JUDGES & LAWYERS BREAST CANCER ALERT

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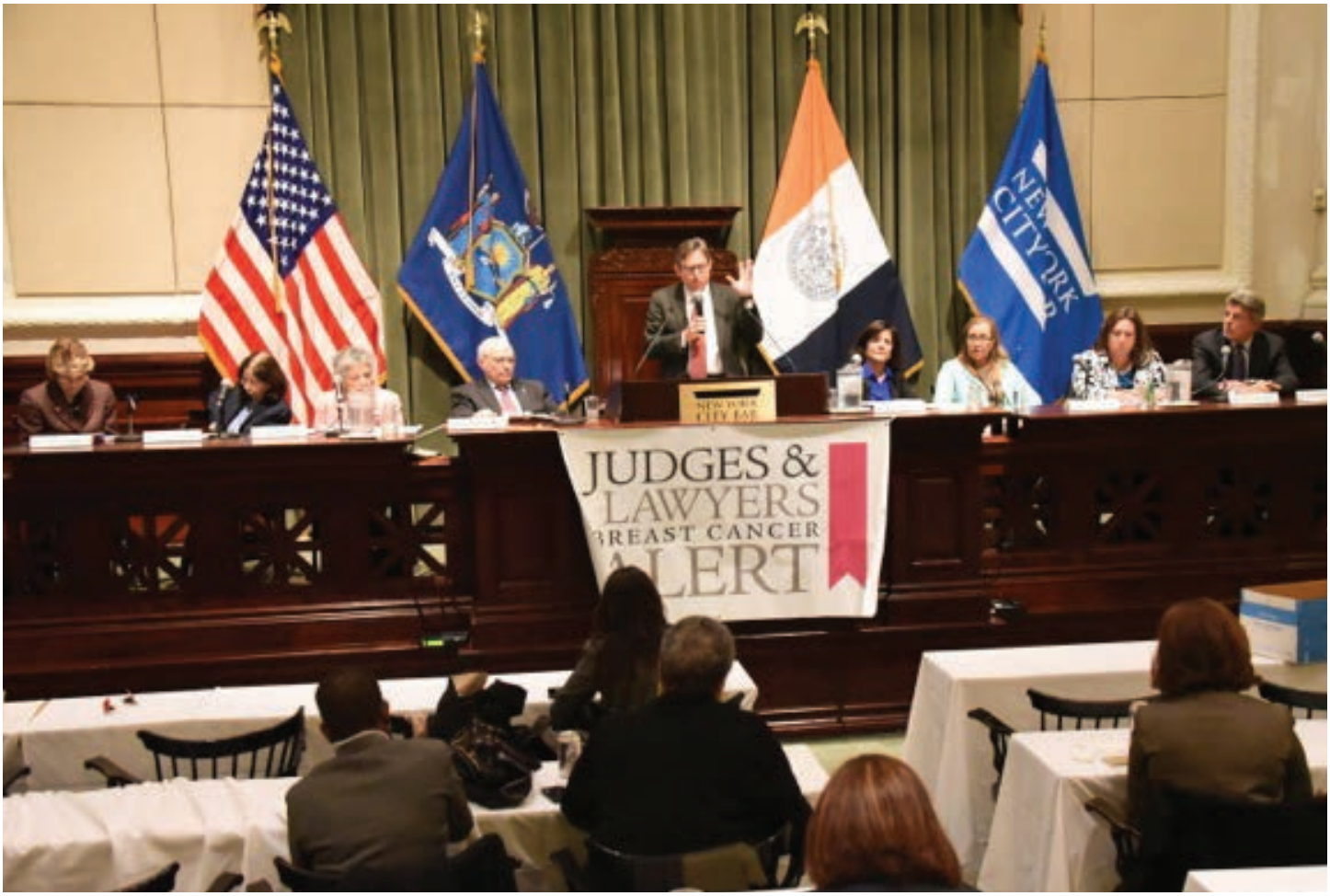
JALBCA 2015 SYMPOSIUM - "THE DCIS CONTROVERSY THROUGH THE LENS OF BETTER SCIENCE: WILL PRESIDENT OBAMA'S PRECISION MEDICINE INITIATIVE SAVE LIVES?"

