in as JALBCA Co-President two years ago and had received JALBCA’s Leadership Achievement Award in 2018. She then introduced incoming Co-President Hon. Marguerite A. Grays, Administrative Judge, Civil Term, 11th Judicial District.

At the Gala, JALBCA was proud to honor these worthy members of our New York legal community, including our own Sharon Nelles, who has



Sharon Nelles, Martha Samuelson, Hon. Jeffrey Sunshine, Hon. Loretta Preska, Jacqueline Flug, Hon. Janet DiFiore

been a gift to both JALBCA and the Bar:

- **Sharon L. Nelles** - Volunteer Service Award for her many years of service to JALBCA, including as Past Co-President and long-time Board member of JALBCA and as the driving force behind the

Awards Presentation Dinner for nearly 10 years. This award was presented by Co-President Hon. Marguerite Grays. To honor Sharon, more than 80 of her friends in the legal community formed the Nelles Brigade, raising over \$150,000 to fund mammogram vans for unin-

sured and underinsured women in underserved communities in the coming year, and Sharon's firm, Sullivan & Cromwell LLP, and more than 100 of her partners contributed over \$425,000 to support JALBCA and its mission and grantees.

- **Matrimonial Judges of the State of New York** - Leadership Achievement Award. This award was presented by the Honorable Janet DiFiore, Chief Judge of the New York Court of Appeals and Honorary President of JALBCA. Hon. Jeffrey Sunshine, the state-wide coordinating judge for matrimonial matters, accepted the award on behalf of the 52 dedicated matrimonial jurists around the state.

- **Martha S. Samuelson and Analysis Group** - Maite Aquino Memorial Grant Award, accepted by Ms. Samuelson. Ms. Samuelson is Chief Executive Officer of Analysis Group and has been a long-time Host sponsor and supporter of JALBCA. This award was presented by a dear friend of Ms. Samuelson, the Honorable Loretta A. Preska, Judge of the U.S. District Court for the Southern District of New York.

Former Co-President Judith Livingston applauded the honorees and donors and encouraged attendees to contribute to



Hon. Saliann Scarpulla, Hon. Marguerite Grays, Christal Putkowski, Faith Miller, Rich Edlin, Maura Miller

JALBCA. The emcees thanked the sponsors, for whose generosity and good will JALBCA is so profoundly grateful. Executive Director Claire Gutekunst reported on some of JALBCA's 2020-2021 activities. She discussed JALBCA's educational programs and the continuing funds made available for grantees during the year, albeit reduced from the prior year due to the impact of the COVID pandemic on JALBCA's fundraising in 2020.

Attorneys and clients at several of JALBCA's grantees were featured, and they eloquently described the range and impact of legal services made

available to breast cancer community members in need through JALBCA's grants. A highlight of the evening was Christal Putkowski's moving story of how a mammogram she received from JALBCA grantee Project Renewal's ScanVan Project saved her life.

While the pandemic has disrupted many lives, nothing interfered with JALBCA's resilience and ability to accomplish its mission in the last year. Next year will be JALBCA's 30th anniversary bash, and plans are already in place for the celebration at the Ziegfeld Ballroom on May 9, 2022.

JALBCA PROGRAM ON GENETIC TESTING

On March 23, 2021, JALBCA sponsored a program entitled *What Black Women Need To Know about Hereditary Breast Cancer*. The program was introduced by JALBCA's incoming Co-President, Hon. Marguerite Grays. Presenters for this program were Erika Stallings, Esq. and Altovise T. Ewing, Ph.D., LCGC. Ms. Stallings is a JALBCA Board member, BRCA awareness advocate, and Associate General Counsel, Music Product at Facebook, who has spoken and written about her experience as a

BRCA2 mutation carrier. Dr. Ewing is a clinician-scientist with 10+ years of genetic counseling and health disparities research experience, currently working at Genentech, with a passion for health equity and inclusion. Fourteen other bench and bar organizations from across New York State co-sponsored this program.

