No. 02-14-00091-CV

In the Court of Appeals for the Second
District of Texas at Fort Worth

Consultants in Radiology, P.A., Jason W. Skiles, D.O., David W. Simonak, D.O., Fossil Creek Family Medical Center, P.A.,
Appellants

v.

S.K. and C.K., Individually and on Behalf of J.K., A.K., and R.K., Minor Children,
Appellees

On Appeal from the 141st Judicial District Court, Tarrant County, Texas, Hon. John P. Chupp, Presiding

Appellants' Brief

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Oral Argument Requested

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Table of Contents

Index of Authorities

CASES:

STATUTES:

MISCELLANEOUS:

Statement of the Case

Nature of the Case:	This is a medical malpractice case concerning an alleged delay in diagnosing breast cancer. CR 7-11.
Course of the Proceedings:	As relevant here, Appellants objected to the sufficiency of Plaintiffs' Chapter 74 expert reports and moved to dismiss. CR 137-205; 206-273; 274-276. Concurrently with the filing of the Petition, Appellees moved for a determination that the reports were sufficient. CR 6; 18.
Trial Court's Disposition:	The trial court overruled the objections to the expert reports and denied the dismissal motions. CR 299-300.

Statement Regarding Oral Argument

Pursuant to Rule 38.1(e) of the Texas Rules of Appellate Procedure, Appellants believe that oral argument will significantly aid the Court in determining the legal and factual issues presented in this appeal by allowing the parties to emphasize and clarify the written arguments in the brief. Oral argument will allow the parties to illustrate their respective positions regarding causation opinions in the expert reports and whether those statements satisfied the causation element of Section 74.351 of the Texas Civil Practice & Remedies Code. Additionally, oral argument will allow the parties to help the Court understand the medical issues in the case.

Statement of Jurisdiction

This Court has jurisdiction to hear an interlocutory appeal denying a motion to dismiss in a health care liability claim. *Lewis v. Funderburk*, 234 S.W.3d 204, 208 (Tex.

2008); Tex. Civ. Prac. & Rem. Code § 51.014(a)(9). This Court's appellate district includes Tarrant County, among other counties. Tex. Gov't Code § 22.201(b). "The 141st Judicial District is composed of Tarrant County." Tex. Gov't Code § 24.352. Thus, this Court has jurisdiction to determine this interlocutory appeal about the denial of Appellants' objections to the Chapter 74 expert reports and their motions to dismiss.

Issue Presented

Section 74.351 requires that a medical-malpractice plaintiff serve one or more expert reports that, among other things, explain—in a non-conclusory manner—the causal connection between the alleged breaches in the standard of care and the injuries. The expert reports in this case fail to explain why or how the cancer worsened during the delay allegedly caused by Appellants. Did the trial court abuse its discretion in applying the law of 74.351 to the expert reports in this case by concluding the reports were sufficient?

Introduction

Is this appeal yet another arguing that the trial court erred in analyzing and applying the law to Chapter 74 expert reports? Unfortunately[1], yes, but in many ways this appeal is different from the others preceding it. While these expert reports are just "preliminary" and the standard for review is "abuse of discretion," not a very stringent standard, the reports fail these *minimal standards* in a case about an allegedly delayed diagnosis of breast cancer. Other than in a conclusory fashion, the reports here did not explain how the patient's cancer worsened during the period of delay allegedly attributable to the health care providers. Without that explanation of the causal link, the breaches of the standard of care were not connected to the events that occurred due to the alleged delay, i.e. a worse prognosis and more extensive treatment.

Turning to the specific issue in the case, albeit in a simplified fashion, the experts claimed that the patient had breast cancer and that the health care providers delayed diagnosing the cancer. The experts claimed that the delay resulted in additional treatment and a worse prognosis. But the experts provided no factual

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[1] People seem to treat these appeals with some disdain because a reputation developed about a "cottage industry" for expert report litigation. *Philipp v. McCreedy*, 298 S.W.3d 682, 684 (Tex.App.—San Antonio 2009, no pet.). Thus, merely labeling the appeal as involving a Chapter 74 expert report may leave one with a bad taste for what is to follow.

support for the claim that delay actually worsened the patient's cancer. The reports provided no concrete details that the cancer worsened, i.e. that it grew to a certain size, that the staging for the cancer worsened, etc. Moreover, for the patient's specific breast cancer diagnosis (e.g. Stage IIIC), key elements in determining whether cancer was at a different stage at the time of the alleged delay are whether lymph nodes are involved, the number involved, and the location of those involved. Yet the experts provided no meaningful details regarding involvement of lymph nodes. The reports did not connect delay to a worsening of the patient's cancer. Thus, the trial court should not have concluded that the reports passed muster, and it abused its discretion by concluding otherwise. This Court should reverse to correct that error.

Statement of Facts[2]

A. Factually, What Happened?

SK[3] came to Fossil Creek Family Medical Center complaining of "left axilla pain—feels like swollen lymph nodes [times] several weeks." CR 25. Nurse Practitioner Brenda Wilmore examined SK and concluded that that it was mastitis. *Id.* The nurse practitioner and Dr. Simonak ordered a mammogram that occurred a few days later.[4] *Id.* Dr. Skiles interpreted the mammogram as showing "indeterminate

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[2] The case is in its preliminary stages, and no discovery has occurred. Appellants gathered the information for the Statement of Facts from Appellees' pleadings and the three expert reports. But Appellants do not agree that these facts are true—in fact they filed general denials that placed these "facts" and Appellants' allegations in dispute. CR 70, 97, 102. On the other hand, the Court and the parties have to evaluate the expert reports in some context, and the Rules require a Statement of Facts. Thus, Appellants provide this Statement with the understanding that they are not agreeing with these facts nor are they judicially admitting that any of these facts are true.

[3] Consistent with the broadest interpretation of the redaction rules as well as the manner in which the Court docketed this case, Appellants refer to Appellees/Plaintiffs by initials even though their names were fully disclosed by their own counsel and the patient's name was fully disclosed in the expert reports. *See* CR 5, 24, 49, 127. SK, who was the patient, will be referred to by initials "SK" or "the patient." The remaining Appellees/Plaintiffs will be referred to as "her family" or "the family."

[4] At least one expert makes much of the type of mammogram ordered (screening) and that it should have been a different type (diagnostic). CR 29. But a diagnostic mammogram was actually performed, thus leaving this distinction in the type of mammogram irrelevant to any issue in this case. Any purported negligence in ordering the wrong type of mammogram could not have caused any harm because, despite the order, the correct mammogram was actually performed. *See* CR 29, 51.

microcalcifications in the left breast, probably benign." CR 50. He recommended a follow-up study in 3-6 months. *Id.* Dr. Skiles also interpreted an ultrasound of the breast as being without abnormality. CR 51.

About 14 months after the initial visit, the patient returned to the clinic (there had been other visits in the interim) with a complaint of "lump in the left breast [times] several months." *Id.* According to the patient, the mass had "been there for several years," and the nurse practitioner noted that "the left breast is larger than the right." CR 26-27. An exam of her breast revealed a "large palpable mass that is non-tender, irregular moveable with no signs of mastitis." CR 27. The nurse practitioner ordered a diagnostic mammogram and suggested a biopsy. *Id.* This mammogram noted "left breast microcalcifications" with the radiologist concluding that the abnormalities were consistent with mastitis. *Id.* That radiologist recommended annual mammographic screening when SK turned 40, or more than five years after the second mammogram. *Id.*

About two months later, Dr. Simonak saw the patient, diagnosed breast mass, and ordered a biopsy. *Id.* Five days after Dr. Simonak's visit, Dr. Mary Brian performed an in-office biopsy of the left breast that revealed "high grade ductal carcinoma in situ." CR 51, 129. Then a month later, Dr. Brian performed "a left modified radical mastectomy and left sentinel node biopsy." *Id.* Pathology of the

lymph nodes revealed 14 of 28 were positive, resulting in the diagnosis of "multifocal Stage IIIC invasive ductal carcinoma." *Id.*

B. What Did the Expert Reports Say?

With the Petition, SK and her family served two expert reports, one addressing the conduct of Dr. Simonak and Fossil Creek and the other addressing the conduct of Dr. Skiles (and vicariously Consultants in Radiology). The focus—at least on the liability issues—was how the providers caused the cancer diagnosis to be delayed.

The first expert report was from Suraj Achar, M.D., a Clinical Professor of Family and Preventative Medicine at UC San Diego. CR 24. Dr. Achar offered opinions about the care provided by Dr. Simonak, the nurse practitioner, and Fossil Creek. CR 28-31. Dr. Achar claimed that they breached the standard of care by the following:

> (1) Failing to have proper physician supervision of a nurse practitioner because Dr. Simonak failed to ensure that the nurse practitioner documented a physical exam of the breast and lymph nodes, so that no proper diagnosis was made on the first visit (CR 28);
>
> (2) Failing to have a proper physical exam of the breast and axilla because no documented breast or axilla exam was noted until a year after the initial visit (CR 28-29);
>
> (3) Erroneously ordering a screening mammogram instead of a diagnostic one (which ignores the fact that a diagnostic mammogram was actually performed) (CR 29);

(4) Failing to order the follow-up mammogram recommended by the radiologist within 3-6 months of the first mammogram because one was not ordered until approximately 14 months after the initial mammogram (CR 29-30);

(5) Delaying the referral for a breast biopsy because the patient should have been referred for the breast lump found a year after the initial visit and should have been referred at the initial visit (CR 30);

(6) Failing to tell the patient about the initial abnormal mammogram because informing the patient increases the likelihood that the patient will have the recommended follow-up study (CR 30-31); and

(7) Failing (by Fossil Creek) to have appropriate policies and procedures to assure performance and documentation of a breast exam, informing the patient about the abnormal mammogram, and assuring the follow-up study was ordered (CR 31).

Dr. Achar then speculated that an "[e]arly physical exam *may* have found a mass that *may* have led to early referral" because suspicious masses should be biopsied. CR 32. But he did not explain or provide any analysis of what stage the cancer would have been at the time of the "early referral." *Id.* He then stated that earlier referral to a breast surgeon for a biopsy would have uncovered the cancer at an earlier stage – but provided no explanation for why the stage would have been different. *Id.* Dr. Achar also noted that paying attention to the mammogram (and presumably ordering the follow-up study as suggested) would have resulted in an earlier diagnosis of the cancer, again not saying at what stage. *Id.*

Additionally, Dr. Achar attempted to explain that earlier breast cancer diagnoses have better outcomes, but he did not explain where in the process the patient would have been in this case with an "earlier diagnosis." *Id.* In fact, Dr. Achar noted several factors—tumor size, tumor grade, involvement of lymph nodes, hormone receptor status, and genetic testing—affect treatment and prognosis, but none of those factors were mentioned or analyzed at the time of the allegedly missed diagnoses or alleged malpractice. *Id.* Instead, Dr. Achar just said that earlier detection would have made a better prognosis for the patient. *Id.* Dr. Achar then concluded that had the appropriate standard of care been met, then the patient "would have received the recommended follow-up studies, the changes in the size/appearance of the abnormal breast tissue noted, and the diagnosis of breast cancer would have been reached much sooner than it was made." CR 33. He then stated that the failures of Dr. Simonak and Fossil Creek "w[ere] a proximate cause of her injury and its sequelae." *Id.*

Turning to the second report served with the Petition, Jeffrey B. Mendel, M.D. authored a report critical of the radiology Defendants. Dr. Mendel is an Assistant Professor of Radiology at Tufts. CR 55. Dr. Mendel interpreted the various radiology studies in the case. On the standard of care issue, Dr. Mendel opined that Dr. Skiles breached the standard of care because he should have "appreciate[d] the presence and significance of the suspicious microcaclifications of the left breast" and

"recommend[ed] biopsy of the concerning breast tissue." CR 52. For causation, Dr. Mendel stated that Dr. Skiles failure resulted in "extended delay in diagnosis and treatment." *Id.* Had a biopsy been recommended and performed, Dr. Mendel claimed cancer would have been detected earlier rather than a year later. *Id.* No explanation of why the outcome would be improved was given.

Later in the case—but still within the 120 day period—the patient and her family also served an expert report from Peter D. De Ipolyi, M.D., a surgical oncologist. CR 127. Unlike the earlier two reports that kept the criticism to their respective fields, Dr. De Ipolyi's report offered criticisms against all involved. Dr. De Ipolyi stated:

> (1) Dr. Skiles breached the standard of care by not "appreciat[ing] the presence and significance of the suspicious microcalcifications in the left breast" and by not "recommend[ing] biopsy of this concerning breast tissue" (CR 130);
>
> (2) Dr. Simonak breached the standard of care by not "complet[ing] and document[ing] a thorough physical examination of her breast and lymph nodes" and not assuring that the nurse practitioner did as well (CR 130);
>
> (3) Dr. Simonak breached the standard of care by not communicating the mammogram results to the patient "and assur[ing]…the recommended follow-up in 3-6 months" (CR 130); and
>
> (4) Fossil Creek breached the standard of care by not having and enforcing policies and procedures regarding performing and documenting a thorough breast and lymph node exam, assuring communication of the mammogram results to the patient, and

> assuring that the follow-up mammogram was performed (CR 130).

Dr. De Ipolyi discussed how biopsies work and their success, but he never explained why the diagnosis would have been different with an earlier biopsy. CR 132. He also stated that a follow-up mammogram would have resulted in a biopsy without explaining why or what a biopsy then would have shown. *Id.* Finally, he discussed extensively the differences between cancer treatments for a diagnosis of "ductal carcinoma in situ" and "invasive ductal carcinoma" but did not explain why the patient did not just have ductal carcinoma in situ while under the care of these providers or why she did not have invasive ductal carcinoma at her initial presentation. *Id.* Like Dr. Mendel, Dr. De Ipolyi concluded that the providers' negligence "was a proximate cause of [the patient's] injury and its sequelae." CR 133.

C. Procedurally, What Happened?

SK and her family sued. CR 5-22. With the initial petition, they served not only the expert reports from Drs. Achar and Mendel, but they also served discovery and noticed several depositions. CR 5-69. The health care providers answered. CR 70-73, 97-101, 102-105. SK and her family then served Dr. De Ipolyi's report. CR 124-136. As would be expected in an expert report appeal, the health care providers objected to the sufficiency of all the reports, including the causation element. CR 137-205, 206-273, 274-276. The trial court denied the health care providers' dismissal

motions and overruled their objections to the expert reports. CR 299-300. The health care providers appealed. CR 305-310.

Summary of the Argument

This case is not the one where Appellants argue that the Chapter 74 expert report requirement could never be met. Instead, these experts just did not connect the dots to explain causation in this case. The experts did not explain how the cancer worsened during the alleged delay caused by Appellants. The experts did not claim that the cancer was bigger at the end of the delay or that the cancer invaded new territory or that it became inoperable or even just that there was documented evidence of a progressive worsening of the disease. Instead, the experts concluded that the cancer would have been an easily treated form without offering any justification for their assumptions regarding the cancer. Those types of conclusory opinions are insufficient to satisfy the Chapter 74 expert report requirement.

Moreover, the patient has Stage IIIC cancer—a cancer stage that is not driven by the size of the tumor but instead driven by the number and location of involved lymph nodes. The expert reports contained no discussion of the status of lymph nodes that conveyed any concrete information about the number of nodes involved at the time of the delay or, perhaps more importantly, any information about the location of any involved lymph nodes. If the nodes reached a certain numerical level, the cancer would have been diagnosed as Stage IIIC regardless of the timing of the

diagnosis. Moreover, if the cancer involved even just one node in the right area, the cancer still would have been diagnosed as Stage IIIC. Yet the experts ignored lymph nodes in discussing the patient's prognosis at the time of the delayed diagnosis. In light of the critical role played by lymph nodes for this particular diagnosis, no expert report could claim that delay worsened the outcome without a discussion the involvement of lymph nodes at the time of the delay.

In short, the experts never explained why Appellants' alleged delay caused worsened the patient's cancer or her prognosis or treatment. Instead, the experts merely concluded—without discussion of any supportive facts—that the delay worsened the cancer, purportedly changing the severity from ductal carcinoma in situ to invasive carcinoma. But that position ignored the report of the subsequent treating physician Dr. Mary Brian, who diagnosed ductal carcinoma in situ *after* Appellants' involvement ceased. Dr. Brian found exactly what the experts believed should have been found earlier. If Dr. Brian's biopsy report was correct, SK and her family have suffered no harm by the delay.

The expert reports did not provide a factual basis for the conclusions that the cancer worsened. And ample case law requires the reports to provide that factual basis. The trial court improperly applied the Chapter 74 legal requirements to the facts of this case and abused its discretion by concluding that the expert reports were sufficient. This Court should reverse.

Argument

A. Standard of Review

An appellate court reviews the denial of a motion to dismiss for an abuse of discretion. *TTHR, Ltd. Partnership v. Moreno*, 401 S.W.3d 41, 44 (Tex. 2013). A court "abuses its discretion if it acts in an arbitrary or unreasonable manner without reference to guiding rules or principles." *Jelinek v. Casas*, 328 S.W.3d 526, 539 (Tex. 2010)(quoting *Bowie Mem'l Hosp. v. Wright*, 79 S.W.3d 48, 51-52 (Tex. 2002). An appellate court cannot substitute its judgment for the trial court's when reviewing factual matters committed to the trial court's discretion. *Wright*, 79 S.W.3d at 52. But a trial court has no discretion when determining the law or when applying the law to facts. *In re Prudential Ins. Co.*, 148 S.W.3d 124, 135 (Tex. 2004); *Methodist Hosp. of Dallas v. King*, 365 S.W.3d 847, 849 (Tex.App.—Dallas 2012, no pet.).

B. The Requirements for Chapter 74 Expert Reports

A court shall grant a motion challenging the adequacy of an expert report only if the report "does not represent an objective good faith effort to comply" with the statutory definition of an expert report. Tex. Civ. Prac. & Rem. Code § 74.351(*l*); *Columbia North Hills Hosp. Subsidiary, L.P. v. Alvarez*, 382 S.W.3d 619, 624 (Tex.App.—Ft. Worth 2012, no pet.). According to the Texas Civil Practice & Remedies Code, an "expert report" is defined as

> a written report by an expert that provides a fair summary of the expert's opinions as of the date of the report regarding applicable standards of care, the manner in which the care rendered by the physician or health care provider failed to meet the standards, and the causal relationship between that failure and the injury, harm, or damages claimed.

Id. § 74.351(r)(6). An expert report that omits any of these statutory requirements does not represent a good faith effort. *Am. Transitional Care Centers of Tex., Inc. v. Palacios*, 46 S.W.3d 873, 877 (Tex 2001). While the expert report does not have to marshal the plaintiff's proof, it must provide a fair summary of the above elements. *See Wright,* 79 S.W.3d at 52. Ultimately, the report must—with sufficient specificity—inform the defendant of the conduct called into question and provide a basis for the trial court to conclude the claims have merit. *Jelinek*, 328 S.W.3d at 539.

A report cannot merely state the expert's conclusions about the standard of care, breach, and causation. *Palacios,* 46 S.W.3d at 879. Instead, an expert must explain the basis of his statements to link his conclusions to the facts. *Jelinek*, 328 S.W.3d at 539; *Wright,* 79 S.W.3d at 52. A plaintiff may use multiple expert reports to meet the requirements of Chapter 74. Tex. Civ. Prac. & Rem. Code Ann. § 74.351(i).

Importantly, the report must stand on its own. A court reviewing the sufficiency of an expert report is limited to the four corners of the report. *Jelinek*, 328 S.W.3d at 539; *Palacios*, 46 S.W.3d at 879. Inferences from the report are not permitted. *Wright*, 79 S.W.3d at 53. Thus, a court is prohibited from "filling gaps in a report by drawing inferences or guessing as to what the expert likely meant or

intended." *Collini v. Pustejovsky*, 280 S.W.3d 456, 462 (Tex.App.—Ft. Worth 2009, no pet.).

Specifically regarding the causation requirement, an expert report does not sufficiently address the causation element if it merely "provide[s] insight about the plaintiff's claims." *Wright,* 79 S.W.3d at 52. The report must contain sufficiently specific information to demonstrate causation beyond mere conjecture. *Fagadau v. Wenkstern*, 311 S.W.3d 132, 138 (Tex. App.—Dallas 2010, no pet.). While there is no magic-word requirement for an expert report, the report's causation statement cannot be merely the unexplained *ipse dixit* of the expert, and the expert "must go further and explain, to a reasonable degree, how and why the breach caused the injury based on the facts presented." *Jelinek*, 328 S.W.3d at 539-540. The report must include factual statements that support the expert's conclusion that the defendant's actions caused the plaintiff's damages. *Tovar v. Methodist Healthcare Sys. of San Antonio, Ltd.,* 185 S.W.3d 65, 69 (Tex.App.—San Antonio 2005, pet. denied). Thus, the report must explain how the health care provider's specific conduct caused the harm alleged. *Collini*, 280 S.W.3d at 467.

C. Background Information Regarding Breast Cancer

Appellants provide some background information on breast cancer, not to challenge the conclusions of the experts, but to provide the Court with a better understanding of the medical jargon used by the experts. At the time of diagnosis, the

patient had Stage IIIC breast cancer, but the experts did not explain what that means. Stage IIIC has a 49.3% five-year survival rate, which should be compared with Stage IIIB, a 41%, or Stage IV, 14.8%. American Joint Commission on Cancer, Chapter 32: Breast, *Cancer Staging Manual*, 358 (2010). Stage IIIC breast cancer includes "any T," or any tumor size. *Id.* at 360. Thus, tumor size for a Stage IIIC cancer could range from tumor in situ (Tis) to tumor invading the chest wall or skin (T4). *Id.* at 358. A cancer of this stage can have "no evidence of distant mestatases." *Id.* at 360 (noting M0 and defining M0 to not have distant metastases). The key determination for this cancer stage is the involvement of regional lymph nodes, which for this stage requires N3. *Id.* at 360.

> An "N3" categorization for lymph nodes involves metastases in ten or more axillary lymph nodes; or infraclavicular (level III axillary) lymph nodes; or in clinically detected ipsilateral internal mammary lymph nodes in the presences of one or more positive Level I, II axillary nodes; or in more than three axillary lymph nodes and in internal mammary lymph nodes with micrometastases or macrometastases detected by sentinel lymph node biopsy but not clinically detected; or in ipsilateral supraclavicular lymph nodes.

Id. Thus, one could arrive at the N3 categorization via simple arithmetic by adding the number of regional nodes with metastatic disease until to total reaches 10 or more. *Id.* But N3 could also result with significantly fewer nodes involved as long as they are in the correct location, such as any nodal involvement of the infraclavicaular (level III

axillary) lymph nodes. *Id.* The following diagram explains the various locations for the regional lymph nodes:

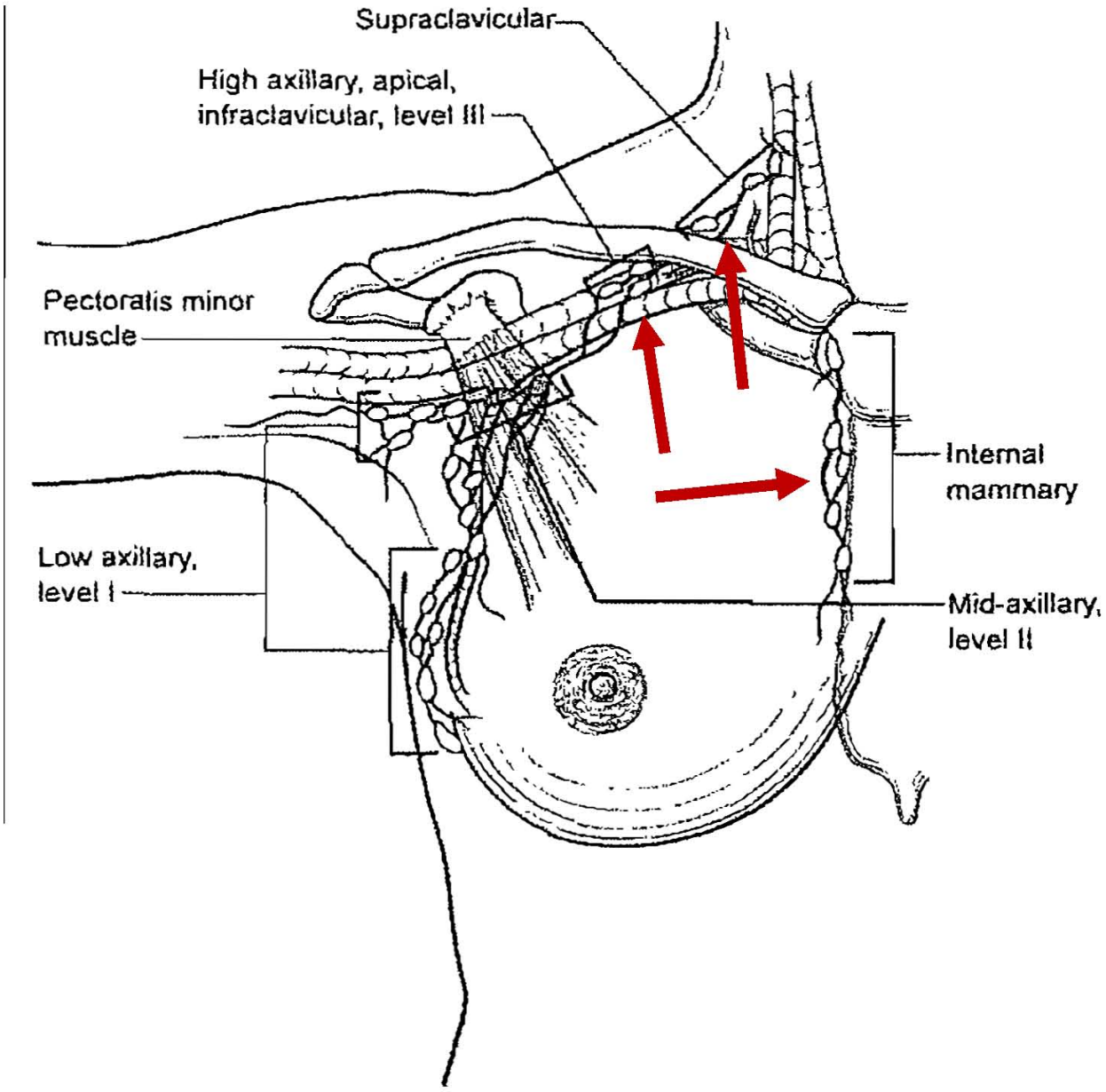

FIGURE 32.1. Schematic of the breast and regional lymph nodes.

Id. at 352 (arrows added). Thus, knowing not only the number of nodes involved but also their location is critical to determining whether a patient has a node categorization of N3—with the number being significantly reduced if nodal involvement includes infraclavicular, supraclavicular, or even internal mammary (pointed out with red arrows on the electronic version of this Brief and black arrows on the printed version). *Id.* at 360. With this backdrop on breast cancer, one has a very basic knowledge to understand what was included—and excluded—from the expert reports.

D. The Trial Court Abused Its Discretion by Concluding that the Reports Were Sufficient on Causation

1. The Cancer Did Not Worsen During the Alleged Delay

One primary problem is that the expert reports never explained how the cancer worsened during the alleged delay caused by the health care providers. In total, the patient was under the care of Dr. Simonak and Fossil Creek from September 2011 through January 2013. And, while Dr. Skiles involvement only occurred in September 2011, the experts theorize that had he recommended biopsy earlier, it would have been performed back in 2011. But what was the cancer stage back in 2011 and what was it when Dr. Mary Brian took over the care and biopsied the breast in January 2013? The expert reports provide no detail from which to conclude anything

regarding the stage of cancer at those times in order to justify the claim that delay worsened the patient's prognosis and treatment.

Is there evidence that the cancer worsened while on Appellants' watch? Surgical oncologist De Ipolyi noted that had the standard of care been met, then the patient would have been "diagnosed with [ductal carcinoma in situ] rather than invasive cancer. CR 132. But that was exactly what Dr. Brian found in January 2013: ductal carcinoma in situ. Dr. De Ipolyi wrote:

> …Sara Krahulec continued to have left breast complaints and was eventually seen by Dr. Mary Brian on January 28, 2013. Dr. Brian performed an in-office core biopsy which [sic] revealed high grade ductal carcinoma in situ.

CR 129. *See also* CR 51 (containing Dr. Mendel's statement "Dr. Brian performed an in-office core biopsy which revealed high grade ductal carcinoma in situ."). It was not until nearly a month later that mastectomy and lymph node biopsy revealed multiple positive lymph nodes. On its face, Dr. Ipolyi's report rejected the very contention espoused by the experts because it explains that even as late as January 28, 2013 the cancer was still just ductal carcinoma in situ without positive lymph nodes until after these health care providers were no longer caring for the patient. None of the experts explained when the lymph nodes became positive or that they became positive before January 28, 2013. In fact, Dr. Brian's diagnosis of ductal carcinoma in situ seemed to

belie the claim that the cancer worsened during the alleged delay instead of occurring after Dr. Brian's care for the patient began.

Because Stage IIIC breast cancer requires a tumor of any size and positive lymph nodes in number or location, the experts should have explained how the lymph nodes became involved due to the alleged delay. But the expert reports were virtually silent on nodal involvement during the alleged delay. In order to connect the breach (delay) to the injury (Stage IIIC cancer), the experts had to explain what transpired with the nodes during the delay. But the experts never described the nodes in any manner that would allow the trial court to conclude that they were "normal" or certainly to conclude that they were not abnormal.

