Stinson v. USA Doc. 62

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF SOUTH CAROLINA COLUMBIA DIVISION

| Beverly Diane Stinson, |) | Case No. 3:01-1987-MJP |
|---------------------------|---|----------------------------------|
| Plaintiff, v. |) | |
| |) | FINDINGS OF FACT, CONCLUSIONS OF |
| United States of America, |) |) LAW, AND ORDER))) |
| Defendant. |) | |
| |) | |

The present action was brought under the Federal Tort Claims Act ("FTCA"), 28 U.S.C. §§ 2671-2680 and 28 U.S.C. § 1346(b). Plaintiff, Beverly Diane Stinson ("Plaintiff"), seeks money damages from the United States of America ("Defendant") for alleged medical negligence on the part of employees of Defendant in administering medical care to her at the Moncrief Army Community Hospital ("MACH") located at Fort Jackson, South Carolina.

The Court conducted a bench trial on July 21st through July 24th of 2003. After carefully considering all testimony and arguments presented at the trial of this matter, and taking into account the credibility and accuracy of the evidence, and studying the applicable law, this Court concludes that Defendant is entitled to judgment.

FINDINGS OF FACT

The Court makes the following findings of fact by preponderance of the evidence and pursuant to Rule 52 of the Federal Rules of Civil Procedure¹:

¹ To the extent any findings of fact constitute conclusions of law, they are adopted as such; to the extent any conclusions of law constitute findings of fact, they are so adopted.

- 1. During the relevant period of time in this matter, Plaintiff was married to an Army serviceman who was stationed at Fort Jackson, South Carolina². As a military dependent, Plaintiff was entitled to receive medical care at MACH located at Fort Jackson. Bench Trial Transcript pp. 2-86 2-88.
- 2. On August 22, 1994, Plaintiff appeared at the MACH Women's Health Maintenance Clinic (OB-GYN Clinic) for a gynecological examination. At the time, Plaintiff was 41 years and 11 months of age. Plaintiff was seen by Barbara C. Leverette, a Nurse Practitioner in the OB/GYN clinic.³
- 3. Nurse Leverette conducted a gynecological examination of Plaintiff, including a clinical breast examination ("CBE"). During the CBE, Nurse Leverette manually palpated Plaintiff's breasts to screen for tissue abnormalities.
- 4. During the CBE, Nurse Leverette palpated a dense mass in Plaintiff's left breast. Nurse Leverette noted that Plaintiff had a "dense mass @ 1:00 left side; right WNL." Nurse Leverette further noted "negative axillary nodes," "non tender," "near menses," and

² The serviceman and the plaintiff were married to each other from September 1978 until they divorced in June 2001. Bench Trial Tr. p. 2-24. Plaintiff is not claiming that her divorce was the result of her breast cancer. Bench Trial Tr. pp. 2-24 — 2-25.

³ Plaintiff testified that she remembers the woman who performed the breast examination and PAP smear was "a white lady with short salt and pepper hair." Bench Trial Tr. 2-31. Nurse Leverette is African-Americian. Nurse Leverette testified that she does not remember Plaintiff, but that she does recognize her handwriting on a medical examination form denoted Moncrief Form 201, P1.'s Ex. 1, and on a Radiologic Consultation Request/Report form, P1.'s Ex. 2. Bench Trial Tr. pp. 2-126 — 2-127, 2-137. Nurse Leverette testified that Moncrief Form 201 was used by the OB/GYN clinic in 1994 for "a well women's maintenance check." Bench Trial Tr. P. 2-125. Based on these medical records, Nurse Leverette was able to testify about the care and treatment she provided to the plaintiff on August 22, 1994. Bench Trial Tr. pp. 2-125 —2-128.

⁴ "Negative axillary nodes" meant that the clinician had palpated under both arm pits and felt for swollen lymph nodes in the axillary area. Bench Trial Tr. p. 2-131. Nurse Leverette testified that the nodes in the axillary react to breast problems that "could be serious or concerning." Bench Trial Tr. pp. 2-132—2-133.

⁵ "Near menses" meant that the patient was within 10 days of her menstrual cycle. Bench Trial Tr. p.2-130 - 2-131. Nurse Leverette testified that the reason she wrote on Moncrief Form 201 that Plaintiff was "near menses" was because, "it is quite common that during a breast exam, if a patient is near the menstrual cycle, because of

"breast self examination reviewed." Pl.'s Ex. 1. Nurse Leverette identified a plan for further care and follow up of the Plaintiff: "①Mammogram slip ②Follow up with MD for increased blood pressure & asthma ③ Return for Dr. Browning to evaluate fibroids & breast (L) this week or after next menses early Sept. ④Smoking cessation discussed." Nurse Leverette also wrote, "Patient voices understanding." Pl.'s Ex. 1.

5. Nurse Leverette testified that she did not believe that the dense mass she felt in Plaintiff's breast was concerning for cancer. Nurse Leverette testified that the terms "dense mass" and "dense area," as she uses them, mean the same. Bench Trial Tr. p. 2-138. She testified that, to her, these terms mean that there is an area of breast tissue which feels firmer than surrounding breast tissue. Bench Trial Tr. p. 2-141. She testified that "just feeling a density" in a patient's breast is not something that concerns her as to it possibly being a cancer. Bench Trial Tr. p. 2-146. Nurse Leverette believes that a breast tissue density does require some follow up action. When asked to state what would be the proper steps to take in her view, Nurse Leverette testified:

the influence of the hormones of [sic] the breast tissue, sometimes women have increased swelling, tenderness, and perhaps nodularity." Bench Trial Tr. pp. 2-131 - 2-132. Nurse Leverette further testified, "women's hormones can fluctuate and it can have a profound effect on the nodularity of the breast." Bench Trial Tr. p. 2-140.