On October 26, 2015, JALBCA sponsored its 20th annual Ellen P. Hermanson Symposium at the New York City Bar Association. Former Co-President Edward Kornreich (Partner, Proskauer Rose LLP) moderated the program. The panel of experts consisted of Deborah Axelrod, MD, Minna Elias, Esq., Judith Livingston, Esq., Larry Norton, MD, and Jay Rappaport, Esq. The panel of judges consisted of former JALBCA Co-Presidents Hon. Helen Freedman and Hon. Karla Moskowitz, together with Hon. Alice Schlesinger. The program was organized by Co-Chairs Martha Golar, Hon. Shirley Werner Kornreich and Barbara Ryan, all three of whom are former JALBCA Co-Presidents. The program was introduced by Co-President Hon. Lynn Kotler.



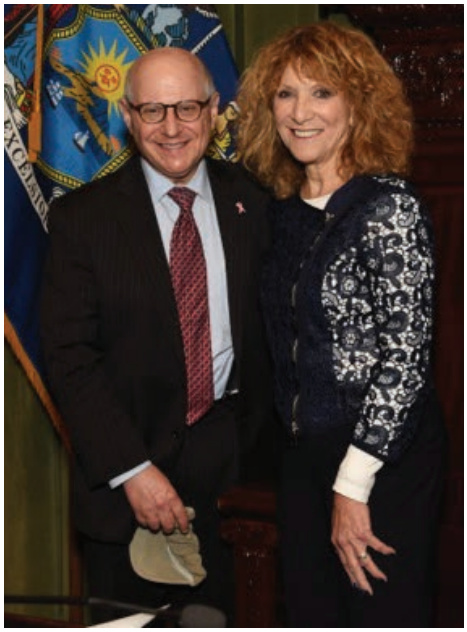
Symposium Panelists from left to right: *Hon. Helen Freedman, Hon. Alice Schlesinger, Hon. Karla Moskowitz, Larry Norton, MD, Edward Kornreich, Judith Livingston, Deborah Axelrod, MD, Minna Elias, and Jay Rappaport*

Background

DCIS (ductal carcinoma in situ) is often referred to as non-invasive cancer or stage 0 breast carcinoma. It is a non-invasive condition where abnormal cells occupy the lining of the milk duct in the breast. Cells of this type are not felt as lumps but are detected by mammogram or when a pathologist examines tissue. DCIS cells look like cancer cells but have not spread beyond the breast duct and remain "in situ." They may never leave the breast duct or they may become invasive and spread throughout the body. In other words, DCIS has the potential to be quiescent or invasive. The range of possibilities inherent in DCIS has caused trepidation among patients and physicians, and has been an intriguing subject for research scientists. Over several decades, the debate *to treat or not to treat* has remained subdued, perhaps due in part to the fact that most patients with DCIS do well and enjoy a favorable prognosis. The approach to DCIS either favors aggressive treatment, including prophylactic mastectomy or lumpectomy and radiation, or favors the "wait and see" approach - vastly different approaches. A recent, widely reported trial supports the wait and see position. To date, DCIS treatment has not been substantively enhanced by genomic indicators.

Dr. Norton's Introduction

Dr. Norton commenced the program by describing DCIS and discussing the recent publications concerning its treatment. He acknowledged the August 2015 articles in JAMA Oncology. The first is "*Breast Cancer Mortality After a Diagnosis of Ductal Carcinoma In Situ*" (referred to as the Narod article). The purpose of Narod's study was to estimate the mortality from breast cancer following a diagnosis of DCIS and to identify risk factors for death from breast cancer. A conclusion reached was that "it has not been shown that preventing invasive recurrences by means of radiotherapy or extensive breast surgery (mastectomy) reduces the risk of breast cancer-specific mortality." The data for the study was abstracted from the most recent Surveillance, Epidemiology, and End Results (SEER) 18 registries research database (November 2013 Submission).



Larry Norton, MD and Julie Ratner

The second article, entitled "*Rethinking the Standard for Ductal Carcinoma in Situ Treatment*"' (referred to as the Esserman article), noted that with the advent of screening, DSIC now accounts for 20-25% of screen-detected breast cancers and, while the presumption in the past was that these lesions were the precursors of cancer and that early removal and treatment would reduce cancer incidence and mortality, long-term epidemiology studies have demonstrated that the routine removal of these lesions has not been accompanied by a reduction in the incidence of invasive breast cancers. Therefore, the author suggested, we should re-think the strategy for detection and treatment of DSIC. The article recommended that surgeons and radiologists stop telling women that DCIS is an emergency and that they should schedule definitive surgery within two weeks of a diagnosis.