Drs. Achar and De Ipolyi complained that Dr. Simonak and Fossil Creek did not physically examine the relevant lymph nodes, leaving a reviewer without data to say whether the nodes were inflamed and abnormal. CR 28-29, 130. But the Achar report noted that the patient's chief complaint back at the initial visit was "left axilla pain—feels like swollen lymph nodes [times] several weeks…." CR 25. That was some data suggesting that lymph nodes were already involved for weeks before any health care provider saw the patient.

Dr. Mendel interpreted the mammogram as "few lymph nodes visible" with "[t]he largest was less than 1 cm on short axis and retains a fatty notch although it appears relatively dense." CR 50. But he gave no data for the locations of these few

lymph nodes. And he gave no understandable meaning to the interpretation of the size of the largest, the retention of the fatty notch, or the density, which presumably had some radiographic significance. To suggest that the one could describe the nodes mentioned as "normal" requires an improper inference regarding the size and appearance of normal nodes. Moreover, Dr. Mendel's inclusion of the "although" clause implied that something is different with the described node.

Additionally, with lymph nodes in breast cancer, like real estate, location makes all the different. Just one positive node in the infraclavicular (Level III axillary) region is sufficient to categorize nodal involvement as N3—meaning the diagnosis of Stage IIIC cancer would remain the same even back in 2011. Plus Dr. Mendel did not quantify the nodal findings—is the few visible nodes less or more than 10, the triggering threshold for N3. Again, exactly what Dr. Mendel meant by "few" was not explained, and to make the conclusion that "few" meant less than 10 requires an improper inference from the report.

The same can be said of the September 2012 CT of the patient's chest. That study apparently demonstrated "two prominent left axillary lymph nodes which have relatively minimal fatty hila but are less than 1 cm on short axis." CR 51. But Dr. Mendel's interpretation of that study gave no guidance of what would be expected in that study or even identified which "axillary" lymph nodes were involved other than to say "left." Is "minimal fatty hila" normal or abnormal? Is less than 1 cm in size a

good or bad finding? Moreover, there are three different axillary level lymph nodes (low, mid, and high), but Dr. Mendel provided no location of the nodes. Even just one high-axillary (or infraclavicular) results in N3 and the cancer being staged as Stage IIIC.

Finally, in the later mammogram in November 2102, Dr. Mendel noted that the lymph nodes appeared "larger and more numerous" than either the earlier mammogram or the CT. *Id.* But he did not explain the significance of that finding, whether the number was more or less than 10, or the location of those nodes. As with Dr. Mendel's other descriptions of lymph nodes, a court has to infer too much about the meaning of the size, the quantity, and the location to supply the link missing from the expert reports and justify the conclusion that the cancer worsened during the delay allegedly caused by the health care providers.

The so-called delay purportedly resulted in Stage IIIC breast cancer, a cancer that is dependent on the involvement of lymph nodes in certain number or location. But the expert reports provided no data to supporting a conclusion that the lymph nodes were cancer free back when the diagnosis was allegedly delayed—or even that the lymph nodes were not normal when Dr. Brian diagnosed ductal carcinoma in situ.

Additionally, if tumor size matters for this particular diagnosis, the experts gave no information factually supporting that the tumor grew in size. Back in 2011, the "cancerous" area was just "microcalcifications clustered in the upper outer quadrant"

that were "amorphous and pleomorphic *without* associated mass or architectural distortion." CR 50, 129. The CT in 2012, according to Dr. Mendel, still did not show a discernible tumor mass, only a "focal asymmetry of the breast paryenchma." CR 51. And while there were more microcalcifications in the 2012 mammogram, Dr. Mendel still did not describe a tumor, just another "focal asymmetry." But given Stage IIIC, tumor size does not matter because a person is graded with that stage with certain lymph node findings and "any tumor." American Joint Commission on Cancer, Chapter 32: Breast, *Cancer Staging Manual*, 360 (2010).

One final point about the experts' failure to explain how the delay worsened the patient's case: none of the experts accounted for the fact that during the period of alleged delay, the patient was pregnant. The initial mammogram occurred in September 2011. Shortly thereafter, the patient returned to the clinic on December 13, 2011 (or within the first three months following that mammogram) "because she found out she was pregnant." CR 26. This visit was roughly three weeks after a previous visit to the clinic, implying that the pregnancy was a relatively new finding for the patient. Despite this important change in the patient's condition, the experts never explained that any type of breast cancer screening/testing or treatment could occur while a patient was pregnant. Could a patient undergo a follow-up mammogram within the 3-6 months of the initial mammogram while pregnant? Could the patient undergo a biopsy while pregnant? Could the patient undergo

surgical removal of the breast cancer while pregnant? Could the patient undergo radiation treatment for breast cancer while pregnant? Could the patient under chemotherapy for breast cancer while pregnant? None of the experts addressed this important limitation on the health care providers' ability to diagnose and treat cancer. Moreover, none of the experts addressed whether the cancer could have advanced to Stage IIIC while the patient was pregnant and potentially unable to undergo diagnostic testing or definitive treatment. The pregnancy gap is another causation problem that the experts never explained, and thus they never explained how the health care providers' alleged delay actually worsened the patient's cancer.

The Chapter 74 experts did not factually explain the cancer's stage back in 2011 when the health care providers allegedly delayed the diagnosis, and thus they did not explain how the delay caused the cancer to worsen. Because the expert reports did not address this issue, the trial court had to make inferences from the report. Yet any inference is improper. The trial court abused its discretion by applying the law for Chapter 74 reports to the reports in question, and this Court should reverse that abuse of discretion.

2. Besides Unsupported Conclusions, the Experts' Reports Did Not Link the Alleged Delay to Worsened Cancer

Analysis of the causation statements in the three expert reports reveals that none of the reports provided the missing link to establish causation. The trial court abused its discretion in concluding otherwise.

Dr. Achar's report included the following "causation" statements:

> It is my opinion beyond a reasonable medical probability, based on my training and education and experience [sic], that the negligent acts/omissions of Dr. Simonak and Fossil Creek…outlined above were each a proximate cause of the extended delay in diagnosis and treatment of [the patient's] breast cancer.
>
> Had appropriate care been rendered, more likely than not, [the patient] would have received the recommended follow-up studies, the changes in the size/appearance of the abnormal breast tissue noted, and the diagnosis of breast cancer would have been made sooner than it was made.
>
> It is my opinion that each of these acts and omission of negligence was a proximate cause of her injury and its sequelae.

CR 33. Those statements were just conclusions without any explanation tying the standard of care breaches to the injury claimed.

The report contained other statements that touch on causation. For example, when discussing the need for a physical examination of the breast, Dr. Achar noted that a physical exam could detect a mass that then should be biopsied, so that it "may have led to an earlier diagnosis and earlier treatment plan." CR 32. But that

statement did not explain how the status of the lymph nodes would have been different had a mass been found earlier.

Dr. Achar also claimed that a "biopsy would have uncovered the cancer at an earlier stage leading to a less invasive treatment approach," but he never explained how that biopsy would have changed cancer being detected in the lymph nodes or why the nodes would not have been cancerous if biopsied earlier. *Id.* Remember, the biopsy actually performed only noted ductal carcinoma in situ. Either the cancer spread in the intervening month to the mastectomy or a biopsy alone cannot determine whether lymph nodes will contain cancer.

Along these lines, Dr. Achar asserted that discussing the first mammogram findings with the patient "would have [resulted] in an earlier diagnosis and treatment of her cancer." *Id.* Dr. Achar again provided no analysis of the lymph node issue. Moreover, there was no explanation of how a mere discussion would have changed what then transpired—a biopsy, another mammogram, the patient's willingness to undergo those procedures. (Admittedly, Dr. De Ipolyi's report discussed the fact that patients who know of their abnormal findings and cancer risk tend to follow-up with recommended procedures, but Dr. Achar's report is silent on that issue.)

Finally, Dr. Achar stated the fact that treatment depends on Stage and that earlier diagnosis would have meant an earlier stage. *Id.* But this final statement provided no insight regarding the causation and merely reiterated the varying factual

pieces missing from this puzzle. First, "treatment depends on multiple aspects," including a host of things not known at any point during the alleged delay, like "tumor size, tumor grade, involvement of lymph nodes, hormone receptor status, and genetic testing." *Id.* In fact, with the exception of information gathered *after* Appellants involvement was complete, we have no information on any of these factors—particularly nodal involvement. In the end, the only statement that attributes causation here was that earlier cancer detection would have resulted in a better treatment and a better chance of survival. But that statement was an unsupported conclusion without any explanation or factual connection to the case, legally deficient under Chapter 74.

Dr. Achar's report essentially said that the delay caused her cancer prognosis to be worse and nothing more. It provided no details on what the stage would have been with a timely diagnosis or explained why the delay worsened the patient's prognosis. The report was conclusory and did not satisfy the causation requirement for a Chapter 74 expert report. *Cf. Granbury Minor Emergency Clinic v. Thiel*, 296 S.W.3d 261, 271 (Tex.App.—Ft. Worth 2009, no pet.)(defining conclusory as "expressing a factual inference without stating the underlying facts on which the inference is based and finding expert report sufficient where it discussed the patient's condition over time so that it explained how the delay harmed the patient). The trial court abused its discretion in applying the law of Chapter 74 expert reports to Dr. Achar's report.

Turning to Dr. Mendel's report, he too had similar conclusory proximate cause statements. In his "causation" section, Dr. Mendel wrote:

> …the failures of Dr. Skiles to identify and report abnormalities in [the patient's] left breast resulted in an extended delay in diagnosis and treatment of her disease. The basis for this opinion is that if the abnormalities were correctly identified, described, and reported to the ordering physician with a recommendation for biopsy, then a biopsy of the left breast would have been performed, the diagnosis of cancer would more likely than not have been reached within days following the reporting of the mammogram(s), and decisions regarding definitive care would more likely than not have been made within days following the reporting of the mammogram(s) rather than in 2013.

CR 52. He went on to claim that the negligence of Dr. Skiles "was a proximate cause of her injury and its sequelae." CR 53. He made a similar statement of Dr. Skiles failures "proximately causing an unnecessary extended delay in the diagnosis and treatment of [the patient's] breast cancer—without any explanation of why. CR 52. But he never explained what the biopsy findings back then would have been let alone explain what the status of the lymph nodes would have been. Like Dr. Achar's report, Dr. Mendel's report required that the court infer that the lymph nodes would have been negative and that the cancer at the time of the delay would have been diagnosed in a stage more favorable to the patient. But such inferences are not permitted.

As discussed previously, Dr. Mendel did mention lymph nodes in his review of some of the radiology studies. *See* CR 50-51. But he did not explain the significance of his interpretation of those lymph nodes or explain why that would have changed

the patient's stage with an earlier diagnosis. Those minimal and cryptic discussions of lymph nodes did not solve the gap in the expert reports. *See*, *supra*, pp. 19-21.

Dr. De Ipolyi's report contained the most extensive discussion under a section labeled "causation" but provideed no new insight on how the patient's cancer stage was worsened by the delay. As with the other experts, Dr. De Ipolyi stated that the cancer would have been discovered sooner with appropriate treatment and that the negligence was "a proximate cause of her injuries and resulted in an extended delay in diagnosis and treatment of [the patient's] breast cancer," or similar statements. CR 131, 133. But those statements were conclusions without an explanation, failing to meet the expert report requirement.

And while the report contained several paragraphs discussing why catching cancer earlier results in better treatment and prognosis than catching it later, those statements did not answer the question of whether this delay actually harmed the patient. CR 131-132 (containing the discussion of "Causation and Damages"). Dr. De Ipolyi explained the differences in biopsies and their sensitivity in detecting cancer. CR 131-132. But he then just concluded that an earlier biopsy would have resulted in a diagnosis of "ductal carcinoma in situ…rather than invasive cancer." CR 132. He made a similar statement about his opinion that the patient should have been

told about the initial mammogram findings, resulting in a biopsy.[5] *Id.* He did not, however, explain what information a biopsy would have found or why the nodes would not have been positive. In short, that statement did not explain why the earlier cancer prognosis and treatment would have been different than Stage IIIC.

Dr. De Ipolyi also went to some lengths to discuss the different treatment options between ductal carcinoma in situ and invasive cancer. *Id.* But he never explained how he could claim the cancer at the time of the delay as being just ductal carcinoma in situ as opposed to Stage IIIC. He never explained why the lymph nodes would not have been sufficiently involved to move the staging to IIIC. Instead, Dr. De Ipolyi just concluded—without explanation—that the cancer would have been ductal carcinoma had it been earlier diagnosed. That type of conclusion without explanation renders an expert report deficient.

The reports essentially just contained the general platitude that earlier diagnosis would have resulted in a better prognosis for the patient. The reports provided no analysis that factually connects a worsened cancer prognosis to the delay other than the general platitude that delay is bad. Instead, the experts appeared to assume that an

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[5] While Dr. De Ipoyli's statement of causation on the issue of telling the patient is more complete than Dr. Achar's statement regarding similar standard of care opinions, Dr. De Ipoyli's statement does not solve the causation problem because it just ends with a biopsy. He still never connected his biopsy opinions with an explanation of why an earlier biopsy would have resulted in a better cancer stage.

earlier diagnosis would have resulted in a prognostically better stage of the cancer. But the experts never said why the staging would have been better with an earlier diagnosis. These expert reports—alone or in combination—were deficient in their statement of causation. The trial court abused its discretion in applying the law of Chapter 74 expert reports to the reports in this case, and this Court should correct that abuse of discretion.

3. Case Law Demonstrates Appellants Are Correct

Some courts complain that Chapter 74 expert-report litigation is a morass still in need of guidance,

> The trial court acknowledged the ongoing difficulty arising from the requirements of Chapter 74, specifically noting on the record that litigants and attorneys need guidance. In fact, the trial court expressed frustration that the trial courts are merely pawns in the "little game" of expert report litigation.

Philipp, 298 S.W.3d at 684. While there is probably some truth to the fact that a case can be found in this context saying just about anything, the bulk of the cases support Appellants' position in this appeal. Some cases find similar reports deficient—an obvious example of how these reports are deficient—but other cases find dissimilar reports sufficient—another example of the flaw with these expert reports.

In *Garcia v. Allen*, this Court evaluated the sufficiency of expert reports in a case about the alleged failure to diagnose a brain tumor. 337 S.W.3d 366 (Tex.App.—Ft. Worth 2011, no pet.). After significant discovery, i.e. deposing four experts, and five

years after the case began, the physician re-urged a dismissal motion, which the trial court then denied. *Id.* at 368-369. The initial expert report stated that the patient had a tumor evident on the original radiology study and that by the time it was diagnosed it was inoperable. *Id.* at 370. The discussion of the initial study explained the benign findings in the surrounding tissues, supporting the expert's belief that the tumor was initially operable. *Id.* And the report explained that the tumor grew to the point of being inoperable during the period it went undiagnosed. *Id.* This Court agreed with the trial court that the report sufficiently explained causation.

By contrast, the reports here provided no differences between the findings over the two time periods. Instead, the reports assumed a better prognostic stage of cancer when the diagnosis was allegedly delayed—without offering any explanation of why the situation worsened during the delay. Unlike the reports here, the *Garcia* report at least explained that treatment could no longer occur because the tumor was now "inoperable." The *Garcia* case demonstrates that the trial court abused its discretion because that expert report contained what is missing in this case—a statement showing that the cancerous condition actually changed in the intervening period. Without an explanation of how the cancer changed during the alleged delay, the expert reports did not satisfy the causation requirement of Chapter 74.

A second example from the case law is *Estorque v. Schafer*, 302 S.W.3d 19 (Tex.App.—Ft. Worth 2009, no pet.). While the expert report in question listed a

host of consequences that resulted from the alleged negligence, the report never explained why the list of problems occurred, or how the negligence caused that list. *Id.* at 28-29. And the expert did not explain how proper treatment would have prevented the list of injuries. *Id.* at 29. This Court concluded that the report was deficient because it only explained causation in a conclusory fashion, essentially assuming a better outcome with different treatment. *Id.*

The reports here offered a problem quite similar to *Estorque*. These reports included the fact that the prognosis and treatment would have been better for the patient but never explained why the prognosis and treatment would have been better. Instead, the experts assumed—and did not explain—a better cancer stage with an earlier diagnosis. *Estorque* supports Appellants' position that the trial court abused its discretion in finding the expert report sufficient.

Granbury Minor Emergency Clinic, a case involving a delayed diagnosis of appendicitis, provides another good contrast to this case, highlighting what is missing from these expert reports. 296 S.W.3d at 264. In that case, the expert explained what condition existed at the time of the varying delays, which allowed this Court to conclude how the delay actually harmed the patient:

> In this case, the diagnosis of [the patient's] appendicitis was delayed due to Dr. Salas' failure to obtain the appropriate clinical history or complete an adequate physical examination and perform the appropriate diagnostic testing…Because of the delay the appendicitis progressed until the appendix became gangrenous and ruptured thereby spilling

> bacteria into her peritoneal cavity…require[ing]…a portion of this twenty-two year old's colon…to be surgically removed…When [the patient] initially presented to the Granbury Minor Emergency Clinic and was seen by Dr. Salas on August 28, 2006, she was not yet complaining of pain that was localized to the right lower quadrant. This is indicative of an early appendicitis. The second time [the patient] was seen…the pain was localizing to the right side which is indicative of an acute appendicitis with irritated parietal peritoneum most commonly associated with increased swelling of the appendix without perforation. Thus, if Dr. Salas had acted within the standard of care and timely diagnosed [the patient], her appendix would not have ruptured….

Id. at 271-272. At the two times when delay occurred, the expert factually relayed what occurred with the patient, including the signs and symptoms and the likely meaning of those signs, and that the appendix had not ruptured. Thus, the expert connected the ruptured appendix to the delay and demonstrated that appropriate treatment would have prevented the harm.

Again, these expert reports stand in stark contrast. The experts presumed an earlier stage but never factually explained why an earlier diagnosis would have resulted in an earlier stage. In fact, the very fact the experts relied on to support a better prognosis with an earlier diagnosis was the exact diagnosis made by Dr. Brian when she performed the biopsy: ductal carcinoma in situ. CR 51 and 129. The experts never explained why the delay attributable to these experts changed the diagnosis. Moreover, the experts never explained what her lymph node status was during the alleged delay, and thus the experts did not establish any fact supporting the conclusion

that an earlier diagnosis would have been better for the patient. The trial court did not properly apply the law of Chapter 74 expert reports to these expert reports and thereby abused its discretion in finding the expert reports sufficient.

Another example where the list of problems resulting from the alleged negligence did not sufficiently connect breach to injury is *Collini*, 280 S.W.3d at 467. In that case, the expert described the physical harm from taking a drug and recited the conclusions of other doctors that the harm was related to the drug use, but the expert still did not explain how the drug caused the problems or, perhaps more importantly, how the specific prescriptions caused the problems. *Id.* Thus, the report was insufficient on causation. *Id.* at 467-468. The expert reports here are similarly deficient. The experts merely spouted off that the delay caused different treatments and prognosis, but the reports never explained why the delay resulted in those differences, i.e. how the cancer would have been staged differently with earlier treatment. The trial court abused its discretion by concluding otherwise.

Comparison cases are not limited to this Court, and the Dallas Court of Appeals' opinion in *Mosely v. Mundine* provides another excellent contast in a cancer case. 249 S.W.3d 775 (Tex.App.—Dallas 2008, no pet.). In that case, the physician failed to recognize a 1 cm lung nodule that became a 6 cm mass extending into the lung tissue with undetermined metastasis during the intervening 21 months. *Id.* at 780. While not discussing involvement of lymph nodes, the discussion demonstrated

the growth of the tumor in concrete fashion—the tumor grew 5 cm and invaded the lung tissue. The expert explained that the delay worsened the prognosis, requiring more invasive and aggressive treatment, something understandable given the size difference and invasiveness of the tumor when ultimately diagnosed. *Id.* at 780-781. The Dallas Court of Appeals found the expert report sufficient.

But the expert reports here provided no concrete details about how the patient's breast cancer advanced during the alleged delay. The experts asserted without any factual support that the tumor would have been more easily treated with an earlier diagnosis. But the experts did not justify that conclusion with data about the growth and invasion of the tumor—as the expert did in *Mosely*. The experts' causation opinions were conclusory, and the trial court abused its discretion in concluding that the reports met the Chapter 74 expert report requirements.

One final example of supportive cases comes from a memorandum opinion from one of the Houston appellate courts. *Kapoor v. Estate of Klovenski*, 2010 WL 3721866 (Tex.App.—Houston [14th Dist.] 2010, no pet.)(mem. op.). In a similar fashion to this case, the expert opined:

> Optimal outcomes in the treatment of malignant diseases such as cancer are based on early diagnosis; a thorough understanding of the likely behavior of the malignant disease process; prompt, comprehensive, and aggressive treatment; and frequent and thorough follow-up for the possibility of recurrence and/or metastasis. I find Dr. Kapoor's failure to timely diagnose the cancer in the left thigh of his patient…of a four month period of time…directly resulted in the spread of this cancer

> beyond therapeutic (surgical, radiation, and chemotherapy, as provided) control, leading to [the patient's] ultimate debilitating and painful death, none of which, it is probable, would have occurred had Dr. Kapoor initially diagnosed the cancer in his patient's leg successfully.

Id. at 4. The Houston appellate court noted that failure to diagnose cancer cases require scrutiny of "(1) the effect of cancer development over time on the patient's prognosis, and (2) the potential effectiveness of treatments for the patient's type of cancer." *Id.* (citations omitted). That court then concluded that the expert report was deficient because the expert "failed to connect her conclusion to any specific fact" regarding the treatability of the cancer—before or after eventual diagnosis. *Id.* at *5. In fact, the platitude about earlier treatment did not carry the day because it required an inference that different treatment would have been available that would have improved the patient's situation. *Id.*

While slightly more nuanced, the issue is quite similar here. The experts expressed platitudes about earlier treatment being better and what earlier and later treatments for breast cancer were. The experts did not, however, explain why the treatments would have been available for the patient with an earlier diagnosis, i.e. why the cancer would have been at a stage permitting the "early" treatment. In total, the series of cases demonstrates that the trial court abused its discretion in finding these expert reports sufficient. For cases where the expert reports were sufficient, those reports provided information not contained in these reports to justify the courts'

conclusions. For cases where the expert reports were deficient, the expert reports here contained similar flaws. Case law supports Appellants' position that the expert reports were insufficient, and the trial court abused its discretion by applying that case law to these expert reports. This Court should correct that error.

The one case Appellants found that took a significantly more relaxed approach to a causation statement in a similar expert report is this Court's opinion in *Palone v. Shearer*, 287 S.W.3d 229 (Tex.App.—Ft. Worth 2009, no pet.). In that case, the medical issue was a 22-month delay in diagnosing breast cancer that was supported by two expert reports. *Id.* at 232. One expert noted that there was "documented evidence of progressive growth and development of breast cancer" and concluded that the negligence in delaying the diagnosis "increased [the patient's] risk of metastic breast cancer and subsequent morbidity and mortality and constitutes medical negligence." *Id.* at 236. The other expert noted that the delay harmed the patient because the "breast cancer could have been treated if timely diagnosed, without the necessity of mastectomies and as likely her prognosis was worsen[ed] by delay of diagnosis as well." *Id.* This Court concluded the reports sufficiently addressed causation. *Id.* at 237.

But a significant distinction exists with the expert reports—one expert noted that there was "documented evidence of progressive growth and development of breast cancer," seeming to imply that the cancer grew through the varying stages for

breast cancer until diagnosed. *Id.* at 236. In contrast, these experts provide no factual information that demonstrated an actual worsening of the cancer except for the experts' unsupported conclusions. The experts gave no information about the stage with an earlier diagnosis; no information about nodal involvement with an earlier diagnosis; no information about tumor size with an earlier diagnosis. Instead the trial court had to improperly infer what the stage and nodal involvement would have been with an earlier diagnosis, and that inference is one that is not allowed. This one aberrant case should not justify the trial court's conclusions regarding these reports, especially when these reports did not contain the factual evidence of progressive growth of the cancer as did the expert in the earlier case.

As a whole, the case demonstrates the trial court's abuse of discretion. Expert reports need to provide some factual basis to support the expert's conclusion that delay caused harm. Here, the expert reports have no factual basis for the conclusion that an earlier diagnosis would have been at a better cancer stage, and the trial court misapplied the law of Chapter 74 expert reports to the reports in this case. This Court should reverse.

Wherefore, Appellants Consultants in Radiology, P.A., Jason W. Skiles, D.O., David W. Simonak, D.O., Fossil Creek Family Medical Center, P.A. pray that this Court reverse the trial court's orders denying their motions to dismiss and overruling their objections and remand this case to the trial court for a determination of whether

an extension of the expert report deadline is appropriate. Appellants Consultants in Radiology, P.A., Jason W. Skiles, D.O., David W. Simonak, D.O., Fossil Creek Family Medical Center, P.A. pray for recovery of their appellate costs and for such other relief to which they may be entitled.

Respectfully submitted,

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CERTIFICATE OF SERVICE

On April 14, 2014, I served a true and correct copy of Appellants' Brief Appellee's counsel, Mr. James E. Girards, by email and then subsequently served a paper copy on April 15, 2014, by certified mail, return receipt requested.

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DAVID M. WALSH IV

CERTIFICATE OF COMPLIANCE

Relying on the word count in Microsoft Word (2007), I certify that this computer-generated document contains 9,373 words, excluding the caption, identity of parties and counsel, table of contents, index of authorities, statement of the case, issues presented, statement of jurisdiction, statement of procedural history, signature, proof of service, and certificate of compliance. The text for the body of this document is in 14-point font, and the footnotes are in 14-point font.

DAVID M. WALSH IV

Appendix Tab 1: Order Denying Defendants David W. Simonak, D.O. & Fossil Creek Family Medical Center's Motion to Dismiss and Overruling Objections

FILED
TARRANT COUNTY
3/14/2014 4:11:36 PM
THOMAS A. WILDER
DISTRICT CLERK

CAUSE NO. 141-268032-13

S K , and	§	**IN THE DISTRICT COURT**
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	§	
vs.	§	**TARRANT COUNTY, TEXAS**
	§	
CONSULTANTS IN RADIOLOGY, P.A., JASON W. SKILES, D.O. DAVID W. SIMONAK, D.O. and FOSSIL CREEK FAMILY MEDICAL CENTER, P.A. SERVICES, INC.	§	**141ST JUDICIAL DISTRICT**

ORDER DENYING DEFENDANTS DAVID W. SIMONAK, D.O. & FOSSIL CREEK FAMILY MEDICAL CENTER'S MOTION TO DISMISS AND OVERRULING OBJECTIONS

After reviewing the pleadings and other documents on file in this case and hearing arguments of counsel the Court finds the motion should be denied and Defendants David W. Simonak, D.O. & Fossil Creek Family Medical Center's Objection to Plaintiff's Expert Report should be overruled.

IT IS THEREFORE ORDERED that Defendants David W. Simonak, D.O. & Fossil Creek Family Medical Center's Motion to Dismiss is hereby DENIED. IT IS FURTHER ORDERED that Defendants David W. Simonak, D.O. & Fossil Creek Family Medical Center's Objections to Plaintiff's Expert Report are OVERRULED.

SIGNED this 25th day of February, 2014.

JUDGE PRESIDING

Appendix Tab 2: Order Denying Defendants Jason W. Skiles, D.O. and Consultants in Radiology, P.A.'s Motion to Dismiss And Overruling Objections

FILED
TARRANT COUNTY
3/14/2014 4:11:36 PM
THOMAS A. WILDER
DISTRICT CLERK

CAUSE NO. 141-268032-13

IN THE DISTRICT COURT

each Individually

	§	
	§	
vs.	§	**TARRANT COUNTY, TEXAS**
	§	
CONSULTANTS IN RADIOLOGY, P.A., JASON W. SKILES, D.O. DAVID W. SIMONAK, D.O. and FOSSIL CREEK FAMILY MEDICAL CENTER, P.A. SERVICES, INC.	§	**141ST JUDICIAL DISTRICT**

ORDER DENYING DEFENDANTS JASON W. SKILES, D.O. AND CONSULTANTS IN RADIOLOGY, P.A.'S MOTION TO DISMISS AND OVERRULING OBJECTIONS

After reviewing the pleadings and other documents on file in this case and hearing arguments of counsel the Court finds the motion should be denied and Defendants Jason W. Skiles, D.O. and Consultants in Radiology, P.A.'s Objection to Plaintiff's Expert Report should be overruled.

IT IS THEREFORE ORDERED that Defendants Jason W. Skiles, D.O. and Consultants in Radiology, P.A.'s Motion to Dismiss is hereby DENIED. IT IS FURTHER ORDERED that Defendants Jason W. Skiles, D.O. and Consultants in Radiology, P.A.'s Objections to Plaintiff's Expert Report are OVERRULED.

SIGNED this 25th day of February, 2014.

JUDGE PRESIDING

Appendix Tab 3: Tex. Civ. Prac. & Rem. Code § 74.351

Vernon's Texas Statutes and Codes Annotated
Civil Practice and Remedies Code (Refs & Annos)
Title 4. Liability in Tort
Chapter 74. Medical Liability (Refs & Annos)
Subchapter H. Procedural Provisions (Refs & Annos)

V.T.C.A., Civil Practice & Remedies Code § 74.351

§ 74.351. Expert Report

Effective: September 1, 2013
Currentness

(a) In a health care liability claim, a claimant shall, not later than the 120th day after the date each defendant's original answer is filed, serve on that party or the party's attorney one or more expert reports, with a curriculum vitae of each expert listed in the report for each physician or health care provider against whom a liability claim is asserted. The date for serving the report may be extended by written agreement of the affected parties. Each defendant physician or health care provider whose conduct is implicated in a report must file and serve any objection to the sufficiency of the report not later than the later of the 21st day after the date the report is served or the 21st day after the date the defendant's answer is filed, failing which all objections are waived.

