



# JALBCA

JUDGES AND LAWYERS BREAST CANCER ALERT

Vol. 15 No. 7

Editor: Martha L. Golar, Esq.

December 2011

## JANUARY JALBCA PROGRAM

- DATE:** January 17, 2012
- TIME:** 6:30 – 7:30 PM
- PLACE:** Skadden Arps Skate Meagher & Flom  
Four Times Square (between 6th Avenue & Broadway)
- TOPIC:** “Update on JALBCA’s Mammogram Van Program”
- SPEAKER:** Mary Solomon, Project Renewal, Scan Van Director

(This is a rescheduling of the November program.)

## ANNUAL SYMPOSIUM - FDA ACCELERATED APPROVAL PROCESS

JALBCA presented its sixteenth annual Ellen P. Hermanson Memorial Symposium on October 31 at the New York City Bar Association. The CLE sponsor for the program was the Women’s Bar Association of the State of New York. The non-judge panelists consisted of Nancy Neveloff Dubler, LLB (Montefiore Medical Center), Larry Norton, MD (Memorial Sloan Kettering Cancer Center), John Winter, Esq. (Patterson Belknap Webb & Tyler LLP) and Chan Lee, Esq. (Pfizer Inc.).

### *Background*

This year’s program focused on the FDA’s accelerated cancer drug approval process and also touched on the FDA medical device approval process. The hastened approval process permits drugs to be marketed before the stringent testing required by the FDA is fully completed. There is, of course, an ever-present public demand for new cancer drugs. The expedited methods

used by the FDA for drug approval came about largely in response to the AIDS crisis and the urgent call for access to drug trials for anti-viral agents. The FDA has essentially three mechanisms to expedite drug approval in certain situations: Accelerated Approval, Fast Track and Priority Review. Compassionate use allows a drug under investigation, and not approved, to be used in a given case. It is a fourth possible basis for patient use, but not for FDA approval. Accelerated Approval utilizes surrogate endpoints in clinical trials to demonstrate the effectiveness of the drug in issue. The term Priority Review refers to the drug application’s place in line relevant to the FDA approval process. The Fast Track method is designed to encourage the drug sponsor to consult with the FDA while it is developing the drug – it is a 14-year old process which requires subsequent trials to confirm a benefit for sustained approval.

While the chemotherapy drug Avastin (manufactured by Genentech) was not the topic for the evening, the panel discussed the controversy surrounding this drug because it is emblematic of the need to balance safety, responsible science and expedited access to cancer treatment. Avastin was approved for certain cancer indications, but not for metastatic breast cancer. It was approved by the FDA via the Fast Track procedure for metastatic breast cancer. Thereafter, the confirmatory Phase IV clinical trials did not bear out the hoped-for benefits for breast cancer patients. Genentech appealed the decision to withdraw this approval. Subsequent to the Symposium, the FDA Commissioner upheld the decision to withdraw approval of the use of this drug in metastatic breast cancer treatment in combination with Paclitaxel, for patients who had not received chemotherapy for metastatic HER2 negative breast cancer.

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## Panel Discussion

Nancy Dubler commenced the program by discussing bioethics and presenting her arguments for not changing how the FDA does business with respect to drug approval. She noted that the agency is starved for funds and under-staffed and, therefore, ill-equipped to do the job required of it. Good science requires money. She also noted that, in the U.S., a great deal of money is being spent to affect policy but that science should not be subject to politics. “Bad science pushes good science out of the way”, she said, and “bad science goes into policies that make some people rich and it is not useful to people’s health...medicine is too fraught with conflicts at the present time.”