Ms. Stallings was the first presenter. She reported that, according to the CDC, black women are 42% more likely to die from breast cancer than white women

and, according to the American College of Radiology and Society of Breast Radiology, black women are more likely to be diagnosed with triple negative breast cancer, a diagnosis associated with one of the genetic cancer mutations. The rates of genetic counseling, according to a 2017 study, show that black women were less likely to be referred for genetic counseling and testing even though they are more likely to have these hereditary mutations (BRCA1 and BRCA2).

Dr. Ewing then picked up the presenta-

Presenters



Erika Stallings, Esq.
BRCA awareness advocate and
Attorney, Facebook Music



Altovise T. Ewing, Ph.D., LCGC
Senior Science Lead and Strategist,
Global Health Equity and Population
Science team, Genentech

tion. White women are diagnosed with breast cancer more often than black women. However, when looking at the death rate, black women are significantly more likely to die from the disease. Many factors contribute to the overall risk of being diagnosed with breast cancer - environmental, lifestyle, social determinants, personal and family health history, and genetics. As for the five-year survival rate, black women are less likely to survive than those of European ancestry and, in addition, more likely to be diagnosed at a younger age and with a more aggressive form of the disease, *i.e.*, triple negative breast cancer. Dense breast tissue is another issue.

Dr. Ewing questioned how we should address some of these disparities. Genetic counseling is one valuable tool to help an individual establish her own risk and tailor her medical care to manage this risk. It helps the individual and the family understand how to manage the risk, for example, by undergoing screening more frequently. Typically, the process of genetic counseling is done by a certified or licensed genetic counselor but sometimes a physician or even a nurse can provide this counseling. Throughout the country there are approximately 5,000 certified genetic counselors. Their certification is provided by the American Board of Genetic Counseling. They are translators of genetic information and can be specialized in a variety of fields. Telehealth counseling is becoming more widespread and available. Counseling can be obtained before or after a test

result is received. Currently, less than 2% of the members of this profession are identified as African American, and 97% of counselors represent as being non-Hispanic.

Genetic testing can reveal if there are genetic mutations, or variants, in one's DNA. Tests can look at one gene in particular or be multi-gene panel tests where they look at multiple genes at a time. Some of the larger scale tests can include gene sequencing. Results can be either positive (detection of genetic change/variant known to cause disease), negative (test did not find genetic change/variant known to cause disease) or a "variant of unknown significance" (insufficient information about the genetic change/variant to classify it as normal disease-causing factor). Black women are more likely to receive variants of unknown significance which, in turn, leads to an inability of genetic testing to accurately or precisely inform their medical management.

She explained that it often is recommended to take at least a three-generation pedigree when going for genetic counseling. One discusses personal medical history during such a session. This can be important, for example, where the client is an adoptee. Clients will also be asked if genetic testing was done in the past because, with the progress in the field of genetic testing, an updated genetic test may be appropriate. Breast cancer susceptibility genes can be grouped into multiple classes - high, moderate and low-penetrance. Dr. Ewing referred to

the National Comprehensive Cancer Network (NCCN) guidelines for hereditary cancer testing criteria, which criteria must be met in order to qualify for genetic testing. The National Society of Genetic Counselors has a website to help individuals locate genetic counselors.

Ms. Stallings then described her own story, indicating that her mother was first diagnosed in her 20's with breast cancer and, it was later learned, carried a BRCA2 mutation and triple negative breast cancer. One thing to remember, she reminded the audience, is that both men and women can pass on the mutation. She shared that she underwent preventative intervention via surgery once she learned, through genetic testing, that she was a carrier of the BRCA2 mutation. She also plans future preventative surgery to keep at bay other types of cancer that are associated with the mutation.

