

JUDGES & LAWYERS BREAST CANCER ALERT

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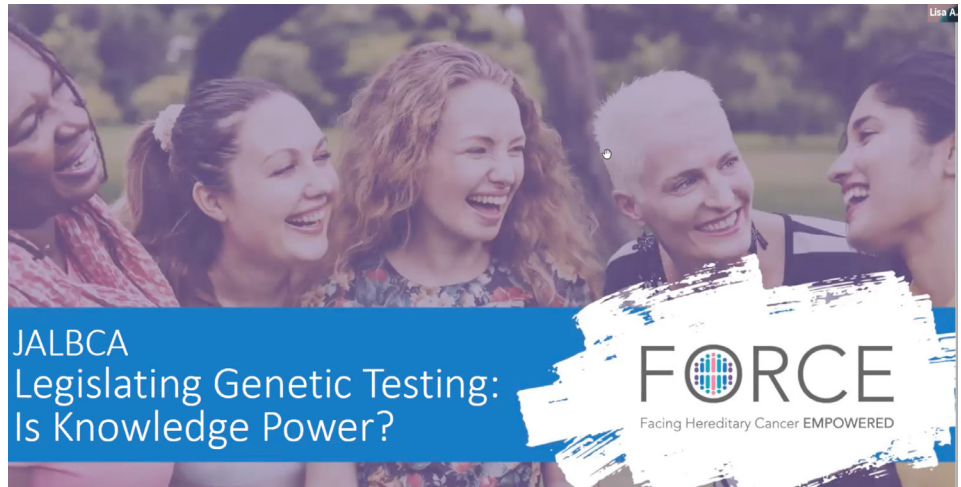
Editor: Martha L. Golar, Esq.

Winter 2021

JALBCA ANNUAL SYMPOSIUM 2020

JALBCA presented its 24th Annual Ellen P. Hermanson Memorial Symposium on December 9, 2020, entitled “*Legislating Genetic Testing: Is Knowledge Power?*” The program consisted of a mock legislative hearing that addressed whether our nation’s healthcare system can and should do more to empower Americans with knowledge about their genetic predisposition to cancer. The two-hour CLE program was presented via Zoom and consisted of a legislative panel and many testifying witnesses. The program was sponsored by The Ellen Hermanson Foundation and the bench and bar of the Southern District of New York. We enjoyed the benefit of two supporting organizations: SHARE and The Women’s Bar Association of the State of New York. The hard work of putting together this program was accomplished by three Co-Chairs, Desirée Ripo, Esq., Erika Stallings, Esq., and Virginia K. Trunkes, Esq., and Symposium Subcommittee members Amy D. Carlin, Esq., Hon. Barbara Jaffe, Sandra Lespinasse and Rian A. Silverman, Esq.

The mock legislative panel was comprised of Hon. Barbara Jaffe (NYS Supreme Court, JALBCA Board member), Hon. Keith Powers (Member, New York City Council and Committee on Health), Hon. Alan D. Scheinkman (then-Presiding Justice, Appellate Division, Second Judicial Dep’t., JALBCA Board member) and Erika Stallings, Esq. (BRCA awareness advocate and attorney, Facebook Music). Each questioned the witnesses.



Hon. Barbara Jaffe



Hon. Alan D. Scheinkman



Hon. Keith Powers



Erika Stallings, Esq.

The testifying witnesses at the mock legislative hearing included:

- Patrick J. Burke, Esq., Partner, Chair of Data Technology & Cybersecurity Group, Phillips Nizer LLP
- Kristen C. Kim, Esq., Associate General Counsel, Chief Regulatory Counsel, Memorial Sloan Kettering Cancer Center
- Anya Prince, MPP, JD, Associate Professor of Law, Iowa College of Law, and Member of the University of Iowa Genetics Cluster
- Kathryn M. Rattigan, Esq., Robinson & Cole LLP's Data Privacy & Cybersecurity Team and Business Litigation Group
- Lisa A. Schlager, Vice President of Public Policy, FORCE (Facing Our Risk of Cancer Empowered)
- Julia A. Smith, MD, PhD, NYU Langone Perlmutter Cancer Center, Assistant Clinical Professor, Department of Medicine at NYU Grossman School of Medicine
- Fran Visco, JD, President, National Breast Cancer Coalition

