JALBCA

JUDGES AND LAWYERS BREAST CANCER ALERT

Vol. 18 No. 2 | Editor: Martha L. Golar, Esq. | March 2013

SAVE THE DATE
JALBCA ANNUAL DINNER

DATE: Monday, May 13, 2013
PLACE: Cipriani Wall Street, NY, NY
TIME: Silent auction
6 p.m. cocktails; 7 p.m. dinner

HONOREES:
Commercial Division Judges of New York County
Leadership Achievement Award

U.S. Litigation Team at UBS
Maite Aquino Memorial Grant Award
and

HONORING:
Outgoing Co-President Edward S. Kornreich

TOMOSYNTHESIS MAMMOGRAPY COMING TO SOUTHHAMPTON HOSPITAL

Thanks to a substantial commitment from the Ellen Hermanson Foundation, a state-of-the-art breast screening technology will become available at Southampton Hospital on Long Island. The Foundation is making a minimum grant of $220,000 to underwrite the purchase of a tomosynthesis 3D mammography system. This technology transcends the capabilities of traditional digital mammography. Julie Ratner, the Chair of the foundation and sister of the late Ellen Hermanson, announced the commitment. Digital tomosynthesis may replace conventional mammography in time, but is not yet considered the standard of care for breast cancer screening. It is approved by the FDA for breast cancer screening.

It is an imaging technique in which multiple X-rays of one object are taken from a discrete number of angles. The x-ray tube moves in an arc around the breast. Cross-sectional images taken are used to reconstruct 3-D images of the object being scanned. Tomosynthesis differs from computed tomography because the range of angles used is less than 360 degrees, which is used in CT scanning. Mammography usually takes two x-rays of each breast from different angles: top to bottom and side to side. The breast is pulled away from the body, compressed, and held between two glass plates to ensure that the whole breast is viewed. Regular mammography records the pictures on film, and digital mammography records the pictures on the computer.

The National Cancer Institute of the National Institutes of Health provides this description of the procedure:

> "Three-dimensional (3D) mammography, also known as breast tomosynthesis, is a type of digital mammography in which x-ray machines are used to take pictures of thin slices of the breast from different angles and computer software is used to reconstruct an image. This process is similar to

how a computed tomography (CT) scanner produces images of structures inside of the body. 3D mammography uses very low dose x-rays, but, because it is generally performed at the same time as standard two-dimensional (2D) digital mammography, the radiation dose is slightly higher than that of standard mammography. The accuracy of 3D mammography has not been compared with that of 2D mammography in randomized studies. Therefore, researchers do not know whether 3D mammography is better or worse than standard mammography at avoiding false-positive results and identifying early cancers."
http://www.cancer.gov/cancertopics/factsheet/detection/mammograms (lasted visited March 6, 2013)

NEWS BRIEFS

Settlement of Aetna Lawsuit Regarding Ingenix Databases

In December 2012, Aetna, Inc. reached a settlement in In re: Aetna UCR Litigation, U.S. District Court, District of New Jersey, Nos. MDL-2020 and 07-03541, a lawsuit brought to challenge insurer reimbursement of out-of-network medical services and supplies. The Litigation Center for the American Medical Association and the State Medical Societies joined multiple state societies to bring suit against Aetna, Cigna and WellPoint for physician underpayments due to the insurers' use of Ingenix (a UnitedHealth Group subsidiary) databases to set out-of-network reimbursement rates. The lawsuit alleged that Aetna used a faulty database and systematically underpaid claims for services delivered by out-of-network providers. Plaintiffs argued that the Ingenix databases (i.e., the Prevailing Healthcare Charges System Database and the MDR Payment System) consistently understated "usual, customary and reasonable" (UCR) rates that are used as the basis for out-of-network payment amounts. The UCR is supposed to represent the "going rate" that health care professionals charge for their services in a particular geographic area of the country.