(b) If, as to a defendant physician or health care provider, an expert report has not been served within the period specified by Subsection (a), the court, on the motion of the affected physician or health care provider, shall, subject to Subsection (c), enter an order that:

(1) awards to the affected physician or health care provider reasonable attorney's fees and costs of court incurred by the physician or health care provider; and

(2) dismisses the claim with respect to the physician or health care provider, with prejudice to the refiling of the claim.

(c) If an expert report has not been served within the period specified by Subsection (a) because elements of the report are found deficient, the court may grant one 30-day extension to the claimant in order to cure the deficiency. If the claimant does not receive notice of the court's ruling granting the extension until after the 120-day deadline has passed, then the 30-day extension shall run from the date the plaintiff first received the notice.

(d) to (h) [Subsections (d)-(h) reserved]

(i) Notwithstanding any other provision of this section, a claimant may satisfy any requirement of this section for serving an expert report by serving reports of separate experts regarding different physicians or health care providers or regarding different issues arising from the conduct of a physician or health care provider, such as issues of liability and causation. Nothing in this section shall be construed to mean that a single expert must address all liability and causation issues with respect to all physicians or health care providers or with respect to both liability and causation issues for a physician or health care provider.

(j) Nothing in this section shall be construed to require the serving of an expert report regarding any issue other than an issue relating to liability or causation.

(k) Subject to Subsection (t), an expert report served under this section:

(1) is not admissible in evidence by any party;

(2) shall not be used in a deposition, trial, or other proceeding; and

(3) shall not be referred to by any party during the course of the action for any purpose.

(*l*) A court shall grant a motion challenging the adequacy of an expert report only if it appears to the court, after hearing, that the report does not represent an objective good faith effort to comply with the definition of an expert report in Subsection (r)(6).

(m) to (q) [Subsections (m)-(q) reserved]

(r) In this section:

(1) “Affected parties” means the claimant and the physician or health care provider who are directly affected by an act or agreement required or permitted by this section and does not include other parties to an action who are not directly affected by that particular act or agreement.

(2) “Claim” means a health care liability claim.

(3) [reserved]

(4) “Defendant” means a physician or health care provider against whom a health care liability claim is asserted. The term includes a third-party defendant, cross-defendant, or counterdefendant.

(5) “Expert” means:

(A) with respect to a person giving opinion testimony regarding whether a physician departed from accepted standards of medical care, an expert qualified to testify under the requirements of Section 74.401;

(B) with respect to a person giving opinion testimony regarding whether a health care provider departed from accepted standards of health care, an expert qualified to testify under the requirements of Section 74.402;

(C) with respect to a person giving opinion testimony about the causal relationship between the injury, harm, or damages claimed and the alleged departure from the applicable standard of care in any health care liability claim, a physician who is otherwise qualified to render opinions on such causal relationship under the Texas Rules of Evidence;

(D) with respect to a person giving opinion testimony about the causal relationship between the injury, harm, or damages claimed and the alleged departure from the applicable standard of care for a dentist, a dentist or physician who is otherwise qualified to render opinions on such causal relationship under the Texas Rules of Evidence; or

(E) with respect to a person giving opinion testimony about the causal relationship between the injury, harm, or damages claimed and the alleged departure from the applicable standard of care for a podiatrist, a podiatrist or physician who is otherwise qualified to render opinions on such causal relationship under the Texas Rules of Evidence.

(6) “Expert report” means a written report by an expert that provides a fair summary of the expert's opinions as of the date of the report regarding applicable standards of care, the manner in which the care rendered by the physician or health care provider failed to meet the standards, and the causal relationship between that failure and the injury, harm, or damages claimed.

(s) Until a claimant has served the expert report and curriculum vitae as required by Subsection (a), all discovery in a health care liability claim is stayed except for the acquisition by the claimant of information, including medical or hospital records or other documents or tangible things, related to the patient's health care through:

(1) written discovery as defined in Rule 192.7, Texas Rules of Civil Procedure;

(2) depositions on written questions under Rule 200, Texas Rules of Civil Procedure; and

(3) discovery from nonparties under Rule 205, Texas Rules of Civil Procedure.

(t) If an expert report is used by the claimant in the course of the action for any purpose other than to meet the service requirement of Subsection (a), the restrictions imposed by Subsection (k) on use of the expert report by any party are waived.

(u) Notwithstanding any other provision of this section, after a claim is filed all claimants, collectively, may take not more than two depositions before the expert report is served as required by Subsection (a).

Credits

Added by Acts 2003, 78th Leg., ch. 204, § 10.01, eff. Sept. 1, 2003. Amended by Acts 2005, 79th Leg., ch. 635, § 1, eff. Sept. 1, 2005; Acts 2013, 83rd Leg., ch. 870 (H.B. 658), § 2, eff. Sept. 1, 2013.

Notes of Decisions (1838)

V. T. C. A., Civil Practice & Remedies Code § 74.351, TX CIV PRAC & REM § 74.351

Current through the end of the 2013 Third Called Session of the 83rd Legislature

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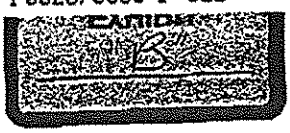
Appendix Tab 4: Expert Report Of Suraj Achar, M.D. (redacted)



EXPERT OPINION OF SURAJ ACHAR, M.D.

This report is written at the request of The Girards Law Firm and is written in order to comply with *Texas Civil Practices & Remedies Code* § 74.351. I have been informed that subsection (k) of the statute provides that an expert opinion prepared under this law is not admissible in evidence by any party; shall not be used in a deposition, trial, or other proceeding; and shall not be referred to by any Defendant during the course of any proceeding in this case. All opinions expressed herein are based upon reasonable medical probability.

I have reviewed the medical care given to patient during the time period from September 2011 to present by Fossil Creek Family Medical, Dr. David Simonak, Dr. Jonathan Snead, Texas Breast Specialists, Dr. Mary Brian, Dr. Jason Skiles, Dr. Renita Butler, and Texas Health Harris Methodist Southlake Hospital. I have also been provided with the Expert Opinion of Jeffrey B. Mendel, M.D.

QUALIFICATIONS

I am a family physician licensed to practice medicine by the State of California. I received the MD degree at Buffalo School of Medicine at State University of New York. Thereafter, I completed an Internship and Residency in Family and Preventive Medicine at the University of California School of Medicine at San Diego. Subsequently, I served as a volunteer for the organization Doctors without Borders in Kenya. Following my term with Doctors without Borders, I took a job as a clinician and faculty member of the Ventura County Family Medicine Residency. I also returned to San Diego, where I completed a Fellowship in Sports Medicine at UCSD. I am board certified in Family Medicine, with added qualifications in Sports Medicine. I have continuously been involved in the practice of family medicine at all times relevant hereto.

Since 2001, I have served as a Clinical Professor of Family and Preventive Medicine at the University of California School of Medicine at San Diego. I teach medical students, resident and fellows at the university and I practice clinical family medicine. I have served as the Medical Director of the UCSD La Jolla Family and Sports Medicine for 5 years. Seventy percent of my time is spent rendering direct patient care, with the rest divided between teaching, research and administrative responsibilities. My teaching includes faculty supervision of the resident family medicine clinic. I have direct experience in formulating and reviewing the adequacy of, and compliance with, policies and procedures applicable to physicians and entities providing family medical care. For the past five years, I have served on the Clinical Quality Assurance Committee at UCSD. Likewise, I have taught and lectured at national meetings on the family physician's obligations in ordering and following up on mammograms. My curriculum vitae is attached hereto, and further outlines my training, education, and experience.

In my current practice, I see patients complaining of breast pain, axillary swelling and breast swelling and masses. I routinely order imaging studies of the breast including mammograms, ultrasound and follow-up studies, as indicated, for patients. I am intimately familiar with the ordering of screening and diagnostic mammograms, the communication to the patient of the results of mammograms, and proper methods of following up on such mammograms. I am familiar with the standard of care as it applies to family medicine physicians and family medicine practices regarding these issues. All opinions expressed in this report are based on reasonable medical probability.

I understand that in Texas, "negligence", when used with respect to a physician, means the failure to use ordinary care; that is, doing that which a physician of ordinary prudence would not have done under the same or similar circumstances, or failing to do that which a physician of ordinary prudence would have done under the same or similar circumstances.

I understand that in Texas as to a physician, "ordinary care" means that degree of care, which would be used by a physician of ordinary prudence under the same or similar circumstances.

I understand that in Texas, "negligence", when used with respect to a family medicine practice, means the failure to use ordinary care; that is, doing that which a family medicine practice of ordinary prudence would not have done under the same or similar circumstances, or failing to do that which a family medicine practice of ordinary prudence would have done under the same or similar circumstances.

I understand that in Texas as to a family medicine practice, "ordinary care" means that degree of care, which would be used by a family medicine practice of ordinary prudence under the same or similar circumstances.

I understand that in Texas, "proximate cause" means that cause that was a substantial factor in bringing about an event, and without which cause such event would not have occurred. In order to be a proximate cause, the act or omission complained of must be such that a physician using ordinary care would have foreseen that the event, or some similar event, might reasonably result therefrom. I understand that there may be more than one proximate cause of an event.

PATIENT HISTORY

At the time of the initial visit on 9/19/11 for the chief complaint of "left axilla pain-feels like swollen lymph nodes x several weeks-slight pain to the right axilla" patient, was 33 year old. On this day she was seen by nurse practitioner Brenda Wilmore, FNP, BC. In the HPI (history of present illness section) Brenda Wilmore noted "pain in the left axilla/breast, deep pain feels like "mastitis." Nurse practitioner Brenda Wilmore went on to perform a physical exam. In the neck section of the exam she checked for lymphadenopathy. Although she examined and documented a detailed exam of her overall appearance, head exam, skin exam, eye exam, ear exam, oropharynx exam, neck exam, thymid exam, heart exam, lung exam, extremities exam, and neurological exam she failed to document that she examined the chief areas of complaint the breast or the axilla. Her assessment repeated the complaint of "Pain, upper arm, pain in the left axilla/breast." She started an antibiotic Bactrim DS tablet. She also gave her a prescription for the pain, Ultram. She ordered a screening mammogram. She did not order a diagnostic mammogram. Despite not making a clear diagnosis nurse practitioner Wilmore does not document any consultation with her supervising physician.

On 9/22/11 patient had a diagnostic mammogram despite the order for a screening mammogram above. The mammogram was ordered under the name of David Simonak, MD. The mammogram was documented to have dense tissue with punctate calcifications involving only the left breast, the same side she had pain and swelling. The impression included

"indeterminate microcalcifications in the left breast, probably benign. A follow up study is recommended in 3 to 6 months." The study was categorized as BI-RADS 3. Dr. Simonak or NP Brenda Wilmore did not sign the copy that was provided to me.

On 9/23/11 NP Wilmore generated a telephone encounter where she is noted that patient needed an ultrasound of the left breast. On 9/26/11 Patient had an ultrasound of her left breast and axillary region, which was read as normal.

On 10/06/11 Eric Wroten saw her for a post-op visit. She was seen also on 10/25/11 also for the same condition status post left dupuytren's fasciotomy.

On 11/02/11 patient appears to be seen for the first time since the complaint of breast and axillary pain and swelling by David Simonak, DO. On this visit she had already completed the abnormal mammogram attributed to an order from Dr. Simonak. In the physical exam section there is no exam noted of the axilla or breast. She was diagnosed with hypothyroidism and EBV.

On 11/22/11 Dr. Simonak again saw her. Again no exam was made of the breast or axilla. Again no note was made that the patient was informed of the abnormal mammogram. On 12/13/11 she was seen again "because she found out she was pregnant.

On 4/12/12 patient again goes to see Dr Simonak. Now it is over 6 months since the abnormal mammogram results. At this time she complains of dorsal arm pain. Again no exam is made of the breast or the axilla. Again there is no mention that patient was informed of the abnormal mammogram or the need to repeat the mammogram in 3-6 months. No mammogram was ordered despite the radiology request.

On 6/1/2012 Brenda Wilmore FNP sees her. Again no exam is made of the breast or the axilla. Again no mention that patient was informed of the abnormal mammogram or the need to repeat the mammogram in 3-6 months. No mammogram was ordered despite the radiology request.

On 7/10/12 she again sees Dr. Simonak. The chief complaint at this time is left sided rib pain. Again no exam is made of the breast or the axilla. Again there is no mention that the patient was informed of the abnormal mammogram or the need to repeat the mammogram in 3-6 months. No mammogram was ordered despite the radiology request.

On 7/30/12 Brenda Wilmore FNP sees her. Again no exam is made of the breast or the axilla. Again there is no mention that patient was informed of the abnormal mammogram or the need to repeat the mammogram in 3-6 months. No mammogram was ordered despite the radiology request.

On 9/13/12 Dr. Simonak sees her. Again no exam is made of the breast or the axilla. Again there is no mention that patient was informed of the abnormal mammogram or the need to repeat the mammogram in 3-6 months. No mammogram was ordered despite the radiology request.

On 11/29/12 Brenda Wilmore FNP sees her for a chief complaint of the lump in left breast x several months. Nurse practitioner Wilmore notes in the history of present illness that the mass in

the left breast has "been there for several years and that the left breast is larger than the right." It appears that despite the fact the FNP Wilmore had ordered the mammogram herself she asks the patient what the results of the mammogram are and she documents that the patient states the mammogram was negative despite the results to the contrary. It appears that neither the patient nor nurse Wilmore understood the abnormal reading of the mammogram or the need to repeat the mammogram. Nurse practitioner Wilmore notes the first documented breast exam since the patient complained of the breast pain. Her breast exam is severely abnormal with a large breast, large palpable mass that is non-tender, irregular moveable with no signs of mastitis. She correctly diagnoses a breast mass and orders now diagnostic breast imaging. She also suggests a biopsy. No referral is made to a breast surgeon despite the diagnosis and exam that is consistent with cancer, not mastitis.

On 11/30/12 a mammogram was done where the radiologists note left breast microcalcifications. The radiologist falsely concludes that she has prior mastitis and the abnormalities are consistent with mastitis and read as BI-RADS 2. It is recommended to restart annual screening mammogram at age 40.

On 1/16/13 Dr. Simonak sees her for a chief complaint of the breast milk culture of the left breast. No breast exam is performed or documented even though the FNP noted such a severely abnormal exam previously. No mention of the previously severely abnormal exam is mentioned. In fact no mention of review of the prior records is made. She is on Zithromax although it is not clear based on this note why she is on this antibiotic. She is diagnosed with mastitis without a documented exam of the breast.

On 1/23/13 Dr Simonak again sees her. No history or exam of the breast mass is noted but she is diagnosed now with a breast mass and it is noted that she is to proceed with a biopsy.

On 1/28/13 an ultrasound guided biopsy was performed by Dr. Mary Brian, which showed high-grade ductal carcinoma. This ultrasound-guided biopsy was completed within 5 days of the order above.

STANDARDS OF CARE

The standard of care for a family medicine physician treating a patient complaining of breast pain such as patient requires that the physician complete and document a thorough physical examination of the breast and lymph nodes. If the family medicine physician has a Family Nurse Practitioner see the patient for these complaints, the physician must assure that the Family Nurse Practitioner completes and documents a through physical examination of the breast and lymph nodes. Minimal standards of care require that the physician order a diagnostic mammogram, as opposed to a screening mammogram when treating a patient such as patient. Further, the standard of care further requires that the family medicine physician communicate the results of such mammograms to the patient directly, make certain that the patient understands the results of the mammograms, and assure that any recommended follow-up studies occur within the appropriate time frame.

The standard of care for a family medicine practice treating a patient complaining of breast pain such as patient : requires that the family medicine practice have and enforce adequate policies and procedures to assure that: 1) all physicians and family nurse practitioners

perform and document a thorough physical examination of the lymph nodes and breast for patients complaining of breast pain; 2) mammogram results are communicated to directly to the patient; and 3) recommended follow-up studies occur within the appropriate time frame.

VIOLATIONS OF THE STANDARD OF CARE

1. **Lack of proper physician supervision**
2. **Lack of proper physical exam including a severe delay in examining the breast and axilla**
3. **Erroneous order of a screening mammogram when diagnostic mammogram is required**
4. **Lack of follow up of the mammogram as recommended by radiology and required by the standard of care**
5. **Delay in referral to breast surgeon despite an exam that was consistent with cancer**
6. **Failure to share information about the abnormal breast imaging studies with the patient**
7. **Failing to have and enforce adequate policies and procedures**

1. Lack of proper physician supervision

My review of the medical records and materials related to patient's care leads me to conclude that, based on reasonable medical probability, Dr. David Simonak fell below the applicable standards of care in his treatment of patient by failing to properly supervise his nurse practitioner Brenda Wilmore. On September 19, 2011, Brenda Wilmore, FNP saw patient for these complaints, yet Dr. Simonak failed to assure that FNP Wilmore completed and documented a through physical examination of the breast and lymph nodes.

In general nurse practitioners and PA are considered physician extenders. They usually work in a team that includes physicians. They generally can take care of 90% of the clinical problems that they encounter daily but do need help with the most difficult clinical scenarios when they do not know the diagnosis or the condition that the patient faces is dangerous or has a high risk. At the time of this visit Texas Law required physician supervision of nurse practitioners. Perhaps one reason for the supervision relates to limited training given to nurse practitioners as compared to physicians.

This case illustrates the critical importance of working as a team and having physician supervision. Ultimately there was no proper diagnosis made on the first visit on 9/19/11. At this time Brenda Wilmore, FNP, BC diagnosed the patient with "pain in the upper arm." In general physicians usually make a diagnosis that is more focused than a symptom. When they use a symptom as a diagnosis it is an acknowledgement that the condition is yet to be clearly diagnosed. When a nurse practitioner does not know the diagnosis then that would be a great opportunity to discuss the patient with her supervising physician. This is the intent of Texas law and discussion when no clear diagnosis is made is consistent with the standard of care. No discussion is made and documented between the FNP and her supervising doctor, which is contrary to the law and the standard of care. Dr. Simonak's failures to adequately supervise FNP Wilmore in this case is below the standard of care.

2. Lack of proper physical exam including severe delay in examining the breast and axilla

My review of the medical records and materials related to patient's care leads me to conclude that, based on reasonable medical probability, Dr. David Simonak fell below the applicable standards of care in his treatment of patient by failing to complete and document a thorough physical examination of her breast and lymph nodes.

On 9/19/11 Brenda Wilmore FNP noted "pain in the left axilla/breast, deep pain feels like "mastitis." However, Brenda Wilmore FNP did not perform and document a physical exam of the either the axilla or the breast. After ordering a mammogram, which was noted to be abnormal in the region that the patient felt the swelling no doctor or nurse practitioner performed an exam of the axilla or breast. Dr Simonak saw the patient twice in November of 2011 and did not perform an exam of the breast despite the abnormal mammogram and her complaints in September 2011. He also saw her in April 2012. Although she complained of arm pain at the time he still did not document a breast exam or axillary exam. She was seen 4 more times by either the nurse practitioner Wilmore or Dr Simonak without an exam of the breast or axilla.

The standard of care when seeing a patient with a complaint is to perform a pertinent physical exam. When a patient complains of pain the standard of care requires at least an exam of the area that the patient complains about. This was not done. At the UCSD School of Medicine we teach all the medical students, residents, fellows and even nurse practitioners that they must examine all parts of an exam that are relevant for the differential diagnosis. This includes the area that the patient complains has pain or swelling. Failure to do this is below the standard of care for both nurse practitioners and physicians.

3. Erroneous order of screening mammogram when diagnostic mammogram is required

My review of the medical records and materials related to patient's care leads me to conclude that, based on reasonable medical probability, Dr. David Simonak fell below the applicable standards of care in his treatment of patient by failing to order a diagnostic mammogram, as opposed to the screening mammogram for patient.

When she is was seen on 9/19/11, a screening mammogram was ordered. A screening mammogram is not indicated in a 33 year old female unless there is a specific indication such as a family history of breast cancer. When a patient has a complaint of swelling or pain or a mass, doctors can order mammograms to evaluate the symptoms and or abnormal exam. In these cases doctors and all physician extenders must order a diagnostic mammogram. A diagnostic mammogram includes extra views and alerts the radiologist to the special concerns. Also a diagnostic mammogram requires that the radiologist be present at the time of the procedure or after to speak to the patient about the results. Diagnostic mammograms improve the sensitivity to detect cancer. Failure to order a diagnostic mammogram on 9/19/11, as well as on subsequent visits, was below the standard of care.

4. Lack of follow up of the mammogram as recommended by radiology and required by the standard of care

My review of the medical records and materials related to patient's care leads me to conclude that, based on reasonable medical probability, Dr. David Simonak fell below the applicable standards of care in his treatment of patient by failing to assure that the

recommended follow-up breast imaging was ordered in 3-6 months and occurred within this time frame.

When the radiologist reported the results of the mammogram on 9/22/11, he recommended that the patient get a repeat mammogram in 3-6 months because of the risk of cancer. Failure to order the repeat mammogram as directed by the radiologist is below the standard of care. When doctors get radiologic results that are abnormal they are generally required to act on these results. If they do not follow the recommendations they need to explain to the patients why they are not following the recommendations of the radiologists and explain their thinking. A good example would be if the test had a risk to the patient such as radiation exposure in with a CT scan. However, a mammogram has almost no risk of radiation exposure or injury to a patient. Failure to follow the recommendation in this case is a breach of the standard of care.

5. Delay in referral to breast surgeon despite exam that was consistent with cancer

My review of the medical records and materials related to patient's care leads me to conclude that, based on reasonable medical probability, Dr. David Simonak fell below the applicable standards of care in his treatment of patient by failing to assure that when his PA felt a breast lump for which she was worried that the patient had cancer that she properly referred her to a breast surgeon.

On 11/29/12 patient was seen by Brenda Wilmore FNP for a chief complaint of the lump in left breast x several months. On this visit the FNP feels that the patient does not have mastitis but rather has a condition that requires a biopsy. She orders a diagnostic mammogram but for some reason does not refer the patient to a breast surgeon. Primary care physicians and FNP's must refer patients when they feel the patient has cancer to surgeons capable of doing a biopsy to identify the cancer. Ultimately however she does not make the referral but rather orders another mammogram. This leads to further delay in the diagnosis. She is seen six weeks later by Dr Simonak who again does not order a surgical consult. Later that month in January 2013, Dr Simonak finally orders the consult with a breast surgeon. Within five days she is seen by a surgeon and has a biopsy the same day that shows the cancer. Ultimately the delay is diagnosis actually goes back to her first visit on 9/19/11 when she could have been referred and seen by a surgeon. The delay to refer the patient to a breast surgeon is below the standard of care and leads to worsening outcomes for patient.

6. Failure to share information about the abnormal breast imaging studies with the patient

My review of the medical records and materials related to patient's care leads me to conclude that, based on reasonable medical probability, Dr. David Simonak fell below the applicable standards of care in his treatment of patient by failing to communicate the results of the September 22, 2011 mammogram to patient directly and failing to make certain that patient understood the results of the mammogram.

Perhaps the most important breach in the standard of care relates to the delay in getting the information to the patient about her abnormal studies. When the abnormal 2011 mammogram results and recommendation for follow-up were received by Dr. Simonak and Fossil Creek Family Medical Center, patient should have been informed of the result. Both Dr. Jason Skiles (the radiologist) and Dr. Simonak (the primary care physician) were required to share this

critical information to the patient. Fossil Creek Family Medical Center, P.A. was required to have policies to assure that this type of critical information is communicated to the patient. Information sharing is so critical because this will lead to a vastly improved chance that the patient gets her follow up mammogram in a timely manner. Information sharing, more likely than not, would have led pt. to question her symptoms and the medical teams lack of a diagnosis and request faster follow up care. Information sharing, more likely than not, would have led pt. to the conclusion that she would have liked to see a specialist like the specialist who ultimately diagnosed her. Regardless, failure to share the information about her abnormal mammogram and exam led pt. to falsely believe that her breast symptoms were not cancer, delayed the ultimate diagnosis, and worsened her outcome.

For each of the reasons stated above, under the definitions listed above, I must conclude that Dr. Simonak was negligent in his care and treatment of patient.

7. Failing to have and enforce adequate policies and procedures

My review of the medical records and materials related to patient's care leads me to conclude that, based on reasonable medical probability, Fossil Creek Family Medical Center, P.A. fell below the applicable standards of care in its treatment of patient by failing to have and enforce adequate policies and procedures to assure that Dr. Simonak and Brenda Wilmore, FNP performed and documented a thorough physical examination of patient's lymph nodes and breast when she presented complaining of breast pain. Further, Fossil Creek Family Medical Center, P.A. fell below the applicable standards of care by failing to have and enforce policies and procedures assuring that patient's mammogram results were communicated directly to her, and that the follow-up studies occur within the recommended 3-6 months. Under the definitions listed above, I must conclude that Fossil Creek Family Medical Center, P.A. was negligent in its care and treatment of patient.

APPROPRIATE PATIENT CARE

Dr. Simonak ordered the September 22, 2011 screening mammogram and ultrasound in response to patient's breast pain. As such, he was clearly aware of these complaints and should have performed and documented a complete physical examination of her breast and lymph nodes. He did not, and he also failed to assure that Brenda Wilmore, FNP completed and documented a through physical examination of the breast and lymph nodes. Dr. Simonak should have ordered a diagnostic mammogram, as opposed to the screening mammogram. And finally, Dr. Simonak should have communicated the abnormal results of the September 22, 2011 mammogram to patient directly, made certain that she understood these results, and assured that she had the recommended follow-up studies in 3-6 months.

Fossil Creek Family Medical Center, P.A. should have had and enforced adequate policies and procedures in place to assure that Dr. Simonak and Brenda Wilmore, FNP performed and documented a thorough physical examination of patient's lymph nodes and breast when she presented complaining of breast pain. Further, Fossil Creek Family Medical Center, P.A. fell below the applicable standards of care by failing to have and enforce policies and procedures assuring that patient's mammogram results were communicated directly to her, and that the follow-up studies occur within the recommended 3-6 months.

Outcomes if appropriate steps been taken

1. **Evaluation of an occult cancer and the role of the physical exam.**

Mammogram although a great tool is not the only tool for the diagnosis of breast cancer Early physical exam may have found a mass that may have led to early referral. Of note Up to date states "A clinically suspicious mass should also be biopsied, regardless of imaging findings, as about 15 percent of such lesions can be mammographically occult (Barlow WE, Lehman CD, Zheng Y, et al. Performance of diagnostic mammography for women with signs or symptoms of breast cancer. J Natl Cancer Inst 2002; 94:1151.) An earlier physical exam may have led to an earlier diagnosis and earlier treatment plan.

2. **Early or immediate referral would have more likely than not led to an earlier diagnosis and treatment protocol.**

Ultimately when referred to a breast specialist, patient, had a visit and rapid biopsy resulting in rapid diagnosis. The goal of the initial biopsy is to obtain sufficient diagnostic material using the least invasive approach and to avoid surgical excision of benign lesions. Ultimately the biopsy would have uncovered the cancer at an earlier stage leading to a less invasive treatment approach.

3. **A careful response to the mammogram would have more likely than not led to an earlier diagnosis and earlier therapy.**

"The majority of breast cancers are are associated with abnormal mammographic findings." (Smart CR, Hartmann WH, Beahrs OH, Garfinkel L. Insights into breast cancer screening of younger women. Evidence from the 14-year follow-up of the Breast Cancer Detection Demonstration Project. Cancer 1993; 72:1449.). Had Dr. Simonak and Brenda Wilmore, FNP paid attention and shared the information on the risk of breast cancer with patient, she more likely than not would have had an earlier diagnosis and treatment of her cancer.

4. **Breast cancer treatment depends significantly on the stage at diagnosis and earlier diagnosis would have detected the cancer at an earlier stage.**

Treatment of breast cancer depends on multiple aspects including but not limited to tumor size, tumor grade, involvement of lymph nodes, hormone receptor status and genetic testing. Tumor size and involvement of lymph nodes often depends specifically on the time of detection. Breast cancer survival has improved with mammography because of the earlier detection of tumors when they are smaller and have spread less. Had earlier detection happened for patient her prognosis would have been better and likely her treatment would have been less toxic, less invasive and less debilitating. Most importantly patient would have had a better outcome and chance of survival.

CAUSATION & DAMAGES

It is my opinion beyond a reasonable medical probability, based on my training and education and experience, that the negligent acts/omissions of Dr. Simonak and Fossil Creek Family Medical Center, P.A. outlined above were each a proximate cause of the extended delay in diagnosis and treatment of patient's breast cancer.

Specifically, the failure to conduct and document a physical examination prevented healthcare providers from being aware of the clusters of abnormal tissue in patient's left breast, much less tracking its size/appearance over time. Moreover, by all indications in the medical records, Dr. Simonak never communicated nor explained the abnormal results of the mammogram to his patient. He didn't take any steps to assure that patient had a follow-up study within the recommended 3-6 months. Fossil Creek Family Medical Center, P.A. had no policy or system in place to assure that the follow-up took place. As such, it is clear that patient was unaware that she needed to have a follow-up mammogram in 3-6 months. Had appropriate care been rendered, more likely than not, patient would have received the recommended follow-up studies, the changes in the size/appearance of the abnormal breast tissue noted, and the diagnosis of breast cancer would have been reached much sooner than it was made.

In sum, it is my opinion beyond a reasonable medical probability, based on my training and education and experience, that Dr. David Simonak and Fossil Creek Family Medical Center, P.A. were negligent in their care of patient. Further, it is my opinion that each of these acts and omissions of negligence was a proximate cause of her injury and its sequelae.