Dr. Norton disagreed with the articles' recommendation. Although DCIS has a very small chance of spreading beyond the duct and metasticizing, when it does, it impacts mortality. It, therefore, should be treated. In perhaps 10% of the cases, Dr. Norton explained, an invasive cancer is found in the vicinity of the DCIS. He made two overarching comments: first, the treatment "controversy" is not a real controversy because there are a few outliers whose opinions about proper treatment for DCIS ("watchful waiting") differ from a majority of oncologists (more aggressive treatment), but by the media bringing attention to these different opinions it gives the impression that there is a 50-50 division of opinion in the medical profession, which is not the case. Second, Dr. Norton suggested that precision or personalized medicine will not result in a sea change in oncology practice - oncologists already personalize their care of patients and treat individuals. Personalized medicine is defined by treating individuals by taking account of things that can be measured – i.e., estrogen receptors, HER2. Oncologists and breast surgeons already do this. What is novel is the technology that allows DNA to be measured, from which a strong hypothesis can be drawn about a patient's potential responsiveness to a particular drug.

Background on Precision Medicine

With precision medicine, treatments ideally are targeted to the genetic profile of a patient *and* the tumor. The JALBCA program attempted to address whether, with the additional data that might become available from precision medicine research and data collection, clinicians may soon have a reliable way to predict which DCIS patients may need aggressive treatment.

The move toward precision medicine is not a new concept. In an article in the New England Journal of Medicine in 2010, the Commissioner of the Food and Drug Administration (FDA), Dr. Margaret Hamburg, and the Director of the National Institutes of Health (NIH), Dr. Francis Collins, expressed commitment to advance genomic medicine which affords a targeted approach against cancer. Several years hence, through Executive action in the form of a budgetary initiative, personalized or precision medicine has been given a new platform. President Obama's Precision Medicine Initiative (PMI) was announced in early 2015 to advance the field of precision oncology-it promises tailored therapies, informed by large databases of information on individual tumor genomics. President Obama's budgetary initiative involved

Symposium judges, moderator and expert panelists, Symposium co-chairs and Co-President Lynn Kotler.

a request of a $215 million investment as part of his 2016 budget proposal. Of these funds, $130 million would go to the NIH, and $70 million would be given to the NCI to identify genomic drivers in cancer and apply that knowledge to the development of more effective cancer treatment. The FDA would get $10 million, and the Office of the National Coordinator for Health Information Technology would get $5 million. An increase in biomedical research initially will be focused on cancer, and then applied to other diseases.

Program

The panel discussion commenced by addressing medical malpractice considerations in treating DCIS and the challenges in providing the standard of care in an era of exponential advancement in understanding cancer.

The essential elements of medical malpractice are (1) a deviation or departure from good and accepted medical practice [breach in the duty of care] and (2) evidence that such departure was a proximate cause of the injury. Edward Kornreich asked what kind of DCIS fact pattern would be pursued by a plaintiff's attorney. Judith Livingston indicated that there has to be a departure from the standard of care and the patient has a right to decide what to do with his/her own body. Thus, if a doctor pursued a targeted therapy, i.e., an experimental treatment, if the patient was fully informed of her/his choices, and the patient elected to pursue the course of treatment, this would not be actionable. Jay Rappaport noted that the physician should document the information he gave the patient and the patient's choice.

Judge Schlesinger said that the treatment decision is one the patient must make with her doctor and she needs all the information to do this. The standard of care goes to the individual history that the doctor is required to take and it differs from informed consent. The doctor, therefore, she explained, must tell the patient the upside and downside of the SEER study. Dr. Norton responded that the SEER data (used in the Narod article, discussed above) was unaudited data and "unaudited data is not data"; it is not very reliable. The SEER data was only observational. In addition, he added that there are other endpoints of value to the patient besides death, e.g., the importance to avoid more life-altering therapies, but SEER just measures survival.

Jay Rappaport offered that the standard of care is set by the plaintiff's expert - for a case to go to a jury, the plaintiff must call a doctor who testifies that there was a departure from the standard of care, this is so even with informed consent. In the courtroom, he explained, this sets the standard of care. Judge Freedman later noted that in NYC there is no provision for a court to appoint the expert and even in Federal court, where court-appointed experts are permissible, it is not done often. She explained that there really is no such thing as an impartial expert and, in addition, there is the complicating issue of who pays for the expert. Judge Freedman did note one exception where courts find experts to be so incredible that their testimony is prohibited – after a *Frye* or *Daubert* hearing.