The focus of the mock hearing was a hypothetical bill (the HEART Act), which, if enacted, would fund genetic testing and require primary care providers and obstetrician-gynecologists to include genetic testing for the BRCA1 and BRCA2 genes as part of annual checkups/physicals of young (ages 15-39) women, offering patients the option to opt out. The objectives of the proposed bill would be to increase awareness of the risks of breast and ovarian cancer in young women and enable them to make informed decisions before facing a crisis. The sample bill was discussed in light of existing laws, which primarily included the following:

1. Health Insurance Portability and Accountability Act (HIPAA) (<https://www.govinfo.gov/content/pkg/PLAW-104publ191/pdf/PLAW104publ191.pdf>), which protects genetic information when shared with health care providers and contains a privacy and security rule, both discussed during the hearing;

2. The Genetic Information Non-Discrimination Act (GINA) (<https://www.eeoc.gov/statutes/genetic-information-nondiscrimination-act-2008>), which protects against discrimination by covered health insurers and employers by prohibiting them from discriminating against employees on the basis of genetic information. GINA's health-insurance and employment provisions both prohibit requesting, requiring, or purchasing genetic information;

3. The Patient Protection and Affordable Care Act (ACA), as amended in 2010, known as the "Affordable Care Act", "PPACA" or "Obamacare." The ACA rendered moot some of GINA's most central provisions. With respect to privacy of personal health information, the ACA protects against insurers' use of all medically relevant information, not just genetic data. It also guarantees coverage of certain preventive health services (including BRCA testing for certain women and mammograms for women ages 40 and up, but not including screening and preventive services needed once someone learns they carry a mutation - *i.e.*, annual breast MRIs starting at age 25, alternating with annual mammograms starting at age 30, screening for ovarian cancer, risk-reducing surgeries (bilateral salpingo-oophorectomy/hysterectomy and bilateral mastectomy)). After the ACA was enacted, health insurers could no longer make eligibility decisions based on any medically relevant risk-related information, including genetic information;

4. Clinical Laboratory Improvement Amendments (CLIA) (Lab certifications, etc.), which applies to the primary regulatory body for laboratories that perform genetic testing, the Center for Medicare and Medicaid Services (CMS). Laboratory tests, including genetic tests, are subject to federal oversight when performed for clinical or diagnostic purposes, with the objective to ensure the accuracy, reliability, and timeliness of test results, regardless of where the test was performed. New York is one of only two states in the country that has a state laboratory accreditation framework that exceeds the floor set by the federal CLIA statute. As such, clinical laboratories in New York State are governed by the NYS Clinical Evaluation Laboratory Program;

5. The Federal Policy for the Protection of Human Subjects, a/k/a, the "Common Rule" (45 C.F.R. Part 46), which regulations outline the basic provisions for institutional review boards, informed consent, and assurances of compliance;

6. New York Public Health Law Article 24-A, which regulates "human research" (as defined under the law). This NYS law differs in many key ways from the federal Common Rule. This state law is pre-empted if a research institution has voluntarily opted to apply the federal Common Rule to its research;



Patrick J. Burke, Esq.



Kristen C. Kim, Esq.



Anya Prince, MPP, JD



Kathryn M. Rattigan, Esq.



Lisa A. Schlager



Julia A. Smith, MD, PhD



Fran Visco, JD

7. New York’s Genetic Testing Law – Civil Rights Law § 79-l, which sets forth specific requirements related to written consent for genetic tests and disclosure of genetic test results. In addition, any person who consents to a genetic test must be advised that s/he/they may want to seek professional genetic counseling;

8. New York’s Access to Patient Information – Public Health Law §§ 17 and 18, which contain provisions relevant to a patient’s request for and access to the patient’s own medical information. Questions often require an analysis to determine whether a particular provision of these state laws is pre-empted by federal HIPAA;

9. Mandatory Genetic Testing in New York. NYS has several types of mandatory genetic testing laws (e.g., newborn screening tests); and

10. Duty To Warn and Genetic Testing. Genetic testing related to inheritable conditions can also raise ethical and legal questions that become a balancing act between a patient’s privacy rights and a “duty to warn” related family members who also may be at risk for the genetic condition. Courts have not generally recognized a “duty to warn” family members of a patient’s genetic test results that would justify overriding the patient’s privacy protections. However, two notable non-New York cases have addressed this issue with opposite results. These are: *Safer v. Estate of Pack*, 677 A.2d 1188, 1192 (N.J. Super. Ct. App. Div. 1996) and *Pate v. Threlkel*, 661 So. 2d 278, 282 (Fla. 1995).