Pursuant to the settlement, Aetna will set up three funds, totaling $120 million, for physicians and others to make claims – a general settlement fund, a subscriber prove-up fund and a provider prove-up fund. The total pay-out from the combined prove-up funds will be $60 million. The general settlement fund will be the source of payment of any expenses incurred in administering the settlement, and any incentive payments to representative plaintiffs, attorneys' fees and costs awarded by the court. The settlement does not cover injunctive relief against Aetna that would cover future actions, and this aspect of the suit is working its way through the courts.

The Aetna settlement would cover patients who used out-of-network providers from March 1, 2001 to the present, and cover out-of-network providers from June 3, 2003 to the present. The litigation began in July 2007. The settlement must be approved by U.S. District Judge Stanley Chesler in Newark, New Jersey. It is reported that Aetna may void the settlement if too many people decide not to participate in it.

The suit followed the settlement by Aetna and other insurers with the New York Attorney General over their use of this database. The NY Attorney General had obtained an undertaking to fund an independent database, FAIR Health, to set rates. Aetna is the first plan to settle in those series of lawsuits. In 2009, UnitedHealth Group settled an earlier class-action suit for $350 million brought by the AMA Litigation Center and state societies regarding Ingenix and out-of-network payments. Additional class action suits against other companies that used this database are still pending. They include a case with California Psychological Association against the WellPoint/Anthem companies, and other cases with NJPA against CIGNA and Horizon Blue Cross Blue Shield of New Jersey.

Clinical Trials – FDA Releases Draft Guidances

On November 20, 2012, the Food and Drug Administration (FDA) issued two draft guidance documents related to the conduct of clinical trials, particularly with regard to modernizing clinical trial oversight. See 77 Fed. Reg. 69,631-69,633 (Nov. 20, 2012).

The first draft guidance is intended to assist institutional review boards (IRBs), investigators, and sponsors in determining whether the criteria for IRB approval of research are satisfied. The key consideration is whether the risks to subjects are minimized and reasonable in relation to anticipated benefits. The draft discusses the IRB's role in reviewing (1) the qualifications of the clinical investigator; (2) the adequacy of the facility in which the research will take place; and (3) the determination of whether an investigational new drug application or investigational device exemption application is necessary for the proposed investigation. When finalized, the guidance will supersede part of the FDA's January 1998 guidance entitled "Institutional Review Boards Frequently Asked Questions – Information Sheet Guidance for Institutional Review Boards and Clinical Investigators."

The second draft guidance addresses some of the difficult issues that arise when electronic source data are used in clinical trials. It is intended to provide guidance to sponsors, contract research organizations, data management centers, and investigators on capturing, using, and archiving electronic data in FDA-regulated clinical investigations. The guidance addresses the reliability, quality, integrity, and traceability of electronic source data.

The draft guidances are available at:
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM307779.pdf

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf

Final HIPAA Rule Expands Patients' Rights

The final HIPAA rule was published in the Federal Register on January 25, 2013. It expands certain individual rights, among which are the right to access protected health information that is maintained electronically and the right to restrict disclosures to health plans when paying out of pocket.

Previously, individuals enjoyed a right of access that was limited to the right to review or obtain copies of their protected health information to the extent it was maintained in the designated record set(s) of a covered entity. The Health Information Technology for Economic and Clinical Health Act expanded this right to cover a right to an electronic copy of protected health information that is maintained in an electronic health record. The final HIPAA rule further extends the right to all designated record sets maintained electronically. The covered entity must provide the requesting individual with access to the electronic information in the electronic form or format requested if it can be readily produced in that format. If not, the covered entity must provide it in a readable electronic form and format agreed to by both parties. For example, the parties could agree to a computer disc containing a PDF file, sending a secure email with a Word file, or providing access through a secure web-based portal. If the individual rejects all electronic format possibilities, a hard copy can be provided.

Other clarifications were made in the final HIPAA rule. For example, if the designated record set contains electronic links to images or data, those images or other data must be included in the electronic copy that is provided. If the record is in a mixed form – part paper and part electronic – the covered entity can provide the combination without being obligated to scan the paper documents in order to create a single electronic copy. Direct access is not required to be provided by the covered entity to the individual. Other clarifications were made in the final HIPAA rule.