The question-and-answer session then commenced. During this period, it was explained that a mutation can be passed on to both sons and daughters from both fathers and mothers. One questioner asked about the cost of genetic counseling and whether a positive finding makes life insurance more expensive to obtain. Dr. Ewing explained people learn about genetic counseling when engaged in family planning, or after being diagnosed with a condition, or in other contexts. If you meet criteria, she indicated that most insurance companies do abide by the NCCN guidelines to determine eligibility. She also referred to Federal law that prohibits discrimination in employment based on genetic information but added that this would not protect an individual in connection with obtaining life or disability insurance. An attendee questioned how one gets into the genetic counseling field, and Dr. Ewing referred to the accreditation council for genetic counselors to learn about the profession and programs.

(Dr. Ewing's PowerPoint slides may be viewed at https://jalbca.org/wp-content/uploads/2021/03/JALBCA-Presentation_March-23.pdf and a video recording of the program is available at <https://vimeo.com/531469819>.)

NEWS ITEMS

Myocardial Infarction Accelerates Breast Cancer via Innate Immune Reprogramming

A study reported in the July 13, 2020 issue of *Nature Medicine* found that myocardial infarction (MI) can accelerate breast cancer growth and cancer-specific mortality in mice and humans. In the mouse models of breast cancer, MI caused epigenetic changes that reprogrammed immune-fighting monocytes in bone marrow to become immune-suppressing monocytes that can hasten tumor growth. Citing to two 2016 studies, the researchers state that “(m)onocytes are key regulators of the tumor microenvironment and elevated levels of circulating monocytes correlate with poor clinical outcomes in a variety of cancers. Monocytes and monocyte-derived macrophages have a multitude of tumor-promoting accessory functions and these include fostering tumor immune evasion and angiogenesis, as well as tumor cell proliferation, migration, invasion and metastasis.”

The researchers also found that patients with early-stage breast cancer who experienced cardiovascular events after diagnosis had increased risk of recurrence and cancer-specific death. The preclinical and clinical results of the study, they concluded, show that myocardial infarction induces alterations in systemic homeostasis, triggering cross-disease communication that accelerates breast cancer.

(Source: Koelwyn, G.J., Newman, A.A.C., Afonso, M.S. et al., *Myocardial infarction accelerates breast cancer via innate immune reprogramming*, *NAT MED* 26, 1452–1458 (2020). <https://doi.org/10.1038/s41591-020-0964-7>.)

New FDA-Approved Therapy for Metastatic Triple Negative Breast Cancer

On April 22, 2020, the Food and Drug Administration granted accelerated approval to Trodelvy (chemical name: sacituzumab govitecan-hziy) for adult patients with metastatic tri-

ple-negative breast cancer who received at least two prior therapies for metastatic disease. FDA granted sacituzumab govitecan-hziy orphan drug, fast track, and breakthrough therapy designation. Subsequently, on April 7, 2021, the FDA granted regular approval for Trodelvy to treat certain people with unresectable locally advanced or metastatic triple-negative breast cancer. Locally advanced breast cancer is breast cancer that has spread to tissue near the breast. Unresectable means the cancer cannot be removed with surgery. Triple-negative breast cancer is cancer that has no receptors for the hormones estrogen and progesterone, and no receptors for the HER2 protein – all of which limit the medicines that are available to treat this type of cancer.

Trodelvy is an immune targeted therapy medicine and is delivered intravenously. Trodelvy is called an antibody-drug conjugate whereby the monoclonal antibody sacituzumab is conjugated (attached) to the SN-38 chemotherapy. It is the first Trop-2–related therapy to be approved by the FDA. Antibody–drug conjugates are designed to deliver toxic drugs directly to cancer cells. The antibody component binds to the Trop-2 protein on the surface of cancer cells. The entire antibody–drug conjugate is drawn into the cancer cell and the cytotoxin is released, killing the cancer cell.

The most common adverse reactions ($\geq 25\%$ of patients) were nausea, neutropenia (which means the person has abnormally low levels of neutrophils, a type of white blood cell), diarrhea (which can cause dehydration, low blood pressure and severe kidney problems), fatigue, anemia, vomiting, alopecia, constipation, rash, decreased appetite, and abdominal pain.

