Introduction
Breast cancer is often considered one of the treatable malignancies, especially if found at an early stage. Therefore, a potentially “missed diagnosis” can bring about fear, mistrust, and perhaps a “viable claim” (e.g., could have been found in an earlier, curable stage) for the increased risk of harm resulting from failure to diagnose and lack of timely treatment.

Inflammatory breast cancer (IBC) is an uncommon form of breast cancer and usually accounts for only one to six percent of all breast cancer diagnoses. It is a form of invasive breast cancer that progresses quickly and the prognosis is poor, even if the disease is apparently localized (Kleer, van Golen, & Merajver, 2000).

Three biological features make inflammatory breast cancer unique (United States Department of Health and Human Services, National Cancer Institute [NCI], 2006).
1. It progresses rapidly and is considered the most lethal type of locally advanced breast cancer.
2. It is highly angiogenic (new blood vessels provide nutrients to proliferating cells), angioinvasive (invading walls of blood vessels), and staged T4 immediately upon diagnosis.
3. Its aggressive behavior is characteristic of the tumor from its inception.

The designation “inflammatory” stems from the clinical appearance which mimics an acute inflammation of the breast. Inflammatory breast cancer is considered a clinical diagnosis. Pathologists rely on the finding of dermal lymphatic involvement to confirm the clinical diagnosis (Kleer et al., 2000). At first presentation, patients diagnosed with IBC are often treated for mastitis. While most breast infections respond to antibiotics, IBC does not, as the dermal involvement (inflammation) is not from infection, but from the blood vessel wall invasion, and dilated dermal lymphatic vessels clogged by tumor emboli. In fact, symptoms of IBC usually do not get better or worse from the antibiotics as an infection would. Therefore, when symptoms (i.e., mastitis, tenderness, nipple retraction) persist more than two or three weeks despite treatment, more definitive testing and a breast biopsy should be performed to determine whether cancer is present (NCI, 2006).

This case review illustrates some of the strategies used to defend a radiologist. It required testimony of not only expert radiologists, but also of a breast surgeon and pathologist.

The review involves a case in which our firm represented a radiologist from a small hospital. His role in this case, though seemingly minimal, became more primary once discovery was completed. This review will demonstrate how location of the tumor as well as the histology helped the jury find in favor of the radiologist.

The History
In October 1996, the plaintiff underwent a mammogram which revealed scattered calcifications, dense breast tissue, and benign changes that were considered stable. During a primary clinic visit in June 2000, a certified nurse practitioner and the clinic physician evaluated the plaintiff. At that time the plaintiff was 62 years of age, and the standard of care was a yearly mammogram. As it had been nearly four years since her last mammogram, a mammogram was ordered and completed in July 2000. There was no indication in the records that a breast examination was performed. The screening mammogram report was read by a radiologist as incomplete, needing additional imaging evaluation (representing a Category 0 according to BI-RADS standards). A nodular density was noted on the right side, and an ultrasound and spot compression view was ordered. The screening report noted a small nodule outer right breast which was new since October 1996.

In early September 2000, the plaintiff underwent additional testing at the local hospital. A radiologist (and the defendant in this case) performed a spot compression mammogram and right breast sonogram. The spot compression mammogram, as reported by the defendant radiologist, revealed a four millimeter nodular density localized on cone down magnification (used for a closer
view of an area of concern), smoothly outlined, and of low density radiopaque character, probably representing a small fibroadenoma or cyst. The sonogram noted, at the 10 to 11 o’clock position of the right breast, a 0.5 cm smoothly outlined nodule with no posterior acoustic shadowing which was solid in nature with no adjacent mass. The recommendation was for a repeat bilateral mammogram in one year.

The plaintiff continued with follow up at her primary care clinic in February, March, and April 2001 for routine physical examination, illness, and smoking cessation advice respectively, but without breast complaints. The medical records did not indicate that a breast examination was performed during those visits.

