JALBCA

JUDGES AND LAWYERS BREAST CANCER ALERT

Vol. 16 No. 4 Editor: Martha L. Golar, Esq. August 2012

SAVE THE DATE

SUSAN KOMEN RACE FOR THE CURE

September 9, 2012

9:00 a.m.

Central Park

Join Team JALBCA by
Registering On-line as Part of the Team

SAVE THE DATE

**SEVENTEENTH ELLEN P. HERMANSON MEMORIAL LECTURE/
JALBCA ANNUAL SYMPOSIUM**

Date: December 3, 2012

Topic: To be announced

Place: Association of the Bar of the City of New York
42 West 44th St., NY, NY; 2nd Floor Meeting Hall

Sponsor: The Ellen P. Hermanson Foundation

Presenters: JALBCA and Post-Treatment Resource Program of Memorial Sloan Kettering Cancer Center

NYS Passes a Breast Density Inform Law

In June 2012, Governor Cuomo signed a law that relates to the duties of providers of mammography services to notify and inform patients if a mammogram demonstrates dense breast tissue. Providers will be required to provide an explanation of what it means to have dense breast tissue and a recommendation to consult with the patient's physician about additional screening.

The sponsors of the original bill were Senator John J. Flanagan (2nd Senate District)(S6769B-2011) and Assemblymember Ellen Jaffee (95th District) (A9586D-2011). The new law amends New York Public Health Law by adding a new section 2404-c. The intent of the law is to raise awareness of the impact that breast density can have on diagnosing breast cancer, thus giving women a greater ability to make educated decisions about their own health and save lives.

The justification provided in the Senate bill stated that:

"…Cancer is four to six times more likely in women with dense breast tissue and 40% of women have dense tissue. According to a 2010 study published in the Annals of Surgical Oncology, 71% of all breast cancers occur in women with dense breast tissue. Mammograms fail to detect about half the tumors present in dense breast tissue as dense tissue obscures the presence of the tumors. Follow-up studies after a similar dense breast tissue law passed in Connecticut in 2009 show that for women with dense tissue, the addition of a screening ultrasound nearly doubles the number of cancers found by mammography alone. In New York State, that number extrapolates to at least 2000 cancers a year in women who are told their mammogram results are "normal/negative," but who, in actuality, have invasive breast cancer. Missed cancers, growing undetected until at a later stage, are less treatable, least survivable and most expensive to treat…

A woman's breast density is determined through the mammography exam. Breast density not only dramatically compromises the effectiveness of a mammogram, but is, in and of itself, a risk factor for developing breast cancer…Unfortunately, there is currently no protocol for density information to be shared with patients… states are recognizing that, for a significant percentage of women, the mammography notification requirements are not sufficient. The report a woman receives after her mammogram is required to be a summary, in lay language, of her mammographic findings. Information about breast density is a material medical finding which must be shared with patients. This legislation will give women with dense tissue the information to talk to their physician about getting adequate baseline and follow-up screening. Without it, women with dense tissue may be effectively denied equal access to early cancer detection without even knowing it."

Connecticut, Texas and Virginia have enacted Breast Density Inform laws. It is reported that 13 states introduced legislation in the 2012 session. Federal Bill HR3102 (Breast Density and Mammography Reporting Act of 2011) was introduced last year. Are You Dense, Inc. is a 501(c)(3) public charity that works to raise awareness about the issue. Information about it can be accessed at http://areyoudense.org.

Pfizer Settles Prempro Lawsuits Settlement.

In a securities filing with the SEC in May 2012, Pfizer, Inc. disclosed that it has paid $896 million to resolve about 60 percent of the cases alleging its menopause drugs caused cancer in women. This translates into an average of about $150,000 a case. Pfizer has now settled about 6,000 lawsuits, and it has set aside an additional $330 million to resolve the remaining 4,000 suits. The lawsuits alleged a resulting increase in the risk of breast cancer, and a high risk of other serious side effects including ovarian cancer, gallbladder cancer, lupus, scleroderma, stroke, blood clots, severe asthma, and pulmonary embolisms.

