JUDGES & LAWYERS BREAST CANCER ALERT

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JALBCA FEBRUARY PROGRAM – THE POWER OF PLANNING

HIGHLIGHTS:

- **the legal documents you need to ensure your wishes are honored**
- **the conversations you want to have now to face the future**
- **the person who should speak for you if you become incapacitated**

On February 7, 2019, JALBCA presented a program, co-sponsored by the New York Women's Bar Association and CaringKind, on "THE POWER OF PLANNING: Making Critical Ethical, Medical and Legal Decisions in Advance of Health Crises". Peter J. Strauss, Esq. and Hon. Bernice D. Siegal co-chaired the program. Mr. Strauss (JALBCA Board member and a trusts and estates and elder law attorney and Senior Partner at Pierro, Connor & Strauss) moderated the program, and Eileen Zenker, LCSW (a Certified Care Manager with The New Jewish Home), Sarah Egan, MD (community hospital physician with Hospice of New York), Judith Schwarz, RN, PhD (Clinical Director, End of Life Choices New York) and special guest Vivienne Duncan, Esq. (Director, Cancer Advocacy Project, City Bar Justice Center) spoke. The panelists discussed the challenges presented by incapacity and terminal illness and the importance of advance directives.

Pictured (L-R): *Vivienne Duncan, Esq., Peter J. Strauss, Esq., Sarah Egan, MD, Judith Schwarz, RN, PhD, Eileen Zenker, LCSW*

Jed Levine, President and CEO of CaringKind, introduced the program. He explained that CaringKind is an organization primarily for caregivers for people with dementia or Alzheimer's, with a target geography in the five boroughs of New York City. It has 80 support groups, early stage programs, educational programs, and a MedicAlert NYC Wanderer's Safety Program. It also provides social work services and care planning. The organization "speaks" English, Spanish and Chinese and has translation services in 200 languages. Mr. Levine described CaringKind as New York's central address for things related to dementia and Alzheimer's. CaringKind has a 24-hour Helpline at 646.744.2900 and is located at 360 Lexington Avenue, 3rd Floor, NY, NY 10017. Additional information can be obtained at the organization's website, www.caringkindnyc.org.

Mr. Strauss, who addressed basic New York law and practice, spoke to certain New York rules of professional conduct, particularly Rule 1.14, which allows an attorney to disclose information that would otherwise be confidential when a client has

Pictured (L-R): *Sandra Lespinasse, Esq., Vivienne Duncan, Esq., Judith Schwarz, RN, PhD, Hon. Bernice D. Siegal, Eileen Zenker, LCSW, Sarah Egan, MD, Peter J. Strauss, Esq., Joan D. Levenson, Esq.*

diminished capacity and there is a risk of substantial harm. The client "is still the boss," and even if the attorney does not agree with the client's instructions, the attorney's job is to advocate for the client's wishes. The rule appears to authorize an attorney to institute a guardianship proceeding for the client to protect a client when serious risk of harm exists. Mr. Strauss stated that Rule 1.6 encompasses confidentiality, similar to the physician-patient privilege. Further, he mentioned rules on conflict of interest and provided a historical context for advance directives. He referred to the 1914 landmark New York Court of Appeals decision, Schloendorff v. Society of N.Y. Hospital, where Justice Benjamin Cardozo articulated the doctrine of informed consent. Justice Cardozo wrote, "Every human being of adult years and sound mind has a right to determine what shall be done with his body, and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages".

From that decision, the corollary, i.e., the right to refuse treatment, arose. When one becomes incapacitated, one does not lose the right to refuse treatment, but such right is exercised through the patient's representative: an agent under a health care proxy, a surrogate under the Family Health Care Decisions Act or a guardian who has health care powers. If a person has not executed a health care proxy, there is a risk that a surrogate or guardian might make choices that are not in accordance with the individual's wishes and values. The authority of an agent appointed under a health care proxy is effective only when the patient is unable to make decisions (ability to give "informed consent"), until there has been a determination by a physician or a court to the effect that a patient can give informed consent. The standard of capacity to execute a health care proxy is relatively low. The agent speaks for the incapacitated person and is obligated to make decisions in accordance with that person's wishes, not to make decisions based solely on the agent's view of the patient's best interests. To learn a person's wishes, the two should talk and be guided by a living will and/or a MOLST order (Medical Order on Life Sustaining Treatment) in the patient's chart. In New York, a person can only have one health care agent at a time. The principal should always choose a successor agent. The best choice to serve as agent should not be the person with the greatest medical knowledge but a person with the emotional and psychological strength to act in accordance with the person's wishes.