- A. The next step would have been a mammogram and a recheck."
- Q. And did you prescribe a mammogram and a recheck?
- A. I did.
- Q. Would the next step be a breast biopsy?
- A. Not at all.
- Q. And why do you say that?
- A. Well, that's why you use the mammogram, you have to identify an area to be biopsied. And like I said, certain times of the month a woman's breast may have nodularities, meaning small areas that feel thicker, and you may be concerned about it. But I have seen many times I have checked a patient again after the menstrual cycle, those densities are gone.

Bench Trial Tr. p. 2-142.

- 6. As part of Plaintiff's follow up care, on August 22, 1994, Nurse Leverette made a written request for a radiologic consultation. Nurse Leverette wrote on the request for a mammogram: "Dense area 1:00 left breast." P1.'s Ex. 2. Nurse Leverette testified that she was alerting the radiologist to what she had found. Bench Trial Tr. p. 2-147.
- 7. The Radiologic Consultation Request/Report form, P1.'s Ex. 2, shows that Plaintiff's mammogram was requested on August 22, 1994, and that it was performed on August 23, 1994. Nurse Leverette testified that this was not an urgent, emergency mammogram. Bench Trial Tr. p. 2-143. She testified that if it had been, she would have noted that fact in the medical records. Id.
- 8. The mammogram film was read by radiologist Ann Davis, M.D. Dr. Davis' radiology report reads as follows:

⁶ A mammogram is a procedure by which the breasts are x-rayed. X-ray films produced during the procedure are then interpreted by a radiologist.

"BILATERAL MAMMOGRAMS: Using film screen technique and a dedicated mammography unit, mammography is performed in the craniocaudal and oblique lateral projections bilaterally. There are no prior films available.

The architecture of the breasts is symmetrical. The breasts are relatively dense. There are a few scattered benign appearing calcifications present. There are no suspicious calcifications. There is no secondary change of malignancy.

IMP: No radiographic evidence of malignancy.

A. DAVIS, MD/mf

Mammography has a significant false-negative rate estimated to be 10%, even with clinically palpable breast carcinoma. The clinical decision regarding the management of a solitary palpable breast mass should be little affected by the mammographic diagnosis."

P1.'s Ex. 2.

- 9. Nurse Leverette testified that in the normal course of business she would have seen a copy of the mammogram report because she was the clinician who ordered the test. Bench Trial Tr. p. 2-145. She testified that the mammogram report was negative for cancer and that it was further evidence to her that Plaintiff did not exhibit a serious or concerning problem in her left breast. Bench Trial Tr. p. 2-146. Nurse Leverette testified that the mammogram report gave her no cause to refer the plaintiff to a surgeon for a breast biopsy consultation. Id.
- 10. After the mammogram, Plaintiff was asked to return to the OB-GYN Clinic so that Dr. Browning, the chief of the clinic, could consult with her about her breast. Bench Trial Tr. p. 2-31. Dr. Browning asked Plaintiff questions about her family history for cancer, which she told him was negative, and examined her breasts. Dr. Browning told Plaintiff that

he wanted to see her again when her menstrual cycle started.⁷ Plaintiff told Dr. Browning that her menstrual cycle would start on September 2, 1994, and she received an appointment slip from the OB-GYN Clinic for September 2, 1994.

- 11. On September 1, 1994, Plaintiff was seen in the MACH Internal Medicine Clinic by Nurse Practitioner James Dunkin. P1.'s Ex. 103. On that visit, Plaintiff told Nurse Dunkin that the OB-GYN Clinic had found fibroids in her uterus and a "lump" in her left breast.⁸
- 12. On September 2, 1994, Plaintiff came to the OB-GYN Clinic for the follow up examination ordered by Nurse Leverette. Dr. John B. Browning examined Plaintiff. Dr. Browning testified that Plaintiff "was referred to me by Ms. Leverette for menstrual bleeding abnormality, as well as a concern of an abnormal breast exam." Bench Trial Tr. p. 3-96. Dr. Browning testified that he examined Plaintiff's breasts and did a pelvic exam to determine the size and shape of her uterus. Bench Trial Tr. p. 3-96. He testified that he did not find any breast nodule or lump, or anything else alarming for breast cancer. He testified that he did find "increased nodularity." Bench Trial Tr. p. 3-101. Dr. Browning explained that the

⁷ There is no written medical record of this breast examination by Dr. Browning done on August 23, 1994. Plaintiff first testified that she does not remember what Dr. Browning told her that day about her breasts, but that she does remember that Dr. Browning told her to return to see him when her menstrual cycle started, "so he could feel if there were any difference in my breast at that time." Bench Trial Tr. p. 2-32. Plaintiff later testified, after her memory was refreshed on cross-examination by her affidavit, that on the same day she got the results of her mammogram, "Dr. Browning came in and examined my breasts himself and told me everything was fine." Bench Trial Tr. p. 2-96.