I hold these opinions to a reasonable degree of medical certainty. I reserve the right to extend or amend these opinions as additional materials become available for my review.

Sincerely yours,

Suraj Achar, M.D.
Professor of Family and Preventive Medicine
University of California at San Diego School of Medicine

Appendix Tab 5: Expert Report Of Jeffrey B. Mendel, M.D. (redacted)

EXPERT OPINION OF JEFFREY B. MENDEL, M.D.

This report is written at the request of The Girards Law Firm and is written in order to comply with *Texas Civil Practices & Remedies Code* § 74.351. I have been informed that subsection (k) of the statute provides that an expert opinion prepared under this law is not admissible in evidence by any party; shall not be used in a deposition, trial, or other proceeding; and shall not be referred to by any Defendant during the course of any proceeding in this case. All opinions expressed herein are based upon reasonable medical probability.

I have reviewed the medical care given to patient during the time period from September 2011 to present by Fossil Creek Family Medical, Dr. David Simonak, Dr. Jonathan Snead, Texas Breast Specialists, Dr. Mary Brian, Dr. Jason Skiles, Dr. Renita Butler, and Texas Health Harris Methodist Southlake hospital. I have specifically reviewed the following diagnostic studies:

- Diagnostic mammogram performed on 22 September 2011
- Left breast ultrasound performed on 26 September 2011
- CT Chest without contrast performed on 25 September 2012
- Diagnostic mammogram performed on 30 November 2012
- Left breast ultrasound performed on 30 November 2012

As is my usual practice, I initially performed a blind review of the studies with no knowledge of the radiology reports or patient's subsequent clinical course. I then reviewed the radiology reports.

QUALIFICATIONS

I am a board certified physician licensed to practice medicine by the States of Massachusetts, Rhode Island, New Hampshire and Maine. I received the MD degree at Tufts University School of Medicine in Boston, Massachusetts in 1977. Thereafter, I completed an Internship in Internal Medicine at Norwalk Hospital in Norwalk, Connecticut, followed by a Residency in Radiology at the Hospital of St. Raphael in New Haven, Connecticut. From 1981 to 1983, I completed a Fellowship in Nuclear Medicine at Harvard Medical School in Boston, Massachusetts. I am a Diplomate of the American Board of Radiology and the American Board of Nuclear Medicine. Since 1983, I have continuously been involved in the practice of Radiology at numerous hospitals.

I have taught Radiology at Harvard University and Tufts University School of Medicine. From 2003 to 2008, I was directly involved in training 4th year Tufts Medical Center residents rotating through breast imaging. I have lectured on breast imaging at national and international meetings. Likewise, I have conducted research studies directly related to the detection of breast cancer. I have published in numerous peer-reviewed publications on the topics of breast lesions, needle biopsy of the breast, and the interpretation of screening mammography. My curriculum vitae is attached hereto, and further outlines my training, education, and experience.

I am intimately familiar with the performance and interpretation of breast imaging studies, including analog and digital mammography, ultrasound and breast MRI. I am familiar with the

standard of care as it applies to breast imaging read in a variety of practice settings. All opinions expressed in this report are based on reasonable medical probability.

I understand that in Texas, "negligence", when used with respect to a physician, means the failure to use ordinary care; that is, doing that which a physician of ordinary prudence would not have done under the same or similar circumstances, or failing to do that which a physician of ordinary prudence would have done under the same or similar circumstances.

I understand that in Texas as to a physician, "ordinary care" means that degree of care which would be used by a physician of ordinary prudence under the same or similar circumstances.

I understand that in Texas, "proximate cause" means that cause that was a substantial factor in bringing about an event, and without which cause such event would not have occurred. In order to be a proximate cause, the act or omission complained of must be such that a physician using ordinary care would have foreseen that the event, or some similar event, might reasonably result therefrom. I understand that there may be more than one proximate cause of an event.

PATIENT HISTORY / RADIOLOGICAL FINDINGS

In September 2011, Patient was a 33 year old mother of two children. She presented to her primary care physician, Dr. David Simonak, complaining of left sided breast pain. The mammogram of September 22, 2011 and ultrasound of September 26, 2011 were ordered as a result of this complaint.

September 22, 2011 Mammogram

On my blinded review, the mammogram demonstrates microcalcifications clustered in the upper outer quadrant of the left breast. These are principally in the mid portion of the breast but some are noted to extend more posteriorly. These calcifications are noted on the magnified, focally compressed views to be both amorphous and pleomorphic without associated mass or architectural distortion. Additionally, there are scattered groups of amorphous microcalcifications in adjacent portions of the same quadrant. There are a few lymph nodes visible in the left axilla on the oblique view and not on the right. The largest is less than 1 cm in short axis and retains a fatty notch although it appears relatively dense. There are virtually no microcalcifications in the right breast.

Dr. Jason Skiles interpreted the mammogram, and described "scattered punctuate benign appearing calcifications" in the left breast. He further described "some clustering of calcifications in the upper outer quadrant of the left breast." His Impression was as follows:

> Impression: Indeterminate microcalcifications in the left breast, probably benign. A follow-up study is recommended in 3 to 6 months. Computer-aided detection was utilized.
>
> BI-RADS category 3 : Probably benign finding(s).

September 26, 2011 Breast Ultrasound

The ultrasound of September 26, 2011 is unremarkable. The "Breast Ultrasound Tech Sheet" indicates that the breast was scanned from approximately 11:00 to 7:00 as well as the axilla. Specifically, no suspicious lymph nodes were detected.

Dr. Jason Skiles interpreted the breast ultrasound as unremarkable. His Impression was as follows:

> Impression: No sonographic abnormality is identified in the area of left axillary pain.

September 25, 2012 CT Scan of Chest

Approximately one year later, on September 25, 2012, Patient had a CT scan of her chest for unrelated medical issues. The CT scan demonstrates two prominent left axillary lymph nodes which have relatively minimal fatty hila but are less than 1 cm in short axis. Also visible is focal asymmetry of the breast parenchyma in the left upper outer quadrant.

In November 2012, she again presented to the office of her primary care physician, complaining of her left breast. Dr. Simonak ordered the mammogram of November 30, 2012 and ultrasound of November 30, 2012 as a result of this complaint.

November 30, 2012 Mammogram & Breast Ultrasound

On my blinded review, the diagnostic mammogram of November 30, 2012 demonstrates a marked increase in the number of microcalcifications, which now also involve at least the upper inner quadrant. There is also new focal asymmetry in the upper outer quadrant, corresponding to the largest area of microcalcifications and to the area of suspicious calcifications on the September 2011 mammogram. The left axillary lymph nodes appear larger and more numerous than on the September 2011 mammogram and, in fact, appear larger than on the September 2012 CT.

The left breast ultrasound of 30 November 2012, according to the "Breast Ultrasound Tech Sheet" demonstrated "hypoechoic patches with calcifications seen throughout lt. breast". The images confirm this appearance with the largest regions of abnormal breast parenchyma at 12 and 2 o'clock.

Patient continued to have left breast complaints and was evaluated by Dr. Mary Brian on January 28, 2013. Dr. Brian performed an in-office core biopsy which revealed high grade ductal carcinoma in situ. On February 22, 2013, Dr. Brian performed a left modified radical mastectomy and left sentinel node biopsy. Subsequent pathology confirmed that patient had multiple positive lymph nodes (14 out of 28) and she was diagnosed with multifocal Stage IIIC invasive ductal carcinoma.

STANDARDS OF CARE

The standard of care for physicians interpreting radiological studies in patients such as patient requires that the physician recognize the presence and significance of suspicious clusters of microcalcifications in breast tissue and recommend prompt biopsy.

VIOLATIONS OF THE STANDARD OF CARE

My review of the medical records and radiological studies related to patient's care leads me to conclude that, based on reasonable medical probability, Dr. Jason Skiles fell below the applicable standards of care in his treatment of patient by failing to appreciate the presence and significance of the suspicious microcalcifications in the left breast. Further, it is my opinion that Dr. Skiles fell below the applicable standards of care by failing to immediately recommend biopsy of the concerning breast tissue.

Under the definitions listed above, I must conclude that Dr. Skiles was negligent in his care and treatment of patient related to his September 2011 interpretation of the digital mammogram for these reasons. Had Dr. Skiles acted within applicable standards of care, he would have recommended prompt biopsy of the left breast which would have most likely resulted in the breast cancer being diagnosed and treated before spreading to the lymph nodes.

APPROPRIATE PATIENT CARE

In order to comply with applicable standards of care, Dr. Skiles should have recognized and appreciated that the September 22, 2011 mammogram demonstrated a highly suspicious cluster of microcalcifications in the upper outer quadrant of the left breast. The presence of adjacent groups of microcalcifications should have raised the possibility of multifocal disease in his mind. These findings warranted a recommendation for prompt biopsy, BI-RADS 4c, which Dr. Skiles should have recommended.

Unfortunately, Drs. Skiles failed to take these actions, thereby proximately causing an unnecessary extended delay in the diagnosis and treatment of patient breast cancer.

CAUSATION & DAMAGES

It is my opinion beyond a reasonable medical probability, based on my training and education and experience, that the negligent acts and omissions of Dr. Skiles outlined above were each a proximate cause of patient's injury and related sequelae.

Specifically, the failures of Dr. Skiles to identify and report the abnormalities in patient's left breast resulted in an extended delay in diagnosis and treatment of her disease. The basis for this opinion is that if the abnormalities were correctly identified, described, and reported to the ordering physician with a recommendation for biopsy, then a biopsy of the left breast would have been performed, the diagnosis of breast cancer would more likely than not have been reached within days following the reporting of the mammogram(s), and decisions regarding definitive care would more likely than not have been made within days following the reporting of the mammogram(s) rather than in 2013.

In sum, it is my opinion beyond a reasonable medical probability, based on my training and education and experience, that Dr. Jason Skiles was negligent in his care of patient. Further, it is my opinion that each of these acts and omissions of negligence was a proximate cause of her injury and its sequelae.

I hold these opinions to a reasonable degree of medical certainty. I reserve the right to extend or amend these opinions as additional materials become available for my review.

Sincerely yours,

Jeffrey B. Mendel, M.D.

Appendix Tab 6: Expert Report of Peter D. De Ipolyi, M.D. (redacted)

EXPERT OPINION OF PETER D. De IPOLYI, M.D.

This report is written at the request of The Girards Law Firm and is written in order to comply with *Texas Civil Practices & Remedies Code* § 74.351. I have been informed that subsection (k) of the statute provides that an expert opinion prepared under this law is not admissible in evidence by any party; shall not be used in a deposition, trial, or other proceeding; and shall not be referred to by any Defendant during the course of any proceeding in this case. All opinions expressed herein are based upon reasonable medical probability.

I have reviewed the medical care given to patient during the time period from September 2011 to present by Fossil Creek Family Medical, Dr. David Simonak, Dr. Jonathan Snead, Texas Breast Specialists, Dr. Mary Brian, Dr. Jason Skiles, Dr. Renita Butler, and Texas Health Harris Methodist Southlake Hospital. I have also been provided with the Expert Opinion of Jeffrey B. Mendel, M.D. as well as the Expert Opinion of Suraj Achar, M.D.

QUALIFICATIONS

I am a physician licensed to practice medicine by the State of Texas. I received the MD degree at Boston University School of Medicine in Boston, Massachusetts. Thereafter, I completed an Internship in Straight Surgery at Ben Taub General Hospital in Houston, Texas. I completed a two year Residency in General Surgery at Baylor College of Medicine Affiliated Hospitals in Houston, Texas followed by an additional three year surgical Residency at Christus St. Joseph Hospital in Houston, Texas. Subsequently, I completed a Fellowship in Surgical Oncology at the Stehlin Foundation for Cancer Research. I am board certified by the American Board of Surgery. Since 1973, I have served as a member of the Surgical Staff at Christus St. Joseph Hospital. Likewise, since 1974, I have served as the Associate Scientific Director for the Stehlin Foundation for Cancer Research. I have continuously been involved in the practice of medicine at all times relevant hereto. My curriculum vitae is attached hereto, and further outlines my training, education, and experience.

In my current practice, I see patients complaining of breast pain. I have performed/documented physical examinations on such patients, ordered mammograms for such patients, and managed their follow-up when indicated. I routinely review such studies, follow up on such studies, and use the results of studies to care for patients. In doing so, I have significant experience in recognizing the presence and significance of suspicious clusters of microcalcifications in breast tissue prior to any surgery. I have performed surgery on numerous patients who have had abnormal mammograms such as Sara Krahulec. I am intimately familiar with the interpretation of mammograms, the communication to the patient of the results of mammograms, and proper methods of following up on such mammograms. The standard of care related to the communication of, and following up on, abnormal mammogram results is precisely the same for family medicine doctors, oncologists, and surgical oncologists. I am familiar with the standard of care as it applies to physicians regarding these issues. Throughout my career, have cared for patients with breast cancer, from ductal carcinoma in situ (DCIS) to invasive cancer. I am intimately familiar with the methods of diagnosing these cancers, the treatments they require, and the prognosis that each carries. I have personally performed biopsies of breast tissue, partial mastectomies, total mastectomies, sentinel node biopsies, and lymph node dissections.

And finally, throughout my career I had occasion to serve on the Patient Advocacy, Quality Improvement, Utilization Review & Quality Assurance, and Executive Committees at Christus St. Joseph Hospital. I served in similar roles throughout my clinical private practice with Surgical Oncology Consultants of Houston. As such, I have experience in formulating and reviewing policies and procedures regarding the reporting of abnormal test results, in both at the hospital and private practice clinic setting. I am familiar with the standards of care regarding the same. All opinions expressed in this report are based on reasonable medical probability.

I understand that in Texas, "negligence", when used with respect to a physician, means the failure to use ordinary care; that is, doing that which a physician of ordinary prudence would not have done under the same or similar circumstances, or failing to do that which a physician of ordinary prudence would have done under the same or similar circumstances.

I understand that in Texas as to a physician, "ordinary care" means that degree of care which would be used by a physician of ordinary prudence under the same or similar circumstances.

I understand that in Texas, "negligence", when used with respect to a medical practice, means the failure to use ordinary care; that is, doing that which a medical practice of ordinary prudence would not have done under the same or similar circumstances, or failing to do that which a medical practice of ordinary prudence would have done under the same or similar circumstances.

I understand that in Texas as to a medical practice, "ordinary care" means that degree of care which would be used by a medical practice of ordinary prudence under the same or similar circumstances.

I understand that in Texas, "proximate cause" means that cause that was a substantial factor in bringing about an event, and without which cause such event would not have occurred. In order to be a proximate cause, the act or omission complained of must be such that a physician using ordinary care would have foreseen that the event, or some similar event, might reasonably result therefrom. I understand that there may be more than one proximate cause of an event.

PATIENT HISTORY

In September 2011, patient, a 33 year old female, presented to Fossil Creek Family Medical Center, P.A. complaining of left sided breast pain. On September 19, 2011, Brenda Wilmore, FNP saw patient for these complaints. No physical exam of the breast was performed or documented. However, Dr. David Simonak ordered a screening mammogram for these complaints, which was performed September 22, 2011.

Dr. Jason Skiles interpreted the mammogram, and described "scattered punctuate benign appearing calcifications" in the left breast. He further described "some clustering of calcifications in the upper outer quadrant of the left breast." His Impression was as follows:

Impression: Indeterminate microcalcifications in the left breast, probably benign. A follow-up study is recommended in 3 to 6 months. Computer-aided detection was utilized.

BI-RADS category 3 : Probably benign finding(s).

No one at Fossil Creek Family Medical Center, P.A., including Dr. Simonak, communicated or explained the results of the abnormal mammogram to patient . No follow-up study was recommended or occurred 3-6 months later. Fossil Creek Family Medical Center, P.A. did not have or enforce a policy or procedure that assured that patient's mammogram results were communicated directly to her, and that the follow-up study occurred within the recommended 3-6 months. No follow-up study was performed for more than 14 months; no biopsy was performed.

Instead, patient continued to have left breast complaints and was eventually seen by Dr. Mary Brian on January 28, 2013. Dr. Brian performed an in-office core biopsy which revealed high grade ductal carcinoma in situ. On February 22, 2013, Dr. Brian performed a Left modified radical mastectomy and Left sentinel node biopsy. Subsequent pathology confirmed that patient had multiple positive lymph nodes (14 out of 28) and she was diagnosed with multifocal Stage IIIC invasive ductal carcinoma.

Radiologist Dr. Jeffrey Mendel performed a blinded review of the September 22, 2011 mammogram as follows:

On my blinded review, the mammogram demonstrates microcalcifications clustered in the upper outer quadrant of the left breast. These are principally in the mid portion of the breast but some are noted to extend more posteriorly. These calcifications are noted on the magnified, focally compressed views to be both amorphous and pleomorphic without associated mass or architectural distortion. Additionally, there are scattered groups of amorphous microcalcifications in adjacent portions of the same quadrant. There are a few lymph nodes visible in the left axilla on the oblique view and not on the right. The largest is less than 1 cm in short axis and retains a fatty notch although it appears relatively dense. There are virtually no microcalcifications in the right breast.

Dr. Mendel states that September 22, 2011 mammogram demonstrated a highly suspicious cluster of microcalcifications in the upper outer quadrant of the left breast, and that the presence of patient adjacent groups of microcalcifications raises the possibility of multifocal disease. He concludes that Dr. Jason Skiles fell below the applicable standards of care in his treatment of by: 1) failing to appreciate the presence and significance of the suspicious microcalcifications in the left breast, and 2) by failing to immediately recommend biopsy of the concerning breast tissue.

STANDARDS OF CARE

1. The standard of care for physicians interpreting radiological studies in patients such as patient . requires that the physician recognize the presence and significance of suspicious clusters of microcalcifications in breast tissue and recommend prompt biopsy.

2. The standard of care for a physician treating a patient complaining of breast pain such as patient requires that the physician complete and document a thorough physical examination of the breast and lymph nodes. Further, the standard of care further requires that the physician communicate the results of abnormal mammograms to the patient directly, make certain that the patient understands the results of the mammograms, and assure that any recommended follow-up studies occur within the appropriate time frame.

3. The standard of care further requires that the entity/medical practice have and enforce adequate policies and procedures to assure that: a) all physicians/health care providers perform and document a thorough physical examination of the lymph nodes and breast for patients complaining of breast pain; b) mammogram results are communicated directly to the patient; and c) recommended follow-up studies occur within the appropriate time frame.

VIOLATIONS OF THE STANDARD OF CARE

1. My review of the medical records and radiological studies related to patient's care leads me to conclude that, based on reasonable medical probability, Dr. Jason Skiles fell below the applicable standards of care in his treatment of patient by failing to appreciate the presence and significance of the suspicious microcalcifications in the left breast. Further, it is my opinion that Dr. Skiles fell below the applicable standards of care by failing to immediately recommend biopsy of this concerning breast tissue. Under the definitions listed above, I must conclude that Dr. Skiles was negligent in his care and treatment of patient.

2. My review of the medical records and materials related to patient's care leads me to conclude that, based on reasonable medical probability, Dr. David Simonak fell below the applicable standards of care in his treatment of patient by failing to complete and document a thorough physical examination of her breast and lymph nodes. In the event his nurse practitioner saw his patients, Dr. Simonak failed to assure that his nurse practitioner completed and documented a through physical examination of the breast and lymph nodes. Dr. Simonak also fell below the standard of care by failing to communicate the results of the September 22, 2011 mammogram to patient directly, failing to make certain that patient understood the results of the mammogram, and assure that the recommended follow-up in 3-6 months. Under the definitions listed above, I must conclude that Dr. Simonak was negligent in his care and treatment of patient.

3. My review of the medical records and materials related to patient's care leads me to conclude that, based on reasonable medical probability, Fossil Creek Family Medical Center, P.A. fell below the applicable standards of care in its treatment of patient by failing to have and enforce adequate policies and procedures to assure that Dr. Simonak and FNP Wilmore performed and documented a thorough physical examination of patient's lymph nodes and breast when she presented complaining of breast pain. Further, Fossil Creek Family Medical Center, P.A. fell below the applicable standards of care by failing to have and enforce policies and procedures assuring that patient abnormal mammogram results were communicated directly to her, and that the follow-up studies occur within the recommended 3-6 months. Under the definitions listed above, I must conclude that Fossil Creek Family Medical Center, P.A. was negligent in its care and treatment of patient.

APPROPRIATE PATIENT CARE

The results of the September 22, 2011 mammogram were clearly abnormal. Dr. Mendel observed that the mammogram demonstrated a highly suspicious cluster of microcalcifications in the upper outer quadrant of the left breast, and that the presence of adjacent groups of microcalcifications raised the possibility of multifocal disease. In order to meet the minimal standards of care, Dr. Skiles should have recognized that this cluster of suspicious microcalcifications in the left breast had a high probability of being cancerous and immediately recommend biopsy of the concerning breast tissue.

Dr. Simonak ordered the September 22, 2011 screening mammogram and ultrasound in response to patient's breast pain. As such, he was clearly aware of these complaints and should have performed and documented a complete physical examination of her breast and lymph nodes. He did not, and he also failed to assure that FNP Wilmore completed and documented a through physical examination of the breast and lymph nodes. The failure to conduct and document a physical examination prevented healthcare providers from being aware of the clusters of abnormal tissue in patient's left breast, much less tracking its size/appearance over time. Most important, Dr. Simonak should have communicated the abnormal results of the September 22, 2011 mammogram to patient directly, made certain that she understood these results, and assured that she had the recommended follow-up studies in 3-6 months. In fact, he could and should have ordered the follow-up study immediately so that it could have been scheduled within the recommended time period. Had appropriate care been rendered, more likely than not, patient would have received the recommended follow-up studies, the changes in the size/appearance of the abnormal breast tissue noted, and the diagnosis of breast cancer would have been reached much sooner than it was made.

Fossil Creek Family Medical Center, P.A. should have had and enforced adequate policies and procedures in place to assure that Dr. Simonak and FNP Wilmore performed and documented a thorough physical examination of patient lymph nodes and breast when she presented complaining of breast pain. Worse still, Fossil Creek Family Medical Center, P.A. should have had and enforced policies and procedures assuring that patient's mammogram results were communicated directly to her, and that the follow-up studies occur within the recommended 3-6 months. This would have been a simple matter of flagging her chart, and following up with a phone call or letter.

CAUSATION & DAMAGES

It is my opinion beyond a reasonable medical probability, based on my training and education and experience that the negligent acts/omissions of Dr. Skiles, Dr. Simonak and Fossil Creek Family Medical Center, P.A. outlined above were each a proximate cause of her injuries and resulted in an extended delay in diagnosis and treatment of patient's breast cancer.

Had Dr. Skiles properly recommended a biopsy following the September 22, 2011 mammogram, more likely than not a Fine Needle Aspiration Biopsy (FNAB) or Core Needle Biopsy (CNB) would have been performed within a short period. In fine needle aspiration biopsy (FNAB), the physician uses a very thin needle attached to a syringe to withdraw a small amount of tissue from the suspicious area. In core needle biopsy, a slightly larger, hollow needle is used to withdraw small cylinders (or cores) of tissue from the abnormal area in the breast. FNAB and

CNB are most commonly done in the doctor's office with local anesthesia. The tissue samples are then sent to a lab, where a pathologist examines them under a microscope to determine if they show cancer.

Both FNAB and CNB are sensitive/accurate in terms of diagnosing breast cancer, certainly far greater than 50%. In fact, the sensitivity rate of large-core needle biopsy for the diagnosis of breast cancer has been shown to be in the 95% + range. Had an FNAB or CNB been performed shortly after the 2011 mammogram, more likely than not, it would have resulted in patient being diagnosed with ductal carcinoma in situ, or DCIS, rather than invasive cancer.

Likewise, had Dr. Simonak or Fossil Creek Family Medical Center, P.A. told their patient that she needed a follow-up study in 3-6 months, or followed up as noted above, it is probable that patient would have had the follow-up mammogram and resulting recommendation for biopsy. In my experience, very rarely do patient who know that they might have cancer fail to follow up. In any case, more likely than not, had an FNAB or CNB been performed 3-6 months following the 2011 mammogram been performed, it too would have resulted in patient being diagnosed with DCIS rather than invasive cancer.

DCIS refers to a cancer started in a duct (the tube that carries the milk from the lobule to the nipple) that has not spread to the nearby breast tissue or other organs.) DCIS is the most treatable form of breast cancer that carries the best prognosis. Had patient been properly diagnosed shortly after the mammogram, or shortly after the recommended follow-up period, her treatment would have most likely been lumpectomy with radiation or mastectomy surgery. Chemotherapy is not required for DCIS, and patient's prognosis would have been excellent. By definition, there is no risk of distant recurrence since the cancer is noninvasive. For women having lumpectomy with radiation, the risk of local recurrence ranges from 5-15 percent. For women having mastectomy, the risk of local recurrence is less than 2 percent. Large clinical trials, conducted by the National Surgical Adjuvant Breast and Bowel Project, show that the overall 15 year survival rate exceeded 85%, with the incidence of death from breast cancer less than 5 percent. Quite simply, with timely follow-up exams and biopsy, patient would likely not have required chemotherapy and/or died from breast cancer.

Because Dr. Skiles, Dr. Simonak, and Fossil Creek Family Medical Center, P.A. failed to provide timely/proper follow-up and care, patient's breast cancer was not diagnosed and treated before it spread. Pathology following her February 2013 surgery revealed multiple positive lymph nodes (14 out of 28) and she was diagnosed with multifocal Stage IIIC invasive ductal carcinoma. The treatment and prognosis for this cancer is vastly different than DCIS. Treatment for multifocal Stage IIIC invasive ductal carcinoma involves modified radical mastectomy surgery (removing the whole breast that has cancer, many of the lymph nodes under the arm, the lining over the chest muscles, and often part of the chest wall muscles) followed by radiation therapy (using high-energy x-rays or radiation to kill cancer cells or keep them from growing) and chemotherapy (using drugs to stop the growth of cancer cells, either by killing the cells or by stopping them from dividing.) Based upon the most recent numbers published by the National Cancer Data Base, patient has a less than 50% chance of surviving 5 years, even with the best treatment available.

In sum, it is my opinion beyond a reasonable medical probability, based on my training and education and experience, that Dr. Jason Skiles, Dr. David Simonak and Fossil Creek Family Medical Center, P.A. were negligent in their care of patient Further, it is my opinion that each of these acts and omissions of negligence was a proximate cause of her injury and its sequelae.

I hold these opinions to a reasonable degree of medical certainty. I reserve the right to extend or amend these opinions as additional materials become available for my review.

Sincerely yours,

Peter D. de Ipolyi, M.D.

Oral Argument is Neither Requested Nor Needed

No. 02-14-00091-CV

In the Court of Appeals for the Second
District of Texas at Fort Worth

Consultants in Radiology, P.A., Jason W. Skiles, D.O., David W. Simonak, D.O., Fossil Creek Family Medical Center, P.A.,
Appellants

v.

S.K. and C.K., Individually and on Behalf of J.K., A.K., and R.K., Minor Children,
Appellees

On Appeal from the 141st Judicial District Court, Tarrant County, Texas, Hon. John P. Chupp, Presiding

APPELLEES' BRIEF

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Appellees - Plaintiffs:	S. K. and C. K., Individually and on Behalf of J.K., A.K., and R.K., Minor Children,
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STATEMENT ON ORAL ARGUMENT

Appellees believe the matter is adequately presented in the Briefs and that the Court should simply affirm the trial court's decision denying the motion to dismiss and overruling the objections to the expert reports. Should the Court grant oral argument, Appellees respectfully request that they be permitted to participate in same.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

STATEMENT OF THE CASE

Nature of the case: Appellees sued Appellants for medical malpractice and seek damages caused by their negligence.

Course of proceedings and Trial court disposition: On September 10, 1013, Appellees, filed their Original Petition, Request for Disclosure, Request for Production, Chapter 74 expert reports and CVs of Suraj Achar, M.D., a family practitioner, and Jeffrey Mendel, M.D., a radiology physician, and Motion to Approve Expert Reports/CVs in the 141st District Court of Tarrant County, Texas against Appellants. (CR 5-69). Appellees alleged that Appellants were both directly and vicariously negligent in its treatment and care of S. K. (CR 5-69.) On October 1, 2013, Appellants David Simonak, M.D & Fossil Creek Family Medical Center filed their Objections to Plaintiffs' Motion to Approve expert Reports and CVs. (CR 137-205). On October 2, 2013, Appellees filed the Chapter 74 expert report/CV of Peter D. de Ipolyi, M.D. (CR 124-136). Appellants Jason Skiles, M.D., Consultants in Radiology, P.A., Appellants David W. Simonak, D.O. and Fossil Creek Family Medical Center filed objections to the sufficiency of Suraj Achar, M.D, Jeffrey B. Mendel, M.D. and Peter D. De Ipolyi, M.D.'s reports. (CR 137-205, 206-273, 274-276).

On February 25, 2013, the Honorable trial court overruled the objections and denied Appellants' motion to dismiss. (CR 299-300) . Meanwhile, the discovery is stayed and Plaintiffs are at risk for losing needed discovery information due to the passage of time.

ISSUE PRESENTED

1. Did the Trial Court Properly Exercise Its Discretion by Overruling Appellants' Objections to Appellees' Expert Reports and Denying their Motion to Dismiss Because the Reports Constitute a Good Faith Effort to Comply With the Requirements of § 74.351?