Mr. Strauss explained what a DNR (Do Not Resuscitate) is. It is a medical order executed in the hospital which gives instructions as to a patient's wishes if her or his heart stops or she or he stops breathing. The patient or the health care agent may sign a DNR order. A MOLST is a physician's order placed in a patient's chart, usually executed in a hospital setting and toward the end of life. A living will was discussed. Some attorneys prepare a combination document, i.e., one which is both a health care proxy and a living will. If the person's advocate is not available (such as where there is no health care proxy), the living will stands as an expression of the person's wishes which is to be honored under New York court decisions. Mr. Strauss recommended against lawyers drafting documents which include phrases in a living will such as "heroic measures" or "my death is imminent," as the meaning of these phrases is not at all clear; for example, a procedure which is considered heroic at one point in time may become routine in later years.

Eileen Zenker spoke next. She explained that in evaluating a person's ability to make decisions, it is advisable to see them in their home. She highlighted four lawsuits: (1) the case of Karen Ann Quinlan, where her mechanical life support was withdrawn but she still had a feeding tube for more than nine years; (2) the 1963 case of Nancy Cruzan, where the U.S. Supreme Court decided that states could have a "clear and convincing evidence" standard for decisions to withdraw feeding tubes; (3) the case of Terri Schiavo, a right-to-die case, where a 26-year old woman fell into an irreversible persistent vegetative state after suffering a cardiac arrest, was kept alive by artificial feeding from 1990 until 2005 and, after a protracted legal battle, when the feeding tube

was removed, she died (her husband sought to have the tube removed but her parents fought against this); and (4) the more recent case of Grace Lee, a 28-year old woman from Long Island, N.Y., diagnosed with inoperable brain cancer, who became locked in a legal battle with her conservative Christian parents over terminating her treatment. The N.Y. Court of Appeals ruled she was competent to make a decision on removing her artificial ventilation and feeding tubes, but she changed her mind after her father told her she would go to hell if she removed life support. She returned home and eventually died after her ventilator malfunctioned.

Ms. Zenker discussed "truth telling." She explained that some cultures have a "don't tell momma" approach to disclosing terminal health conditions and the workaround for professionals in this situation is to let people know directly about their health care issues. In Western countries, 80% to 90% of patients are told of their diagnoses. She noted that clinical practices have changed over the years. For example, a 1961 survey showed 88% of physicians did not discuss a diagnosis of cancer but, by 1978, 98% disclosed this diagnosis.

There is no single conversation one can have to cover all the possible decisions with which one may be faced. She mentioned the "Conversation Project" and an interactive program known as "prepare for the care." Family dynamics can be the biggest obstacle for medical practitioners. There has been a major shift over time from a paternalistic to a shared landscape. Health care providers struggle with balancing autonomy and beneficence, which illustrates the importance of advance directives. People need to be taught how to ask the right questions. She noted that people in New York increasingly suffer from social isolation. It is important to let the person who is one's health care proxy know that they have been so selected. In addition, since a proxy may have died, the health care proxy needs to be updated from time to time.

Judith Schwarz has been providing counseling and expertise in this area for over 20 years. She identified several common themes. First, after first learning from the patient if s/he is in pain, she first asks if there is an advance directive and whether it was completed before, or after, the last diagnosis. Advance directives should be reviewed after occurrence of one of the 5 D'S: death of a family member or friend, divorce, decline in health, change in diagnosis and after a decade (at least once every 10 years). Often there is an assumption that relatives understand what the person's wishes are, which may not be the case. Second, usually there is an adult child involved who claims that "dad won't talk about it." Ms. Schwarz has learned that "there are worse things than death." Too often the family is consumed by guilt. Most people fear being perpetually dependent on mechanical devices. In such cases, she suggests a time-limited trial to return the patient to quality of life and, if this is not possible, to switch the patient from unsuccessful, aggressive interventions to palliative care. Third, one family member claims to know what the patient wants (often a daughter and usually the child who lives the closest geographically) and believes the others do not.

Ms. Schwarz encourages a family to meet or arrange a conference call before a crisis, with the goal of identifying mom's wishes and of developing a plan of care. She advised people to make multiple copies of the advance directive that results from such a conference. Often the more distant siblings feel badly about what the "in the know" sibling has to do. They arrive to deal with the situation but have a different understanding of what should be done than the adult child who is aware of the mother's wishes. Ms. Schwarz noted that an advance directive is only as good as the last conversation held. The person with the legal authority to decide, the health care agent, needs to know the values, wishes, fears, and hopes of the person with the advance directive and be able to interpret these into choices. Approximately 25 to 30 percent of all adults in the United States have some form of an advance directive.