⁸ Trial testimony by both Nurse Leverette and Dr. Browning dispute Plaintiff's claim that a "lump" had been found in her breast. The medical records state that on August 22, 1994, Nurse Leverette palpated a "dense mass," which she also termed a "dense area." Nurse Leverette testified that if she had felt a "distinct mass," or a "lump," that she would have so noted and would have described its characteristics in the medical records, such as its shape, firmness, whether mobile or fixed, tender or not tender, and whether the patient was aware of it. Bench Trial Tr. p. 2-149 - 2-150. She testified that it is "very unlikely" that she told Plaintiff that she had a lump because, "it was not a lump, it was a dense area." Bench Trial Tr. p. 2-151. Regarding Dr. Browning, he testified that he does not use the term "lump" in his clinical practice. Bench Trial Tr. p. 3-102.

increased nodularity was a bilateral, fibrocystic condition, which he found in both of Plaintiff's breasts. Bench Trial Tr. p. 3-101. He testified that the condition is consistent with tissue changes found in a pre-menopausal woman resulting from hormonal fluctuations, and was not a condition worrisome for cancer. Dr. Browning testified that it was not the standard of care to make a referral of Plaintiff for a biopsy of her breasts under these circumstances. Bench Trial Tr. pp. 3-111 - 3-112.

13. Based on his September 2nd examination of Plaintiff, Dr. Browning wrote in the patient's medical records the following:

Here recheck of uterine size and complaints of metrorrhagia. Cycles q 2-3 weeks. Also with questionable lump in left breast by Ms. Leverette at last exam. Mammogram within normal limits 22/August/94. Objective Findings: Increased nodularity but without discrete mass. No skin changes, no discharge. Bimanual: Uterus, approximately 8-10 weeks, mobile and nontender. Assessment: Metrorrhagia, probable leiomyoma. Plan: Follow up 9/September for endometrial biopsy and repeat breast exam.

P1.'s Ex. 3.

Dr. Browning explained that "nodularity" is "not a term that we use to describe a suspicious lesion or a suspicious mass." Bench Trial Tr. p. 3-10l. Dr. Browning testified that to describe a suspicious lesion or mass, "I typically use the term 'discrete mass'." <u>Id.</u> Dr. Browning testified that, "I might further characterize that as to how it feels. It might be a cystic mass or a solid mass. I might characterize it as far as its mobility, mobile or fixed. I might describe it as painful or non-painful, and I would usually give a size and a location." Bench Trial Tr. p. 3-101.

14. Plaintiff testified that when Dr. Browning examined her on September 2, 1994, that he only examined her breasts and did not conduct any examination regarding the

uterine fibroids which had been causing abnormal bleeding.⁹ Bench Trial Tr. pp. 2-52 - 2-54. Plaintiff testified that Dr. Browning told her, regarding her breasts, that "he did not feel...anything to alarm him, that from the mammogram and from the two exams that I was fine." Bench Trial Tr. p. 2-53. Plaintiff also testified that on September 2, 1994, Dr. Browning told her that she did not need another mammogram for 5 years.¹⁰ Finally, Plaintiff testified that she was not told of a follow up examination for her on September 9, 1994.¹¹

- 15. Plaintiff did not return to the OB-GYN Clinic on September 9, 1994.
- 16. Following her examination on September 2, 1994, Plaintiff used MACH facilities a number of times for various medical problems. Bench Trial Tr. pp. 2-28, 2-29, 2-80, 2-81, 2-88. On April 5, 1995, she underwent a breast examination in the Internal Medicine Clinic, which was noted in the medical records as being a negative breast examination. Def.'s Ex. 17. Up until March 11, 1996, Plaintiff did not complain to MACH personnel about problems with her breasts. See Bench Trial Tr. pp. 2-88 2-90.
- 17. Plaintiff testified that in December 1995 or January 1996 she "woke up one morning and my breasts was changed." Bench Trial Tr. p. 2-44. She noticed that the shape of her breasts did not look the same. <u>Id.</u> She testified that, "the end of December, the beginning of January, is when I noticed the dimple." Bench Trial Tr. p. 2-47. She testified

⁹ Dr. Browning testified that he was sure that he did both a breast examination and a pelvic examination. He testified that he knows he did these examinations because he charted them and that he does not chart examinations which he has not made. Bench Trial Tr. p. 3-96 - 3-97. See P1.'s Ex. 3.

¹⁰ Dr. Browning testified that he would have told her she needed a mammogram every year. Bench Trial Tr. p. 3-116.

¹¹ The clinical note written by Dr. Browning on September 2, 1994, contains the entry, "Plan: Follow up 9/September for endometrial biopsy and repeat breast exam." Dr. Browning testified that the fact that he made this entry containing a set date for the follow up examination means that he had determined that his calendar permitted him to see the plaintiff on that date and that he believed that he would have told her to return on that date. Bench Trial Tr. pp. 3-103 - 3-105.

that she tried to get in touch with the Internal Medicine Clinic, planning to ask a clinician to get her a referral to the OB-GYN Clinic. Bench Trial Tr. p. 2-45. Plaintiff testified that she could not get through on the telephone. She testified that because she could not get through to the Internal Medicine Clinic, that she decided to go to the MACH "walk-in" clinic. Bench Trial Tr. p. 2-45.