STATEMENT OF FACTS

On September 19, 2011, S. K. presented to Fossil Creek complaining of breast tenderness and pain. She was seen by Brenda Wilmore, FNP. No physical examination was performed. S. K.'s primary care physician, Dr. Simonak referred her for a breast mammogram and ultrasound. On September 22, 2011, the mammogram was performed and interpreted by Dr. Skiles. The mammogram showed a highly suspicious cluster of microcalcifications in the upper outer quadrant of the left breast, with adjacent groups of microcalcifications raising the possibility of multifocal disease. These abnormal findings should have led Dr. Skiles to recommend prompt biopsy, but he did not. Instead, Dr. Skiles reported "indeterminate microcalcifications in the left breast, probably benign" and recommended a follow-study in 3-6 months. The mammogram report was sent to Dr. Simonak at Fossil Creek, but neither Fossil Creek nor Dr. Simonak communicated the abnormal results to S. K. or informed her that a follow-up study should be done within 3-6 months. No follow-up study was ordered or scheduled. No biopsy of the breast tissue was performed.

S. K. continued to have left breast complaints, and eventually saw breast specialist Dr. Mary Brian on January 28, 2013. Dr. Brian performed an in-office core biopsy which revealed high grade ductal carcinoma in situ. On February 22, 2013, Dr. Brian performed a left modified radical mastectomy and left sentinel node biopsy. Subsequent pathology confirmed that the cancer had spread to the lymph nodes, and she was diagnosed with multifocal Stage IIIC invasive ductal carcinoma.

As a result of the invasive cancer, she has had to undergo chemotherapy and radiation therapy. Her prognosis is now very poor.

SUMMARY OF ARGUMENT

The Trial Court did not abuse its discretion by overruling Appellants' objections to the three expert reports. Under settled case law, expert reports are sufficient for purposes of Chapter 74 when they provide a fair summary of the expert's opinions regarding the applicable standards of care, defendant failed to meet the standards, and causation. *See Baylor Univ. Med. Ctr. v. Rosa,* 240 S.W.3d 565, 570 (Tex. App. – Dallas 2007, pet. denied) (expert reports are to be read together). The reports are very detailed and very specific. The Appellants were identified by name or collectively where appropriate, the experts are qualified by expertise, experience, education, and knowledge, each individual defendant is linked to the applicable standard of care, each individual defendant is identified in connection with how that standard was breached, and Drs. Achar, De Ipoly, and Mendel connect everything together for purposes of causation. All reports detail the links between the Appellants' negligence and S. K.'s injuries, and when the reports are read together, as required, they sufficiently address causation. The trial court properly concluded that Appellant's objections were meritless, similar to this Court's decision in a very similar case, *Polone v. Shearer*, 287 S.W.3d 229 (Tex.App.—Fort Worth 2009, no pet.). In fact, the similarities between the instant case and *Polone* are so striking that one wonders why this appeal should not be deemed completely frivolous and brought in bad faith - and treated accordingly.

In the alternative, should the Court conclude that the reports are somehow insufficient under section § 74.351, the Court should exercise its authority to grant a thirty-day extension to cure any deficiencies.

ARGUMENT

A. Standard of Review

Courts of appeals "apply an abuse of discretion standard in reviewing a trial court's decision" with respect to Chapter 74 expert reports. *See American Transitional Care Ctrs. of Tex., Inc. v. Palacios*, 46 S.W.3d 873, 875 (Tex. 2001); *see also Bowie Mem'l Hosp. v. Wright*, 79 S.W.3d 48, 53 (Tex. 2002) ("we review a trial court's decision about whether a report constitutes a good-faith effort to comply with the Act under an abuse-of-discretion standard"); *Kelly Ryan Cook, P.A. v. Spears*, 275 S.W.3d 577, 579 (Tex. App. – Dallas 2008, no pet.) A trial court abuses its discretion when it acts arbitrarily or unreasonably without reference to any guiding rules and principles. *Walker v. Gutierrez*, 111 S.W.3d 56, 62 (Tex.2003). "When reviewing matters committed to the trial judge's discretion, an appellate court may not substitute its judgment for that of the trial judge." *Baylor University Med. Ctr. v. Rosa*, 240 S.W.3d 565 (Tex. App. – Dallas 2007, pet. denied). Under § 74.351:

- The reports cannot each be read in isolation, as Appellants suggest by attacking the reports individually. They must be read together in determining whether the requirements of Section 74.351 have been met. *Rosa*, 240 S.W.3d at 570.
- The reports collectively must inform the defendant of the specific conduct called into question and provide a basis for the court to conclude the claims have merit. The reports are not to be judged by the standards of a summary judgment hearing and are not required, at this stage of the proceedings, to meet the *Daubert/Robinson* test for admissibility at trial. *Christian Care Centers, Inc. v. Golenko*, 328 S.W.3d 637, 641

(Tex. App. – Dallas 2010, n.p.h.); *American Transitional Care Centers of Texas, Inc. v. Palacios*, 46 S.W.3d 873, 879 (Tex. 2001).

At this stage of the proceedings, the expert reports are not to be measured by whether or not they are trial-worthy. Under Civil Practice & Remedies Code § 74.351:

> To constitute a good faith effort to comply with the statutory requirements, an expert report must inform the defendant of the specific conduct called into question and provide a basis for the trial court to determine that the claims have merit. It does not need to marshal all of the plaintiff's proof, but it must include a fair summary of the expert's opinion on each of the elements identified in the statute: the applicable standard of care, the breach or deviation from the standard of care, and the causal relationship between the breach and the injury.

Golenko, 328 S.W.3d at 647.

Point I **The Trial Court Properly Exercised its Discretion by Overruling Appellant's Objections to the Expert Reports Because the Reports Constitute a Good Faith Effort to Comply With the Requirements of § 74.351 and Provide a Fair Summary of the Experts' Opinions Regarding the Standards of Care, Breach of Those Standards, and Causation.**

The trial court properly exercised its discretion in rejecting the challenges made to the reports because the reports constitute an objective good-faith effort to comply with § 74.351, providing a fair summary of each expert's opinions regarding the applicable standards of care, how Appellant's conduct failed to meet those standards, and causation.

A. An Expert Report is Sufficient Under § 74.351 When it Provides a Fair Summary of the Expert's Opinions Regarding the Applicable Standards of Care, Defendant's Failure to Meet the Standards, and Causation.

The Court should affirm the trial court's conclusion that the expert reports met the standards imposed by Civil Practice & Remedies Code § 74.351. To constitute a valid report under § 74.351, the expert report must provide a --

> fair summary of the expert's opinions as of the date of the report regarding applicable standards of care, the manner in which the care rendered by the

> physician or health care provider failed to meet the standards, and the causal relationship between that failure and the injury, harm, or damages claimed.

Tex. Civ. Prac. & Rem. Code §74.351(r)(6). Appellees' experts are not required to use "any particular 'magic words'" to pass muster under the statute. *Wright*, 79 S.W.3d at 53 (Tex. 2002). Instead, when a plaintiff timely files an expert report and a defendant objects to the report and/or seeks dismissal because of the report's purported inadequacy, the trial court may grant the motion "*only* if it appears to the court, after hearing, that the report does not represent an objective good faith effort to comply with the definition of an expert report in Subsection (r)(6)." Tex. Civ. Prac. & Rem. Code § 74.351(l) (emphasis added). Accordingly, this Court may not grant a motion to dismiss or sustain objections to the sufficiency of the report when presented with such a good faith effort.

Plaintiffs may satisfy their statutory requirements by filing reports from multiple experts. "Nothing in this section shall be construed to mean that a single expert must address all liability and causation issues with respect to all physicians or health care providers or with respect to both liability and causation issues for a physician or health care provider." Tex. Civ. Prac. & Rem. Code § 74.351(i); *see also Packard v. Guerra*, 252 S.W.3d 511, 527 (Tex. App. – Houston [14th Dist.] 2008, pet. denied); *Palafox v. Silvey*, 247 S.W.3d 310, 314 (Tex. App. – El Paso 2007, no pet.). Accordingly, the Court must read reports from multiple experts together in determining whether the Chapter 74 standards have been satisfied. The Court must not, as Defendants suggest, look to information outside the four-corners of those reports to determine their adequacy. In this case, the reports collectively provide the required information under Chapter 74.

B. The Reports Sufficiently Establish the Qualifications of the Experts to Opine Regarding the Standard of care Applicable to Appellants, Breaches of the Standard of Care, and Causation.

All experts are qualified to give an opinion regarding the standard of care applicable to them. Under § 74.401(a), a person may qualify as an expert with respect to medical standards of care when the person:

> (1) is practicing medicine at the time such testimony is given or was practicing medicine at the time the claim arose;
>
> (2) has knowledge of accepted standards of medical care for the diagnosis, care, or treatment of the illness, injury, or condition involved in the claim; and
>
> (3) is qualified on the basis of training or experience to offer an expert opinion regarding those accepted standards of medical care.

Tex. Civ. Prac. & Rem. Code § 74.401(a). A court may also consider whether the witness is board certified in an area relevant to the claim and whether the physician is actively practicing medicine in areas relevant to the claim. Tex. Civ. Prac. & Rem. Code § 74.401(c).

When evaluating an expert's qualifications under Chapter 74, "the proper inquiry concerning whether a physician is qualified to testify is not the physician's area of practice but the stated familiarity with the issues involved in the claim before the court." *Concentra Health Serv., Inc. v. Everly*, 2010 WL 1267775, *4 (Tex. App. – Fort Worth 2010, no pet.). A physician with practical knowledge of what is customarily and usually done under the circumstances confronting the defendant is competent to testify. *Id.* The reports and CVs here reveal highly qualified physicians experienced in the fields in which they offer opinions.

With respect to causation, the report of Peter DeIpolyi, MD shows his qualifications and that but-for Defendants' negligence: 1) the cancer would have been confined to a DCIS state

rather than an invasive cancer state, 2) the patient would most likely have had a lumpectomy rather than a mastectomy, 3) the patient would have had no residual risk of distant recurrence, 4) the patient would not have undergone chemotherapy, and 5) the patient would not have had the cancer spread to other parts of her body. The report also establishes that the negligence changed the patient's survival rate from 85% survival at 15-years to a less than 50% survival at 5-years. This is far more causation data than was necessary to overrule defendants' objections in *Polone.* This court should follow *Polone* and affirm the trial court. The distinction that Defendants here attempt to draw between the instant case and *Polone* is nonsensical and should be rejected.

Alternative Request for Thirty-Day Extension

Should the Court find the reports deficient, the Court should grant an extension under § 74.351(c). *See Leland v. Brandal*, 257 S.W.3d 204, 207 (Tex. 2008); *Ogletree v. Matthews*, 262 S.W.3d 316 (Tex. 2007). The reports represent a good faith effort to comply with the statute. If the Court does not agree, Appellees request the Court grant a thirty-day extension to cure any deficiency. Indeed because the reports are, if deficient, clearly not "absent," the only appropriate remedy is a thirty-day extension to cure the deficiencies.

CONCLUSION AND PRAYER

FOR THESE REASONS, Appellees ask this Court to affirm the trial court's order denying Appellant's motion to dismiss and overruling its objections to the expert reports and remand this case for trial, or in the alternative grant a 30-day extension to cure any deficiencies, and grant Appellees such further relief to which they are justly entitled.

Respectfully submitted,

THE GIRARDS LAW FIRM

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CERTIFICATE OF COMPLIANCE

Pursuant to Texas Rule of Appellate Procedure 9.4(i)(3), the undersigned counsel - in reliance upon the word count of the computer program used to prepare this document - certifies that this brief contains 3,748 words, excluding the words that need not be counted under Texas Rule of Appellate Procedure 9.4(i)(l).

/s/ James E. Girards

James E. Girards

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the above and foregoing has been served upon all counsel of record via electronic filing, or certified mail, return receipt requested, on this 5th day of May, 2014 as follows:

/s/ James E. Girards

_____

James E. Girards

ORAL ARGUMENT CONDITIONALLY REQUESTED

No. 02-14-00091-CV

In the Court of Appeals for the Second
District of Texas at Fort Worth

Consultants in Radiology, P.A., Jason W. Skiles, D.O., David W. Simonak, D.O., Fossil Creek Family Medical Center, P.A.,
Appellants

v.

S.K. and C.K., Individually and on Behalf of J.K., A.K., and R.K., Minor Children,
Appellees

On Appeal from the 141st Judicial District Court, Tarrant County, Texas, Hon. John P. Chupp, Presiding

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APPELLEES' BRIEF
APPENDIX TO APPELLEES' BRIEF

In compliance with rule 38.1(j) of the Texas Rules of Appellate Procedure, Appellees submit this Appendix to their brief containing the following items:

TAB A: Expert Report and CV of Suraj Achar, M.D.

TAB B: Expert Report and CV of Jeffrey Mendel, M.D.

TAB C: Expert Report and CV of Peter De Ipoly, M.D.

APPENDIX TAB A

EXPERT OPINION OF SURAJ ACHAR, M.D.

This report is written at the request of The Girards Law Firm and is written in order to comply with *Texas Civil Practices & Remedies Code* § 74.351. I have been informed that subsection (k) of the statute provides that an expert opinion prepared under this law is not admissible in evidence by any party; shall not be used in a deposition, trial, or other proceeding; and shall not be referred to by any Defendant during the course of any proceeding in this case. All opinions expressed herein are based upon reasonable medical probability.

I have reviewed the medical care given to patient during the time period from September 2011 to present by Fossil Creek Family Medical, Dr. David Simonak, Dr. Jonathan Snead, Texas Breast Specialists, Dr. Mary Brian, Dr. Jason Skiles, Dr. Renita Butler, and Texas Health Harris Methodist Southlake Hospital. I have also been provided with the Expert Opinion of Jeffrey B. Mendel, M.D.

QUALIFICATIONS

I am a family physician licensed to practice medicine by the State of California. I received the MD degree at Buffalo School of Medicine at State University of New York. Thereafter, I completed an Internship and Residency in Family and Preventive Medicine at the University of California School of Medicine at San Diego. Subsequently, I served as a volunteer for the organization Doctors without Borders in Kenya. Following my term with Doctors without Borders, I took a job as a clinician and faculty member of the Ventura County Family Medicine Residency. I also returned to San Diego, where I completed a Fellowship in Sports Medicine at UCSD. I am board certified in Family Medicine, with added qualifications in Sports Medicine. I have continuously been involved in the practice of family medicine at all times relevant hereto.

Since 2001, I have served as a Clinical Professor of Family and Preventive Medicine at the University of California School of Medicine at San Diego. I teach medical students, resident and fellows at the university and I practice clinical family medicine. I have served as the Medical Director of the UCSD La Jolla Family and Sports Medicine for 5 years. Seventy percent of my time is spent rendering direct patient care, with the rest divided between teaching, research and administrative responsibilities. My teaching includes faculty supervision of the resident family medicine clinic. I have direct experience in formulating and reviewing the adequacy of, and compliance with, policies and procedures applicable to physicians and entities providing family medical care. For the past five years, I have served on the Clinical Quality Assurance Committee at UCSD. Likewise, I have taught and lectured at national meetings on the family physician's obligations in ordering and following up on mammograms. My curriculum vitae is attached hereto, and further outlines my training, education, and experience.

In my current practice, I see patients complaining of breast pain, axillary swelling and breast swelling and masses. I routinely order imaging studies of the breast including mammograms, ultrasound and follow-up studies, as indicated, for patients. I am intimately familiar with the ordering of screening and diagnostic mammograms, the communication to the patient of the results of mammograms, and proper methods of following up on such mammograms. I am familiar with the standard of care as it applies to family medicine physicians and family medicine practices regarding these issues. All opinions expressed in this report are based on reasonable medical probability.

I understand that in Texas, "negligence", when used with respect to a physician, means the failure to use ordinary care; that is, doing that which a physician of ordinary prudence would not have done under the same or similar circumstances, or failing to do that which a physician of ordinary prudence would have done under the same or similar circumstances.

I understand that in Texas as to a physician, "ordinary care" means that degree of care, which would be used by a physician of ordinary prudence under the same or similar circumstances.

I understand that in Texas, "negligence", when used with respect to a family medicine practice, means the failure to use ordinary care; that is, doing that which a family medicine practice of ordinary prudence would not have done under the same or similar circumstances, or failing to do that which a family medicine practice of ordinary prudence would have done under the same or similar circumstances.

I understand that in Texas as to a family medicine practice, "ordinary care" means that degree of care, which would be used by a family medicine practice of ordinary prudence under the same or similar circumstances.

I understand that in Texas, "proximate cause" means that cause that was a substantial factor in bringing about an event, and without which cause such event would not have occurred. In order to be a proximate cause, the act or omission complained of must be such that a physician using ordinary care would have foreseen that the event, or some similar event, might reasonably result therefrom. I understand that there may be more than one proximate cause of an event.

PATIENT HISTORY

At the time of the initial visit on 9/19/11 for the chief complaint of "left axilla pain-feels like swollen lymph nodes x several weeks-slight pain to the right axilla" patient was 33 year old. On this day she was seen by nurse practitioner Brenda Wilmore, FNP, BC. In the HPI (history of present illness section) Brenda Wilmore noted "pain in the left axilla/breast, deep pain feels like "mastitis." Nurse practitioner Brenda Wilmore went on to perform a physical exam. In the neck section of the exam she checked for lymphadenopathy. Although she examined and documented a detailed exam of her overall appearance, head exam, skin exam, eye exam, ear exam, oropharynx exam, neck exam, thyroid exam, heart exam, lung exam, extremities exam, and neurological exam she failed to document that she examined the chief areas of complaint the breast or the axilla. Her assessment repeated the complaint of "Pain, upper arm, pain in the left axilla/breast." She started an antibiotic Bactrim DS tablet. She also gave her a prescription for the pain, Ultram. She ordered a screening mammogram. She did not order a diagnostic mammogram. Despite not making a clear diagnosis nurse practitioner Wilmore does not document any consultation with her supervising physician.

On 9/22/11 patient had a diagnostic mammogram despite the order for a screening mammogram above. The mammogram was ordered under the name of David Simonak, MD. The mammogram was documented to have dense tissue with punctate calcifications involving only the left breast, the same side she had pain and swelling. The impression included

"indeterminate microcalcifications in the left breast, probably benign. A follow up study is recommended in 3 to 6 months." The study was categorized as BI-RADS 3. Dr. Simonak or NP Brenda Wilmore did not sign the copy that was provided to me.

On 9/23/11 NP Wilmore generated a telephone encounter where she is noted that patient needed an ultrasound of the left breast. On 9/26/11 patient had an ultrasound of her left breast and axillary region, which was read as normal.

On 10/06/11 Eric Wroten saw her for a post-op visit. She was seen also on 10/25/11 also for the same condition status post left dupuytren's fasciotomy.

On 11/02/11 patient appears to be seen for the first time since the complaint of breast and axillary pain and swelling by David Simonak, DO. On this visit she had already completed the abnormal mammogram attributed to an order from Dr. Simonak. In the physical exam section there is no exam noted of the axilla or breast. She was diagnosed with hypothyroidism and EBV.

On 11/22/11 Dr. Simonak again saw her. Again no exam was made of the breast or axilla. Again no note was made that the patient was informed of the abnormal mammogram. On 12/13/11 she was seen again "because she found out she was pregnant.

On 4/12/12 patient again goes to see Dr Simonak. Now it is over 6 months since the abnormal mammogram results. At this time she complains of dorsal arm pain. Again no exam is made of the breast or the axilla. Again there is no mention that patient was informed of the abnormal mammogram or the need to repeat the mammogram in 3-6 months. No mammogram was ordered despite the radiology request.

On 6/1/2012 Brenda Wilmore FNP sees her. Again no exam is made of the breast or the axilla. Again no mention that patient was informed of the abnormal mammogram or the need to repeat the mammogram in 3-6 months. No mammogram was ordered despite the radiology request.

On 7/10/12 she again sees Dr. Simonak. The chief complaint at this time is left sided rib pain. Again no exam is made of the breast or the axilla. Again there is no mention that the patient was informed of the abnormal mammogram or the need to repeat the mammogram in 3-6 months. No mammogram was ordered despite the radiology request.

On 7/30/12 Brenda Wilmore FNP sees her. Again no exam is made of the breast or the axilla. Again there is no mention that patient was informed of the abnormal mammogram or the need to repeat the mammogram in 3-6 months. No mammogram was ordered despite the radiology request.

On 9/13/12 Dr. Simonak sees her. Again no exam is made of the breast or the axilla. Again there is no mention that patient was informed of the abnormal mammogram or the need to repeat the mammogram in 3-6 months. No mammogram was ordered despite the radiology request.

On 11/29/12 Brenda Wilmore FNP sees her for a chief complaint of the lump in left breast x several months. Nurse practitioner Wilmore notes in the history of present illness that the mass in

the left breast has "been there for several years and that the left breast is larger than the right." It appears that despite the fact the FNP Wilmore had ordered the mammogram herself she asks the patient what the results of the mammogram are and she documents that the patient states the mammogram was negative despite the results to the contrary. It appears that neither the patient nor nurse Wilmore understood the abnormal reading of the mammogram or the need to repeat the mammogram. Nurse practitioner Wilmore notes the first documented breast exam since the patient complained of the breast pain. Her breast exam is severely abnormal with a large breast, large palpable mass that is non-tender, irregular moveable with no signs of mastitis. She correctly diagnoses a breast mass and orders now diagnostic breast imaging. She also suggests a biopsy. No referral is made to a breast surgeon despite the diagnosis and exam that is consistent with cancer, not mastitis.

On 11/30/12 a mammogram was done where the radiologists note left breast microcalcifications. The radiologist falsely concludes that she has prior mastitis and the abnormalities are consistent with mastitis and read as BI-RADS 2. It is recommended to restart annual screening mammogram at age 40.

On 1/16/13 Dr. Simonak sees her for a chief complaint of the breast milk culture of the left breast. No breast exam is performed or documented even though the FNP noted such a severely abnormal exam previously. No mention of the previously severely abnormal exam is mentioned. In fact no mention of review of the prior records is made. She is on Zithromax although it is not clear based on this note why she is on this antibiotic. She is diagnosed with mastitis without a documented exam of the breast.

On 1/23/13 Dr Simonak again sees her. No history or exam of the breast mass is noted but she is diagnosed now with a breast mass and it is noted that she is to proceed with a biopsy.

On 1/28/13 an ultrasound guided biopsy was performed by Dr. Mary Brian, which showed high-grade ductal carcinoma. This ultrasound-guided biopsy was completed within 5 days of the order above.

STANDARDS OF CARE

The standard of care for a family medicine physician treating a patient complaining of breast pain such as patient requires that the physician complete and document a thorough physical examination of the breast and lymph nodes. If the family medicine physician has a Family Nurse Practitioner see the patient for these complaints, the physician must assure that the Family Nurse Practitioner completes and documents a through physical examination of the breast and lymph nodes. Minimal standards of care require that the physician order a diagnostic mammogram, as opposed to a screening mammogram when treating a patient such as patient. Further, the standard of care further requires that the family medicine physician communicate the results of such mammograms to the patient directly, make certain that the patient understands the results of the mammograms, and assure that any recommended follow-up studies occur within the appropriate time frame.

The standard of care for a family medicine practice treating a patient complaining of breast pain such as patient requires that the family medicine practice have and enforce adequate policies and procedures to assure that: 1) all physicians and family nurse practitioners

perform and document a thorough physical examination of the lymph nodes and breast for patients complaining of breast pain; 2) mammogram results are communicated to directly to the patient; and 3) recommended follow-up studies occur within the appropriate time frame.

VIOLATIONS OF THE STANDARD OF CARE

1. **Lack of proper physician supervision**
2. **Lack of proper physical exam including a severe delay in examining the breast and axilla**
3. **Erroneous order of a screening mammogram when diagnostic mammogram is required**
4. **Lack of follow up of the mammogram as recommended by radiology and required by the standard of care**
5. **Delay in referral to breast surgeon despite an exam that was consistent with cancer**
6. **Failure to share information about the abnormal breast imaging studies with the patient**
7. **Failing to have and enforce adequate policies and procedures**

1. Lack of proper physician supervision

My review of the medical records and materials related to patient's care leads me to conclude that, based on reasonable medical probability, Dr. David Simonak fell below the applicable standards of care in his treatment of patient by failing to properly supervise his nurse practitioner Brenda Wilmore. On September 19, 2011, Brenda Wilmore, FNP saw patient for these complaints, yet Dr. Simonak failed to assure that FNP Wilmore completed and documented a through physical examination of the breast and lymph nodes.

In general nurse practitioners and PA are considered physician extenders. They usually work in a team that includes physicians. They generally can take care of 90% of the clinical problems that they encounter daily but do need help with the most difficult clinical scenarios when they do not know the diagnosis or the condition that the patient faces is dangerous or has a high risk. At the time of this visit Texas Law required physician supervision of nurse practitioners. Perhaps one reason for the supervision relates to limited training given to nurse practitioners as compared to physicians.

This case illustrates the critical importance of working as a team and having physician supervision. Ultimately there was no proper diagnosis made on the first visit on 9/19/11. At this time Brenda Wilmore, FNP, BC diagnosed the patient with "pain in the upper arm." In general physicians usually make a diagnosis that is more focused than a symptom. When they use a symptom as a diagnosis it is an acknowledgement that the condition is yet to be clearly diagnosed. When a nurse practitioner does not know the diagnosis then that would be a great opportunity to discuss the patient with her supervising physician. This is the intent of Texas law and discussion when no clear diagnosis is made is consistent with the standard of care. No discussion is made and documented between the FNP and her supervising doctor, which is contrary to the law and the standard of care. Dr. Simonak's failures to adequately supervise FNP Wilmore in this case is below the standard of care.

2. Lack of proper physical exam including severe delay in examining the breast and axilla

recommended follow-up breast imaging was ordered in 3-6 months and occurred within this time frame.

When the radiologist reported the results of the mammogram on 9/22/11, he recommended that the patient get a repeat mammogram in 3-6 months because of the risk of cancer. Failure to order the repeat mammogram as directed by the radiologist is below the standard of care. When doctors get radiologic results that are abnormal they are generally required to act on these results. If they do not follow the recommendations they need to explain to the patients why they are not following the recommendations of the radiologists and explain their thinking. A good example would be if the test had a risk to the patient such as radiation exposure in with a CT scan. However, a mammogram has almost no risk of radiation exposure or injury to a patient. Failure to follow the recommendation in this case is a breach of the standard of care.

5. Delay in referral to breast surgeon despite exam that was consistent with cancer

My review of the medical records and materials related to patient's care leads me to conclude that, based on reasonable medical probability, Dr. David Simonak fell below the applicable standards of care in his treatment of patient by failing to assure that when his PA felt a breast lump for which she was worried that the patient had cancer that she properly referred her to a breast surgeon.

On 11/29/12 patient was seen by Brenda Wilmore FNP for a chief complaint of the lump in left breast x several months. On this visit the FNP feels that the patient does not have mastitis but rather has a condition that requires a biopsy. She orders a diagnostic mammogram but for some reason does not refer the patient to a breast surgeon. Primary care physicians and FNP's must refer patients when they feel the patient has cancer to surgeons capable of doing a biopsy to identify the cancer. Ultimately however she does not make the referral but rather orders another mammogram. This leads to further delay in the diagnosis. She is seen six weeks later by Dr Simonak who again does not order a surgical consult. Later that month in January 2013, Dr Simonak finally orders the consult with a breast surgeon. Within five days she is seen by a surgeon and has a biopsy the same day that shows the cancer. Ultimately the delay is diagnosis actually goes back to her first visit on 9/19/11 when she could have been referred and seen by a surgeon. The delay to refer the patient to a breast surgeon is below the standard of care and leads to worsening outcomes for .

6. Failure to share information about the abnormal breast imaging studies with the patient

My review of the medical records and materials related to patient's care leads me to conclude that, based on reasonable medical probability, Dr. David Simonak fell below the applicable standards of care in his treatment of patient by failing to communicate the results of the September 22, 2011 mammogram to patient directly and failing to make certain that patient understood the results of the mammogram.

Perhaps the most important breach in the standard of care relates to the delay in getting the information to the patient about her abnormal studies. When the abnormal 2011 mammogram results and recommendation for follow-up were received by Dr. Simonak and Fossil Creek Family Medical Center, patient should have been informed of the result. Both Dr. Jason Skiles (the radiologist) and Dr. Simonak (the primary care physician) were required to share this

Outcomes if appropriate steps been taken

1. Evaluation of an occult cancer and the role of the physical exam.

Mammogram although a great tool is not the only tool for the diagnosis of breast cancer Early physical exam may have found a mass that may have led to early referral. Of note Up to date states "A clinically suspicious mass should also be biopsied, regardless of imaging findings, as about 15 percent of such lesions can be mammographically occult (Barlow WE, Lehman CD, Zheng Y, et al. Performance of diagnostic mammography for women with signs or symptoms of breast cancer. J Natl Cancer Inst 2002; 94:1151.) An earlier physical exam may have led to an earlier diagnosis and earlier treatment plan.

2. Early or immediate referral would have more likely than not led to an earlier diagnosis and treatment protocol.

Ultimately when referred to a breast specialist patient had a visit and rapid biopsy resulting in rapid diagnosis. The goal of the initial biopsy is to obtain sufficient diagnostic material using the least invasive approach and to avoid surgical excision of benign lesions. Ultimately the biopsy would have uncovered the cancer at an earlier stage leading to a less invasive treatment approach.

3. A careful response to the mammogram would have more likely than not led to an earlier diagnosis and earlier therapy.

"The majority of breast cancers are are associated with abnormal mammographic findings." (Smart CR, Hartmann WH, Beahrs OH, Garfinkel L. Insights into breast cancer screening of younger women. Evidence from the 14-year follow-up of the Breast Cancer Detection Demonstration Project. Cancer 1993; 72:1449.). Had Dr. Simonak and Brenda Wilmore, FNP paid attention and shared the information on the risk of breast cancer with patient , she more likely than not would have had an earlier diagnosis and treatment of her cancer.