Dr. Norton started by noting certain advances in cancer research during the past year – work regarding inflammatory cytokines and work in melanoma that resulted in life extension (he noted, however, that the approach probably will not shrink existing tumors, and the U.S. regulatory apparatus looks at tumor shrinkage). As to finding cures for cancer, he remarked that the pharmaceutical industry is doing what it is supposed to do to increase its shareholder value, but this may not translate into answers for science. He reminded the audience that \$7 billion was spent in 2011 for Halloween while only \$5 billion was devoted to all of cancer funding in the NCI annual budget for the year. Dr. Norton discussed the Avastin situation and noted that studies conducted subsequent to the Fast Track approval should have been done with taxol but instead were done with every drug other than taxol; the results were not good so that the FDA had no choice but to withdraw its Fast Track approval.

Judge Moskowitz inquired as to whether it will help or hurt patients to withdraw approval for Avastin use on triple negative metastatic cancer patients. Mr. Winter answered that there are lessons to be learned from the experience. The Judge pursued her line of inquiry by asking what lessons the industry learned. Mr. Winter responded that the risk-benefit analysis required between physician and patient differs from the global assessment that the FDA makes, where the agency balances the risks at a higher level than the individual level.

Chan Lee described the types of accelerated approval processes and clarified that Avastin is still approved for other cancer

indications and that the FDA decision does not prevent continued off-label use of the drug or reimbursement by CMS (and private payers, who tend to follow the CMS practices on reimbursement). The practical impact on the industry is that the manufacturer is prohibited from promoting the drug for the prohibited indication. Dr. Norton added that a judgment as to course of treatment is made at each chemo-administration, on a day-to-day basis, at the physician-patient level.



*Dr. Larry Norton, Memorial Sloan Kettering Cancer Center.*

Judge Freedman asked why the adverse risks for Avastin were considered so toxic for breast cancer and not for other types of cancer. Mr. Winter responded that if the FDA sees a certain level of efficacy, it is more tolerant of risk. Mr. Lee noted that only three drugs have been withdrawn or had their use restricted under the accelerated review process. Mr. Winter added that, under New York law, private insurance companies generally are obligated to reimburse for a medication so long as the relevant compendium lists the medicine for the indication in question and there is evidence-based medicine to support its use for the indication.

Judge Kaye then raised the issue of conflicts of interest, which Mr. Lee acknowledged became an issue for the FDA because industry critics argued that the FDA “made up its mind” in advance of the hearings on whether Fast Track approval should be withdrawn. He said that the risk-benefit analysis is inherently subjective — the U.S. struggled with the decision, Japan

ultimately approved the use of Avastin for breast cancer, and Europe approved it on the same data that was before the FDA. Dr. Norton commented that there is a tremendous bias in academia to get positive results, which also could be considered a conflict (e.g., if research results are produced the researcher will be promoted and money will be made, and yet this is not considered a conflict). He argued that replication of research results is what is important, not a person’s motivations. In his opinion, conflict rules do not prevent cheating; replication is what is required.

The panel next discussed the remedies available to industry. Mr. Winter answered that he could recall only one case in 35 years where a pharmaceutical company sued the FDA and it did not work out well for the company. He suggested that there are strategies they can pursue, however, to reduce the likelihood of reaching the point that Genentech reached with the FDA. For example, a company could work with the FDA to get more time or arrange for a restricted access program. Mr. Lee mentioned that it would be helpful to industry to obtain more definitive guidance when designing trials in the first instance. Dr. Norton noted that a more cooperative process with the FDA would be helpful, but transparency is important. Mr. Winter agreed that more is needed from industry to prove to the FDA that its data can be trusted and that industry is making the FDA a partner in the process.

Judge Freedman asked if other countries do a better job of approving drugs or withdrawing drugs more quickly. Mr. Lee answered that neither Europe nor Japan have a fast approval process, so the U.S. actually has a process that is more tailored to the needs of patients. Dr. Norton added that in Europe the cost of medicine (which is not a factor in the U.S.) is a consideration.