- 18. On March 11, 1996, Plaintiff came to the MACH Primary Care Clinic, which is what plaintiff calls the "walk in" clinic. <u>Accord</u>, Bench Trial Tr. 2-89. Her complaint was that her left breast showed retraction. Def.'s Ex. 7, p. 26. Plaintiff was examined, and a mammogram was ordered. Id.
- 19. On March 15, 1996, a mammogram was done on Plaintiff and the films showed changes from the August 1994 mammogram films. The mammogram radiology report notes a "3 cm spiculated mass in the left mid breast" and a "2 cm dense lymph node in the left upper outer quadrant." The films were interpreted as "very suspicious for malignancy." <u>Id.</u>
- 20. On March 18, 1996, Plaintiff underwent a physical exam and surgical consultation. On that date, Plaintiff met with James D. Reid, M.D., a MACH surgeon. Dr. Reid testified that during Plaintiff's surgical consultation with him on March 18, 1996, she gave a history of "dimpling in left nipple" since November or December 1995, and of noting lumps in the left axilla (left arm pit) since December 1995. Bench Trial Tr. p. 3-139; Def.'s Ex. 7, pp. 28 & 40.
- 21. On March 18, 1996, Dr. Reid conducted a hands-on physical examination on Plaintiff, to include a clinical breast examination. Bench Trial Tr. p. 3-139. Dr. Reid

explained that CBEs are part of his clinical practice as a general surgeon, since general surgeons provide treatment for breast disease. <u>Id.</u> Dr. Reid's physical examination of the plaintiff noted "dimpling of the nipple," and identified a "discrete mass" in Plaintiff's left breast which was "suspicious for breast cancer." Bench Trial Tr. pp. 3-139 - 3-140. A fine needle aspiration of the mass "was non-diagnostic of cancer." Def.'s Ex. 7, p. 40; Bench Trial Tr. p. 3-142. Consequently, Dr. Reid did an excisional biopsy of Plaintiff's left breast on March 28, 1996. The pathology report of the tissue sample taken during the excisional biopsy confirmed an infiltrating ductal carcinoma. Def.'s Ex. 7, pp. 42, 48, 54; Bench Trial Tr. p. 3-143.

- 22. Following the confirmation of breast cancer, Dr. Reid consulted with Plaintiff and advised her that he would not be able to perform a lumpectomy or breast conservation surgery because he would be unable to gain an adequate margin of normal tissue between the mass and the nipple areolar complex. Bench Trial Tr. p. 3-144. Dr. Reid testified that "breast conservation surgery" is an attempt to remove the tumor while leaving an adequate margin of normal tissue to insure that a "functional breast" remained. Bench Trial Tr. p. 3-147. Dr. Reid testified that "the nipple areolar complex is an intrinsic portion of a normal appearing breast." Bench Trial Tr. p. 148. Consequently, Dr. Reid recommended to Plaintiff that she undergo an modified radical mastectomy, in which the breast, the nipple areolar complex, and some of the lymph nodes from the axilla would be removed. Bench Trial Tr. p. 3-148.
- 23. Plaintiff accepted Dr. Reid's recommendation. Bench Trial Tr. p. 3-149. Thereafter, on April 4, 1996, Dr. Reid performed a modified left radical mastectomy on

- Plaintiff. Plaintiff testified that Dr. Reid told her that the nipple of her breast could not be saved because the tumor was located at the nipple, and that was why he did a modified radical mastectomy. Bench Trial Tr. p. 2-85 2-86.
- 24. Dr. Reid marked tissue samples taken during the surgery and the samples were sent to a pathologist. Bench Trial Tr. p. 3-150. Pathology reports from analysis of the breast tissue and axillary contents indicated a T2 tumor with 12 of 17 axillary nodes positive for ductal carcinoma, with no distant metastasis. Bench Trial Tr. p. 3-151; Def.'s Ex. 7, pp. 56-59, 64-65.
- 25. In May 1996, Plaintiff moved to New York City and lived with her mother for a period of time, Bench Trial Tr. p. 2-104, until moving into her own apartment. Plaintiff received post-surgical chemotherapy and other health care in New York City. Bench Trial Tr. pp. 2-99 2-100. She underwent chemotherapy treatments from June 1996 into March 1997. Bench Trial Tr. p. 2-56. For five years following her chemotherapy, through June, 2002, Plaintiff was on a sustained medical regimen of Tamoxifen, which is an estrogen suppressing drug designed to reduce the risk of cancer recurrence. Bench Trial Tr. pp. 2-62, 4-70.
- 26. At the time of trial, Plaintiff continued to reside in New York City and her medical condition did not show any evidence of recurrent cancer. Bench Trial Tr. p. 2-75.

CONCLUSIONS OF LAW

1. The United States is the proper defendant in this action pursuant to 28 U.S.C. § 1346(b) and the Federal Tort Claims Act, 28 U.S.C. § 2671 et seq.