4. Breast cancer treatment depends significantly on the stage at diagnosis and earlier diagnosis would have detected the cancer at an earlier stage.

Treatment of breast cancer depends on multiple aspects including but not limited to tumor size, tumor grade, involvement of lymph nodes, hormone receptor status and genetic testing. Tumor size and involvement of lymph nodes often depends specifically on the time of detection. Breast cancer survival has improved with mammography because of the earlier detection of tumors when they are smaller and have spread less. Had earlier detection happened for patient her prognosis would have been better and likely her treatment would have been less toxic, less invasive and less debilitating. Most importantly patient would have had a better outcome and chance of survival.

CAUSATION & DAMAGES

It is my opinion beyond a reasonable medical probability, based on my training and education and experience, that the negligent acts/omissions of Dr. Simonak and Fossil Creek Family Medical Center, P.A. outlined above were each a proximate cause of the extended delay in diagnosis and treatment patient 's breast cancer.

Specifically, the failure to conduct and document a physical examination prevented healthcare providers from being aware of the clusters of abnormal tissue in patient 's left breast, much less tracking its size/appearance over time. Moreover, by all indications in the medical records, Dr. Simonak never communicated nor explained the abnormal results of the mammogram to his patient. He didn't take any steps to assure that patient had a follow-up study within the recommended 3-6 months. Fossil Creek Family Medical Center, P.A. had no policy or system in place to assure that the follow-up took place. As such, it is clear that patient was unaware that she needed to have a follow-up mammogram in 3-6 months. Had appropriate care been rendered, more likely than not, patient would have received the recommended follow-up studies, the changes in the size/appearance of the abnormal breast tissue noted, and the diagnosis of breast cancer would have been reached much sooner than it was made.

In sum, it is my opinion beyond a reasonable medical probability, based on my training and education and experience, that Dr. David Simonak and Fossil Creek Family Medical Center, P.A. were negligent in their care of patient . Further, it is my opinion that each of these acts and omissions of negligence was a proximate cause of her injury and its sequelae.

I hold these opinions to a reasonable degree of medical certainty. I reserve the right to extend or amend these opinions as additional materials become available for my review.

Sincerely yours,

Suraj Achar, M.D.
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CURRICULUM VITAE

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Education

1989-1993	State University of New York at Buffalo School of Medicine M.D.
1985.1989	University of California at Santa Cruz University of Poitiers, France B.A. French Literature with Honors, Phi Beta Kappa

Professional Training

2002-2005	Research Fellowship UCSD School of Medicine, CREST Program (Clinical Research Enhancement through Supplemental Training)
2000.2001	Fellowship in Sports Medicine, University of California at San Diego School of Medicine (UCSD)
1993.1996	Internship and Residency, UCSD Family and Preventive Medicine
2004	Pain experts Mentorship Program. University of Wisconsin School of Medicine and UCLA School of Medicine

Professional Licensure and Certification

Fellow of the American Academy of Family Physicians
Diplomate of the American Board of Family Practice 1996, Recertification 2003
Certificate of Added Qualifications in Sports Medicine 2001-present
California Medical License Number: G80093
Drug Enforcement Agency Number: BA4296073

Employment

2001-present	Associate Clinical Professor ~~Medical Director: UCSD La Jolla Family and Sports Medicine~~ University of California School of Medicine Department of Family & Preventive Medicine *Full scope of outpatient family practice, research & teaching*
1997.2000	Santa Paula Clinic Staff Physician & Clinical Instructor Ventura County Medical Center Family Medicine Residency *Full scope of family practice including inpatient care & obstetrics*

Leadership Experience

Univeristy of California School of Medicine

2008-	Medical Director: UCSD La Jolla Family and Sports Medicine
2002-	Associate Director UCSD Primary Care Sports Medicine Fellowship
2002-	Director of the Sports Medicine Elective 431 UCSD School of Medicine
2001.2003	Director of Family Medicine Clerkship UCSD School of Medicine
1995.1996	Chief Resident, UCSD Family Medicine Residency Program

Doctors Without Borders: *International non-profit medical organization*

1996	Medical Director, Children's Therapeutic Feeding Center, Kenya Doctors without Borders

Honors

2002	Faculty Teacher of the Year, UCSD Department of Family Medicine
1997	Walter Kemp Award Finalist (Notable publication by family physician)
1996	Resident Teacher Award Society of Teachers of Family Medicine
1996	Behavior Medicine Award UCSD Department of Family Medicine
1994	Outstanding Exhibit Award: Poster Presentation: *Understanding Colposcopy*: AAFP Scientific Assembly, Anaheim CA
1993	Cum Laude, Commendation from the Dean State University of New York School of Medicine

Publications

Journals

- Taylor KS, Zoltan TB, Achar SA. Medical illnesses and injuries encountered during surfing. Current Sports Med Rep. 2006 Sep;5(5):262-7. Review
- Achar SA. Kundu S. Norcross WA. Diagnosis of Acute Coronary Syndrome. Am Fam Physician. 2005 Jul 1;72(1):119-26.
- Zoltan T. Taylor K. Achar S. Health Issues for Surfers. Am Fam Physician. 2005 Jun 15;71(12):2313-7.
- Achar S. Developmental Dysplasia of the Hip. The Core Content Review of Family Medicine. Vol 33. No 8. Nov 2002
- Achar S. Kundu S. Principles of Office Anesthesia. Infiltrative Anesthesia. Am Fam Physician. Am Fam Physician. 2002 Jul 1;66(1):91-4
- Kundu S. Achar S. Principles of Office Anesthesia: Topical Anesthetics. Am Fam Physician. 2002 Jul 1;66(1):99-102
- Achar S. Principles of Skin Biopsies For The Family Physician. American Family Physician. 1996 Dec; 54(8):2411-8.

Textbooks

- Achar, Chan, Von Wagner, Cuenca, SWANSON'S FAMILY MEDICINE REVIEW, Sixth Edition edited by Alfred Tallia, MD, MPH, FAAFP; Joseph E. Scherger, MD, MPH; and Nancy Dickey, MD. 2008
  - Upper Extremity Injuries
  - Lower Extremity: Strains and Sprains

- Preparticipation Evaluation
- Fracture Management
- Exercise Prescription
- Female Athlete Triad
- Infectious Disease and Sports

- Achar, S. Espinoza, A. Common Sports Injuries. Conn 's Current Therapy 2008. Robert E. Rakel, MD, and Edward T. Bope, MD
- Bracker M, Achar S. May T. Buller JC, Wooten W. Musculoskeletal Problems in Children. Family Medicine: Principles and Practice 6th ed. Robert Taylor, editor. NY. Springer. 2002
- Achar S. Spinal Stenosis. 5 Minute Sports Medicine Consult. Mark Bracker editor. Lippincott Williams & Wilkins. 2001
- Kundu S. Achar S. Atlantoaxial Instability. 5 Minute Sports Medicine Consult. Mark Bracker editor. Lippincott Williams & Wilkins. 2001
- Achar S. Taylor. Osteochondritis Dissecans. 5 Minute Sports Medicine Consult. Mark Bracker editor. Lippincott Williams & Wilkins. 2001
- Achar S. Khalifa A. Dural A. Anterior Interosseous Syndrome. 5 Minute Sports Medicine Consult. Mark Bracker editor. Lippincott Williams & Wilkins. 2001
- Achar S. Metacarpal Base/Shaft fracture I-V. 5 Minute Sports Medicine Consult. Mark Bracker editor. Lippincott Williams & Wilkins. 2001

Miscellaneous

- Achar S. Serious Substances of Abuse: Performance-Enchancing Drugs and Supplements. Audio-Digest Family Practice. Vol 53, Issue 46 December 14th, 2005. ISSN 0271-1362

Editing

- Assistant Editor. 5 Minute Sports Medicine Consult. Lippincott Williams & Wilkins. 2001
- Guest Series Editor:
  American Family Physician. Procedures in Family Medicine 2002
- Reviewer. American Family Physician. 2001-present

Research

- Sub Investigator: *Phase II Randomized, Double-Blind, Placebo- and Active-Controlled, Multicenter, Parallel Group Proof of Concept Study of the Analgesic Effects of RN624 in Adult Patients with Chronic Low Back Pain. 2007-2008*
- Principal Investigator: *Impact of Sports Participation on Violence Prevention and Health Maintenance*
- Principal Investigator: *Predictive Value of the Thumb to Forearm Flex Test on Rates of Progression Through Labor in Nulliparous Women: A Pilot Study*
- Principal Investigator: *Self reported health outcomes versus participation in the individual sports of ballet and gymnastics: A sibling case control study*
- Associate Investigator:
  1. Substantivity of Sunblock in the Open Ocean Environment
  2. Prospective evaluation of the symptomatic medial plica

Teaching

- **UCSD Physician Prescribing Course: (occurs ~ 5 times a year) 2002-present**
- The Physician Prescribing Course is a two and one-half day small group CME program designed to improve the participant's prescribing behavior by providing education on the legal, biomedical and clinical aspects of prescribing drugs, especially controlled drugs. Topics in this course include:
    - State Laws and Medical Board Guidelines for the Prescription of Controlled Drugs
    - PRESCRIBING LAWS OF CALIFORNIA AND CALIFORNIA MEDICAL BOARD GUIDELINES
    - PROBLEM-ORIENTED MEDICAL RECORDS MBC GUIDELINES ON PRESCRIBING FOR CHRONIC PAIN
    - FIBROMYALGIA
    - Pharmacology of Narcotics
    - Non-Narcotic Alternatives for Chronic Pain
    - Diagnosis and Treatment of Arthritis

- Director Problem Based Learning in Anatomy Upper Extremity Nerve Injury and Brachial Plexus 2005 - 2006
- Director of Problem based learning series for UCSD family medicine residents
- Director Sports Medicine Selective University of California School of Medicine
- Lecturer/Instructor UCSD School of Medicine
    - ERM (Endocrinology, Reproduction, Metabolism)
    - SOM-202A - The Doctor/Patient Relationship
    - SOM_201A - Introduction to Clinical Medicine
    - Primary Care 401
    - Family Medicine Selective 426

Presentations: Regional/National

Feb 14, 2009 Doctors on Sidelines Urgent Diagnosis Not to Miss
Minor Traumatic Brain Injury/Concussion
Traumatic C Spine Injuries

Little League Elbow to Severs Disease: Diagnosis and Management of Appophyseal Injuries in Children

Advances in the Practice of Pediatrics: San Diego 2009
Rady's Childrens Hospital

June 30, 2008 Hematology/Oncology Review
Common Neurological Problems
AAFP Family Medicine Board Review
Seattle, Washington June 1-7th
Greensboro, North Carolina, June 20-28

March 2008 Motion is Lotion: Evidence Based Reasons to Prescribe Exercise

Topics and Advances in Internal Medicine
San Diego Hilton, CA.

Oct. 2007 *Office Evaluation and treatment of the Dizzy patient*
American Academy of Family Physicians
Annual Scientific Assembly, Chicago, Il

Oct 2007 *Performance Enhancing Drugs & Supplements: Update 2007*
American Academy of Family Physicians
Annual Scientific Assembly, Chicago Il.

Oct. 2007 *Advanced Case Based Sports Medicin: Pediatric and Adult*
American Academy of Family Physicians
Annual Scientific Assembly, Chicago Il

Jan 2007 *Supplements in Performance Enhancement and Weight loss.* 4th annual
Natural Supplements: An Evidence-Based Update La Jolla California

2006-2007 **QICM Primary Care Course: San Diego CA. Department of Corrections and Rehabilitation**
Evaluation and treatment of Chest pain
Evaluation and treatment of arrhythmias in primary care
Evaluation of the dizzy patient
Common problems in musculoskeletal care
Prescribing errors
Common Neurological problems
Anatomy of Medical Errors

Nov 2006 American College of Sports Medicine Southwest Chapter 26th annual Meeting. San Diego Ca. **Evidence-based Exercise Guidelines and Outcomes.**

Oct. 2006 *Office Evaluation and treatment of the Dizzy patient*
American Academy of Family Physicians
Annual Scientific Assembly, Washington D.C

Oct. 2006 *Advanced Case Based Sports Medicine*
American Academy of Family Physicians
Annual Scientific Assembly, Washington D.C

Sept 2005 *Performance Enhancing Drugs & Supplements: The Taylor Hooton Story*
Annual Clinical Lecture Series
American Academy of Family Physicians
Annual Scientific Assembly, San Fransisco, CA.

Sept 2005 *Weekend Warrior: Sidelined by Overuse Injuries*
American Academy of Family Physicians

Annual Scientific Assembly, San Fransisco, CA.

Sept 2005 *Evaluating the dizzy patient*
Procedures Lecture Series
American Academy of Family Physicians
Annual Scientific Assembly, San Fransisco, CA.

March 2005 *"Juicing" Performance Enhancing Drugs and Supplements"*
2005 Topics and Advances in Internal Medicine
Catamaran Resort Hotel, SD CA

Oct 2004 *Physical Vulnerabilities in Children*:
Annual Clinical Lecture Series
American Academy of Family Physicians Annual Scientific Assembly
World Organization of Family Physicians
Orlando, Florida

Oct 2004 *Keep Running: Diagnoses, treatment and prevention of running injuries.*
American Academy of Family Physicians Annual Scientific Assembly
World Organization of Family Physicians
Orlando, Florida

June 2004 "Slip and pop, a *little* pain when you walk"
"14 Month old limp"
San Diego Academy of Family Physicians
47th annual postgraduate symposium
San Diego, CA Loews Coronado Bay resort

March 2004 California Senate Select Committee on Government Oversight:
Chairwoman Senator Speier
Juicing by Eighteen: Adolescents' Use of Steroids and Performance-enhancing Drugs: *Health Concerns with Performance-enhancing Substances*
Sacramento, CA

Feb 2004 Repetitive Motion Injuries: *Cubital and Carpel Tunnel Syndrome*
Topics and Advances in Internal Medicine
Catamaran Resort Hotel, San Diego, CA

Oct 2003 American Academy of Family Physicians Annual Scientific Assembly
New Orleans, LA
"Commonly under diagnosed musculoskeletal problems in children"

Sept 2003 *Doctors Without Borders: Life on the Frontlines*
Grand Rounds Scripps Hospital San Diego California

March 2003 *"Motion is lotion: Evidence based reasons to prescribe exercise"*

"Heel pain: Cases from the frontlines"
Topics and Advances in Internal Medicine
Doubletree Hotel Mission Valley, San Diego CA

2002-2003 AB 487: Get A Grip On Pain!
UCSD Physicians Assessment & Continuing Education (PACE) &
San Diego Academy of Family Physicians
Town and Country Convention, SD
September 2002, January 2003, February 2003

- *"When narcotics are not the answer"*
- *"Probing the puzzle of osteoarthritis"*
- *"Motion is Lotion: Fibromyalgia in the millennium"*

2003-present *Prescribing laws of California, Medical Board Guidelines*
The use of controlled substances in medical practice, law 2241.5"
PROBLEM ORIENTED MEDICAL RECORDS - MBC GUIDELINES ON PRESCRIBING FOR CHRONIC PAIN
Prescribers Course
UCSD Physicians Assessment & Continuing Education (PACE)

Oct 2002 American Academy of Family Physicians Annual Scientific Assembly
San Diego CA

- *"Commonly under diagnosed musculoskeletal problems in children"*
- *"Neonatal hyperbilirubinemia and hypoglycemia"*

Aug 2002 Wilderness Medicine
Snowmass, Colorado

- *"Outbreak 2001"*
- *"Bioterrorism and related topics"*
- *"Disaster medical relief: The humanitarian work of Doctors Without Borders"*

June 2002 *"Performance enhancing drugs and supplements"*
San Diego Academy of Family Physicians
46th annual postgraduate symposium
San Diego, CA Loews Coronado Bay resort

Nov 2001 *Evaluation of the "Slump" test in the diagnosis of sciatica.*
San Diego Academy of Family Practice: all members meeting

Jan 1998 *"International preventive health"*
UCLA Health Care Symposium
Preventive care and the role of health care professional

1997 Keynote Lecturer: "*Long term effects of malnutrition on developmental milestones"* World Organization of Early Childhood Development

Sept 1994 Moderator: *"Dilemmas in cardiovascular disease"*
American Academy of Family Physicians Annual Scientific Assembly
Boston, Massachusetts

Journal/Radio/TV Interviews

April 2009 Delay Return to Play a Day After Concussion, Family Practice News April 1st 2009, Vol 39. No. 7

April 2009 Pardon Me Myths. Current Heath. San Diego Union Tribune. April 14th, 2009

June 2007 Health Benefits of Exercise: Weight watchers.com Interview

Dec 2006 Suraj Achar Maneuver Alleviates Paroxysmal Positional Vertigo.
Family Practice News 01 December 2006 (Vol. 36, Issue 23, Page 46)

Nov 2006 Suraj Achar. Peptide Test Flags Heart Risks in Young Athletes
Family Practice News 15 November 2006 (Vol. 36, Issue 22, Page 18)

March 2005 Steroids in Baseball: "These Days with Tom Fudge KPBS-FM San Diego

May 2004 Anabolic Steroid Abuse amongst American Youth: Canadian Broadcasting Network

Fall 2000 The Human Condition; A 26-Part Television Series About Health & Wellness in the 21st Century, PBS

Aug 1997 KUSI News San Diego: Guest on morning news
July 1997 "These Days" with Dan Erwin KPBS-FM, San Diego
Dr Suraj Achar, Doctors without Borders

Workshops
San Diego Family Practice Consortium: UCSD Family and Internal Medicine, Scripps Clinic Chula Vista Family Medicine, NAVY Family Medicine, UCSD School of Medicine,

- 5 hour musculoskeletal workshop, given twice a year 2001-present
  "Upper Extremity: Examination, Common Problems & Injection"
  "Foot and Ankle: Examination, Common Problems & Injection"
  "Shoulder: Examination, Common Problems & Injection"
  "Knee: Examination, Common Problems & Injection"
  "Back: Examination, & Manipulation/Acupuncture"

- Workshop includes
  - Anatomy presentation

- Physical Exam techniques
- Case presentations in small groups with multiple trained facilitators from sports medicine
- Injection techniques and procedures
- Prosection with fresh frozen cadaver

Medical Legal Consulting

2004-2009 California Medical Board Expert Reviewer
2005-2008 California Department of Corrections Reviewer
2003- Expert Witness

Team Physician/Community Involvemnt

- Head Team Physician
- San Diego Sockers (MISL: Major Indoor Soccer League)
- Kearny High School (1999-present)
- UCSD varsity athletics (1999-present)

1999-present Medical Director California State Games
Olympic-style competition for California's amateur youth athletes. Over 5000 athletes compete in 20 different sports from archery to field hockey to gymnastics, at various locations throughout San Diego

1999-present House Doctor, San Diego Symphony
2000, 2001 Medical Director: 7th & 8th Annual UCSD Cancer Luau Longboard Invitational

Languages
French and Spanish

Professional Organizations
1993-present American Academy of Family Physicians, California Chapter
2001-present American Medical Society of Sports Medicine

Hobbies Classical Guitar, Scuba Diving, Soccer, Golf, Sea Kayaking

APPENDIX TAB B

EXPERT OPINION OF JEFFREY B. MENDEL, M.D.

This report is written at the request of The Girards Law Firm and is written in order to comply with *Texas Civil Practices & Remedies Code* § 74.351. I have been informed that subsection (k) of the statute provides that an expert opinion prepared under this law is not admissible in evidence by any party; shall not be used in a deposition, trial, or other proceeding; and shall not be referred to by any Defendant during the course of any proceeding in this case. All opinions expressed herein are based upon reasonable medical probability.

I have reviewed the medical care given to patient during the time period from September 2011 to present by Fossil Creek Family Medical, Dr. David Simonak, Dr. Jonathan Snead, Texas Breast Specialists, Dr. Mary Brian, Dr. Jason Skiles, Dr. Renita Butler, and Texas Health Harris Methodist Southlake hospital. I have specifically reviewed the following diagnostic studies:

- Diagnostic mammogram performed on 22 September 2011
- Left breast ultrasound performed on 26 September 2011
- CT Chest without contrast performed on 25 September 2012
- Diagnostic mammogram performed on 30 November 2012
- Left breast ultrasound performed on 30 November 2012

As is my usual practice, I initially performed a blind review of the studies with no knowledge of the radiology reports or patient 's subsequent clinical course. I then reviewed the radiology reports.

QUALIFICATIONS

I am a board certified physician licensed to practice medicine by the States of Massachusetts, Rhode Island, New Hampshire and Maine. I received the MD degree at Tufts University School of Medicine in Boston, Massachusetts in 1977. Thereafter, I completed an Internship in Internal Medicine at Norwalk Hospital in Norwalk, Connecticut, followed by a Residency in Radiology at the Hospital of St. Raphael in New Haven, Connecticut. From 1981 to 1983, I completed a Fellowship in Nuclear Medicine at Harvard Medical School in Boston, Massachusetts. I am a Diplomate of the American Board of Radiology and the American Board of Nuclear Medicine. Since 1983, I have continuously been involved in the practice of Radiology at numerous hospitals.

I have taught Radiology at Harvard University and Tufts University School of Medicine. From 2003 to 2008, I was directly involved in training 4th year Tufts Medical Center residents rotating through breast imaging. I have lectured on breast imaging at national and international meetings. Likewise, I have conducted research studies directly related to the detection of breast cancer. I have published in numerous peer-reviewed publications on the topics of breast lesions, needle biopsy of the breast, and the interpretation of screening mammography. My curriculum vitae is attached hereto, and further outlines my training, education, and experience.

I am intimately familiar with the performance and interpretation of breast imaging studies, including analog and digital mammography, ultrasound and breast MRI. I am familiar with the

standard of care as it applies to breast imaging read in a variety of practice settings. All opinions expressed in this report are based on reasonable medical probability.

I understand that in Texas, "negligence", when used with respect to a physician, means the failure to use ordinary care; that is, doing that which a physician of ordinary prudence would not have done under the same or similar circumstances, or failing to do that which a physician of ordinary prudence would have done under the same or similar circumstances.

I understand that in Texas as to a physician, "ordinary care" means that degree of care which would be used by a physician of ordinary prudence under the same or similar circumstances.

I understand that in Texas, "proximate cause" means that cause that was a substantial factor in bringing about an event, and without which cause such event would not have occurred. In order to be a proximate cause, the act or omission complained of must be such that a physician using ordinary care would have foreseen that the event, or some similar event, might reasonably result therefrom. I understand that there may be more than one proximate cause of an event.

PATIENT HISTORY / RADIOLOGICAL FINDINGS

In September 2011, patient was a 33 year old mother of two children. She presented to her primary care physician, Dr. David Simonak, complaining of left sided breast pain. The mammogram of September 22, 2011 and ultrasound of September 26, 2011 were ordered as a result of this complaint.

September 22, 2011 Mammogram

On my blinded review, the mammogram demonstrates microcalcifications clustered in the upper outer quadrant of the left breast. These are principally in the mid portion of the breast but some are noted to extend more posteriorly. These calcifications are noted on the magnified, focally compressed views to be both amorphous and pleomorphic without associated mass or architectural distortion. Additionally, there are scattered groups of amorphous microcalcifications in adjacent portions of the same quadrant. There are a few lymph nodes visible in the left axilla on the oblique view and not on the right. The largest is less than 1 cm in short axis and retains a fatty notch although it appears relatively dense. There are virtually no microcalcifications in the right breast.

Dr. Jason Skiles interpreted the mammogram, and described "scattered punctuate benign appearing calcifications" in the left breast. He further described "some clustering of calcifications in the upper outer quadrant of the left breast." His Impression was as follows:

> **Impression:** Indeterminate microcalcifications in the left breast, probably benign. A follow-up study is recommended in 3 to 6 months. Computer-aided detection was utilized.
>
> **BI-RADS category 3 :** Probably benign finding(s).

September 26, 2011 Breast Ultrasound

The ultrasound of September 26, 2011 is unremarkable. The "Breast Ultrasound Tech Sheet" indicates that the breast was scanned from approximately 11:00 to 7:00 as well as the axilla. Specifically, no suspicious lymph nodes were detected.

Dr. Jason Skiles interpreted the breast ultrasound as unremarkable. His Impression was as follows:

> **Impression**: No sonographic abnormality is identified in the area of left axillary pain.

September 25, 2012 CT Scan of Chest

Approximately one year later, on September 25, 2012, patient had a CT scan of her chest for unrelated medical issues. The CT scan demonstrates two prominent left axillary lymph nodes which have relatively minimal fatty hila but are less than 1 cm in short axis. Also visible is focal asymmetry of the breast parenchyma in the left upper outer quadrant.

In November 2012, she again presented to the office of her primary care physician, complaining of her left breast. Dr. Simonak ordered the mammogram of November 30, 2012 and ultrasound of November 30, 2012 as a result of this complaint.

November 30, 2012 Mammogram & Breast Ultrasound

On my blinded review, the diagnostic mammogram of November 30, 2012 demonstrates a marked increase in the number of microcalcifications, which now also involve at least the upper inner quadrant. There is also new focal asymmetry in the upper outer quadrant, corresponding to the largest area of microcalcifications and to the area of suspicious calcifications on the September 2011 mammogram. The left axillary lymph nodes appear larger and more numerous than on the September 2011 mammogram and, in fact, appear larger than on the September 2012 CT.

The left breast ultrasound of 30 November 2012, according to the "Breast Ultrasound Tech Sheet" demonstrated "hypoechoic patches with calcifications seen throughout lt. breast". The images confirm this appearance with the largest regions of abnormal breast parenchyma at 12 and 2 o'clock.

Dr. Renita Butler interpreted the mammogram, and described "diffuse microcalcifications in the superior in the superior left breast" that she felt were "uniform in morphology and size, favoring a benign etiology." Her interpretation of the ultrasound describes that there was "no solid or cystic mass." Her Impression and Recommendation was as follows:

Impression:

1. Diffuse benign appearing left breast microcalcifications. A history of repeat left-sided mastitis was elicited. The microcalcifications are consistent with dystrophic calcifications from prior mastitis.

2. No mammographic or sonographic evidence of malignancy.

Recommendation:

1. Annual screening mammogram at age 40, or per family history of breast cancer.

2. Continue self breast examination. BI-RADS 2: Benign -- Routine Followup.

patient continued to have left breast complaints and was evaluated by Dr. Mary Brian on January 28, 2013. Dr. Brian performed an in-office core biopsy that revealed high grade ductal carcinoma in situ. On February 22, 2013, Dr. Brian performed a left modified radical mastectomy and left sentinel node biopsy. Subsequent pathology confirmed that patient had multiple positive lymph nodes (14 out of 28) and she was diagnosed with multifocal Stage IIIC invasive ductal carcinoma.

STANDARDS OF CARE

The standard of care for physicians interpreting radiological studies in patients such as patient requires that the physician recognize the presence and significance of suspicious clusters of microcalcifications in breast tissue and recommend prompt biopsy.

The standard of care for physicians interpreting radiological studies in patients such as patient further requires that the physician appreciate the significance of any marked increase in segmental microcalcifications in breast tissue, the presence of any new area of focal asymmetry, and any enlargement of the axillary lymph nodes when compared to the prior mammograms. The minimal standards of care require that the physician recommend emergent biopsy should these findings be present.

VIOLATIONS OF THE STANDARD OF CARE

My review of the medical records and radiological studies related to patient 's care leads me to conclude that, based on reasonable medical probability, Dr. Jason Skiles fell below the applicable standards of care in his treatment of patient by failing to appreciate the presence and significance of the suspicious microcalcifications in the left breast. Further, it is my opinion that Dr. Skiles fell below the applicable standards of care by failing to immediately recommend biopsy of the concerning breast tissue.

Under the definitions listed above, I must conclude that Dr. Skiles was negligent in his care and treatment of patient related to his September 2011 interpretation of the digital mammogram for these reasons. Had Dr. Skiles acted within applicable standards of care, he would have recommended prompt biopsy of the left breast which would most likely have resulted in the breast cancer being diagnosed and treated at a before spreading to the lymph nodes.

My review of the medical records and radiological studies related to patient's care leads me to conclude that, based on reasonable medical probability, Dr. Renita Butler fell below the applicable standards of care in her treatment of patient by failing to appreciate the significance of the marked increase in segmental microcalcifications in the left breast, the presence of a new area of focal asymmetry, and the enlargement of the left axillary lymph nodes when compared to the 2011 mammogram. These findings were highly suspicious for invasive breast cancer. Further, it is my opinion that Dr. Butler fell below the applicable standards of care by failing to recommend emergent biopsy of the concerning breast tissue.

Under the definitions listed above, I must conclude that Dr. Butler was negligent in her care and treatment of patient related to her November 2012 interpretation of the digital mammogram for these reasons. Had Dr. Butler acted within applicable standards of care, she would have recommended prompt biopsy of the left breast which would most likely have resulted in the cancer being diagnosed and treated at a much earlier stage

APPROPRIATE PATIENT CARE

In order to comply with applicable standards of care, Dr. Skiles should have recognized and appreciated that the September 22, 2011 mammogram demonstrated a highly suspicious cluster of microcalcifications in the upper outer quadrant of the left breast. The presence of adjacent groups of microcalcifications should have raised the possibility of multifocal disease in his mind. These findings warranted a recommendation for prompt biopsy, BI-RADS 4c, which Dr. Skiles should have recommended.

In order to comply with applicable standards of care, Dr. Butler should have appreciated the significance of the marked increase in segmental microcalcifications in the left breast visible on the November 30, 2012 mammogram, the presence of a new area of focal asymmetry, and the enlargement of the left axillary lymph nodes when compared to the 2011 mammogram. Dr. Butler should have recognized these findings as being highly suspicious for invasive breast cancer, and recommended an emergent biopsy of the concerning breast tissue, BI-RADS 5.