These suits alleged that its Wyeth and Pharmacia & Upjohn units failed to properly warn women about the health risks associated with Prempro and related menopause drugs. Prempro (which combined estrogen and progestin hormones) was originally introduced by Wyeth, which was acquired by Pfizer in 2009. The drugs were being taken to relieve symptoms of menopause, including hot flashes and mood swings. The Women's Health Initiative study, sponsored by the National Institutes of Health, was published in 2002. It found that, rather than Prempro providing protection from cardiovascular problems, it was linked to an increased risk of stroke, blood clots, heart attacks and breast cancer.

Litigation Scorecard.

Pfizer and its units have lost 11 of 21 jury cases over the menopause drugs since 2006, according to data compiled by Bloomberg. Some of the verdicts against Pfizer were vacated or reversed and some awards were reduced. Pfizer resolved some of the verdicts through settlements. Other decisions are on appeal. Of the more than 10,000 claims alleging that the menopause drugs caused breast cancer, more than 8,000 were consolidated in a federal Multi District Litigation (MDL) in Arkansas, styled *In re Prempro Products*, 03-cv-015070-WRW, U.S. District Court, Eastern District of Arkansas (Little Rock). Other suits were brought in state courts in Pennsylvania, Nevada and Minnesota. The MDL cases are returned to their home courts for trial, after discovery and motion practice. Two suits, for example, were returned to federal court in Connecticut for jury trials. In one case, it was reported that in April 2012 the federal jury ordered Pfizer to pay at least $4 million in damages, as well as punitive damages in an amount to be assessed. In the other, a separate federal jury in Bridgeport, Connecticut, found Pfizer was not liable for the breast cancer death of a woman who died after taking the company's menopause medicines. The jury concluded in that case that Wyeth officials properly warned the plaintiff of the risks.
(Source: http://www.bloomberg.com/news/2012-06-19/pfizer-paid-896-million-in-prempro-accords-filing-shows-1-.html)

Antibody-Drug Conjugates - A New Type of Targeted Therapy Used for Cancer

Antibody-drug conjugates (ADCs) are new types of investigational medicine

being tested for several types of cancer. An ADC is a combination of a targeted monocloncal antibody, a stable linker (linking the antibody to the cytotoxic), and a potent cytotoxic. It is designed to deliver potent anticancer toxins to tumors. As it travels through the bloodstream, it attaches only to malignant cells that bear the target protein. The targeted monoclonal antibody is produced in the laboratory and mimics antibodies made by a person's immune system. The linkers must keep the toxin attached to the antibody while it floats through the bloodstream and assure that the toxin is released inside the cancer cell.

In summary, ADCs are designed to accomplish three tasks: (1) selectively bind to specific antigens expressed on the surface of cancer cells, (2) deliver the toxic payload specifically to tumor cells that overexpress target tumor-associated antigens, where the cytotoxic will be released inside the cell, and (3) remain stable in circulation to prevent systemic release of the cytotoxic before it reaches the target tumor cell. ADCs avoid the need to give toxic drugs separately, thereby avoiding chemotherapy side effects and also avoiding harm to healthy tissue. ADCs allow the use of toxins that are hundreds of times as potent as typical chemotherapy agents and, therefore, would be too toxic to give alone. ADCs, however, can have side effects (*e.g.*, T-DM1, discussed below, apparently can lower blood platelet levels). Additionally, they can be expensive.

One example of an ADC is Trastuzumab emtansine (T-DMI), being developed by Genentech, part of the Roche Group. T-DMI binds to the HER2 protein, as would Herceptin. The three components of T-DM1 are trastuzumab (the monoclonal antibody that selectively binds to HER2 antigens on the surface of tumor cells), cytotoxic agent DMI (a derivative of maytansine, a potent antimitotic drug) and a linker (which remains stable in circulation before it enters the cells that are over-expressing HER2).