- 2. This Court has jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331 and 1346.
- 3. Under the FTCA, the United States may be held liable for personal injury caused by the negligent act or omission of employees of the United States acting within the scope of their employment under the same circumstances where the United States, if a private person, could be responsible to the claimant in accordance with the law of the place where the act or omission occurred. 28 U.S.C. §§ 1346(b) & 2674. As a waiver of sovereign immunity, the FTCA must be strictly interpreted and applied. United States v. Sherwood, 312 U.S. 584, 590 (1941); Gould v. U.S. Department of Heath & Human Services, 905 F.2d 738, 741 (4th Cir 1990) (en banc).
- 4. Under the FTCA, procedural mailers are governed by federal law. <u>Id.</u> In regards to substantive legal issues, the FTCA directs the court to look to the laws of the state where the act or omission occurred in order to determine whether a complaint in negligence warrants relief. <u>Dumont v. United States</u>, 80 F.Supp.2d 576, 581 (D.S.C. 2000); <u>Todd v. United States</u>, 570 F. Supp 670, 677 (D.S.C. 1983). <u>See also 28 U.S.C. § 2671</u>. In this case, Plaintiff alleges negligence at Moncrief Army Hospital, Fort Jackson, South Carolina. Therefore, South Carolina law governs this action because South Carolina is the site of the alleged tort. 28 U.S.C. § 1346(b).
- 5. Generally, three elements are necessary to establish a cause of action for negligence, i.e., (1) a duty of care owed to the plaintiff by the defendant; (2) a breach of that duty by a negligent act or omission; and (3) damage proximately caused by the breach of duty. See Sherrill v. Southern Bell Tel. & Tel. Co., 197 S.E.2d 283, 285 (S.C. 1973).

- 6. In a medical professional negligence matter, a physician commits malpractice by not exercising that degree of skill and learning that is ordinarily possessed and exercised by members of the profession in good standing acting in the same or similar circumstances. Durham v. Vinson, 602 S.E.2d 760, 766 (S.C. 2004). Additionally, medical malpractice lawsuits have specific requirements that must be satisfied in order for a genuine factual issue to exist. Specifically, a plaintiff alleging medical malpractice must provide evidence showing (1) the generally recognized and accepted practices and procedures that would be followed by average, competent practitioners in the defendants' field of medicine under the same or similar circumstances, and (2) that the defendants departed from the recognized and generally accepted standards. Pederson v. Gould, 341 S.E.2d 633, 634 (S.C. 1986); Cox v. Lund, 334 S.E.2d 116, 118 (S.C. 1985). Also, the plaintiff must show that the defendants' departure from such generally recognized practices and procedures was the proximate cause of the plaintiff's alleged injuries and damages. Green v. Lilliewood, 249 S.E.2d 910, 913 (S.C. 1978). The plaintiff must provide expert testimony to establish both the required standard of care and the defendants' failure to conform to that standard, unless the subject matter lies within the ambit of common knowledge so that no special learning is required to evaluate the conduct of the defendants. Pederson, 341 S.E.2d at 634.
- 7. Negligence cannot be inferred from an injury or bad result. South Carolina law does not recognize the doctrine of res ipsa loquitur. See, e.g., Hadfield v. Gilchrist, 538 S.E.2d 268, 275 (S.C. App. 2000). Thus, "[t]he plaintiffs' burden of proof cannot be met by relying on the theory that the thing speaks for itself or that the very fact of injury indicates a

failure to exercise reasonable care." <u>Reiland v. Southland Equip. Serv. Inc.</u>, 440 S.E. 2d 887, 889 (S.C. App. 1998).

8. Negligence is not actionable unless it is a proximate cause of the injury complained of, and negligence may be deemed a proximate cause only when without such negligence the injury would not have occurred or could not have been avoided. When one relies solely upon the opinion of a medical expert to establish a causal connection between the alleged negligence and the injury, the expert must, with reasonable certainty, state that in his professional opinion, the injuries complained of most probably resulted from the defendant's negligence. Ellis v. Oliver, 473 S.E.2d 793, 795 (S.C. 1996). The expert testimony as to proximate cause must provide a significant causal link between the alleged negligence and the injuries suffered, rather than a tenuous and hypothetical connection. Id.

EXPERT TESTIMONY

9. David L. Kulbersh, M.D., testified for Defendant as an expert in the field of gynecology.¹² Bench Trial Tr. p. 2-190; see id. pp. 2-184 - 3-76. Dr. Kulbersh testified that the medical care given to Plaintiff by Nurse Leverette and Dr. Browning met all applicable standards of care. Bench Trial Tr. pp. 3-21 - 3-26. He explained that breasts are a combination of different tissues, and are composed of the lobules and glands which make the

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¹² Dr. Kulbersh testified that he graduated from the Medical College of Georgia in 1976, did an obstetrical/gynecological residency at the Southwestern School of Medicine in Dallas, Texas, and has been actively practicing gynecology in Lexington, South Carolina since 1980. Bench Trial Tr. p. 2-185. He is a member of the Lexington County Medical Association, the South Carolina Medical Society, the American Medical Association, and is a fellow of the American College of Obstetricians and Gynecologists. Bench Trial Tr p. 2-187. He practices medicine at Lexington Women's Care, West Columbia, S.C., in a practice with seven other physicians, six certified midwives, and a nurse practitioner. Bench Trial Tr. p. 2-184. Dr. Kulbersh sees approximately 75 patients per week and has been screening patients for breast cancer for 27 years. Bench Trial Tr. p. 2-186.

milk, the ducts which funnel the milk to the nipple, the fat tissue which surrounds the glands and ducts, and the suspensory ligaments that hold the breast in place. Bench Trial Tr. p. 2-194. He explained that breasts are lumpy organs and do not feel the same all over. <u>Id.</u> He explained that how a breast feels varies from place to place and that there is a variation during the monthly menstrual cycle. <u>Id.</u>