(Source: *FDA Approves Trodelvy for Metastatic Triple-Negative Breast Cancer*, at <https://www.breastcancer.org/research-news/fda-approves-trodelvy-for-metastat->

[ic-tnbc#:~:text=On%20April%2022%2C%202020%2C%20the%20U.S.%20Food%20and,at%20least%20two%20previous%20treatments-%20for%20metastatic%20disease.](#)

Liquid Biopsy for Breast Cancer

In the last decades, blood-based diagnostics have become one of the major focuses of oncological and translational research (research which tests findings from basic research for clinical effect and/or applicability). Liquid biopsy – a simple blood test - is gaining traction as a personalized cancer screening device, a complement to therapy monitoring and a potential basis for treatment decisions. A liquid biopsy for breast cancer offers advantages over conventional diagnostic methods, such as tissue biopsy. For example, while a tissue biopsy samples tissue from one location, a liquid biopsy may offer the opportunity to detect a tumor anywhere in the body. Both a tissue biopsy and a liquid biopsy can be done without an invasive procedure, at almost any clinic and repeatedly, both in connection with cancer detection and with post-treatment monitoring.

Tumor cells detected in the peripheral blood are commonly referred to as circulating tumor cells (CTCs) and are seen as possible precursors of metastatic disease. In metastatic breast cancer, elevated levels of CTCs have been confirmed as an independent prognostic factor.¹

Beyond CTCs, circulating tumor DNA (ctDNA)(tumor DNA shed in a patient’s circulation) and non-coding RNA are increasingly the focus of translational cancer research. Historically, it has been very difficult to detect the presence of a few cancer cell bio-

1. M. Banyas-Paluchowski and P. Paluchowski, *Liquid biopsy in metastatic breast cancer*, *CANCER DRUG RESIST*, Dec. 19, 2019, 2:1062-1068, <http://dx.doi.org/10.20517/cdr.2019.84>

markers or particles of ctDNA in the blood. In a study published in August 2019 in *Science Translational Medicine*, a highly sensitive liquid biopsy test known as targeted digital sequencing (TARDIS) identified fragments of ctDNA as low as 2 parts per 100,000 in the blood of breast cancer patients, showing promise as a tool for detecting residual cancer following neoadjuvant treatment. This was reported by researchers from the Translational Genomics Research Institute and the Mayo Clinic in Arizona. To effect this level of accuracy, the TARDIS liquid biopsy assay uses a personalized patient-specific testing approach, *i.e.*, it analyzes patient-specific tumors.² This can be customized for each patient but can then be used to monitor the patient over time for, and allow early detection of, tumor recurrence. The investigators reported that they successfully analyzed up to 115 mutations per patient in 80 plasma samples from 33 women with stage I to III breast cancer.

Are we at a point where we have liquid biopsy-guided treatment decisions?

By way of background, approximately three-quarters of all breast cancers are fueled by the hormone estrogen. More than 70% of breast cancers are hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative. Approximately 40% of patients with HR-positive, HER2-negative breast cancer have activating mutations in the gene *PIK3CA*.³ Along with the standard treatments (surgery, radiation, and che-

motherapy), drugs that block estrogen are used to cure women of this cancer. Since the 1980s, there were two widely applied predictive markers in breast cancer to predict treatment success - HR and HER2. This changed in 2019 in connection with a third marker, mutated *PIK3CA*. A *PIK3CA* mutation over-activates the P13K pathway, which in turn is associated with tumor growth, resistance to endocrine treatment and a poor overall prognosis.

There is great interest in how genetic mutations, such as in the protein P13K, may promote resistance to hormone-blocking medications. Research on the usefulness of CTCs and ctDNA for guiding treatment decisions led to the first liquid biopsy-based FDA approval in metastatic breast cancer in May 2019 - the approval of the oral P13K inhibitor alpelisib. The trial sponsor, Novartis, asserted that its phase III randomized, double-blind SOLAR-1 trial was the first phase III breast cancer trial to demonstrate potential viability of using liquid biopsy to select patients for targeted treatment. Based on the SOLAR-1 trial, the FDA approved alpelisib for patients with mutations in ctDNA and/or tumor tissue.