In November 2001, a clinic physician evaluated the plaintiff for pain, swelling, discoloration, and soreness of a lump in her right breast which the plaintiff had noticed about a week earlier, and had worsened. On physical examination, the left breast was normal. The plaintiff reported an exquisitely tender right breast inferior and lateral to the nipple. There was no dimpling of the skin and no retraction, but there was some mild erythema localized inferior to the nipple. The physical examination showed the lump to be rather soft and consistent with an underlying cystic area with no nipple discharge or lymphadenopathy. The assessment demonstrated mastitis and probable cyst in the right breast. The plan entailed a mammogram to be scheduled for early December 2001 and placing the plaintiff on a 14 day regimen of amoxicillin/clavulanate potassium (Augmentin®). Her yearly mammogram had been due in September of 2001, but had not been performed.

The plaintiff returned to her primary care physician at the clinic in early January 2002 complaining of pain with persistent redness and now swelling of her right breast, noting no improvement from the amoxicillin/clavulanate potassium (Augmentin®) treatment. The right breast examination demonstrated induration around the nipple with erythema and no definitive mass. The nipple showed mild retraction and a palpable, tender 1 cm right axillary lymph node, not noted on the examination documented 2 months prior. The physician ordered a different antibiotic, a hot pack to the affected breast four times per day, and a diagnostic mammogram with ultrasound (because the plaintiff had not made an appointment for the ordered mammogram in December 2001). After the mammogram was completed on January 9, 2002 and read by a staff radiologist as negative, the ultrasound was cancelled. When the plaintiff returned to her primary care physician the following week for an examination, the right breast remained indurated, but improved. The physician diagnosed mastitis and prescribed additional antibiotics with a follow up appointment in three weeks.

The plaintiff called her primary care clinic office at the end of January with a status report that her breast had not improved, and she was advised to undergo ultrasound and a biopsy. An ultrasound evaluation was ordered on 18 February 2002 and showed a hypoechoic [“...ultrasound image in which the echoes are weaker or fewer than normal...” (Stedman’s Medical Dictionary for the Health Professions and Nursing, 2005, p.707)] nodule at approximately 10 o’clock to 11 o’clock in the affected breast. No history or indication for the examination was documented on the report.

The primary care clinic physician referred the plaintiff to a consulting breast specialist in St. Louis, Missouri on February 20, 2002. The breast specialist noted that the plaintiff’s right breast demonstrated patchy distributed edema with erythema of the lower two-thirds of the breast. Induration of the breast existed between the 6 and 9 o’clock positions near the nipple. However, extensive edema interfered with locating a definitively palpable mass. The consulting physician noted evidence of peau d’orange, “a French term, meaning orange peel” (Stedman’s Medical Dictionary for the Health Professions and Nursing, 2005, p. 1094), which showed a swollen and pitted skin surface accompanied by stromal infiltration and lymphatic obstruction with edema. The physician also palpated within the axilla two distinct firm mobile areas of lymphadenopathy, with lymph nodes measuring to 3 cm. A biopsy revealed grade III/III infiltrating ductal carcinoma with extensive lymphovascular space invasion.

The consulting physician diagnosed the plaintiff with inflammatory breast cancer [T4] due to the clinical characteristics, which were supported by biopsy, and referred the plaintiff to a medical oncologist for further treatment. The tumor was estrogen and progesterone receptor negative and human epidermal growth factor receptor 2 (HER2/neu) overexpression as documented by immunohistochemical studies. The plaintiff underwent a regimen of anthracycline and taxane which led to marked reduction of edema and complete resolution of the peau d’orange. No underlying masses remained evident. The plaintiff completed four courses with this chemotherapeutic combination in May 2002, followed by four courses of docetaxel (Taxotere®) alone, completed in July of 2002.