Dr. Kulbersh testified that one goal of a medical practitioner doing a clinical breast examination is to determine if a "discrete mass" is present or not, because a discrete mass is a finding that is worrisome for cancer. Bench Trial Tr. p. 2-193 - 2-194. He testified that in his practice he finds many women with "palpable abnormalities that may raise concern," but probably only two to three a month who on examination have a "discrete mass." Bench Trial Tr. p. 2-197. Dr. Kulbersh explained that a "discrete mass" is a space occupying lesion that has three dimensions to it, that feels different from surrounding tissues in the breast, and that would be asymmetrical, that is would feel different from what the clinician would feel in the other breast. Id. A discrete mass, one that does not feel like the normal changes month to month in a woman's breast, must be biopsied. Bench Trial Tr. p. 2-196. Some discrete masses, such as a breast cyst caused by a clogged milk duct, may go away on their own, or if drained with a needle. Bench Trial Tr. p. 2-196. However, a discrete mass which is a carcinoma would remain and would not fluctuate from month to month. Bench Trial Tr. p. 2-197.

Dr. Kulbersh explained that when a clinician palpates a breast, he will feel different things since "every woman is going to have lumpy areas or different areas that don't feel exactly right." Bench Trial Tr. p. 2-195. The clinician's job "is to try to determine what is

significant and what is not." <u>Id.</u> Areas of the breast that feel "thickened," or "fibrotic," or which are "tender," do not "raise the same amount of suspicion as a rock hard, round discrete mass." <u>Id.</u>

Nonspecific findings as to breast tissue, such as nodularity or lumpiness, warrant a mammogram, and other follow up as the examiner deems appropriate. Nurse Leverette did not find a discrete mass, and her follow up as to Plaintiff was proper. She told Plaintiff about breast self examinations, referred her for a mammogram noting the area in question, and referred her to the supervising physician (Dr. Browning) for a follow up breast examination to be done after her menses were complete. Dr. Kulbersh testified that Dr. Browning's care of Plaintiff on September 2, 1994, was appropriate and met standards of care. Dr. Kulbersh testified that sometimes a woman's menstrual cycle makes it more difficult to do a clinical breast examination, particularly the time right before her period. He testified that hormone changes can cause tissue densities that disappear after a woman has her period, which is what happened in the Plaintiff's case.

Dr. Kulbersh explained that in Nurse Leverette's deposition, she described what was probably a fibrocystic change and that he did not believe that Nurse Leverette was feeling a cancer. Bench Trial Tr. p. 3-22. He based that opinion on the way Nurse Leverette described the mass, on the negative mammogram that was "90 percent effective," on the fact that Dr. Browning examined Plaintiff two more times and found no mass, and on the fact that there was another negative breast exam in April of 1995. <u>Id.</u>; Def.'s Ex. 17. In Dr. Kulbersh's opinion, in August 1994 Plaintiff probably had carcinoma in her left breast in a non-palpable state. Bench Tr. pp. 3-27, 3-67. In Dr. Kulbersh's opinion, because the cancer

was not palpable and did not appear on the mammogram done on August 23, 1994, a surgeon would not have done a biopsy even if Plaintiff had been referred for one. Bench Trial Tr. pp. 3-72 - 3-74. Dr. Kulbersh explained, "you can't take a needle and just randomly stick it all through the breast." Bench Trial Tr. p. 3-73. Dr. Kulbersh also opined that had Plaintiff's breast cancer been found in August 1994, if Plaintiff had cancer in her lymph nodes at that time, the treatment required would be "much more aggressive" than a lumpectomy and there would be a need for chemotherapy. Bench Trial Tr. p. 3-30.

As to the follow up appointment scheduled for September 9th which Plaintiff missed, Dr. Kulbersh testified that there are circumstances where the standard of care would require the physician to further follow up with the patient if she did not return. In Plaintiff's case, the standard of care did not mandate a follow up. Bench Trial Tr. pp. 3-31 - 3-33. Neither the two clinical breast examinations nor the mammogram showed a discrete mass and there was no evidence of a malignancy. Further, if a follow up CBE had been done on September 9, 1994, Dr. Kulbersh did not think it would have shown anything different from the week before. Bench Trial Tr. p. 3-33.

10. David L. Page, M.D., testified for Defendant as an expert in the field of anatomic pathology.¹³ In order to form opinions in this case, Dr. Page studied breast tissue

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¹³ Dr. Page is Director of Anatomic Pathology, Department of Pathology, at Vanderbilt University Medical Center, Nashville, TN. Dr. Page received his undergraduate degree from Yale University in 1962, and his medical degree from Johns Hopkins School of Medicine in 1966, where he graduated Phi Beta Kappa. Bench Trial Tr. p. 4-35. Dr. Page has been a professor of pathology at Vanderbilt University Medical School since 1972. Bench Trial Tr. p. 4-33. He is board certified in anatomic pathology and in dermatopathology. Bench Trial Tr. p. 4-37. Dr. Page explained that the field of anatomic pathology is divided into "autopsy pathology" and "surgical pathology." Bench Trial Tr. p. 4-34. Dr. Page has focused on the field of surgical pathology, "where we deal with samples that are removed surgically. . . by some physician . . . , and laboratories associated with supporting the evaluation of those materials in order to provide treating physicians with diagnosis and