Unfortunately, Drs. Skiles and Butler failed to take these actions, thereby proximately causing an unnecessary extended delay in the diagnosis and treatment of patient 's breast cancer.

CAUSATION & DAMAGES

It is my opinion beyond a reasonable medical probability, based on my training and education and experience, that the negligent acts of Drs. Skiles and Butler outlined above were each a proximate cause of patient 's injury and related sequelae.

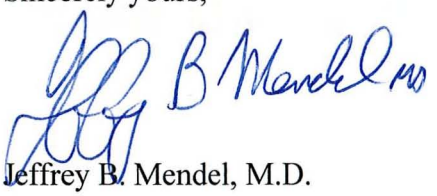
Specifically, the failures of Drs. Skiles and Butler to identify and report the abnormalities in patient 's left breast resulted in an extended delay in diagnosis and treatment of her disease. The basis for this opinion is that if the abnormalities were correctly identified, described, and reported to the ordering physician with a recommendation for biopsy, then a biopsy of the left breast would have been performed, the diagnosis of breast cancer would more likely than not have been reached within days following the reporting of the mammogram(s), and decisions

regarding definitive care would more likely than not have been made within days following the reporting of the mammogram(s) rather than in 2013.

In sum, it is my opinion beyond a reasonable medical probability, based on my training and education and experience, that Dr. Jason Skiles and Dr. Renita Brown were negligent in their care of patient . Further, it is my opinion that each of these acts and omissions of negligence was a proximate cause of her injury and its sequelae.

I hold these opinions to a reasonable degree of medical certainty. I reserve the right to extend or amend these opinions as additional materials become available for my review.

Sincerely yours,



Jeffrey B. Mendel, M.D.

Curriculum Vitae

NAME: Jeffrey Brian Mendel, MD

ADDRESS: 180 Otis Street, West Newton, MA 02465

OFFICE: 617-237-0374

CELL: 617-519-6186

E-MAIL: Jeffrey_Mendel@alumni.brown.edu

EDUCATION

Undergraduate

1969-1973 Sc.B. Brown University, Environmental Engineering, Providence, RI

Medical School

1973-1977 MD Tufts University School of Medicine, Boston, MA

POSTDOCTORAL TRAINING

Internship and Residencies:

1977-1978 Intern, Internal Medicine, Norwalk Hospital, Norwalk, CT

1978-1980 Resident, Radiology, Hospital of St. Raphael, New Haven, CT

1980-1981 Chief Resident, Radiology, Hospital of St. Raphael, New Haven CT

Fellowship

1981-1983 Clinical Fellow, Joint Program in Nuclear Medicine, Harvard Medical School, Boston, MA

LICENSURE AND CERTIFICATION:

1978 National Board of Medical Examiners

1981 Diplomate, American Board of Radiology

1983 Massachusetts License Registration #50755

1983 Diplomate, American Board of Nuclear Medicine

2006 ACLS Certified

2008 Maine License Registration #017685

2010 Rhode Island Registration #13160

2010 New Hampshire #14769

ACADEMIC APPOINTMENTS:

1990-2002 Clinical Instructor of Radiology, Harvard University

2001-present Assistant Professor of Radiology, Tufts University School of Medicine

HOSPITAL APPOINTMENTS:

1983-1987 Director of Nuclear Medicine, Carney Hospital, Boston, MA

1983-1987 Staff Radiologist, Carney Hospital, Boston, MA

1983-1987 Radiation Safety Officer, Carney Hospital, Boston, MA

1984-1987 Staff Radiologist, The Arbor Hospital, Boston, MA

1987-1990 Chief of Radiology, Sancta Maria Hospital, Cambridge, MA

1987-1990 Radiation Safety Officer, Sancta Maria Hospital, Cambridge, MA

1989-2001 Staff Radiologist, Beth Israel Deaconess Medical Center, Boston, MA

1993-1998 Director of Radiology, McLean Hospital, Belmont, MA

1993-2005 Consultant in Radiology, Department of Internal Medicine, McLean Hospital, Belmont, MA

1999-2001	Chief, Section of Informatics; Department of Radiology, Beth Israel Deaconess Medical Center, Boston, MA
2001-2008	Chair, Department of Radiology, Caritas St. Elizabeth's Medical Center, Boston, MA
2002-2008	Radiology Residency Program Director, Caritas St. Elizabeth's Medical Center, Boston, MA
2002-2008	Staff Radiologist, Kindred Hospital, Boston, MA
2009-present	Consultant Radiologist, Saint Elizabeth's Medical Center, Boston, MA
2010-present	Staff Radiologist, Memorial Hospital, Pawtucket, RI
2012-present	Staff Radiologist, Parkland Medical Center, Derry, NH
2012-present	Radiation Safety Officer, Parkland Medical Center, Derry, NH

AWARDS AND HONORS

1973	Tau Beta Pi Engineering Honor Society
2006	Top 25 Innovators in Health Imaging and IT
2009	Who's Who in America
2008-2009	Distinguished Teacher Award, Tufts School of Medicine

HOSPITAL, MEDICAL SCHOOL, OR UNIVERSITY COMMITTEE ASSIGNMENTS

1983	Project Director, Nuclear Medicine Upgrade, Carney Hospital, Boston, MA
1983-1987	Radiation Safety; Laboratory, Carney Hospital, Boston, MA
1985	Project Director, Digital Angiography, Carney Hospital, Boston, MA Directed selection, acquisition, architectural design & installation of digital angiographic suite
1987-1990	Executive; Quality Assurance, Emergency Unit; Radiation Safety Committees, Sancta Maria Hospital, Cambridge, MA
1996-1997	Coordinator, Steroid Premedication Project, Beth Israel Deaconess Medical Center, Boston, MA
1996-2001	Medicare Compliance; Clinical System's Users Group, Beth Israel Deaconess Medical Center, Boston, MA
1996.2001	Compliance Education Project, CareGroup, Boston, MA

1997-2001	Project Director, PACS Acquisition, Beth Israel Deaconess Medical Center, Boston, MA. Directed selection, purchase & installation of Picture Archiving and Communication System.
1997-2001	Project Director, RIS Acquisition Beth Israel Deaconess Medical Center, Boston, MA. Directed selection, purchase and installation of Radiology Information System.
1997-2001	Director, Radiology Utilization Management Group, Beth Israel Deaconess Medical Center, Boston, MA
2001-2008	Chairs and Executive Committee, Caritas St. Elizabeth's Medical Center, Boston, MA
2001-2009	Member, Board of Directors, Caritas St. Elizabeth's Health Professionals, Caritas St. Elizabeth's Medical Center, Boston, MA
2001-2006	Member, Board of Directors, Caritas Medical Group
2001-2006	Co-Medical Director, Caritas Christi Diagnostic Support Services, Inc. Caritas St. Elizabeth's Medical Center, Boston, MA
2001-2008	Patient Care Assessment Sub-Committee, Caritas St. Elizabeth's Medical Center, Boston, MA
2001-2008	Cancer Care Committee, Caritas St. Elizabeth's Medical Center, Boston, MA
2003-2006	Chair, Joint Conference Committee of Medical Staff
2002-2008	Co-chair, PACS Executive Committee
2004-2006	Caritas Clinic Governance Committee, Caritas St. Elizabeth's Medical Center, Boston MA

OTHER MEDICAL ACTIVITIES

1987-1997	Professional Education; Board of Directors, American Cancer Society, Cambridge, MA
1989-present	President and Founder of The Diagnostic Center, Cambridge, MA
1998-2001	Principal Advisor for Centricity PACS design, General Electric Healthcare IT
1998-2002	Advisory Board – General Electric Integrated Imaging Systems
1998	Consultant: ZA Associates, Radiology department reorganization
1999-2002	Consultant: Clinician Support Technologies, Web-based integration of hospital information systems
1999-2002	Co-founder (November 1999) GE PACS Users Group, RSNA, Chicago, IL
2002-present	Physician Advisory Committee, Harvard Pilgrim Health Care,Wellesley, MA

2002-2009 Blue Cross Blue Shield of Massachusetts Advisory Committee, Boston, MA

2002-2011 Philips Medical Systems Medical Advisory Board

2006-present Principal Advisor for mammography workstation design, McKesson Medical Imaging Group

2007-2011 Advisory Board, Rcadia Medical Imaging

2007-present Consultant, 20/20 Healthcare Partners

2007-present Strategic Advisor, McKesson Corporation

2009-2011 Consultant, Fuji Medical Systems

2009-present Consultant, Philips Medical Systems

2010-present Consulting Radiologist, Salem Radiology

2010-present Chief Radiology Advisor, Partners in Health – Mirebalais Hospital

2011-present Senior Advisor, iRadX

2011-present Advisory Board, Dorsata

TRAINING OF GRADUATE STUDENTS/POST DOCTORAL

2003-2008 4th year Tufts Medical Center residents rotating through breast imaging

TEACHING RESPONSIBILITY

1978 Cardiac and Pulmonary Disease, lecture series for paramedic students, Norwalk Hospital, Norwalk, CT

1981 Radiology Resident teaching and organization of lecture series--Hospital of St. Raphael, New Haven, CT

1983-1987 Medical Grand Rounds; Continuing Medical Education lecture; Nursing Grand Rounds; resident teaching, Carney Hospital, Boston, MA

1985-1986 Continuing Medical Education lectures, Medical East Community Health Plan (Health Maintenance Organization) Braintree, MA

1986-1989 Associate in Nuclear Medicine; Radiology Resident Rounds, Beth Israel Hospital, Boston, MA

1987-1990 Medical Grand Rounds; Surgical Grand Rounds; CCU Course; Nursing Grand Rounds, Sancta

Maria Hospital, Cambridge, MA

1992-2001 Senior Teaching Faculty, Harvard Medical School, Core Curriculum in Radiology

1995-2003 Teaching Faculty, Harvard Medical School, Advanced Radiology Clerkship

1996-1999 Radiology Physics: Introductory Lecture Series, Radiology Residents, Beth Israel Deaconess Medical Center, Boston, MA

1997 Macy's Scholar Program Host, Harvard Medical School

1998-2002 Radiological Anatomy for Paramedics, South Middlesex EMS

2004-2006 Designed radiology course for first year anatomy course at Tufts University School of Medicine with Dr. Priscilla Slanetz

2007-2012 Tufts University School of Medicine, Boston, MA First Year Anatomy Course Lecture Series

Topics: Introduction to Radiology
Radiology of the Upper and Lower Limbs
Radiology of the Thorax.
Radiology of the GI System
Radiology of the Head and Neck

PROFESSIONAL SOCIETIES

1981-2003 American College of Nuclear Physicians

1981-2001 New England Roentgen Ray Society

1981-present Society of Nuclear Medicine

1982-present Radiological Society of North America

2008-present European Society of Radiology

RESEARCH INTERESTS

2001-2003 Principal Investigator: CATSCAN Trial: Coronary Assessment by Computed Tomographic Scanning and Catheter Angiography: A Multi-center Trial

2004-present The Tufts University Digital Human Anatomy Project

2006-2007 Principal Investigator: Comparison of Computed Radiography Mammography and Film-Screen Mammography for Specimen Radiographs, Needle Localization Procedures and in

	Women with Dense Breasts
2007-2009	Principal Investigator: Contrast CT Imaging of Coronary Venous System
2007-2009	Principal Investigator: DETERMINE Trial: DEfibrillators To REduce Risk by Magnetic ResoNance Imaging Evaluation
2008-2009	Data collection for FDA submission on new CAD system for Digital Mammography
2010	Breast Tomosynthesis reader trial – General Electric
2010	Study Coordinator – Pilot Study of the Comparative Accuracy of Amulet versus FCRm in Detection of Breast Cancer
2011-2012	Iterative reconstruction and low kVp imaging: effects on image quality
2012	Perceived vs. Quantitative Image Quality: Effects of partial and full iterative reconstruction on image appearance

EDITORIAL BOARDS AND ACTIVITY

1995-2001	Editor--Imaging Update: A quarterly publication of the Department of Radiology of Beth Israel Deaconess Medical Center, Boston, MA

BIBLIOGRAPHY:

Peer Reviewed Papers

1. **Mendel JB**, Markowitz RI. Retropharyngeal bleeding in haemophilia. Br J Radiol. 1981; 54(642):521-3

2. Siddon RL, Chin LM, Zimmerman RE, **Mendel JB**, Kaplan WD. Utilization of parasternal lymphoscintigraphy in radiation therapy of breast carcinoma. Int J Radiat Oncol Biol Phys. 1982; 8(6):1059-63

3. Heller GV, Royal HD, McKay RG, **Mendel JB**, Parker JA, Silverman KJ, Kolodny GM, Grossman W, Aroesty JM. Radionuclide analysis of peak filling rates during pacing-induced ischemia. J Nucl Med 1983; 24:P87

4. Boyd JB, **Mendel JB**. Mechanisms of skeletal changes associated with vascular malformations. Plastic Surg Res Council, May 1983; 125-8

5. **Mendel JB**, Taylor GA, Treves S, Chang TH, Retik A, Bauer S. Testicular torsion in children: scintigraphic assessment. Pediatr Radiol 1985; 15(2):110-5

6. Charron M, **Mendel JB**, Kolodny GM. Unusual complication of scrotal abscess. Clin Nucl Med 1988; 13(10):76

7. **Mendel JB**, Linares R, Gomori J, Fields S, Yago, M. Clinical trial of remote radiologist services for a military base. Milit. Med. 1990; 155(2):52-4

8. Edelman RR, Mattle HP, Wallner B, Bajakian R, Kleefield J, Kent C, Skillman JJ, **Mendel JB**, Atkinson DJ. Extracranial carotid arteries: evaluation with "black blood" MR angiography. Radiology 1990; 177(1):45-50

9. Kolodny GM, Raptopolous V, Simon M, **Mendel JB**, Barbaras LG, Tal I, Kressel HY. A low-cost, full-function picture archiving and communications system using standard PC hardware and the traditional 4-over-4 display format. Am J Roentgenol (1999 Mar) 172(3):591-4

10. Copeland J, **Mendel JB**, Practical quality standards for digital display monitors. Progress in Biomedical Optics and Imaging, 2000 1(21):315-322

11. Mithofer K, Rachlin JR, Kleefield J, **Mendel JB**, Glazer P. Intradural lumbar vertebral disk herniation: a case report and review. Orthopedics (2002 Apr) 25(4):437-9

12. Copeland J, Melhus CS, Horton RC, Venkatakrishnan V, Zamenhof RG, **Mendel JB**. Practical quality control standards for digital display monitors. Proc SPIE 3976,315 (2000) published online 2003

13. Slanetz PJ, Grandpre LE, Yeh ED, Kopans DB, **Mendel JB**. Effect of Tamoxifen on breast tissue density in premenopausal breast cancer. Breast J. 2004 Jan-Feb; 10(1):27-32

14. Hoffmeister PS, **Mendel JB**, Chaudhry GM, Patel J, Almasry I., Haffajee CI, Orlov MV. Evaluation of Left Atrial and Posterior Mediastinal Anatomy By Multi-Detector Helical Computed Tomography Imaging: Relevance to Ablation. Submitted for publication to PACE, 2006

15. Ko JM, Nicholas MJ, **Mendel JB**, Slanetz PJ. Prospective assessment of computer-aided detection in interpretation of screening mammography. Am J Roentgenol 2006; 187:1-13

16. **Mendel JB,** Long MT, Cappelen BS, Lee DL, Slanetz PJ. MR-Guided Core Needle Biopsy of the Breast: Technique, Pearls, and Pitfalls (submitted for publication Radiographics)

17. Garcia MJ, Lessick J, Hoffmann MH, CATSCAN Study Investigators
Accuracy of 16-Row Multidetector Computed Tomography for the Assessment of Coronary Artery Stenosis. JAMA, July 26, 2006; 296: 403 - 411
(**Mendel JB** Caritas Saint Elizabeth's Medical Center, Boston, Mass; 9 patients)

18. **Mendel JB,** Long M, Slanetz PJ. CT-guided core needle biopsy of breast lesions visible only on MRI. Am J Roentgenol July 2007; 189:1-5

19. Karavas AN, Lee D, **Mendel JB,** Hackford A. A novel interventional approach to sigmoid volvulus. EJR 67(2): e83-e86

20. Li JH, Haim M, Movassaghi B, **Mendel JB**, Chaudhry GM, Haffajee CI, Orlov MV. Segmentation and Registration of 3D Rotational Angiogram on Live Fluoroscopy to Guide AF Ablation: A New On-Line Imaging Tool. Heart Rhythm 2009; 6:231-237

21. **Mendel JB**, Fruauff K, Upgrade Rate in Breast Biopsies: The Effect of Vacuum-Assisted Devices (in preparation)

22. Slanetz PJ, Wu S, **Mendel JB** Percutaneous Excision: A Viable Alternative to Manage Benign Breast Lesions. Can Assoc Radiol J 2010 Jul 7

23. Zoubin A, Li J, Merchan, JA, Nijhof N, **Mendel JB** Orlov MV. Coronary sinus anatomy by computerized tomography, overlaid on live fluoroscopy can be successfully used to guide left ventricular lead implantation: a feasibility study. J Interv Card Electrophysiol 2012; online Nov 30

Non Peer-Reviewed

1. **Mendel JB** Emerging Technologies for the Electrophysiology Lab. Cath Lab Digest, Supplement to October 2007; 15(10): 15-20

2. **Mendel JB** Breast magnetic resonance imaging. Virtual Mentor. 2007; 9(11):754-757

3. **Mendel JB** Storage Dilemmas in the MDCT World. Radiology Business Journal June/July 2009

Abstracts

1. Hoffmeister P, **Mendel JB,** Orlov MV, Chaudhry GM, Shukla G, Patel J, Almasry I, Haffajee CI. Variability of left atrial and posterior mediastinal anatomy on multi-detector helical computed tomography imaging: Relavance to ablation. Heart Rhythm 2005; 2:S220-221 Abstracts of the 26th Annual Scientific Sessions of Heart Rhythm Society, New Orleans, USA

2. Prospective assessment of computer-aided detection in interpretation of screening mammography Ko JM, Nicholas MJ, **Mendel JB**, Slanetz PJ.. American Roentgen Ray Society 106th Annual Meeting, Vancouver, B.C. April 2006 – MAGNA CUM LAUDE AWARD

3. Akrivakis ST, Orlov MV, Chaudhry M, Hahn P, **Mendel JB**, Armstrong J, Merchan JA, Marchese TF, Sweck T, Haffajee CI. Initial Experience With Stereotaxis/Carto Integration For Left Atrial Mapping And Ablation. Heart Rhythm 2007; 4: PO1-31. Abstracts of the 28th Annual Scientific Sessions of Heart Rhythm Society, Denver, Colorado, USA

4. **Mendel** JB, Long M, Flibott C. Comparison of Computed Radiography for Mammography and Screen Film Mammography for Specimen Radiography and Needle Localization Procedures. American Roentgen Ray Society, 108th Annual Meeting, Washington, D.C., April 2008

5. Li HJ, Haim M, Movassaghi B, **Mendel JB**, Chaudhry GM, Haffajee CI, Orlov MV. Segmentation And Registration Of 3D Rotational Angiogram On Live Fluoroscopy To Guide AF Ablation: A New On-Line Imaging Tool. Heart Rhythm 2008:5: PO4-42. Abstracts of the 29th Annual Scientific Sessions Of the Heart Rhythm Society, San Francisco, California, USA

Scientific Presentations/Exhibits

1. Levin D, **Mendel JB**. The lateral chest radiograph: normal and abnormal hilar anatomy. Annual Meeting of the Radiologic Society of North America, Chicago IL. November 1997

2. Cappelen C, **Mendel JB**, Lee D, Ierardi J, Puryear R, Gillis C, Carballo D, Slanetz PJ. MR-Guided Core Needle Biopsy of the Breast: Technique, Pearls and Pitfalls. Educational Exhibit presented at the 90th Annual Meeting of the Radiological Society of North America, December 2004. **Honors:** Certificate of Merit, Selected for publication in *RadioGraphics*, Selected for category 1 CME credit

3. Hoffmeister PS, **Mendel JB**, Orlov MV, Chaudhry M, Shukla G, Patel J, Almasry, I, Haffajee CI. Variability of left atrial and posterior mediastinal anatomy on multi-detector helical computed tomography imaging: relevance to ablation. Presented at Heart Rhythm Scientific Sessions, New Orleans, LA, May 2005

4. Long M, Flibott C, **Mendel JB**. Comparison of computed radiography for mammography and screen film mammography for specimen radiography and needle localization procedures. Presented at 108th Annual Meeting of the American Roentgen Ray Society, Washington, D.C., April 2008. **Honors:** MAGNA CUM LAUDE

5. Davidoff A, Lee DL, Tsai SS, Slanetz PJ, Smith EH, **Mendel JB**. The Common Vein: An Integrated Web-based Educational System That Applies Universal Principles to Structure and Reveals How They Apply in Health and Disease. Annual Meeting of the Radiologic Society of North America, Chicago IL. November 2007

6. Davidoff A, Allison C, Lee DL, **Mendel JB** The Aorta: A web-based educational tool integrating the basic sciences of the aorta with the clinical sciences. Annual Meeting of the Radiologic Society of North America, Chicago IL. November 2007

Invited Lectures

1. Invited Lecture: Advances in Neuroradiology, Neurology Fellowship, BU Medical School, Boston, MA, 1994

2. Keynote Lecture; PACS: Future Course for Clinical Productivity, GE PACS Users Group, Annual Meeting of the Radiologic Society of North America, Chicago IL. November 1998

3. Invited Lecture: PACS: Why now? CIO Forum, Superior Consulting 2000

4. **Mendel JB**. Refresher course: PACS quality assurance and acceptance testing
   Annual Meeting of the Radiologic Society of North America, Chicago IL. November 2000

5. PACS at BIDMC Two Years Later. Joint Program in Nuclear Medicine Seminar. Beth Israel

Deaconess Medical Center, Boston, MA. June 2001

6. **Mendel JB**. Refresher course: PACS quality assurance and acceptance testing. Annual Meeting of the Radiologic Society of North America, Chicago IL. November 2001

7. Surgical Grand Rounds, St. Elizabeth's Medical Center, Boston, MA: Interventional Radiology- Present and Future. June 2002.

8. Residents Conference-Neuroradiology- Beth Israel Deaconess Medical Center, Boston, MA, September 2002.

9. **Mendel JB**. Refresher course: PACS quality assurance and acceptance testing. Annual Meeting of the Radiologic Society of North America, Chicago IL. November 2002

10. Didactic course on Radiation Safety and Fluoroscopy for non-radiology physicians; Caritas St. Elizabeth's Medical Center, February 2003

11. Invited Speaker: Core Lecture to Residents, "Radiology and Technology". Beth Israel Deaconess Medical Center, Boston, MA, March 2003

12. Invited Speaker: Teleradiology for the 21st Century. Massachusetts Radiological Society, Waltham, MA March 2003.

13. Invited Speaker: Core Lecture to Residents, "Radiology and Technology". Beth Israel Deaconess Medical Center, Boston, MA, June 2003

14. Co-Director Imaging Strategies for Primary Care Providers, Boston, MA, Tufts University School of Medicine Continuing Medical Education, October 2003

15. Invited Lecturer, Imaging Strategies for Primary Care Providers, Boston, MA, Tufts University School of Medicine Continuing Medical Education, October 2003. Title: Strengths and Limitations of Plain film, US, CT, and MRI

16. Invited Lecturer, Imaging Strategies for Primary Care Providers, Boston, MA, Tufts University School of Medicine Continuing Medical Education, October 2003. Title: Imaging Strategies for Memory Problems

17. Invited Lecturer, OB/GYN Grand Rounds, Caritas St. Elizabeth's Medical Center, Boston, MA, Topic: Uterine Fibroid Embolization, November 2003.

18. **Mendel JB**, Weiser J. Refresher course: PACS quality assurance and acceptance testing. Annual Meeting of the Radiologic Society of North America, Chicago IL. November 2003

19. Co-Director Imaging Strategies for Primary Care Providers, Boston, MA, Tufts University School of Medicine Continuing Medical Education, September 2004

20. Invited Lecturer, Imaging and Treatment Strategies in Primary Care Medicine, Boston, MA, Tufts University School of Medicine Continuing Medical Education, September 2004. Title: Using PACS in the Office of the Patient's Care Giver—Breakthrough in Communication

21. Invited Lecturer, Imaging and Treatment Strategies in Primary Care Medicine, Boston, MA, Tufts

University School of Medicine Continuing Medical Education, September 2004. Title: Strengths and Limitations of Plain Film, US, CT, and MRI

22. Invited Lecturer, Breast Cancer Care, Newton YMCA, Newton, MA, October, 2004

23. Hands-on ultrasound workshop, Real-Time Ultrasound in the Anatomy Laboratory. Tufts University School of Medicine, March 2005

24. Multidetector CT: Gating, Scoring, Reconstruction and LV Function-How to do it. Presented at Cardiac Imaging Review Course, New England Roentgen Ray Society, April 2005.

25. Medical Grand Rounds, "Cardiac CT 2005: Where do we stand?", Caritas St. Elizabeth's Medical Center, Boston, MA, May 2005

26. Integrated Breast Imaging: The Challenges for Caritas Christi Breast Center Development and Integration Project 10/22/05

27. Invited Speaker, Cardiac CT—State-of-the-Art 2006. Resident Grand Rounds, Tufts-New England Medical Center, Boston, MA. March 2006.

28. Program Director, Imaging and Treatment Strategies in Primary Care Medicine, Tufts University School of Medicine Continuing Medical Education, Boston, MA, April 2006.

29. Invited Lecture, Imaging and Treatment Strategies in Primary Care Medicine, Tufts University School of Medicine Continuing Medical Education, Boston, MA, April 2006. Lecture Title: Neuroimaging and Evaluation for Early Dementia.

30. Invited Lecture, Imaging and Treatment Strategies in Primary Care Medicine, Tufts University School of Medicine Continuing Medical Education, Boston, MA, April 2006. Lecture Title: Advances in Imaging

31. Invited Lecture, Imaging and Treatment Strategies in Primary Care Medicine, Tufts University School of Medicine Continuing Medical Education, Boston, MA, April 2006. Lecture Title: Imaging Strategies for the Work-up of Metastatic Disease.

32. Invited Lecturer, 8th Annual International Symposium on Multidetector-Row CT, San Francisco, CA, June, 2006. Lecture Title: Lung CAD: Are we finally ready for prime time?

33. Invited Lecturer, 8th Annual International Symposium on Multidetector-Row CT, San Francisco, CA, June, 2006. Lecture Title: Emphysema. New imaging techniques and therapies.

34. Invited Lecturer, 8th Annual International Symposium on Multidetector-Row CT, San Francisco, CA, June, 2006. Lecture Title: MDCT for the breast: Adjunct to breast MRI

35. Invited Lecturer, 8th Annual International Symposium on Multidetector-Row CT, San Francisco, CA, June, 2006. Lecture Title: Advanced Processing Functions – Separate workstations vs. PACS integration: How to choose.

36. Combined Medical/Surgical Grand Rounds, "Breast MR: Integration into Clinical Practice", Melrose-Wakefield Hospital, Melrose, MA. September 2006.

37. Medical Grand Rounds, "Breast MR: Integration into Clinical Practice", Lawrence Memorial Hospital, Medford, MA. November 2006.

38. Invited Speaker: Lung Cancer—Early Detection for Life; at Radiological Society of North America, Chicago, IL, November 2006.

39. Invited Speaker, Cardiac CT— How to do it. Resident Grand Rounds, Tufts-New England Medical Center, Boston, MA. March 2007.

40. Invited Moderator, Multi Detector CT Imaging 2007, Nashville, TN, April 2007. Cardiac Imaging and cardiology

41. Invited Lecturer, Multi Detector CT Imaging 2007, Nashville, TN, April 2007. Lecture Title: EP planning, Integration of CT with the EP lab.

42. Program Director, 5th Annual Imaging and Treatment Strategies in Primary Care Medicine, Tufts University School of Medicine Continuing Medical Education, Boston, MA, April 2007.

43. Invited Lecture, 5th Annual Imaging and Treatment Strategies in Primary Care Medicine, Tufts University School of Medicine Continuing Medical Education, Boston, MA, April 2007. Lecture Title: Update in Lung Imaging.

44. Invited Lecture, 5th Annual Imaging and Treatment Strategies in Primary Care Medicine, Tufts University School of Medicine Continuing Medical Education, Boston, MA, April 2007. Lecture Title: Cardiac CT – Where are we heading? Best Use Strategies

45. Invited Lecture, 5th Annual Imaging and Treatment Strategies in Primary Care Medicine, Tufts University School of Medicine Continuing Medical Education, Boston, MA, April 2007. Lecture Title: The strengths and weaknesses of MRI – Strategies in Use.

46. Invited Lecture, New England Roentgen Ray Society Cardiac Course, April 2007. Lecture Title: Multidetector CT: Gating, Scoring, Reconstruction, and LV Function – How to Do It

47. Medical Grand Rounds, "MRI of the Breast: What you need to know?", Caritas St. Elizabeth's Medical Center, Boston, MA, May 2007

48. Invited Lecturer, 9th Annual International Symposium on Multidetector-Row CT, San Francisco, CA, June, 2007. Lecture Title: Advanced Processing Functions: Separate Workstations vs. PACS Integration: How to Choose.

49. Invited Lecturer, 9th Annual International Symposium on Multidetector-Row CT, San Francisco, CA, June, 2007. Lecture Title: Lung Nodule CAD Finally Ready for Prime Time?