In conclusion, the panelists offered these thoughts. Mr. Winter mentioned the balance between patient autonomy and what the regulators say is needed for the general populace, which cannot always be reconciled. Mr. Lee noted that Avastin may be a problem but that it is a good problem to have. Dr. Norton urged more dialogue and transparency in the process and cooperation between pharma and regulators. He believes that Fast Track approval is important, as are confirmatory trials, and believes



Genentech will now conduct the trials they should have conducted earlier, which may be a good by-product of the experience. He also reiterated that the FDA does not have the support it needs to do its job and Americans need to be aware of this.

Finally, Co-President Edward Kornreich discussed patient options for reimbursement. He noted that under non-ERISA plans, New York has an external review requirement if insureds want to challenge insurance company denials of claims and, under ERISA plans, the new law passed by the Obama Administration requires that ERISA plans have such external review (except those plans that are grandfathered).

## NEWS ITEMS

### Myriad Litigation

This litigation was the topic of last year’s symposium and involves the testing for BRCA1 and BRCA2 genes. The plaintiffs in the Myriad litigation – the American Civil Liberties Union (ACLU) and the Public Patent Foundation (PUBPAT) - filed a petition with the United States Supreme Court on December 6, 2011, asking the Court to review the Federal Circuit’s split decision upholding certain patents on breast cancer genes, *i.e.*, patents on isolated DNA. The divided Federal Circuit Court, in July 2011, ruled that companies can obtain patents on the genes but invalidated patents on methods of comparing gene sequences. The District Court below had previously invalidated all

of the patents challenged by the plaintiffs.

The lawsuit against Myriad Genetics and the University of Utah Research Foundation, which hold the patents on the genes, charges that the challenged patents are illegal and restrict both scientific research and patients’ access to medical care and that patents on human genes violate the First Amendment and patent law because genes are “products of nature.” The plaintiffs have argued that the Myriad patents give them exclusive rights to perform diagnostic tests on the BRCA1 and BRCA2 genes, thereby preventing patients with hereditary breast and ovarian cancer from obtaining diagnostic care (*i.e.*, accessing alternate tests or obtaining comprehensive

second opinions about their test results) elsewhere and permitting Myriad to control the terms and cost of testing. The plaintiffs have also argued that the patent grants prevent researchers from even looking at the genes without first obtaining Myriad’s consent.

The ACLU reports that the original lawsuit was brought by researchers, genetic counselors, patients, breast cancer and women’s health groups, and medical professional associations representing 150,000 geneticists, pathologists and laboratory professionals. The petition can be viewed at the following website: [www.aclu.org/free-speech-womens-rights/association-molecular-pathology-v-myriad-genetics-inc-petition-writ](http://www.aclu.org/free-speech-womens-rights/association-molecular-pathology-v-myriad-genetics-inc-petition-writ)

## JALBCA COURTHOUSE ALERT

As part of the JALBCA 2011 Courthouse Alert, the screening program in October through December resulted in over 200 mammography screenings and one breast cancer diagnosis. Approximately one-quarter of these people required follow-up. An additional van is to provide services in April 2012. See the table, below, for information as to specific locations:

<b>Date</b>	<b>Location</b>	
10/5/2011	Suffolk County Family Court	14
10/6/2011	Bronx Supreme Court House	11
10/12/2011	NYC Supreme Court House	32
10/17/2011	Redhook Court House	9
10/18/2011	Richmond Supreme Court	17
10/19/2011	Kings County Supreme Court (Adams Street)	27
10/21/2011	Queens Family Court	25
10/27/2011	Harlem Justice Center	28
11/10/2011	Kings County Family Court House (Jay St)	31
11/23/2011	Richmond Supreme Court	15
12/1/2011	Bronx Housing Court	16
4/28/2012	Thomas Slater Center - White Plains	
	<b>TOTALS</b>	<b>225</b>

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## CALENDAR/CONTACTS

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### **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***

130 W. 42nd St., 22nd Fl.  
New York, NY 10036  
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**

c/o Jennifer Fiorentino  
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**Address Service Requested**