With this legal background, the panelists/witnesses discussed the mandatory genetic testing required by the hypothetical HEART Act, which would require genetic testing for the BRCA and BRCA1 gene as part of annual checkups/physicals of young women, offering patients the option to opt out.

Katherine Rattigan stated that DNA is

more sensitive than any other type of health information and cannot be de-identified. She explained that DNA is unchangeable and unique to the individual – it cannot be anonymized. She believes this type of proposed law would provide less protection for off-the-shelf medical genetic testing kits, but that people should be encouraged to have genetic tests performed by their provider to learn about a pre-disposition for breast cancer but should be assured of privacy safeguards.

Patrick Burke identified concerns with genetic testing offered by companies which are not in the health business, such as Ancestry DNA and 23andMe. He said some of these companies operate research arms which sell information based on their ever-increasing databases and 80% of customers consent to have the company enter their data into its database. With this commercialization of genetic data, there are no institutional review boards to protect that the research is ethically conducted or to assure protection of privacy. Under European regulation, by contrast, there is a long-held belief in privacy protection. Nonetheless, if information is truly de-identified it can be used and even transferred out of the European Union to places which have inadequate laws to protect information privacy. Apparently, the US would be considered the wild west in terms of data privacy regulation from the European point of view.

Anya Prince testified that current genetic anti-discrimination laws need to be strengthened. GINA covers genetic information in health insurance (not property, casualty or disability insurance) and employment, but it does not include manifested conditions or prevent use of genetic information for education, licensing and other purposes. It applies to state and local governments and some federal employees but only employers with 15 or more employees (though some states cover employ-

ers with fewer employees). She also suggested that restrictions on use of genetic information for discrimination purposes should be extended to disability, life insurance and long term care insurance policies and mentioned that, with life and long term care policies which contain a HIPAA waiver, these policies do not prevent insurers from discriminating based on genetic information. Additionally, no private right of action is available under GINA.

Lisa Schlager discussed multi-gene testing, which is more common currently. Other mutations - besides BRCA1 and BRCA2 - are known (e.g., ATM, BRIP1, CDH1, CHEK2, PAB2, and RAD51C/D) and some mutations are more common than BRCA mutations (e.g., Lynch syndrome, which encompasses five genes, and falls under the category of hereditary colorectal cancer syndromes). Thus, if one tests only for BRCA, one is missing 50% of the women who may have hereditary genetic cancer mutations. The National Comprehensive Cancer Network guidelines on this subject represent the standard of care for risk management for those who do not have cancer and also for managing people who have mutations and have already had cancer. The most important protection provided by the ACA in this area is coverage for specific cancer screenings and preventative services without co-pays or deductibles. The majority of private/group health plans cover genetic testing for those who meet personal family history criteria - many plans pick and choose which mutations they want to test for.

Ms. Schlager discussed genetic counseling and cascade screening. Genetic counselors (of which there is a shortage) are not recognized as licensed healthcare providers under Medicare – unlike nurse practitioners and physicians who provide genetic counseling services. She would like to see them covered under Medicare, thereby allowing

reimbursement. Cascade screening occurs when an individual is identified by testing with an inherited predisposition to a disease and then genetic testing is extended to his/her at-risk biologic relatives. It allows clinicians to tailor interventions based on whether or not someone is known to carry risks for inherited cancer.

The group also discussed the fact that much of genetic research has occurred in people of European ancestry - the majority of biobanks where research has been done are of people with this background. It was suggested that more diverse communities need to participate in genetic testing and be included in biobanks. Equity also requires increasing the diversity of genetic professionals and researchers – it is not a particularly diverse field – and having more of these persons look like the communities being served. Kristen Kim, speaking on her own behalf and not on behalf of her employer, talked about the waiving of consent (regarding use of one’s genetic information) by those who participate in human subject research. Some research cannot be done without a waiver, and a waiver of consent may not adversely impact the welfare of a subject. New York research law does not allow for waiver of consent, which, she explained, is a reason why New York researchers follow the federal Common Rule rather than New York law. She also discussed de-identification of genetic information. Basic science researchers are very focused on this issue - the issue is to be re-visited every four years in recogni-

tion of the fact that science is always evolving and the ability to re-identify people also will evolve.