On August 26, 2002 the plaintiff noted a new onset of erythema in the right breast. With the plaintiff’s chemotherapy regimen completed, she was referred to a breast surgeon for further treatment. The surgeon scheduled the plaintiff for a right modified mastectomy in September 2002. The pathology report revealed infiltrating ductal carcinoma, grade 2 of 3, measuring 0.9 cm with involvement of 14 of 15 axillary nodes and extensive involvement of axillary angiolymphatic spaces and focal extension beyond her lymph node capsules. A consulting radiation oncologist explained that the plaintiff was at high risk for distant and loco regional recurrence due to the presence of multiple positive lymph nodes, the large size of her primary tumor prior to chemotherapy, the presence of inflammatory disease, as well as the extracapsular nodal extension seen on dissection.

The Case
In October 2002 the plaintiff filed suit against the radiologist who interpreted the spot compression and ultrasound radiographs in September 2000, the hospital where those radiographs were performed, the corporation that owned the
hospital, and the plaintiff’s primary care clinic and physicians. This article addresses only the defense of the radiologist who interpreted the spot compression and ultrasound radiographs. The allegations were that the radiologist:

- Misread the mammogram
- Misread the sonogram
- Failed to diagnose the plaintiff as having infiltrating ductal carcinoma
- Failed to recommend a biopsy of the plaintiff’s right breast to rule out carcinoma
- Misinterpreted the nodule as benign
- Was negligent in his recommendations, given the facts surrounding the plaintiff’s illness history

In January 2003 the defendant radiologist met with his attorney to discuss his involvement in treatment of the plaintiff. His only involvement was to perform a spot compression film and ultrasound of the right breast in September 2000. The plaintiff had undergone a screening mammogram which one of his partners read in July 2000. After review of those specific mammography radiographs, and all mammograms taken prior to and after that date, the defendant radiologist maintained his initial interpretation that the nodule he evaluated remained in the right breast even after the biopsy for suspected breast cancer (the cancer was found in a different part of the breast). Accordingly, he believed that a benign finding was indeed appropriate and was not cause of concern to the physicians who suspected the plaintiff had breast cancer.

Two radiologists, both breast imagers from separate institutions, were consulted to review the films read by the defendant. Both consulting radiologists agreed with the interpretation made by the defendant radiologist. The spot film of September 2000 showed the nodule which had smooth margins and did not appear suspicious. The ultrasound, which both radiologists agreed was not a clear film, showed the oval shaped nodule, which also did not appear suspicious.

The plaintiff’s expert witness radiologist practiced at a women’s center for radiology located in Florida. He was not sure when the plaintiff developed breast cancer in her right breast, but believed it was present in July 2000, two months before the defendant radiologist’s involvement. He stated that the previous mammogram of 1996, which he believed showed an ovoid mass measuring five millimeters compared to the mammogram of July 2000, indicated a small interval change in terms of measurement. The plaintiff’s expert witness radiologist attested that as of September 2000, the mass comprised a six to seven millimeter lesion with irregular borders and that this lesion represented a small invasive cancer, probably infiltrating ductal carcinoma. He further asserted that between September 2000 and January 2002, the cancer changed to inflammatory breast cancer. The problem with this assertion is that inflammatory breast cancer is “inflammatory” from inception. IBC is an aggressive form of breast cancer that is highly angioinvasive and angiogenic, and these characteristics are present from its inception. Signs and symptoms are rapidly progressive with a median duration before diagnosis of less than two months (Kleer et al., 2000).

The main criticism made by the plaintiff’s expert witness radiologist of the defendant radiologist was that he recommended the plaintiff return in 12 months for follow up imaging. The plaintiff’s expert radiologist believed that the defendant radiologist identified the lesion as a solid lesion rather than cystic, and that the defendant should have commented that the borders were somewhat irregular and suspicious, possibly indicating cancer. (The defendant actually read and reported that the nodule represented either a small fibroadenoma or cyst). The plaintiff expert witness radiologist believed that the standard of care dictated a recommendation for the plaintiff to return no later than six months for a subsequent evaluation.

