



JALBCA

JUDGES AND LAWYERS
BREAST CANCER ALERT

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Editor: Martha L. Golar, Esq.

September 2013

THE EIGHTEENTH ANNUAL ELLEN P. HERMANSON MEMORIAL SYMPOSIUM

***Litigating for the Cure: Public Interest, Private Enterprise
and the Role of the Courts in the Business of Cancer Research***

Wednesday, October 9, 2013

6:00 - 8:30 PM

New York City Bar Association

42 West 44th Street, 2nd Floor Meeting Hall

Dr. Larry Norton will present the latest developments in the fight against breast cancer
to be followed by the program

Panel of Judges

Hon. Helen Freedman, NYS, Appellate Divn, 1st Dept.

Hon. Judith S. Kaye, Chief Judge, NYS Court of Appeals (Retired), Moderator

Hon. Loretta Preska, Chief Judge, U.S. District Court, S.D.N.Y.

Panel of Experts

Robert Cook-Deegan, MD, Research Professor, Genome Ethics, Law & Policy, Duke Univ.

Larry Norton, MD, Deputy Physician-in-Chief for Breast Cancer Programs, MSKCC

Joseph Opper, Esq., Partner, Garwin Gerstein & Fisher LLP

Fran Visco, JD, President, National Breast Cancer Coalition

Sponsor

The Ellen P. Hermanson Foundation

Presenting Organizations

Women's Bar Association of the State of New York

The New York Women's Bar Association

Symposium Co-Chairs

Hon. Shirley Werner Kornreich, Mikki Golar, Esq., Barbara A. Ryan, Esq.

CLE

Professional Practice- 2.0 credits, qualification pending

Open to the public without charge - Refreshments will be served

*To reserve a space please email Executive Director, Jennifer Fiorentino
at jenfiorentino@aol.com or call (212) 289-9720*

CANCER SCREENINGS UNDER THE PATIENT PROTECTION AND AFFORDABLE CARE ACT

The Patient Protection and Affordable Care Act (ACA) helps make prevention affordable and accessible for all Americans by requiring health plans to cover preventive services and by eliminating cost sharing (i.e., co-payment or co-insurance) for those services.

Under the ACA, women's preventive health care - such as mammograms, screenings for cervical cancer, prenatal care, and other services - generally must be covered by health plans with no cost sharing. The new rules apply to policies that took effect after September 23, 2010. The rules allow for exceptions where insurers may charge a co-pay for a preventive visit under the following circumstance:

- When the patient is enrolled in a "grandfathered" plan that has made no changes to its benefits and, thus, is not subject to regulation under the health reform law;
- When the physician is out-of-network for the patient's plan; and
- When services for another problem are provided during the same visit.

Grandfathered plans are covered by state laws, which vary, and other federal laws. Many states require that private insurance companies, Medicaid, and public employee health plans provide coverage and reimbursement for specific health services and procedures. In New York, the requirement applies to a baseline mammogram for ages 35-39, every year for 40+, or physician recommendation.

As part of the ACA, Medicare covers the full cost of a mammogram once every 12 months. Women are eligible

for Medicare if they are age 65 and older, are disabled, or have end-stage renal disease. Medicare also pays for a clinical breast exam when it is performed for screening or prevention.

For a current list of government-recommended preventive services that are fully covered under the ACA, you can visit www.healthcare.gov and click on the topic "Prevention". When delivered by an in-network provider, the website indicates that "comprehensive coverage for women's preventive care" includes the following:

1. Anemia screening on a routine basis for pregnant women
2. Breast Cancer Genetic Test Counseling (BRCA) for women at higher risk for breast cancer
3. Breast Cancer Mammography screenings every 1 to 2 years for women over 40
4. Breast Cancer Chemoprevention counseling for women at higher risk
5. Breastfeeding comprehensive support and counseling from trained providers, and access to breastfeeding supplies, for pregnant and nursing women
6. Cervical Cancer screening for sexually active women
7. Chlamydia Infection screening for younger women and other women at higher risk
8. Contraception: Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling, as prescribed by a health care provider for women with reproductive capacity (not including abortifacient drugs). This does not apply to health plans spon-

sored by certain exempt "religious employers."

9. Domestic and interpersonal violence screening and counseling for all women

10. Folic Acid supplements for women who may become pregnant

11. Gestational diabetes screening for women 24 to 28 weeks pregnant and those at high risk of developing gestational diabetes

12. Gonorrhea screening for all women at higher risk

13. Hepatitis B screening for pregnant women at their first prenatal visit

14. HIV screening and counseling for sexually active women

15. Human Papillomavirus (HPV) DNA Test every 3 years for women with normal cytology results who are 30 or older

16. Osteoporosis screening for women over age 60 depending on risk factors

17. Rh Incompatibility screening for all pregnant women and follow-up testing for women at higher risk

18. Sexually Transmitted Infections counseling for sexually active women

19. Syphilis screening for all pregnant women or other women at increased risk

20. Tobacco Use screening and interventions for all women, and expanded counseling for pregnant tobacco users

21. Urinary tract or other infection screening for pregnant women

22. Well-woman visits to get recommended services for women under 65

Open enrollment starts October 1, 2013. Coverage starts as soon as January 1, 2014.



JALBCA'S SUSAN SOLOMON INTERN

Samantha Kopf is a student at Pace University School of Law, having previously attended Barnard College. She worked in publishing and journalism for several years prior to entering law school, and participated in the development of a breast cancer book to be published in 2014. As with all JALBCA interns, Samantha is assisting the co-Chairs of JALBCA's Annual Symposium, researching and drafting materials necessary for this educational effort.