Also, in a study published March 23, 2020, scientists at Memorial Sloan Kettering Cancer Center reported that a liquid biopsy can identify other mutations responsible for drug resistance. This followed a clinical trial with a combination of P13K inhibitors and estrogen-blocking medications. They identified mutations in two additional genes that promote this resistance af-

ter the women in the study were given the blood test before, during, and after treatment. The investigators then looked for any genetic changes which had become more common over this time span. They found that mutations in two genes, *PTEN* and *ESR1*, in fact, became more common. Consequently, this test result may be a basis for customizing a particular treatment since women who are found to have mutations in *PTEN* or *ESR1* at the time of diagnosis may be better off receiving other drugs, such as AKT inhibitors or selective estrogen receptor degraders (SERDs), rather than P13K inhibitors and hormone blockers.⁴

In short, the use of the liquid biopsy seems to show great promise in multiple respects in connection with the diagnosis and treatment of breast cancer. Liquid biopsies are also expected to be used to detect and track other cancers.

2. See TARDIS: New Liquid Biopsy Milestone, Sept. 19, 2019, <https://www.aacc.org/cln/cln-stat/2019/september/19/tardis-new-liquid-biopsy-milestone>

3. Fabrice Andre, *Alpelisib for PIK3CA-Mutated, Hormone Receptor-Positive Advanced Breast Cancer*, N ENGL J MED 380:1929-1940, May16, 2019, <https://www.nejm.org/doi/full/10.1056/NEJMoal813904>.

4. Matthew Tontonoz, *Liquid Biopsy Can Guide Treatment for Women with Metastatic Breast Cancer*, March 23, 2020, <https://www.mskcc.org/news/liquid-biopsy-can-guide-treatment-women-metastatic-breast>

BREAST CANCER RESOURCES

ADELPHI NY STATEWIDE BREAST CANCER

Hotline & Support Program

Adelphi University School of Social Work

Garden City, NY 11530

www.breastcancerhotline@adelphi.edu

CancerCare

275 Seventh Avenue

New York, NY 10001

www.cancercare.org

800.813.HOPE (4673)

CENTER FOR ELDER LAW & JUSTICE

438 Main Street, Suite 1200

Buffalo, NY 14202

www.elderjusticenyc.org

716.853.3087

CITY BAR JUSTICE CENTER/CANCER ADVOCACY PROJECT

42 W. 44th Street

New York, NY 10036

www.citybarjusticecenter.org/projects/cancer-advocacy-project

212.382.4785

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200 West End Avenue, Suite 12 G

New York, NY 10023

www.ellensrun.org

212.840.0916

THE FAMILY CENTER

Judith S. Kaye Project and Maite Aquino Program

493 Nostrand Avenue, 3rd Fl.

Brooklyn, NY 11216

<http://www.thefamilycenter.org/what-we-do/legal-wellness-institute/our-clients-projects/>

718.230.1379, ext. 150

Toll Free: 800.219.4522

GILDA's CLUB NEW YORK CITY

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New York, NY 10014

www.gildasclubnyc.org

212.647.9700

MALE BREAST CANCER COALITION

www.malebreastcancercoalition.org

MEMORIAL SLOAN KETTERING CANCER CENTER

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Educational Forums

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New York, NY 10021

www.mskcc.org

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1429 First Avenue (at 74th Street)

New York, NY 10035

NATIONAL BREAST CANCER COALITION

2001 L Street, NW, Suite 500 PMB#50111

Washington, DC 20036

www.stopbreastcancer.org

202.296.7477

Toll Free: 800.622.2838

SHARE

(Self-Help for Women with Breast or Ovarian Cancer)

65 West 46th Street, Suite 712

New York, NY 10036

212.719.0364

Toll-Free 844-ASK-SHARE (844.275.7427)

www.sharecancersupport.org

Speak to a survivor toll-free: 866.891.2392

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