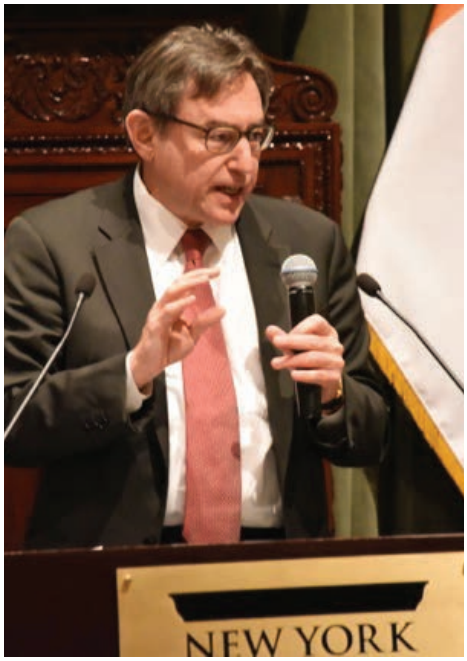
As for the standard of care for non-invasive cancer, Dr. Axelrod added that the last consensus statement on invasive care indicated what constituted acceptable margins for oncology surgeons, but this is not available for non-invasive cancer.

Dr. Norton commented that it was very disturbing that in science decisions

are made based on evidence, whereas in law decisions are based on opinion. He mentioned that Memorial Sloan Kettering Cancer Center does have "endorsable standards of care" and that there is flexibility on the standards for individual decision-making. He referenced the guidelines of the National Comprehensive Cancer Network (NCCN) – a not-for-profit alliance of 25 of the world's leading cancer centers - for stage 0 breast cancer.(See http://www.nccn.org/patients/guidelines/stage_0_breast/index.html#2) (NCCN presently offers guidelines for these conditions: breast cancer Stages 0-IV, colon, esophageal, non-small cell lung, ovarian, pancreatic, and prostate cancers; caring for adolescents and young adults (AYA); chronic myelogenous leukemia; malignant pleural mesothelioma; melanoma; multiple myeloma; lung cancer screening; and soft tissue sarcoma.)

Dr. Norton questioned whether, in an era of information availability, a doctor is permitted to tell a patient who may not want to follow his/her treatment recommendation, to seek other opinions if they choose not to follow his/her recommendation. Judge Schlesinger opined that such a doctor could be sued, since the treating physician has an obligation to tell the patient all the things she needs to know. Dr. Norton, however, noted that there is not a shred of evidence that "watchful waiting" was a proper treatment decision. Moderator Kornreich suggested that where the standard of care is uncertain, it seems that a patient's consent becomes critical.

The conversation then turned to precision medicine and panelist Minna Elias provided a Congressional update on this initiative. She indicated that the FDA has a list of 100 different drugs it says are examples of precision medicine. She explained that with President Obama's PMI, 100,000 people will be studied and data will be collected from people of all ages, ethnic backgrounds, and conditions (including people with and without disease). Electronic record-keeping now makes it easier to collect massive amounts of data. Judge Moskowitz questioned what the time frame was for the Federal study. Ms. Elias explained that it was a longitudinal study, meant to study



Ed Kornreich, Esq. Moderator

people for the rest of their lives.