Further, Ms. Kim noted that a question that comes up increasingly at hospitals is “information blocking”. This is a practice by a health IT developer of certified health IT, health information network, health information exchange, or health care provider that, with certain exceptions, is likely to interfere with access, exchange or use of electronic health information (EHI). The new information blocking rules were put in place under the 21st Century Cures Act and are aimed at ending information-blocking practices that impede the secure exchange and use of EHI. Among other things, hospitals and other providers are required, in order to participate, to provide “prompt” access to information (e.g., study test results) without unreasonable delays. There is a privacy exception, among the other exceptions, so that an actor would not be required to use or disclose EHI in a way that is prohibited under state or federal privacy laws.

Fran Visco’s perspective is that just because we can legislate something doesn’t mean we should- the benefits must significantly outweigh any harm resulting from a medical intervention. She cited to the history of autologous bone marrow transplants where breast cancer patients advocated for insurance reimbursement for the procedure at a time when there was no strong evidence that it was effective. It later turned out that the procedure was not effective. Ms. Visco

provided some arguments in opposition to a statutory mandate of genetic testing (for the BRCA mutation, *i.e.*, the sample statute which provided the premise for the Symposium “hearing”) given that only 5 to 10% of women evidence this mutation. Moreover, she argued, there are five variants for this gene mutation which are of unknown significance. Individuals might pursue irreversible and unnecessary surgery, and a negative test result might also lead to a false sense of security.

By contrast, Dr. Julia Smith supported the need “to get started,” referencing the thousands of lives that have been saved already. She agreed, however, that the mutation variants of uncertain significance are a big problem, which she surmised will decline over time, and that men should be covered as well under a statute to mandate genetic testing. The more we test, she believes, the more cancers we find are under the umbrella of genetic mutations. Also, a statutory mandate would help break down barriers between the those who currently have access to these tests and those who are underserved and underinsured.

The hearing concluded, with everyone having benefitted by listening to arguments on both sides of the question of whether to statutorily mandate genetic testing and by learning about applicable state and federal rules that govern human subject testing and genetic testing in particular. Many thanks to the organizers and participants.

OTHER FALL 2020 JALBCA ACTIVITIES

In addition to the Annual Symposium, JALBCA hosted or co-hosted other activities during Fall 2020.

Legal Issues Affecting Breast Cancer Patients - CLE Program

On October 7, 2020, JALBCA Co-President Jacqueline Flug and Center for Elder Law & Justice attorney Rachel S. Baldassaro moderated a program covering relevant legal issues impacting breast cancer patients. The program covered employment issues, debtor/creditor matters and insurance issues. Employment issues were addressed by Lisa A. Coppola of The Coppola Firm. Debtor/creditor matters were addressed by Terrie Benson Murray, Esq. of Cohen & Lombardo, P.C. Insurance issues were covered by Kelly

Barrett Sarama, Esq., Center for Elder Law & Justice.

Luncheon Co-Sponsored with BWBA

On October 19, 2020, JALBCA and the Bronx Women’s Bar Association sponsored a virtual luncheon which featured a medical expert and male and female cancer survivors who offered powerful accounts of their personal experiences. The keynote speakers at this event included Dr. Louis Braun (breast cancer survivor), Christine Weiss (breast cancer survivor) and Dr. Lisa Wiechmann (New York Presbyterian/Columbia).

Pink & Teal Seminar Co-Sponsored by JALBCA, NYWBA and SHARE

On October 26, 2020, JALBCA and the New

York Women’s Bar Association presented an afternoon webinar in recognition of October as Breast Cancer Awareness Month and September as Ovarian Cancer Awareness Month. The program featured two speakers who are cancer survivors: Theresa Drescher, an author, motivational speaker and personal coach and Andrea Herzberg, a retired sergeant of the NYPD Special Victims Unit. Both women provide services to SHARE (Self-help for Women with Breast or Ovarian Cancer). SHARE is a 44-year old non-profit and survivor-led organization based in New York City, dedicated to providing emotional support and information about breast, metastatic breast, ovarian and uterine cancers through its many free services and programs.

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

ELLEN'S RUN

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

195 West Houston Street

New York, NY 10014

www.gildasclubnyc.org

212.647.9700

MALE BREAST CANCER COALITION

www.malebreastcancercoalition.org

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 10035

NATIONAL BREAST CANCER COALITION

1010 Vermont Avenue, NW, Suite 900

Washington, DC 20005

www.breastcancerdeadline2020.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

SHARSHERET

(for Young Jewish Breast Cancer Survivors)

866.474.2774

www.sharsheret.org

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

80 Broad Street, Suite

1700 New York, NY 10004

www.youngsurvival.org

877.972.1011