Dr. Sarah Egan remarked that the health care proxy is the most important document for a person with a life-threatening illness to have. The traditional medical protocol for health providers is to try to save life. Without advance directives, the patient is likely to get what the culture dictates, which is to do everything and provide aggressive interventions. Many people with a limited prognosis would actually prefer to be at home, surrounded by family. For a doctor, it takes practice to notice a change (deterioration) in a patient. Dr. Egan explained that there is a fear of destroying hope but, she asked, hope for what? Our culture does not have a vocabulary for death. The language of popular culture treats death like a football game, e.g., with phrases such as "he fought so hard." She explained that the focus of hospice is two-fold: symptom management and less aggressive intervention. She mentioned a 2008 JAMA study on end of life discussions. The study's conclusion was that aggressive care is associated with worse bereavement for the caregiver and worse quality of life for the patient. Someone must tell the patient and the patient's family that the patient is dying.

Justice Siegal introduced Vivienne Duncan. Ms. Duncan described the City Bar Justice Center Cancer Advocacy Project as one which assists in three particular areas: life planning, cancer-related employment discrimination and health insurance appeals. The City Bar Justice Center is a current JALBCA grant recipient. In the early years of JALBCA, JALBCA worked with the NYC Bar Association to create a program whereby attorneys volunteered to provide pro bono services on employment discrimination and health insurance appeals. These services

are now provided through the City Bar Justice Center Cancer Advocacy Project. The Project also provides educational functions at which speakers discuss topics such as medical debt. Volunteers assist people without charge; volunteers serve as translators to assist attorneys who prepare documents; and volunteers serve as witnesses (for those signing documents).

The program was followed by a question-and-answer period. One attendee mentioned that she was surprised to learn that if a patient goes into the operating room, this rescinds the DNR. People discussed that surgeons do not want the death on their records- apparently there is a 30-day mortality statistic that surgeons are aware of. Mr. Strauss explained that if you have an emergency at home and call 911/EMS, chances are they will not recognize a DNR. People need an at-home DNR order signed by a physician and this must be renewed every six months. Further, until there is a determination that a patient lacks capacity to give informed consent, the health care proxy does not spring into effect. Dr. Egan, however, mentioned that there is a pink MOLST and pink "non-hospital" DNR which will be honored — if someone is not conscious, then that person does not have capacity.

Attendees were afforded the opportunity to obtain copies of relevant materials, such as combination form "Health Care Proxy, Health Care Declaration and Instruction re Protected Health Care Information" and "Anatomical Donation".

UPDATE ON CELL PHONE RADIATION

NYU Langone sponsored an afternoon lecture at Woodhull Hospital on February 7, 2019 to provide an update on cell phone radiation. The program, entitled "Cell Phone Radiation: Do We Need to Worry", featured Mark Shafer, M.D., Associate Chairman of Radiology, Department of Radiology, NYU Langone Health.

The "problem" was identified as the fact that radio frequency ("RF") radiation (radio waves) are emitted from cell phone antennas and this can be absorbed by the body nearest the emitter. The number of cell phones is increasing rapidly and the number of cell phone calls, length of calls and amount of time the cell phone is in use has increased over time. The power output of the cell phones is related to the strength of the signal coming into the phone — the lower the number of bars, the more the power output. The electromagnetic radiation spectrum includes both non-ionizing radiation (starting with the lowest frequencies (for computers, electrical wiring, and power lines) and increasing to higher frequencies (for TV broadcast, mobile phones, microwaves, Wi-Fi, remote controls, smart meters and radio)) and ionizing radiation (with the highest frequencies used, for example, in diagnostic radiation and therapeutic radiation). Non-iodizing radiation does not have enough energy to break bonds or damage DNA, while ionizing radiation can break bonds and make molecular changes in the cell, including changes in DNA. It has been known since the 1940s, through the work of Nobel Prize winner Hermann Muller, that X-ray irradiation will produce DNA mutations. The RF of mobile phones ranges from 1.9-2.2 GHz, compared to, for example, that of remote controls with 5.8 GHz and microwaves ovens with an even higher frequency of 3-30 GHz. Cordless phones produce less radiation than cell phones.

The effects of non-ionizing radiation on humans, however, are not well known. Heat is delivered to the body, cancer concerns exist and metabolic changes may be implicated (e.g., changes in memory, learning, and cognitive function). The unit to measure RF absorption in humans is called SARS, for Specific Absorption Rate, and it is measured in watts/kg (W/kg). The SAR from cell phones is higher in young children than in adults. Children have smaller heads, which means a larger percentage of the brain is exposed.