NEWS BRIEFS

Neoadjuvant Therapy Options and Clinical Trials in Breast Cancer

A session at the annual American Society of Clinical Oncology (ASCO) meeting, held May 31-June 4, 2013, was devoted to neoadjuvant therapy options in breast cancer. The session was Chaired by Dr. Angela DeMichele, MD, associate professor of medicine at the Hospital of the University of Pennsylvania, Philadelphia. ASCO interviewed her about the subject and her comments follow.

Typically, neoadjuvant or preoperative therapy is used in patients who are candidates to receive chemotherapy. In this usage, chemotherapy is given prior to surgery, rather than post-surgery where it would be used to prevent the cancer from recurring. A series of studies compared giving the same therapy pre- and post- surgery and found that it was equally effective. The benefits to preoperative therapy are several. First, previously inoperable tumors are now down-staged if they respond and can be resected. Second, patients who would need a mastectomy may, through shrinkage of the tumor, now have the opportunity for a lumpectomy and breast conservation. Further, neoadjuvant therapy provides an opportunity to test the effectiveness of the drugs on the tumor and, therefore, also the microscopic cells that may be in the bloodstream. Dr. DeMichele stated that women who have an excellent response to chemotherapy given pre-surgery have good prognosis, and in fact a better prognosis compared to women whose tumors do not respond to the chemotherapy.

Examples of neoadjuvant agents that are currently in development for breast cancer are drugs targeted to

HER2 such as lapatinib and PARP inhibitors in women who have triple-negative breast cancer. A real-time readout on whether a drug is active or not occurs. As a result, the oncologist will know whether the patients do or do not respond to the drugs, unlike the situation after surgery where a large number of patients are treated with drugs which may not be effective. Advance knowledge of whether a drug works on a patient's particular tumor is the ultimate in personalized medicine. The drugs that are actually tested in the neoadjuvant setting are usually the ones that are already known to be safe – not the newest drugs.

Dr. DeMichele also discussed the recent FDA draft guidelines on methods to accelerate drug approval through neoadjuvant therapy clinical trials. In the typical post-surgery clinical trial, a very large adjuvant trial is designed with thousands of patients over 5 to 10 years where the researcher waits to see if the patient getting the new therapy relapses more or less frequently compared to patients who receive the standard of care and, therefore, whether the drug is or is not effective. In a neoadjuvant clinical setting, which can be much smaller (a few hundred patients), the researcher sets up surrogate markers (early indicators that accurately reflect whether a patient's tumor will relapse or whether a patient will die of the disease) and learns much earlier whether the drug is shrinking the tumor more than would occur with the standard of care. Provisional approval from the FDA could be available, with a confirmatory trial to follow.

Additionally, Dr. DeMichele explained what a “pathological com-

plete response” is in connection with a clinical trial. She said that the pathologically complete response is the trial endpoint where the post-surgery pathologist sees in a breast tissue specimen that there are no residual cancer cells, as they have been eradicated from the pre-surgery therapy. This, she said, is highly associated with a good long-term outcome in triple-negative breast cancer and HER2-positive breast cancer. But, in estrogen-receptor-positive breast cancer, tumors paradoxically grow more slowly and tend to be less responsive to chemotherapy and the correlation with attaining a pathologically complete response and actually having a good outcome does not hold very well. Therefore, the drugs that are most likely to follow the FDA neoadjuvant approval pathway are ones that are targeted to patients with HER2-positive or triple-negative breast cancer, and researchers still need to define the appropriate surrogate endpoints for women who have estrogen-receptor-positive breast cancer.

Finally, where it is learned that a tumor does not respond to a drug in neoadjuvant trials, the challenge faced by researchers, where residual tumor remains, will be to determine an appropriate post-surgery treatment. Dr. DeMichele indicated that, in the future, she expects to see the development of post-neoadjuvant trials (strategies to try to add additional therapies after surgery for patients who did not respond well to the pre-surgery treatment).

Source:

<http://www.cancernetwork.com/conference-reports/asco2013/breast-cancer/content/article/10165/2144393>

ANNUAL COURTHOUSE ALERT COCKTAIL RECEPTION KICK-OFF

JALBCA and The Brooklyn Women's Bar Association scheduled its kick-off reception for the annual mammogram van program on Wednesday, September 11, 2013 at the Appellate Division, Second Department Courthouse in Brooklyn. Hon. A. Gail Prudenti served as Honorary Event Chair and Hon. Ellen Spodek and Hon. William C. Thompson (Retired) served as Event Co-Chairs.

CALENDAR/CONTACTS

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
1.800.813.HOPE (4673)

ELLEN's RUN

200 West End Avenue, Suite 12 G
New York, NY 10023
www.ellensrun.org
212.840.0916

GILDA's Club NYC

195 West Houston St.
New York, NY 10014
www.gildasclubnyc.org
212.647.9700

MEMORIAL SLOAN KETTERING CANCER CENTER

Post-Treatment Resource Program
Educational Forums
215 E. 68th St., Ground Fl.
New York, NY 10021
www.mskcc.org
212.717.3527

Bendheim Integrative Medicine Center

1429 First Avenue (at 74th Street)
New York, NY

SHARE

*(Self-Help for Women with Breast
or Ovarian Cancer)*
1501 Broadway, Ste. 704A
New York, NY
www.sharecancersupport.org
212.719.0364
Speak to a survivor toll-free:
1.866.891.2392

TO LIFE!

410 Kenwood Avenue
Delmar, NY 12054
518.439.5975
110 Spring Street
Saratoga Springs, NY 12866
518.587.3820
www.tolife.org

YOUNG SURVIVAL COALITION

61 Broadway
New York, NY
www.youngsurvival.org
646.257.3025

NYU CANCER INSTITUTE

NYU Langone Medical Center
Community Lecture Series
550 First Avenue
New York, NY 10016
212.263.2266

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