

JUDGES & LAWYERS BREAST CANCER ALERT

Vol. 24 No. 2

Editor: Martha L. Golar, Esq.

Spring 2020

We're Going Virtual for 2020!!

JALBCA's Awards Presentation Gala on September 8, 2020

Rescheduled

Date: September 8, 2020

Time: 6 p.m.

At the virtual Gala, JALBCA will honor:

- * Honorable Jenny Rivera, Associate Judge of the New York Court of Appeals - Leadership Achievement Award
- * The IBM Legal Department - Maite Aquino Memorial Grant Award
- * Judith Livingston for her many years of service to JALBCA

We look forward to celebrating JALBCA and our honorees, grantees and sponsors with you!

Registration information will be provided before the event.

JALBCA WELCOMES NEW CO-PRESIDENT JACQUELINE FLUG



Jacqueline P. Flug, Esq. recently was elected to serve a two-year term as Co-President of JALBCA. Ms. Flug has been a member of JALBCA since 2005, serving on the Dinner Committee, Programs Committee, chairing the Lunch & Learn Programs Committee as well as the Grants Committee, and serving as Vice President. Ms. Flug serves as Vice President, Legal & Industry Affairs for Drizly, the country's leading e-commerce platform for on demand

alcohol delivery. Ms. Flug is responsible for regulatory matters, legislative matters and compliance in relation to alcoholic beverage control laws. Prior to joining Drizly in 2019, Ms. Flug served as General Counsel and Vice President of Roosevelt Island Operating Corporation from 2016-2019 and as General Counsel to the New York State Liquor Authority from 2012-2016. Ms. Flug served in the Office of the Mayor as the Administrator for the Assigned Counsel Plan for the Appellate Division First Department, a program that provides private counsel for indigent criminal defendants, from 2008-2012. Ms. Flug began her legal career in 2001 as an Assistant District Attorney in Bronx County, where she prosecuted violent felonies and vehicular homicides.

(continued on page 2)

Ms. Flug served as the President of the Women’s Bar Association of the State of New York (WBASNY) from 2016-2017 and the President of the Bronx Women’s Bar Association from 2007-2008. She serves on various Court Committees, including the Judicial Hearing Officer Screening Committee for the Appellate Division, Second Department and the Central Screening Committee for the Appellate Division, First Department. Ms. Flug proudly

served as a coach for Bronx Middle School I.S. 145 in the Thurgood Marshall Junior High School Mock Trial Competition and served on the Board of the National Organization for Women – NYC.

Ms. Flug received her Juris Doctor *cum laude* from New York Law School and her B.A. in American Studies from SUNY Geneseo.

JALBCA LAW STUDENT INTERN 2019-2020



Elizabeth A. Harvell is JALBCA’s Susan B. Solomon Law Student Intern for 2019-2020. Elizabeth graduated from New York Law School in May 2020, with a concentration in Family Law. At New York Law School, she was a Global Fellow Scholar on a full-tuition scholarship, a Staff Editor on

the *New York Law School Law Review*, and Vice Chair of the Moot Court Association. Prior to law school, she graduated from Wake Forest University with degrees in Philosophy and English, with Honors and Distinction.

During her second year of law school, Elizabeth

interned for past JALBCA president, the Honorable Ellen M. Spodek, at the Kings County Supreme Court in Brooklyn. Elizabeth also spent the fall and spring of 2019 interning for matrimonial judge and JALBCA Vice President, the Honorable Lori S. Sattler, at the New York County Supreme Court. She interned for the matrimonial firm Garr Silpe in the spring of 2020.

As the JALBCA law student intern, Elizabeth manages all social media accounts and updates. She photographed JALBCA members at the Susan G. Komen Race for the Cure, helped compile materials for JALBCA’s 2020 Ellen P. Hermanson Memorial Symposium (which was postponed because of the coronavirus, but will be rescheduled), and is assisting with research for another JALBCA project.

NEWS BRIEFS

FDA Guidance Document on Competitive Generic Therapies- March 2020

A guidance document on Competitive Generic Therapies (Docket Number [FDA-2019-D-0065](#)) was issued in March 2020 by the Office of Generic Drugs in the Center for Drug Evaluation and Research at the Food and Drug Administration (FDA). A copy can be obtained at this link: <https://www.fda.gov/media/136063/download>.