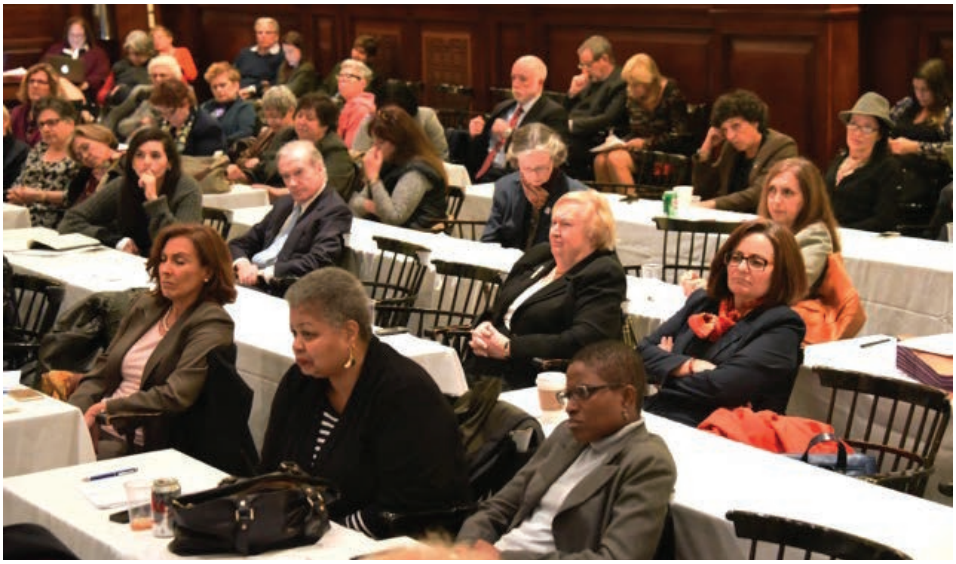
Ms. Elias also described the 21st Century Cures Act which passed the House with a bi-partisan vote of 344-77, with most of the "no" votes coming from the Republican side of the isle. The Senate had not yet acted on a companion bill, but it is being worked on by Patty Murray and Lamar Alexander. Ms. Elias reported that there had been hearings in the House on precision medicine. She noted that the issues for Congress related to reimbursement rates, harmonizing across agencies, and identifying which tests to use (i.e., a doctor can order a test but an insurance company may not pay for its cost). The 21st Century Cures Act would increase the NIH research funding by about $8.75 billion (and NIH by approximately $550 million) over five years, part of which would be allocated to precision medicine. The bill has been criticized on many grounds. Some of these were specifically identified in a Commentary, entitled "*The 21st Century Cures Act- Will It Take Us Back in Time?*", published by The New England Journal of Medicine, June 25, 2015 (*See* http://www.nejm.org/doi/full/10.1056/NEJMp1506964) – and described as proposed changes that "could lead to less salutary outcomes for patients and the health care system".

In a physician's practice of personalized medicine, Dr. Axelrod explained that there must be 10-15 genome tests now available for breast cancer. She said, for example, she looks at germ line mutations, pharmacogenomics, oncotype (predicts risk of recurrence in 10 years for estrogen receptor positive tumors and also is used to predict local recurrence, with each hospital and doctor having their favorite oncotype test). Moderator Kornreich questioned whether the use of this panoply of tests is not the standard of care. Dr. Norton explained that "precision medicine" is a word, a term, but this has been practiced all along. He favors an influx of money for research, though tragically a massive amount of funds is needed but is not being spent. Dr. Norton explained that precision medicine will not result in the same sea change as occurred with penicillin. Instead, it is "science as usual."

Judith Livingston noted that New York, by statute (Public Health Law sec 2805-d(1))(McKinney), dictates what doctors must explain, and the lack of informed consent must be the proximate cause of the harm. Dr. Axelrod added that, per the NYS Department of Education, only 12% of patients understand what they are told and doctors can try to enhance understanding by explaining things visually or asking patients to repeat what they heard.

Lack of informed consent means the failure of the person providing the professional treatment or diagnosis to disclose to the patient such alternatives thereto and the reasonably foreseeable risks and benefits involved as a reasonable… practitioner under similar circumstances would have disclosed, in a manner permitting the patient to make a knowledgeable evaluation. In an action for lack of informed consent, a plaintiff must prove that a reasonably prudent person in the patient's position would not have undergone the treatment or diagnosis if he [or she] had been fully informed and that the lack of informed consent is a proximate cause of his or her injury. Judge Freedman reminded attendees that causation is not even reached if the reasonable person standard cannot be satisfied.

Judge Moskowitz raised the practical issue of insurance company guidelines for the amount of time a physician is permitted to spend with a patient, i.e., if the doctor does not move a patient along



within a prescribed time frame and takes the time needed to educate each patient, there would be an office backlog and working hours would extend late into the night. Therefore, how are insurance guidelines reconciled with the need to inform patients? Dr. Norton noted that communication is a two-way street and not all patients are equally educated and literate; there is an enormous amount of complexity involved in decision-making. Minna Elias asked how informed consent could ever exist where patients do not understand the medical vocabulary being used. Moderator Kornreich also noted there are ways doctors can influence patients that are not limited to words. Judith Livingston indicated that it is the rare case which is solely an informed consent case - most cases are not pursued by plaintiff attorneys solely on a lack of informed consent issue because of the difficulty in proving it.

A question-and-answer period followed the program presentation.

DCIS and Medical Malpractice Case Law

Few cases speak directly to DCIS. Among those that do, some are briefly described, below. The attendees were provided with program materials.