The final HIPAA rule also addressed the right to restrict disclosure of protected health information to health plans when the individual is paying out of pocket. Covered entities will be required to comply with an individual's non-disclosure request if : (1) the disclosure is for the purpose of carrying out payment or health care operations and is not otherwise required by law, and (2) the protected health information pertains solely to a health care item or service for which the individual, or a person acting on behalf of the individual (other than the health plan), has paid the covered entity in full (and not dishonored). Providers, therefore, would need to flag or otherwise identify parts of a record that contain personal health information that is subject to a required restriction in order to make sure it is not inadvertently sent or made accessible to the health plan for payment or healthcare operations purposes. It is the patient, however, and not the provider, who is obligated to notify downstream health care providers of the disclosure restrictions. Provider contracts with an HMO that require the submission of claims may need to be updated to reflect the provider's new obligations to honor the non-disclosure restrictions.

Compulsory Licensing of Drugs

On March 12, 2012, the India Controller General Controller General of Patents, Designs & Trade Marks granted a compulsory license to Natco Pharma Limited (Natco), an Indian drug manufacturer, for Nexavar (sorafenib), an oncology drug made by Bayer AG. The Indian company, thereby, would be authorized to make and sell a generic copy of the patented Bayer cancer drug used for kidney and liver cancer. The Controller found Nexavar eligible for compulsory licensing under the Indian Patent Act because (1) the drug company was not meeting the reasonable requirements of the public, (2) the drug was not reasonably affordable and (3) the patent was not being sufficiently "worked" in India because it was not locally manufactured. The order was appealed by Bayer. Even though Natco would now be required to pay a royalty on net sales of the generic drug to Bayer, the order is cause for alarm for brand-name pharmaceutical makers who argue that this weakens the international patent system and endangers pharmaceutical research, because patents give manufacturers a limited period of marketing exclusivity that help them recover research and development costs. They fear a new supply of cheap generic drugs.

Under a World Trade Organization agreement known as Trade-Related Aspects of Intellectual Property Rights (TRIPS), which came into force on January 1, 1995, countries can issue compulsory licenses on certain drugs that are determined to be unaffordable to a large section of their populations. The TRIPS Agreement set forth specific provisions that recognize and in some cases regulate the granting of compulsory licenses and other non-voluntary uses of patents. Compulsory licenses have in recent years been issued in only a handful of countries – Ecuador, Indonesia, Brazil, and Thailand, and apparently most were for AIDS drugs. India is said to be only the second country, after Thailand, to grant a compulsory license to a cancer drug.

The decision was welcomed by advocates for cheaper generic medicines who see this as a model for developing countries. It is reported that Doctors Without Borders/Médecins Sans Frontières, for example, would like to see other compulsory licenses issued for drugs that treat HIV-AIDS, tuberculosis, hepatitis, and malaria. Indian generic drug makers have been able to produce and market generics for a fraction of the cost charged by multinational pharmaceutical companies that develop the drugs. The non-profit, non-governmental Washington group Knowledge Ecology International is another entity that has taken a position on this subject. Among other things, its statement discusses the evidence regarding the cost of research and development for Nexavar/sorafenib. The group challenges several of the claims made by Bayer in the proceedings, contending the claims are aggressive and sometimes contradictory, and discusses the relevance of research and development costs in making a product available at a reasonably affordable price.
(See http://keionline.org/node/1657)

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 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)*
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 HOTLINE

JALBCA's Hotline is available for attorneys recently diagnosed with breast cancer. To access the Hotline, call the SHARE Hotline (212.382.2111) and ask for referral to JALBCA in order to speak, confidentially, to a judge or lawyer who is a breast cancer survivor. Only a first name, telephone number and best time to reach you is needed.

JALBCA

c/o Jennifer Fiorentino
Executive Director
1324 Lexington Avenue, PMB 324
New York, New York 10128
www.jalbca.org

Address Service Requested