pathology slides created by the MACH pathology laboratory after Plaintiff's breast biopsy and surgery, and the surgical pathology reports associated with them. Bench Trial Tr. pp. 4-44, 4-45. From a study of the slides and the medical records, Dr. Page opined to a reasonable degree of medical certainty, that in August 1994 Plaintiff had ductal cancer in her left breast which had already spread to at least six of her axillary lymph nodes. Bench Trial Tr. pp. 4-67, 4-68. In Dr. Page's opinion, it is medically most probable that the six axillary lymph nodes which had metastatic tumors 3 millimeters or greater in two dimensions when removed in 1996, were cancerous three years before they were removed. Bench Trial Tr. p. 4-69. This would be termed a "regional" metastasis of the breast disease. Bench Trial Tr. p. 4-71. In Dr. Page's opinion, if this set of positive lymph nodes had been diagnosed in Plaintiff in 1994, she certainly would have been offered chemotherapy. Bench Trial Tr. p. 4-72. As to whether or not breast reconstruction surgery would have been an option for Plaintiff in 1994, Dr. Page testified that the decision would be "made between the patient and the operating surgeon." Bench Trial Tr. p. 4-87. He testified that where there were positive lymph nodes, "many surgeons and patients would go ahead and opt for a mastectomy." Id.

Dr. Page opined to a reasonable degree of medical certainty, that the delay in the diagnosis Plaintiff's breast disease from August 1994 to March 1996, has not reduced

guidelines for therapy and prognosis." Bench Trial Tr. p. 4-34. Dr. Page has done extensive research and study in the area of breast disease. In 1999, he received the Distinction in Research award from the Susan G. Komen Foundation. He has authored over 250 papers in the area of his medical specialization which have been peer reviewed and published. Bench Trial Tr. p. 4-39. He has been the associate editor of Human Pathology, one of the four major pathology journals associated with human disease, and currently is on the editorial board of Modem Pathology and the American Journal of Clinical Pathology. Bench Trial Tr. p. 4-38. He serves on numerous medical committees, has lectured extensively, and has numerous other professional distinctions. His current professional focus is "writing papers and book chapters, teaching residents and fellows about surgical pathology in general, and more often breast pathology. . . . "Bench Trial Tr. p. 4-40. The review of tissue slides in order to answer questions about prognosis and care is a large part of Dr. Page's current practice. Id.

Plaintiff's life expectancy. This is because of Plaintiff's type of breast disease and her present years of survival. Bench Trial Tr. pp. 4-72, 4-73. Dr. Page agrees that Plaintiff's breast disease itself has reduced the Plaintiff's life expectancy somewhat, but opined that it is "very, very uncommon" for most breast cancer patients to have the cancer recur after seven or eight years following diagnosis. Bench Trial Tr. pp. 4-81, 4-82.

11. Ivan Backerman, M.D., testified for Plaintiff as an expert in the field of gynecology and women's health care. 14 Dr. Backerman testified that it was appropriate and within the standard of care for Nurse Leverette to order a mammogram. Bench Trial Tr. p. 1-95. He said that it was within the standard of care for Nurse Leverette to wait to get the mammography results before ordering a biopsy. Bench Trial Tr. pp. 1-95 - 1-96. He testified that Nurse Leverette did a thorough examination of Plaintiff in August 1994. Bench Trial Tr. p. 1-107. He testified that Dr. Browning did a professional job in examining Plaintiff's breasts. Bench Trial Tr. p. 1-97. He stated that clinicians can use the term "nodularity" to describe breasts which have fibrocystic conditions. Bench Trial Tr. p. 1-99.

Dr. Backerman testified that he did not know what size Plaintiff's breast cancer was in August and September of 1994. Bench Trial Tr. p. 1-100. He testified that he did not know to a probability what stage Plaintiff's cancer was in August and September 1994. Bench Trial Tr. p. 1-101. He testified that if the cancer was in Plaintiff's lymph nodes it would be categorized as metastatic cancer. <u>Id.</u> However, he testified that he did not know whether Plaintiff had node involvement in 1994. Bench Trial Tr. p. 1-106. He testified that

¹⁴ Dr. Backerman is a retired gynecologist who was a solo practitioner of obstetrics and gynecology in Atlanta before retiring to Florida in 1996. Bench Trial Tr. pp. 1-41.

if there was axillary node involvement in 1994, that the probable surgical procedure which would have been offered to Plaintiff would have been a modified radical mastectomy. Bench Trial Tr. p. 1-106. He testified that if there were five or six nodes involved in August 1994, that Plaintiff probably would have received chemotherapy following surgery. Bench Trial Tr. pp. 1-102, 1-103. He testified that he is not an anatomic pathologist and is not qualified to look at the mitotic rates of tumors. Bench Trial Tr. p. 1-102.