(Ngai v Seaview Radiology Assocs., P.C., 18 Misc3d 1129(A) [Sup Ct, Richmond County, 2008]) Plaintiff, diagnosed with DCIS, brought a malpractice action alleging untimely and improper interpretation of radiographic studies. She claimed that defendants failed to diagnose and treat her for a period of two years. She further claimed the method used by the surgeon to remove the DCIS resulted in a total mastectomy rather than a lumpectomy and the removal of excessive lymph nodes. Defendants filed for summary judgment presenting expert affidavits. The radiologists' expert stated that there was no proximate cause since, even assuming that the DCIS spread in the two year time, the treatment would have been the same. Plaintiff's expert (a surgeon) stated that the films showed microcalcifications which increased two and one half times in the two years, becoming more diffuse and depriving plaintiff of an opportunity to avoid a mastectomy. The court denied summary judgment.

(Smith v University Diagnostic Medical Imaging, P.C. and Einstein College of Medicine, 43 AD3d 344 [1st Dep't 2007]) Summary judgment was granted in defendant's favor in this medical malpractice and wrongful death case. Plaintiffs alleged failure to diagnose and timely treat decedent's DCIS when it was discovered in February 1999. A 1999 biopsy found possible DCIS which, after discussion of various treatment options with the decedent patient, was treated by close observation. Defendant had expressed a preference for non-invasive treatment. Despite regular follow-up, a lump, which was invasive cancer, was discovered in August 2000. The question was whether there was a deviation from accepted medical practice. The court found no deviation in diagnosis and treatment.

A verdict search revealed the following:

Francis v Lewis, 2010 WL4926819 (Sup Ct, Kings County, 2010): Plaintiff, as a result of a bloody nipple, went to defendant, a breast specialist. Defendant performed a biopsy which revealed DCIS. As a result, defendant performed a modified radical mastectomy, followed by reconstruction surgery. Defendant also removed 13 lymph nodes which were negative for cancer and placed plaintiff on Tamoxifen. Plaintiff followed up with defendant annually. Subsequently, plaintiff was found to have metastatic breast cancer. She brought suit alleging failure to perform blood and imaging tests, such as CTs and MRIs. The jury found for defendant.

Byron v Gaston, 2005 WL 6934789 (Sup. Ct., Westchester County, 2005): Plaintiff, a woman in her mid-70's who had DCIS, sued her breast surgeon who had performed a modified radical mastectomy involving the removal of 17 lymph nodes. Plaintiff suffered from lymphedema. Plaintiff claimed that only a lumpectomy had been necessary. The jury awarded plaintiff $1,750,000.

JALBCA LAW INTERN

Tina Seghal is JALBCA's 2015 Susan Solomon Legal Intern. She is presently a law student at Fordham University School of Law and received her B.A. degree from the University of California, Los Angeles, with a major in Political Science. Ms. Seghal previously served a legal internship with the Consumers Law Group in California and as a legal assistant with the Mandel Law Firm in New York, where she assisted attorneys in family law with litigation prep work. Ms. Seghal assisted the Co-Chairs in the preparation of the 2015 Ellen P. Hermanson Memorial Lecture.

REMEMBERING CYNTHIA RUBIN

JALBCA mourns the passing of its beloved former Co-President Cynthia Rubin from breast cancer. Cynthia was a prominent matrimonial attorney in New York and a longstanding member of JALBCA whose contributions to the organization and the breast cancer community were invaluable. We were beneficiaries of her leadership, her assistance on JALBCA's annual dinner committee, and her important work on its grants committee, including the creation of the Judith S. Kaye Project at The Family Center, which provides integrated legal, social and healthcare coordination services to low-income, minority mothers, who are confronting a breast cancer diagnosis. Cynthia will also be remembered for her grace, optimism, indomitable spirit and good cheer.

UPCOMING EDUCATIONAL PROGRAMS / WEBINARS AT SHARE

Lecture

Monday, December 21, 2015
6:30-8:30 pm
Dr. Larry Norton
Breast Cancer Update 2015 – The current state of breast cancer research and treatment
United Federation of Teachers Headquarters
52 Broadway, NY, NY

Webinars

Palliative Care for Women with Cancer
Monday January 11, 2016
6:00-7:30 pm

A Patient Advocate's Report from Advanced Breast Cancer 3 and San Antonio Breast Cancer Symposium 2015
Tuesday, January 12, 2016
12:30-1:30 pm

CALENDAR

ADELPHI NY STATEWIDE BREAST CANCER
Hotline & Support Program
Adelphi University School of Social Work
Garden City, NY 11530
www.breastcancerhotline@adelphi.edu

CancerCare
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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

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)*
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New York, NY
www.sharecancersupport.org
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Speak to a survivor toll-free:
1.866.891.2392

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New York, NY
www.youngsurvival.org
646.257.3025