The defense expert radiologists were then asked to review and compare the radiologic films from October 1996, July 2000, September 2000, January 2002, and February 2002 overall, mammogram to mammogram, and ultrasound to ultrasound. Both defense expert radiologists requested the original films for review. However, it was discovered the original films had been given to the plaintiff’s attorney who indicated the radiographs were lost in the mail when sent to the plaintiff expert radiologist for review. Second generation copies of the radiographic films were obtained for the radiologists to review. When obtaining films, rather than copies on disk, first generation copies are always the “clearest” to review. There is no overshadowing on a first generation copy as there is when, for example, a copy of a copy is made. The more copying that is done, the muddier the films become – and they ultimately become unreadable.

Both defendant expert radiologists, each separately, reviewed the 1996 mammogram to determine the location a 5 mm ovoid mass reported by the plaintiff’s radiology expert. Both defendant expert radiologists reported no such mass was visible and neither found anything on the radiographic film that could have been interpreted as a lesion. They reviewed the July 2000 mammogram and noted a nodule measuring about five to six millimeters, but it was not irregular. The reading radiologist in July 2000 noted this nodule to be “new” when compared to the 1996 film and therefore, by inference, that reading radiologist also did not note a lesion in the 1996 film. The defense expert radiologists reviewed the September 2000 spot film performed by the defendant radiologist and noted a nodule with a portion of the margin not visible, but that the visible margin was smooth. Additionally, the defendant expert radiologists reviewed the September 2000 ultrasound and noted the nodule as being oblong and unsuspicious.

The American College of Radiology (ACR) 2000 guidelines recommend a repeat mammogram one year after unsuspicious (or benign) findings (ACR, 2002). This was recommended by the defendant radiologist, in accordance with the dictated standard of care.

Separately, each defendant expert radiologist reviewed the January 2002 mammogram. While both noted significant changes in this radiographic film, they interpreted the findings...
as benign. Both further noted an enlarged lymph node in the axillary region which had not been reported in the January 2002 mammography report. Each separately reviewed the February 2002 ultrasound and noted diffuse shadowing in the area of the areola as well as inflammatory changes and thickened skin – indications that are highly suspicious for a breast cancer. Important in this 2002 radiographic film was that the five to six millimeter nodule was still located in the same place it had been seen in September 2000 and was unchanged. Therefore, both defendant expert radiologist witnesses believed this nodule was not cancerous.

Approximately one month before trial, the defendant radiologist’s legal counsel contacted the plaintiff’s surgeon, who was not being called as a witness in this case by either side, to discuss the case. On interview, the plaintiff’s surgeon recalled that she had only reviewed the 2002 diagnostic radiographic films when she had met with the plaintiff prior to her surgery. The defendant radiologist’s legal counsel scheduled a meeting with the surgeon and brought the radiographic films of July 2000 (mammogram) and September 2000 (spot compression and ultrasound) for her to evaluate. Based on her observation (the nodule mentioned in both reports), and stipulating that she was not a radiologist, the surgeon asserted that she would not have been alarmed by what she observed and would not have chosen to perform a biopsy.

The plaintiff’s surgeon stated she did not believe that the nodule found on the July 2000 mammogram and the September 2000 spot compression radiographic film was a source for the IBC diagnosed in February 2002. The surgeon also stated that diffusion from disease would have markedly changed the appearance of the nodule, thus making it unidentifiable by 2002. She stated, “IBC does not slowly smolder for two years, but is in fact incredibly fast growing.”

Further, the pathology report from the mastectomy performed in September 2002 indicated that a 0.9 cm nodule was found in the posterior central locale of the right breast. (As previously mentioned, mammogram and ultrasound reports from September 2000 revealed a five to six millimeter nodule in the right outer breast.) The surgeon believed that, post chemotherapy, this nodule was most likely residual from the original tumor. She also indicated that based on location of the inflammation noted at diagnosis, this area was very likely the original source of the cancer, and that the nodule in the right outer breast was simply a benign process which, had it been otherwise, would have been noted in the mastectomy September 2002 pathology report.