Dr. Shafer identified three general types of studies in this area: (1) case control studies (studies of people with central nervous system (CNS) tumors versus people without CNS tumors), (2) cohort studies (tumor development and cell phone use compared over time in a large group) and (3) population studies (looking at whether the rate of certain types of cancers changes over the time frame of the cell phone use). Dr. Shafer reviewed the results from several studies done to date which represent the state of the "science". For example, he discussed a now-dated study of whether there were statistically significant increases in brain or CNS cancers related to a higher amount of cell phone use or whether there was a statistically significant association between intracranial distribution of tumors within the brain and the location of the cell phone. He also mentioned a Danish cohort study which did not find a link between cell phone use and the incidence of glioma, meningioma and acoustic neuroma among people who were cell phone subscribers for 13 years or more.

Other studies were also mentioned — for example, NCI studies (1994-1998), a CERNAT case control study in France (2004-2006), a Swedish study (which did report a statistically significant association of increased brain cancer with cell phone use in people who started use before age 20) and an Israel parotid study. Dr. Shafer cited several issues with the existing cell phone studies: recall bias (people with brain tumors may remember their cell phone differently — most studies lack verifiable data), inaccurate reporting

(people report use more or less than actual use), morbidity and mortality (with short life span from diagnosis, the tumors (gliomas) are difficult to study by way of questionnaires and next of kin can be poor reporters), participation bias (people with CNS tumors are more likely to become participants than healthy people) and, finally, rapidly changing technologies and methods of use. Testimonials, he said, are not a substitute for science. They should not be ignored but, rather, used as a starting point for further investigation.

Dr. Shafer then mentioned the numbers game: is there a safe level of RF (ionizing) radiation? Pregnant women should not be exposed to a radiation dose greater than 5 rads, he said. There are potential health effects (other than cancer) of prenatal radiation exposure. As for the potential carcinogenic effects of prenatal radiation exposure, Dr. Shafer offered a CDC chart, which showed both the estimated childhood cancer incidence and lifetime cancer incidence risk for exposure at age 10 years — both were progressively higher as the radiation dose increased, starting from "no radiation exposure above background" to, ultimately, more than 50 rads. The risk for eventual cancer is higher for a fetus than for a 10-year old.

The FCC has a policy on human exposure to RF electromagnetic fields. The FCC is required by the National Environmental Policy Act of 1969, among other things, to evaluate the effect of emissions from FCC-regulated transmitters on the quality of the human environment. Several organizations have issued recommendations for human exposure to RF electromagnetic fields. The potential hazards associated with RF electromagnetic fields are discussed in OET Bulletin No. 56, entitled "Questions and Answers About the Biological Effects and Potential Hazards of Radio Frequency Electromagnetic Fields." The FCC's exposure guidelines, which specify limits for human exposure to RF emissions from hand-held mobile phones, set an SAR of 1.6 W/kg averaged over one gram of tissue — compliance with this limit must be demonstrated before FCC approval is granted for marketing of a phone in the U.S. The ICNIRP guidelines, used in Europe and most other countries, set less restrictive limits (e.g., 2 W/kg averaged over 10 grams of tissue). Measurements and analysis of SAR in models of the human head have shown that the 1.6 W/kg limit is unlikely to be exceeded under normal conditions of use of cellular and PCS hand-held phones. The same is true for cordless telephones used at home. Testing of hand-held phones is normally done under conditions of maximum power usage and most phone usage is not at such maximum power, thereby offering a margin of safety. However, one must be sure to position the cell phone at a certain distance. Dr. Shafer noted that iPhone's SAR measurement may exceed the FCC exposure guidelines for body-worn operation if positioned less than 15 mm (5/8 inch) from the body.

Dr. Shafer noted, however, that the effect of cell phone use may be years into the future and, therefore, the effect of cell phone radiation exposure may not be known for a long time. There are a number of possible mechanisms of action that science will need to bear out: protein changes (changes in processes such as phosphorylation of protease), transcription changes in the DNA, changes in DNA repair proteins, making the blood-brain barrier more porous, etc.

What is recommended? If you believe the radiation has no effect, he said "good luck" with that. If you are worried but still want to use a cell phone, Dr. Shafer made these recommendations for use: reduce exposure to children, consider a speaker phone, use earphones (wired not blue tooth), use texting, hold an active phone away from the head, do not carry the phone in a pocket or against the body and turn off the phone when possible. If you are even more worried, he offered these recommendations: keep your Wi-Fi router away from where you commonly sit, consider the location of your house phone base station, note whether you have a car with Wi-Fi, note the location of your meter for measuring water/electricity, note whether you live near a broadcast tower, note whether you have a wired house phone, note whether you live near a cell phone tower, do not use your lap top computer on your lap and sit away from the TV. He suggested the possible purchase of an RF detector to measure the electromagnetic radiation from, for example, mobile phones, Wi-Fi, base stations, TVs and towers.