Roche reports that Roche/Genentech has approximately 30 ADCs in the pipeline. Seattle Genetics (of Bothell, Washington), ImmunoGen Inc. (of Waltham, Massachusetts) and Spirogen Ltd. (a privately-owned U.K. company) are companies involved in the development of this new class of cancer drugs.

Childhood Cancer Treatment Poses Similar Risk for Breast Cancer as BRCA Mutations

New study results, presented at the 2012 American Society of Clinical Oncology Annual Meeting, revealed that women treated with radiation to the chest for childhood cancer have a high risk of developing breast cancer similar to that of women with BRCA1/2 mutations. The study was led by Memorial Sloan-Kettering Cancer Center (MSKCC) biostatistician Chaya Moskowitz, PhD. What is novel about the findings is that it demonstrated that women treated with radiation to the chest for childhood cancer have an increased risk for breast cancer comparable to women with BRCA mutations. Prior studies had already shown that these women have an increased risk for breast cancer.

The study analyzed data from more than 1,200 female childhood cancer survivors participating in the Childhood Cancer Survivor Study (CCSS) and 4,570 female first-degree relatives of women participating in the Women's Environmental Cancer and Radiation Epidemiology (WECARE) Study. The findings were these: breast cancer incidence by age 50 among women treated with chest radiation for a childhood cancer was 24 percent compared to 31 percent for carriers of BRCA1 mutations. Among survivors of Hodgkin lymphoma (who were treated with higher doses of radiation), the incidence was 30 percent.

The MSKCC Children's Oncology Group recommends that women treated with radiation of 20 Gy or higher to the chest begin breast cancer surveillance with annual mammography and breast MRI starting at the later of age 25 or eight years after radiation. Women who receive lower doses of chest radiation, however, were also at risk so that they too may benefit from a breast cancer screening. MSKCC reports that approximately 50,000 women in the United States have been treated with chest radiation of 20 Gy or higher and an estimated additional 7,000–9,000 have been treated with radiation of 10–19 Gy.

The study was supported by grants from the National Cancer Institute of the National Institutes of Health. The funds are also being used by Dr. Moskowitz to build a breast cancer risk prediction model for cancer survivors treated with radiation to the chest.

(Source: http://www.mskcc.org/news/press/childhood-treatment-found-pose-similar-risk-breast-brca-mutations)

MEDICAL IDENTITY THEFT

There are two major types of medical identity theft:

- when a physician's professional identifiers are stolen; and
- when a patient's identity has been compromised

Medical identity theft is an issue of concern to Medicare and other agencies responsible for investigating identity theft. It has reportedly become the fastest-growing type of identity theft in the world, with an estimated 2 million people annually becoming victims of identity theft. More than 5,300 physicians have listed themselves in a federal database that tracks medical identity theft. Patient victims of medical identity theft face the risk of receiving improper medical treatment. This is because physicians may make treatment decisions based on someone else's information being in the patient's medical record.

Listed below are the names of several agencies, both government and private, that investigate and provide resources on medical identity theft.

For more information:

- World Privacy Forum (worldprivacyforum.org/)
- Federal Trade Commission (ftc.gov/idtheft)
- CMS Provider Victim Validation/ Remediation Initiative (cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Downloads/ProviderVictimPOCs.pdf)

To file a complaint:

- Federal Trade Commission: 1-877-IDTHEFT (438-4338)
- Medicare: 1-800-MEDICARE (633-4227)
- Office of the Inspector General: 1-800-HHS-TIPS (447-8477)

(Source: http://www.ama-assn.org/amednews/2012/08/06/bisa0806.htm)

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 12G
New York, NY 10023
www.ellensrun.org
212.840.0916

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

JALBCA
c/o Jennifer Fiorentino
Executive Director
1324 Lexington Avenue, PMB 324
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Address Service Requested