The FDA Reauthorization Act of 2017, or FDARA, created a new pathway by which FDA may, at the request of the applicant, designate a drug with “inadequate generic competition” as a competitive generic therapy (CGT). At the request of the applicant, FDA may also expedite

the development and review of an abbreviated new drug application (ANDA) for a drug designated as a CGT.

The FDA guidance provides a description of the process that applicants should follow to request designation of a drug as a CGT and the criteria for designating a drug as a CGT. It also includes information on the actions FDA may take to expedite the development and review of ANDAs for drugs designated as CGTs. The guidance also provides information on how FDA implements the statutory provision for a 180-day exclusivity period for certain first approved applicants that submit ANDAs for CGTs. FDARA created a new type of 180-day exclusivity, different from 180-day patent challenge exclusivity, for the first

approved applicant of a drug with a CGT designation for which there were no unexpired patents or exclusivities listed in the Orange Book (*i.e.*, the FDA’s *Approved Drug Products with Therapeutic Equivalence Evaluations*) at the time of original submission of the ANDA. This new 180-day exclusivity under FDARA, the guidance explains, is intended to incentivize competition for drugs that are not protected by patents or exclusivities and for which there is inadequate generic competition.

Update on Federal Surprise Billing Legislation

Surprise medical billing primarily occurs in two situations: (1) emergency medical services are rendered by an out-of-network provider, **or**

(ii) emergency or non-emergency medical services are rendered by an out-of-network provider in an in-network facility. In both situations, patients and their families have little control over the selection of the out-of-network provider and surprise billing laws are intended to protect them from the unexpected costs that may result.

State Laws

As of the end of December 2019, 28 states had enacted consumer protections to address surprise medical bills. Some states provide more comprehensive protection, going further than others to protect patients from surprise medical bills. But state laws cannot fully protect consumers. They can't help people who have self-funded employer plans, which bear insurance risk for their employees and are offered by many employers. Additionally, federal ERISA law bars states from regulating such plans. States also are restricted from protecting people who receive surprise bills because of air ambulance service (See: *Update on Federal Surprise Billing Legislation: Understanding a Flurry of New Proposals*, December 16, 2019, at <https://www.commonwealthfund.org/blog/2019/states-are-taking-new-steps-protect-consumers-balance-billing-federal-action-necessary>)

The Commonwealth Fund, for example, sets its own criteria for what constitutes comprehensive protection in this area. It would find that a state provides comprehensive protection if its law holds the consumer harmless by limiting his/her financial exposure to normal in-network cost sharing and:

- extends protections to both emergency department and in-network hospital settings;

- applies to enrollees of HMOs and PPOs;
- prohibits providers from balance billing; and
- adopts a specific payment standard or process for resolving payment disputes between providers and insurers.

(See: *States Are Taking New Steps to Protect Consumers from Balance Billing, But Federal Action Is Necessary to Fill Gaps*, July 31, 2019 at <https://www.commonwealthfund.org/blog/2019/states-are-taking-new-steps-protect-consumers-balance-billing-federal-action-necessary>)

Federal Initiatives

At the end of 2019, there were multiple bills at the Federal level to deal with surprise billing, but a final law was not decided upon. In February 2020, the House Education and Labor Committee approved a bill to protect patients from massive surprise medical bills, and the measure was sent to the full House. But a competing bill was supported by the House Ways and Means Committee that is more favorable to doctors and hospitals, who have lobbied hard against the Education and Labor approach because of concern that it will result in them receiving smaller payments.

The split in approach relates to how much the insurer will pay the doctor. The Education and Labor approach also is backed by the House Energy and Commerce Committee and the Senate Health Committee. It would set the payment rate based on the median amount paid for that service in the geographic area, with the option of going to arbitration for some higher-cost bills. The rival Ways and Means approach, which is backed by doctor and hospital groups, would

instead give the payment decisions to an outside arbiter.

[New Insight into Breast Cancer Resistance to Hormone Therapy](#)

New research findings were reported in *Cancer Cell* from an international team led by Baylor College of Medicine scientists, relating to breast cancer resistance to hormone therapy. Specifically, the research related to the function of neurofibromin, a tumor suppressor produced by a particular gene, the NF1 gene. It already was known that the suppression is accomplished by repressing the activity of a cancer driver called Ras. The new finding is that neurofibromin also directly represses gene expression controlled by the estrogen receptor-*α* (ER). Without neurofibromin, Ras and ER functions are both activated and this causes treatment resistance and metastasis for ER+ breast cancer.