JALBCA LAW STUDENT INTERN

Jeanine Botwe is JALBCA's 2018/19 Susan Solomon Legal Intern. She is presently a law student at Fordham University School of Law and received her B.A. degree from Emory University, with a major in Human Health. Ms. Botwe previously served as a research assistant at Rush University Medical Center and, thereafter, worked as a law clerk at both Weissman Law and Adelman Matz, P.C. As a research assistant at Rush, among other things, she managed the medical student volunteer research program and administered participant interviews and pain sensitivity evaluations.

FDA Proposes Update to Mammography Regulations

In a proposed rule on Wednesday, March 27, 2019, the FDA sought to update the mammography regulations that were issued under the Mammography Quality Standards Act of 1992 and the Federal Food Drug, and Cosmetic Act. The rule proposes, among other things, to require that providers of mammograms for breast cancer screening tell women whether they have low density or high density breast tissue. More comprehensively, the FDA is proposing to improve the delivery of mammography services by strengthening the communication of healthcare information; allowing for more informed decision making by patients and providers (by requiring facilities to provide them with additional health information); helping to ensure the availability of qualified mammography personnel; bolstering the medical outcomes audit to provide feedback to improve mammography interpretations; modernizing technological aspects of the standards; and adding additional tools to deal with noncompliant facilities. The proposed changes would require that the lay summary provided to patients identify whether the patient has low or high density breasts and include a prescribed paragraph on the significance of breast density. They would also establish four categories for reporting breast tissue density in the mammography report that is provided to the patient's referring healthcare provider. The proposed rules are available online for 90 days at www.regulations.gov for public comment. (*See* Federal Register Number 2019-05803.)

This article focuses primarily on the aspect of the FDA proposed rule that addresses breast density. Breast density refers to the proportion of fibroglandular tissue in the breast, as seen on a mammography. Mammograms are among the most difficult radiograph images to interpret, according to the Government Accountability Office. Mammograms of breasts with higher density are harder to interpret than those of less dense breasts because the dense tissue can obscure cancer. The CDC also lists dense breast tissue as one of the risk factors for breast cancer. Women with dense tissue, therefore, are often advised to undergo other screening tests in addition to mammograms, such as ultrasound or M.R.I. scans. According to the FDA, one study showed that supplemental ultrasound screening in high-risk women with dense breasts resulted in the detection of 1.1 to 7.2 additional cancers per 1,000 women. The detection of additional cancers has to be weighed against any increase in false positive results. Breasts that are not dense have more fat, which X-rays penetrate easily. The only way to detect dense tissue is with a mammogram; it cannot be felt. Mammography can help detect breast cancer in its earliest, most treatable stages, when it is too small to be felt or detected by any other method, as the proposed rule states. Dense tissue makes cancer harder to find on mammograms because the tissue and tumors both show up as white and blend together. Fat, however, looks black, so tumors stand out more in fatty breasts.

Historically, some doctors have objected to the type of notification that will be required by the proposed rule. They have argued that not all women with dense tissue have the same increased risk of breast cancer, and that reporting the condition could frighten women and lead to unnecessary screening tests and biopsies. Some have also argued that many of the state-mandated letters were too difficult for patients to understand. Currently, 37 states and Washington, D.C., have passed individual laws mandating that women are notified about the density of their breast tissue. States are authorized to require more than this minimum required information.

Discussing the proposed changes, Dr. Laurie Margolies, the section chief of breast imaging at the Mount Sinai Health System in New York (and one of the "expert witnesses" at the JALBCA 2019 annual symposium) was reported to have said that, "(n)ow the 40% or 50% of women who have dense breasts in the U.S. will all be made aware of that fact, and then can learn its significance…This gives women more knowledge, and gives them the ability to make choices about getting a second test. So your next mammogram might be a mammogram *and* an ultrasound, or a mammogram and an MRI." Further, with respect to the portions of the FDA proposed rule which seek to strengthen its regulation of mammography screening facilities, such as notifying patients that testing did not meet the FDA's quality standards, Dr. Margolies said that "(t) hey want to change the timing of informing people that have very suspicious mammography to make sure they are informed much faster than the 30-day standard, which would now be reduced to a 14-day standard." (*See* Nicole Lyn Pesce, March 28, 2019, https://www.marketwatch.com/story/how-the-fdas-proposed-mammogram-changes-could-affect-your-next-breast-exam-2019-03-28).

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