Dr. Backennan testified that when surgeons receive a patient such as Plaintiff for a biopsy, that the surgeon makes his own decision as to whether or not to do a biopsy. Bench Trial Tr. p. 1-105. He agreed that it did not make any difference as to Plaintiff's course of care whether Nurse Leverette specifically diagramed the dense mass she palpated. Tr. p 1-106. However, in Dr. Backerman's opinion any palpable breast mass, no matter what its nature, should be biopsied to rule out cancer. It is Dr. Backerman's opinion that once a breast mass is palpated, cancer must be ruled out conclusively. Only then has the standard of care been met. Dr. Backerman does not believe that a women's health care clinician can meet the standard of care by stopping diagnostic testing with a negative mammogram and with negative clinical breast examinations. Dr. Backerman testified that it is permissible to do a mammogram after a breast mass is palpated. He opined that if the mammogram is suspicious for cancer, then a breast biopsy must be done. He opined that if the mammogram is not suspicious for cancer, then a breast biopsy must still be done to meet the standard of care. In the event of a case such as that of Plaintiff, where a "dense mass" was found and a follow up mammogram was not suspicious, according to Dr. Backerman a fine needle aspiration must be done next. If the fine needle aspiration produces tissue that is positive for

cancer, then an excisional biopsy must be done to determine the extent of the cancer. If the fine needle aspiration is negative, Dr. Backerman opined that then an excisional biopsy must be done to be sure that the breast has no cancer. In sum, in Dr. Backerman's view, once a dense mass is palpated, only after an excisional biopsy is done and the tissue sample proves negative for cancer after pathology analysis, can the clinician tell the patient that there is no reason for concern and still be within the standard of care.

- 12. The court finds that the standard of care applicable to Plaintiff in August and September 1994, once a density was palpated in her left breast on August 22, 1994, was to assess Plaintiff's breasts through a mammogram, to recheck Plaintiffs breasts by a follow up CBE, and to then determine if a biopsy was needed. The Court finds that the standard of care did not require MACH personnel to automatically biopsy Plaintiff's left breast simply because a dense mass had been palpated. The Court finds that other material clinical determinations had to be made before the need for a breast biopsy could be properly determined.
- 13. The Court finds and concludes that medical testimony received at trial proves to a reasonable degree of medical certainty that there was not sufficient clinical evidence in August 1994, or in September 1994, or even as late as a negative CBE done at the MACH Internal Medicine Cline on April 5, 1995, Def.'s Ex. 17, to require that MACH clinicians order a consultation for a breast biopsy of either of Plaintiff's breasts.
- 14. As to the matter of there being no follow up when Plaintiff did not return on September 9, 1994, which fact was not contested by Defendant, the Court finds that under the circumstances proven in this case, it was not the standard of care to follow up when Plaintiff

did not return because she did not have any health conditions that were alarming. Bench Trial Tr. p 2-53. This conclusion as to the standard of care is supported by the expert testimony of Dr. Kulbersh who explained that it was not the standard of care to send out letters and other notices to Plaintiff because her medical diagnosis at that time did not call for it. Bench Trial Tr. pp. 3-31 - 3-33.

Secondly, had Plaintiff returned for a follow up CBE on September 9, 1994, it is most probable based on the expert testimony that a follow up breast exam would not have found evidence of breast disease. The Court accepts that testimony, and notes that the evidence proved that Plaintiff underwent a CBE at the MACH Internal Medicine Clinic on April 5, 1995, which was negative. Def.'s Ex. 17. Further, Plaintiff did monthly self breast examinations and found nothing abnormal until December 1995 or thereafter. Bench Trial Tr. p. 2-79. Also, although Plaintiff returned to MACH a number of times between September 1994 and January 1996, she never complained of problems with her breasts. Consequently, even if the Court found that Defendant was negligent in not affording Plaintiff a fourth CBE on September 9, 1994, the Court cannot say that but for another CBE in September 1994, an earlier discovery of the Plaintiff's cancer would have occurred, or that the Plaintiff's medical circumstances would have been improved.

15. Finally, the Court finds and concludes that medical testimony received at trial proves to a reasonable degree of medical certainty in August 1994 that Plaintiff had a cancerous tumor in her left breast, and that the cancer already had metastasized into Plaintiff's lymphatic system with involvement of at least six axillary nodes. According to Plaintiff's expert, Dr. Backerman, the probable surgical procedure which would have been

offered to Plaintiff under those circumstances would have been a modified radical mastectomy. Bench Trial Tr. p. 1-106. Dr. Backerman testified that if there were five or six lymph nodes involved in August 1994, that Plaintiff probably would have received chemotherapy following surgery. Bench Trial Tr. pp. 1-102, 1-103. The Court finds given the evidence and testimony in this case, Plaintiff has not proven that but for Defendant's conduct, she would have avoided either removal of her left breast or the administration of chemotherapy.

16. The Court concludes that Plaintiff failed to establish by expert testimony the requisite elements of her medical professional negligence claim: the standard of care for a medical practitioner under similar circumstances, a breach of that standard of care, or that any act or omission by Defendant proximately caused the injury sustained by Plaintiff. To the contrary, the credible and reliable testimony, exhibits, and other evidence in the record support a finding that Defendant's medical practitioners utilized the recognized and generally accepted standards, practices and procedures that would be exercised by competent medical practitioners under the circumstances present in this case.

CONCLUSION

Based upon the foregoing, this Court finds and concludes that the United States is not liable and responsible for the alleged damages suffered by the Plaintiff. The Court hereby enters judgment for the United States of America in this matter.

IT IS SO ORDERED.

<u>s/MATTHEW J. PERRY, JR.</u> SENIOR UNITED STATES DISTRICT JUDGE

Columbia, South Carolina

March 30, 2011