The Trial
At trial, the plaintiff’s experts (a surgeon and radiologist) and her treating medical oncologist presented the following key points:

- Tumors generally grow in size and would be expected to grow in the normal course of disease progression.
- It is possible to have cancer in one breast and not the other. Further, one can have a non-cancerous mass and a different cancerous mass, both concurrently in the same breast.
- The pathology report neither asserts nor denies the previously detected nodule was the subsequently detected cancer.
- Those testifying on behalf of the plaintiff believed a biopsy in September 2000 would have revealed a 4 mm invasive ductal carcinoma. At that point (Stage 1), one would expect a 95 % five-year survival rate.
- Seventy percent of breast cancers occur in the outer part of the breast, closest to the axilla.
- Chest wall recurrence carries a 5 to 10 % five-year survival rate.
- The risk of recurrence in any IBC is 50 % at the time of completion of radiation. One-half of patients detected with IBC develop metastatic disease.
- The lymph nodes were removed to reduce the likelihood of recurrence in this patient and to evaluate the efficacy of preoperative chemotherapy. In this patient, 14 of 15 nodes proved positive for tumor at the time of mastectomy and post chemotherapy.
- A patient is never “cured” of breast cancer.
- Two equally trained and qualified radiologists may examine a film and interpret it differently, but if this happens, one of them is probably deviating from the standard of care.
- There is evidence of right breast cancer dating to July 2000 which some examiners might have diagnosed as early as June 2000.
- A recommendation of repeat bilateral mammograms in one year is misleading, because it suggests that there was no significant finding.

The defendant’s experts (a radiologist and pathologist) and the plaintiff’s treating breast surgeon presented diagrams indicating where the nodule was located in the July 2000 mammogram and where the tumor was found in the mastectomy specimen. They asserted the following key points:

- The plaintiff’s cancer was not related to the nodule found in September 2000. This nodule was stable for at least 15 months.
- Biopsy is not indicated for small fibroadenomas of less than 0.5 cm.
- Biopsy is appropriate only when fibroadenomas are large, about three times larger than the one noted in this case, or if they grow over time.
- Infiltrating ductal carcinoma with extensive lymphovascular space invasion was found below the nipple in the deep part of the breast.
- The defendant radiology expert witness stipulated that the defendant acted within the standard of care in his reading of the spot compression and ultrasound performed in September 2000.
- If the nodule found in September 2000 had been cancerous, it would have changed in size, shape, and location over time, but it did not.
• This nodule was not consistent with malignancy and appeared to be benign, contrary to testimony by the plaintiff’s radiology expert.
• Fibroadenomas commonly appear in women of this age.
• One year follow up evaluation was appropriate.
• The nodule biopsied by the plaintiff’s surgeon was located in the midline of the breast behind the nipple and was not in the same area as the nodule previously discussed which was located between the 10 to 11 o’clock positions.

The trial took place over a three-day period. The co-defendant (plaintiff’s primary clinic physician) entered a Motion for Directed Verdict at the close of all evidence, and was sustained, indicating that the plaintiff was unable to prove a case against him. The defendant radiologist’s Motion for Directed Verdict was over-ruled, indicating that the plaintiff could show cause. The case went before the jury on day three at 3:05 in the afternoon and, after deliberating only 30 minutes, a verdict in favor of the defense was returned.

Discussion
Breast cancer, as well as all cancers, is often a topic filled with emotion in a courtroom because of the long term consequences and survival. In this case, the plaintiff was present at the trial, having surpassed the five-year survival statistics.

When evaluating an oncology case, it is important for the legal nurse consultant to have a thorough knowledge about the specific cancer including symptoms, tests required for diagnosis, pathology (e.g. grading, immunohistochemistry panels, and differentiation), staging, and treatments. It is also important to determine early identification and prognosis.

In this case it was important to obtain all of the previous mammograms for comparison from the various institutions. This was essential in order to determine exactly when this nodule was first seen, and if there were any new findings. A significant and important point in this case was the nodule remained in the same location after biopsy. Because breast cancers change over time, and because IBC develops rather quickly, it was highly unlikely that this was the origin of the cancer.

The legal nurse consultant provides strategic expertise while researching specific information related to the case in question and a thorough comprehensive review of all medical records from all sources. By doing so, comparisons can be made based on the evidence.

References

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