This is relevant to treatment options. The researcher found that with neurofibromin-depleted cells in tumors, ER+ breast cancer cells are stimulated by tamoxifen rather than being inhibited, and the depleted cells become sensitive to very low concentrations of estradiol. Therefore, it suggests that tamoxifen or aromatase inhibitors (which work by reducing the estrogen available to tumor cells) and lower estrogen levels available to breast cancer cells would be ineffective for neurofibromin-deficient ER+ breast cancer tumors, according to a co-senior author of the study. Apparently, neurofibromin loss is present in at least 10% of metastatic ER+ tumors.

This is relevant to cancer therapy. It suggests that combination therapy might be effective to treat neurofibromin-depleted ER+ breast cancer: the combination of a selective ER degrader (e.g., fulvestrant,

which works by blocking estrogen from binding to cancer cells) and a MEK inhibitor (e.g., selumetinib or binimetinib, which shuts off a key signaling pathway downstream

of Ras) to inhibit Ras downstream signaling. This combination was tested in animal models and resulted in tumor regression. The next step is to begin clinical trials.

(See: *New insight into breast cancer resistance to hormone therapy*, March 5, 2020 at <https://www.bcm.edu/news/cancer-breast/breast-cancer-resistance-to-hormone-therapy>)

GUIDELINES FOR BREAST SURGEONS DURING THE PANDEMIC

The American Society of Breast Surgeons has offered its *ASBrS Resource Guide to Endocrine Therapy in the COVID-19 Pandemic*. These serve as a supplement to its Executive Summary on recommendations for prioritization, treatment and triage of breast cancer patients during the COVID-19 pandemic. The guidelines are not intended to supersede individual physician judgment, or institutional policy or guidelines. The recommendations are advised to be taken in the context of each institution's resources and prevalence of the COVID-19 pandemic in their region. Further, they are subject to change with changing COVID-19 pandemic severity. The recommendations are broken down into the

following priority categories based on patient condition: (a) Priority A: patient condition is immediately life threatening, clinically unstable, (b) Priority B: patient situation is non-critical but delay beyond 6-8 weeks could potentially impact overall outcome, and (c) Priority C: patient's condition is stable enough that services can be delayed for the duration of the COVID-19 pandemic. As at all times, multidisciplinary patient management is ideal.

As for geriatric patients, specifically, the Society notes that this population needs special consideration when selecting among treatment options because multiple comorbidities and functional issues may be present which can impact both treatment tol-

erance and outcomes. Further, the mortality rate from COVID-19 for patients over age 70 is likely higher than from their breast cancer. After age 70, "the percent of breast cancers that are estrogen positive and will respond to endocrine therapy rises. In patients older than 75 years with comorbid conditions and poor functional status, it may be best to treat with endocrine therapy as the primary therapy with surgical intervention only for clinical progression of disease. Patients older than 80 years have a higher percentage presenting with locally advanced breast cancer as they have stopped screening and having routine breast exams. Primary endocrine therapy for many would be preferable to downstage disease."

ELLEN HERMANSON FOUNDATION- 25TH ANNUAL ELLEN'S RUN

The 25th Ellen's Run is presently scheduled to take place virtually. Ellen's Run is the signature fund-raising event of The Ellen Hermanson Foundation and an innovative, grassroots event, that raises awareness about breast cancer. The Gala celebration will also be held, virtually, on July 25, 2020. Details will follow and should become accessible at www.ellenhermanson.org.

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

THE ELLEN HERMANSON FOUNDATION

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
www.sharecancersupport.org
212.719.0364
Toll-Free 844-ASK-SHARE (844.275.7427)
Speak to a survivor toll-free: 866.891.2392

SHARSHERET

(for Young Jewish Breast Cancer Survivors)
www.sharsheret.org
866.474.2774

TO LIFE!

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

YOUNG SURVIVAL COALITION

80 Broad Street, Suite 1700
New York, NY 10004
www.youngsurvival.org
877.972.1011