50. Invited Lecturer, 8th Annual International Symposium on Multidetector-Row CT, San Francisco, CA, June, 2006. Lecture Title: MDCT for the breast: Adjunct to breast MRI

51. Invited Lecturer, TAHSS program, Tufts University School of Medicine, Boston, MA, July 2007. Lecture Title: Introduction to Radiology

52. Keynote Speaker, SUMMIT annual meeting, RSNA, Chicago, IL. Digital Mammography Workstations, Current and Future Workflow. November 2007

53. Invited Speaker, Techniques in Ultrasound Biopsy. Resident Grand Rounds, Tufts Medical Center, Boston, MA. August 2008.

54. Invited Speaker, Digital Mammography Workflow, GE Medical Systems, Milwalkee, WI, February 2008

55. Invited Speaker, Multi Detector CT Imaging 2008, Baltimore, MD, April 2008. Lecture Title: Cardiac CT in the Cardiac Care Cycle: EP Integration

56. Invited Lecture, New England Roentgen Ray Society Cardiac Course, April 2009. Lecture Title: Basic Principles in Cardiac CT

57. Invited Lecturer, 11th Annual International Symposium on Multidetector-Row CT, San Francisco, CA, May, 2009. Lecture Title: Cardiac CT for Electrophysiology Procedures: Current status and future trends

58. Invited Lecturer, 11th Annual International Symposium on Multidetector-Row CT, San Francisco, CA, May, 2009. Lecture Title: Workflow for outside studies: Techniques for those piles of CD's

59. Invited Lecturer, 11th Annual International Symposium on Multidetector-Row CT, San Francisco, CA, May, 2009. Lecture Title: CT of the Breast: Incidental to Interventional

60. Invited Lecturer, 11th Annual International Symposium on Multidetector-Row CT, San Francisco, CA, May, 2009. Lecture Title: Scan Thin, Read Thick, Store How? What you will need from your PACS and 3D vendors

61. Invited Lecturer 12th Annual International Symposium on Multidetector-Row CT, San Francisco, CA, May, 2010. Lecture Title: Is it Time to Read Every CT in 3D?

62. Invited Lecturer 12th Annual International Symposium on Multidetector-Row CT, San Francisco, CA, May, 2010. Lecture Title: Current Techniques for Quantitative Lung Imaging in Chronic Pumonary Disease

63. Invited Lecturer 12th Annual International Symposium on Multidetector-Row CT, San Francisco, CA, May, 2010. Lecture Title: Ultra Low Dose Cardiac CT – Early Experience

64. Invited Lecturer 12th Annual International Symposium on Multidetector-Row CT, San Francisco, CA, May, 2010. Lecture Title: Breast CT – Practical Approach

65. Invited Speaker, Champions in CT, Hollywood, FL, January 2011. Lecture Title: Integrating 3D Applications: Impact and Challenges

66. Invited Speaker, Breast MRI. Resident Grand Rounds, Tufts Medical Center, Boston, MA. March 2011.

67. Invited Speaker, Ultrasound Intervention: Basic Technique and Biopsy. Resident Grand Rounds, Tufts Medical Center, Boston, MA. March 2011.

68. Invited Lecturer, 13th Annual International Symposium on Multidetector-Row CT, San Francisco, CA, June 2011. Lecture Title: Beyond Dose Reduction: Additional Clinical Applications for Iterative Reconstruction

69. Invited Lecturer, 13th Annual International Symposium on Multidetector-Row CT, San Francisco, CA, June 2011. Lecture Title: Quantitative Tumour Analysis: Is the technology and integration ready for routine clinical use?

70. Invited Speaker, Radiology in Rural Haiti - Implementation. Resident Grand Rounds, Dartmouth-Hitchcock Medical Center, Hanover, NH, September 2011

71. Invited Speaker, Champions in CT, Napa, CA September 2011. Lecture Title: Iterative Techniques in CT: Beyond Dose Reduction

72. Coordinator, Breast Imaging Section, Essentials in Radiology, RSNA, Chicago IL. November 2011

73. Invited Lecturer, Essentials in Radiology, RSNA, Chicago IL. Lecture Title: Breast MRI – The Essentials. November 2011

74. Invited Speaker, Champions in CT, Charlestown, SC May 2012. Lecture Title: Lung Cancer Screening: Now & Tomorrow

75. Invited Speaker, Iterative Reconstruction. Resident Grand Rounds, Tufts Medical Center, Boston, MA. May 2012.

76. Invited Lecturer, 14th Annual International Symposium on Multidetector-Row CT, San Francisco, CA, June 2011. Lecture Title: Technical & Implementation Challenges: The Road to Full Iterative Reconstruction

77. Invited Lecturer, 14th Annual International Symposium on Multidetector-Row CT, San Francisco, CA, June 2011. Lecture Title: Lung Nodule CAD: The effect of Iterative Reconstruction and Dose on Automated Nodule Analysis

78. Invited CME Webinar, Imaging Technology News, Chicago, IL. Title: Iterative Reconstruction in CT: Understanding & Implementation, November 2012

79. Coordinator refresher course, Radiology in the Developing World: Mistakes Made, Lessons Learned RSNA, Chicago, IL, November 2012

80. Invited Lecturer, Radiology in the Developing World, Lecture Title: Creating a Remote Digital Department: Funding is the easy part. November 2012

81. Invited Lecturer, Radiology in the Developing World, RSNA, Lecture Title: What is Radiology Readiness? RSNA, Chicago IL November 2012

82. Invited Speaker, Strategies for Digital Radiology in the Developing World. Grand Rounds, Dartmouth-Hitchcock Medical Center, Hanover, NH, December 2012

APPENDIX TAB C

EXPERT OPINION OF PETER D. De IPOLYI, M.D.

This report is written at the request of The Girards Law Firm and is written in order to comply with *Texas Civil Practices & Remedies Code* § 74.351. I have been informed that subsection (k) of the statute provides that an expert opinion prepared under this law is not admissible in evidence by any party; shall not be used in a deposition, trial, or other proceeding; and shall not be referred to by any Defendant during the course of any proceeding in this case. All opinions expressed herein are based upon reasonable medical probability.

I have reviewed the medical care given to patient during the time period from September 2011 to present by Fossil Creek Family Medical, Dr. David Simonak, Dr. Jonathan Snead, Texas Breast Specialists, Dr. Mary Brian, Dr. Jason Skiles, Dr. Renita Butler, and Texas Health Harris Methodist Southlake Hospital. I have also been provided with the Expert Opinion of Jeffrey B. Mendel, M.D. as well as the Expert Opinion of Suraj Achar, M.D.

QUALIFICATIONS

I am a physician licensed to practice medicine by the State of Texas. I received the MD degree at Boston University School of Medicine in Boston, Massachusetts. Thereafter, I completed an Internship in Straight Surgery at Ben Taub General Hospital in Houston, Texas. I completed a two year Residency in General Surgery at Baylor College of Medicine Affiliated Hospitals in Houston, Texas followed by an additional three year surgical Residency at Christus St. Joseph Hospital in Houston, Texas. Subsequently, I completed a Fellowship in Surgical Oncology at the Stehlin Foundation for Cancer Research. I am board certified by the American Board of Surgery. Since 1973, I have served as a member of the Surgical Staff at Christus St. Joseph Hospital. Likewise, since 1974, I have served as the Associate Scientific Director for the Stehlin Foundation for Cancer Research. I have continuously been involved in the practice of medicine at all times relevant hereto. My curriculum vitae is attached hereto, and further outlines my training, education, and experience.

In my current practice, I see patients complaining of breast pain. I have performed/documented physical examinations on such patients, ordered mammograms for such patients, and managed their follow-up when indicated. I routinely review such studies, follow up on such studies, and use the results of studies to care for patients. In doing so, I have significant experience in recognizing the presence and significance of suspicious clusters of microcalcifications in breast tissue prior to any surgery. I have performed surgery on numerous patients who have had abnormal mammograms such as patient. I am intimately familiar with the interpretation of mammograms, the communication to the patient of the results of mammograms, and proper methods of following up on such mammograms. The standard of care related to the communication of, and following up on, abnormal mammogram results is precisely the same for family medicine doctors, oncologists, and surgical oncologists. I am familiar with the standard of care as it applies to physicians regarding these issues. Throughout my career, have cared for patients with breast cancer, from ductal carcinoma in situ (DCIS) to invasive cancer. I am intimately familiar with the methods of diagnosing these cancers, the treatments they require, and the prognosis that each carries. I have personally performed biopsies of breast tissue, partial mastectomies, total mastectomies, sentinel node biopsies, and lymph node dissections.

And finally, throughout my career I had occasion to serve on the Patient Advocacy, Quality Improvement, Utilization Review & Quality Assurance, and Executive Committees at Christus St. Joseph Hospital. I served in similar roles throughout my clinical private practice with Surgical Oncology Consultants of Houston. As such, I have experience in formulating and reviewing policies and procedures regarding the reporting of abnormal test results, in both at the hospital and private practice clinic setting. I am familiar with the standards of care regarding the same. All opinions expressed in this report are based on reasonable medical probability.

I understand that in Texas, "negligence", when used with respect to a physician, means the failure to use ordinary care; that is, doing that which a physician of ordinary prudence would not have done under the same or similar circumstances, or failing to do that which a physician of ordinary prudence would have done under the same or similar circumstances.

I understand that in Texas as to a physician, "ordinary care" means that degree of care which would be used by a physician of ordinary prudence under the same or similar circumstances.

I understand that in Texas, "negligence", when used with respect to a medical practice, means the failure to use ordinary care; that is, doing that which a medical practice of ordinary prudence would not have done under the same or similar circumstances, or failing to do that which a medical practice of ordinary prudence would have done under the same or similar circumstances.

I understand that in Texas as to a medical practice, "ordinary care" means that degree of care which would be used by a medical practice of ordinary prudence under the same or similar circumstances.

I understand that in Texas, "proximate cause" means that cause that was a substantial factor in bringing about an event, and without which cause such event would not have occurred. In order to be a proximate cause, the act or omission complained of must be such that a physician using ordinary care would have foreseen that the event, or some similar event, might reasonably result therefrom. I understand that there may be more than one proximate cause of an event.

PATIENT HISTORY

In September 2011, patient , a 33 year old female, presented to Fossil Creek Family Medical Center, P.A. complaining of left sided breast pain. On September 19, 2011, Brenda Wilmore, FNP saw patient for these complaints. No physical exam of the breast was performed or documented. However, Dr. David Simonak ordered a screening mammogram for these complaints, which was performed September 22, 2011.

Dr. Jason Skiles interpreted the mammogram, and described "scattered punctuate benign appearing calcifications" in the left breast. He further described "some clustering of calcifications in the upper outer quadrant of the left breast." His Impression was as follows:

Impression: Indeterminate microcalcifications in the left breast, probably benign. A follow-up study is recommended in 3 to 6 months. Computer-aided detection was utilized.

BI-RADS category 3 : Probably benign finding(s).

No one at Fossil Creek Family Medical Center, P.A., including Dr. Simonak, communicated or explained the results of the abnormal mammogram to patient . No follow-up study was recommended or occurred 3-6 months later. Fossil Creek Family Medical Center, P.A. did not have or enforce a policy or procedure that assured that patient's mammogram results were communicated directly to her, and that the follow-up study occurred within the recommended 3-6 months. No follow-up study was performed for more than 14 months; no biopsy was performed.

Instead, patient continued to have left breast complaints and was eventually seen by Dr. Mary Brian on January 28, 2013. Dr. Brian performed an in-office core biopsy which revealed high grade ductal carcinoma in situ. On February 22, 2013, Dr. Brian performed a Left modified radical mastectomy and Left sentinel node biopsy. Subsequent pathology confirmed that patient had multiple positive lymph nodes (14 out of 28) and she was diagnosed with multifocal Stage IIIC invasive ductal carcinoma.

Radiologist Dr. Jeffrey Mendel performed a blinded review of the September 22, 2011 mammogram as follows:

On my blinded review, the mammogram demonstrates microcalcifications clustered in the upper outer quadrant of the left breast. These are principally in the mid portion of the breast but some are noted to extend more posteriorly. These calcifications are noted on the magnified, focally compressed views to be both amorphous and pleomorphic without associated mass or architectural distortion. Additionally, there are scattered groups of amorphous microcalcifications in adjacent portions of the same quadrant. There are a few lymph nodes visible in the left axilla on the oblique view and not on the right. The largest is less than 1 cm in short axis and retains a fatty notch although it appears relatively dense. There are virtually no microcalcifications in the right breast.

Dr. Mendel states that September 22, 2011 mammogram demonstrated a highly suspicious cluster of microcalcifications in the upper outer quadrant of the left breast, and that the presence of adjacent groups of microcalcifications raises the possibility of multifocal disease. He concludes that Dr. Jason Skiles fell below the applicable standards of care in his treatment of patient by: 1) failing to appreciate the presence and significance of the suspicious microcalcifications in the left breast, and 2) by failing to immediately recommend biopsy of the concerning breast tissue.

STANDARDS OF CARE

1. The standard of care for physicians interpreting radiological studies in patients such as patient requires that the physician recognize the presence and significance of suspicious clusters of microcalcifications in breast tissue and recommend prompt biopsy.

2. The standard of care for a physician treating a patient complaining of breast pain such as patient requires that the physician complete and document a thorough physical examination of the breast and lymph nodes. Further, the standard of care further requires that the physician communicate the results of abnormal mammograms to the patient directly, make certain that the patient understands the results of the mammograms, and assure that any recommended follow-up studies occur within the appropriate time frame.

3. The standard of care further requires that the entity/medical practice have and enforce adequate policies and procedures to assure that: a) all physicians/health care providers perform and document a thorough physical examination of the lymph nodes and breast for patients complaining of breast pain; b) mammogram results are communicated directly to the patient; and c) recommended follow-up studies occur within the appropriate time frame.

VIOLATIONS OF THE STANDARD OF CARE

1. My review of the medical records and radiological studies related to patient's care leads me to conclude that, based on reasonable medical probability, Dr. Jason Skiles fell below the applicable standards of care in his treatment of patient by failing to appreciate the presence and significance of the suspicious microcalcifications in the left breast. Further, it is my opinion that Dr. Skiles fell below the applicable standards of care by failing to immediately recommend biopsy of this concerning breast tissue. Under the definitions listed above, I must conclude that Dr. Skiles was negligent in his care and treatment of patient .

2. My review of the medical records and materials related to patient's care leads me to conclude that, based on reasonable medical probability, Dr. David Simonak fell below the applicable standards of care in his treatment of patient by failing to complete and document a thorough physical examination of her breast and lymph nodes. In the event his nurse practitioner saw his patients, Dr. Simonak failed to assure that his nurse practitioner completed and documented a through physical examination of the breast and lymph nodes. Dr. Simonak also fell below the standard of care by failing to communicate the results of the September 22, 2011 mammogram to patient directly, failing to make certain that patient understood the results of the mammogram, and assure that the recommended follow-up in 3-6 months. Under the definitions listed above, I must conclude that Dr. Simonak was negligent in his care and treatment of patient .

3. My review of the medical records and materials related to patient's care leads me to conclude that, based on reasonable medical probability, Fossil Creek Family Medical Center, P.A. fell below the applicable standards of care in its treatment of patient by failing to have and enforce adequate policies and procedures to assure that Dr. Simonak and FNP Wilmore performed and documented a thorough physical examination of patient's lymph nodes and breast when she presented complaining of breast pain. Further, Fossil Creek Family Medical Center, P.A. fell below the applicable standards of care by failing to have and enforce policies and procedures assuring that patient's abnormal mammogram results were communicated directly to her, and that the follow-up studies occur within the recommended 3-6 months. Under the definitions listed above, I must conclude that Fossil Creek Family Medical Center, P.A. was negligent in its care and treatment of patient .

APPROPRIATE PATIENT CARE

The results of the September 22, 2011 mammogram were clearly abnormal. Dr. Mendel observed that the mammogram demonstrated a highly suspicious cluster of microcalcifications in the upper outer quadrant of the left breast, and that the presence of adjacent groups of microcalcifications raised the possibility of multifocal disease. In order to meet the minimal standards of care, Dr. Skiles should have recognized that this cluster of suspicious microcalcifications in the left breast had a high probability of being cancerous and immediately recommend biopsy of the concerning breast tissue.

Dr. Simonak ordered the September 22, 2011 screening mammogram and ultrasound in response to patient's breast pain. As such, he was clearly aware of these complaints and should have performed and documented a complete physical examination of her breast and lymph nodes. He did not, and he also failed to assure that FNP Wilmore completed and documented a through physical examination of the breast and lymph nodes. The failure to conduct and document a physical examination prevented healthcare providers from being aware of the clusters of abnormal tissue in patient's left breast, much less tracking its size/appearance over time. Most important, Dr. Simonak should have communicated the abnormal results of the September 22, 2011 mammogram to patient directly, made certain that she understood these results, and assured that she had the recommended follow-up studies in 3-6 months. In fact, he could and should have ordered the follow-up study immediately so that it could have been scheduled within the recommended time period. Had appropriate care been rendered, more likely than not, patient would have received the recommended follow-up studies, the changes in the size/appearance of the abnormal breast tissue noted, and the diagnosis of breast cancer would have been reached much sooner than it was made.

Fossil Creek Family Medical Center, P.A. should have had and enforced adequate policies and procedures in place to assure that Dr. Simonak and FNP Wilmore performed and documented a thorough physical examination of patient's lymph nodes and breast when she presented complaining of breast pain. Worse still, Fossil Creek Family Medical Center, P.A. should have had and enforced policies and procedures assuring that patient's mammogram results were communicated directly to her, and that the follow-up studies occur within the recommended 3-6 months. This would have been a simple matter of flagging her chart, and following up with a phone call or letter.

CAUSATION & DAMAGES

It is my opinion beyond a reasonable medical probability, based on my training and education and experience that the negligent acts/omissions of Dr. Skiles, Dr. Simonak and Fossil Creek Family Medical Center, P.A. outlined above were each a proximate cause of her injuries and resulted in an extended delay in diagnosis and treatment of patient's breast cancer.

Had Dr. Skiles properly recommended a biopsy following the September 22, 2011 mammogram, more likely than not a Fine Needle Aspiration Biopsy (FNAB) or Core Needle Biopsy (CNB) would have been performed within a short period. In fine needle aspiration biopsy (FNAB), the physician uses a very thin needle attached to a syringe to withdraw a small amount of tissue from the suspicious area. In core needle biopsy, a slightly larger, hollow needle is used to withdraw small cylinders (or cores) of tissue from the abnormal area in the breast. FNAB and

CNB are most commonly done in the doctor's office with local anesthesia. The tissue samples are then sent to a lab, where a pathologist examines them under a microscope to determine if they show cancer.

Both FNAB and CNB are sensitive/accurate in terms of diagnosing breast cancer, certainly far greater than 50%. In fact, the sensitivity rate of large-core needle biopsy for the diagnosis of breast cancer has been shown to be in the 95% + range. Had an FNAB or CNB been performed shortly after the 2011 mammogram, more likely than not, it would have resulted in patient being diagnosed with ductal carcinoma in situ, or DCIS, rather than invasive cancer.

Likewise, had Dr. Simonak or Fossil Creek Family Medical Center, P.A. told their patient that she needed a follow-up study in 3-6 months, or followed up as noted above, it is probable that patient would have had the follow-up mammogram and resulting recommendation for biopsy. In my experience, very rarely do patient who know that they might have cancer fail to follow up. In any case, more likely than not, had an FNAB or CNB been performed 3-6 months following the 2011 mammogram been performed, it too would have resulted in patient being diagnosed with DCIS rather than invasive cancer.

DCIS refers to a cancer started in a duct (the tube that carries the milk from the lobule to the nipple) that has not spread to the nearby breast tissue or other organs.) DCIS is the most treatable form of breast cancer that carries the best prognosis. Had patient been properly diagnosed shortly after the mammogram, or shortly after the recommended follow-up period, her treatment would have most likely been lumpectomy with radiation or mastectomy surgery. Chemotherapy is not required for DCIS, and patient's prognosis would have been excellent. By definition, there is no risk of distant recurrence since the cancer is noninvasive. For women having lumpectomy with radiation, the risk of local recurrence ranges from 5-15 percent. For women having mastectomy, the risk of local recurrence is less than 2 percent. Large clinical trials, conducted by the National Surgical Adjuvant Breast and Bowel Project, show that the overall 15 year survival rate exceeded 85%, with the incidence of death from breast cancer less than 5 percent. Quite simply, with timely follow-up exams and biopsy, patient would likely not have required chemotherapy and/or died from breast cancer.

Because Dr. Skiles, Dr. Simonak, and Fossil Creek Family Medical Center, P.A. failed to provide timely/proper follow-up and care, patient's breast cancer was not diagnosed and treated before it spread. Pathology following her February 2013 surgery revealed multiple positive lymph nodes (14 out of 28) and she was diagnosed with multifocal Stage IIIC invasive ductal carcinoma. The treatment and prognosis for this cancer is vastly different than DCIS. Treatment for multifocal Stage IIIC invasive ductal carcinoma involves modified radical mastectomy surgery (removing the whole breast that has cancer, many of the lymph nodes under the arm, the lining over the chest muscles, and often part of the chest wall muscles) followed by radiation therapy (using high-energy x-rays or radiation to kill cancer cells or keep them from growing) and chemotherapy (using drugs to stop the growth of cancer cells, either by killing the cells or by stopping them from dividing.) Based upon the most recent numbers published by the National Cancer Data Base, patient has a less than 50% chance of surviving 5 years, even with the best treatment available.

In sum, it is my opinion beyond a reasonable medical probability, based on my training and education and experience, that Dr. Jason Skiles, Dr. David Simonak and Fossil Creek Family Medical Center, P.A. were negligent in their care of patient . Further, it is my opinion that each of these acts and omissions of negligence was a proximate cause of her injury and its sequelae.

I hold these opinions to a reasonable degree of medical certainty. I reserve the right to extend or amend these opinions as additional materials become available for my review.

Sincerely yours,

Peter D. de Ipolyi, M.D.

CURRICULUM VITAE

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Straight Surgery
7/1/1967 – 6/30/1968

Residency

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Houston, Texas 77030
General Surgery
7/1/1968 – 6/30/1970

Christus St. Joseph Hospital
1919 LaBranch
Houston, Texas 77002
General Surgery
7/1/1970 – 6/30/1973

Fellowship	The Stehlin Foundation for Cancer Research 1315 St. Joseph Parkway, Ste 1818 Houston, Texas 77002-8299 Surgical Oncology 7/1/1973 – 6/30/1974
License	Texas D8692
Board Certification	American Board of Surgery February 6, 1974 Certificate No. 19982
Teaching and Research Positions	Surgical Staff Christus St. Joseph Hospital Houston, Texas 77002 July 1973 – Present Associate Scientific Director The Stehlin Foundation for Cancer Research Houston, Texas 77002 July 1, 1974 – Present
Affiliated Hospital Appointments and Committees	Cancer Committee Christus St. Joseph Hospital Houston, Texas 77002 Executive Committee Christus St. Joseph Hospital Houston, Texas 77002 Medical Research Committee Christus St. Joseph Hospital Houston, Texas 77002

Patient Advocacy Committee
Christus St. Joseph Hospital
Houston, Texas 77002
Quality Improvement Committee
Christus St. Joseph Hospital
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Section Chief
Department of General Surgery
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Tissue Committee
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Utilization Review and Quality
Assurance Committee
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Professional Organizations

American College of Surgeons
American Medical Association
Harris County Medical Society
Houston Surgical Society
Southwestern Surgical Congress
Texas Medical Association
The New York Academy of Sciences

Work History

Surgical Oncology Consultants of Houston
(The name of the clinic changed.)
1315 St. Joseph Parkway, Ste 1800
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May 12, 2005 - Present

Stehlin & de Ipolyi Oncology Clinic
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Houston, Texas 77002-8299
Private Practice
July 1974 – May 12, 2005

No. 02-14-00091-CV

In the Court of Appeals for the Second
District of Texas at Fort Worth

Consultants in Radiology, P.A., Jason W. Skiles, D.O., David W. Simonak, D.O., Fossil Creek Family Medical Center, P.A.,
Appellants

v.

S.K. and C.K., Individually and on Behalf of J.K., A.K., and R.K., Minor Children,
Appellees

On Appeal from the 141st Judicial District Court, Tarrant County, Texas, Hon. John P. Chupp, Presiding

Appellants' Reply Brief

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Table of Contents

Index of Authorities

Cases:

Miscellaneous:

Introduction

The missing link in the patient's analysis of causation remains missing. To demonstrate that the cancer progressed under Appellants' care, the experts needed to show that it worsened. The experts posit that she had ductal carcinoma in situ ("DCIS"). But the expert reports factually note that SK's physician diagnosed her with DCIS *after* the alleged delay in this case. While the experts discuss how treatment of Stage IIIC cancer is more involved and has a worse prognosis than DCIS, that analysis is irrelevant if the experts never explained how the cancer evolved from DCIS to something else while under Appellants' care. And it is this initial link from Appellants' care to the injury that is missing from the expert reports.

Additionally, we know that the diagnosis of Stage IIIC cancer turns exclusively on the involvement of lymph nodes. Not only is number a factor, but also location. If a certain number of nodes are cancerous, then the threshold for Stage IIIC is attained. But the threshold is also attained with just one node in the correct area. And that is why the experts need at least some discussion of lymph nodes in order to establish causation, especially given the fact that SK had complaints consistent with lymph node involvement from the beginning of the care in question. The involvement of the "right" lymph node at the beginning of the case would mean that the delay did not cause any injury to SK because it would have resulted in a diagnosis of Stage IIIC Cancer. The care, as well as prognosis, would have been the same.

These two problems with the causation analysis explain why this case is different from the *Polone* case. In that case, the expert's analysis did not leave a hole in causation because it explained the progressive worsening of the disease and prognosis. Here, the fact that the treating provider, who cared for SK after Appellants, diagnosed her with DCIS demonstrates why her prognosis and treatment did not worsen due the alleged delay. The facts presented by the experts in this case show a flaw in their causation analysis that needed to be explained in order to demonstrate the causal connection between the alleged negligence and the alleged injury.

One last preliminary point – SK claims that the challenge here is essentially frivolous, in bad faith, and nonsensical. Appellees' Brief, pp. 4 and 9. Yet she never explains how the expert reports meet the challenges raised. And she never says that the challenges raised are not based on actual requirements of an expert report. Instead, she merely reiterates that treatment and prognosis worsened due to the delay without explaining how the delay could have caused harm in light of the fact that her treating physician diagnosed her with DCIS after Appellants completed their care of SK. At that point, she had the very disease state that the experts assume she had at the beginning of the alleged delay. Plus, if this were such a simple case, then why did it take the trial court from November 7, 2013 to February 25, 2014 to decide the issue? The case is just not as simple as SK would have the Court believe, especially in the context of the diagnosis of DCIS by SK's treating physician after the alleged delay caused by the Appellants.

Argument in Reply

A. The Experts' Discussion of Causation Was Deficient Because They Did Not Connect Delay to Injury

The parties appear to agree that the preliminary expert report requirement is a fairly low standard – not the same as litigating on the substance (as in a summary judgment) – and only enough to inform the defendant of the conduct called into question and the trial court that the claims have merit. Appellants' Brief, pp. 12-13; Appellees' Brief, pp. 5-6. But just how low is the standard is where the parties appear to disagree. Appellants believe that the causation statement must contain an explanation of "how and why the breach caused the injury based on the facts presented." *Jelinek v. Casas*, 328 S.W.3d 526, 539-540 (Tex. 2010). Appellees, on the other hand, appear to believe that stringing together a list of alleged harm is sufficient. Appellees' Brief, pp. 8-9. Appellees' position trivializes the causation analysis and should be rejected.

1. The Experts Did Not Explain How Defendants Caused the Cancer to Progress beyond DCIS – Especially Given the Finding of DCIS after Defendants' Involvement Was Complete

Appellees' (and their experts') position is that with proper care, SK would have had a diagnosis of DCIS. Appellees' Brief, p. 8. But that is the exact diagnosis SK had at the end of the delay attributed to Appellants. The following timeline illustrates this point:

- September 19, 2011 through January 23, 2013 – care by Dr. Simonak and Fossil Creek on a variety of occasions (CR 25-27, 128-129);
- September 22-26, 2011 – Dr. Skiles' interpretation of the mammogram (CR 25-26, 50-51, 128-129); and
- January 28, 2013 – breast biopsy by Dr. Mary Brian revealed DCIS (CR 51, 129).

At the end of Appellants' alleged delay, the diagnosis remained the same as the experts contend it would have been without the delay, i.e. "ductal carcinoma in situ." CR 51, 129. Even Appellees' Statement of Facts notes that Dr. Brian's biopsy "revealed high grade ductal carcinoma in situ." Appellees' Brief, p. 3. If, as the experts note, the diagnosis was still DCIS at the end of the alleged delay, then the purported delay did not harm SK.

Of course, Appellants' argument at this early stage is not to claim that the experts' *conclusion* that the delay caused harm is wholly without merit and untenable. Instead, Appellants' point is that the trial court – and Appellants – cannot tell that the claim has any merit because, based on the four corners of the reports, it appears that the claimed delay factually caused no harm. In this context, the experts needed to provide an explanation of why Dr. Brian's finding of DCIS was incorrect and that Stage IIIC cancer existed at the time of her biopsy. This case is an unusual one in that the facts explained by the experts appear to contradict the experts' conclusions. And

all Appellants seek is an explanation of that obvious inconsistency so that a reviewer of the report could understand the rationale and then conclude that the claim has merit.

Appellees discuss the litany of different care and worsened prognosis that resulted because the diagnosis was not confined to DCIS. Appellees' Brief, pp. 8-9. But that discussion misses the entire point of Appellants' Brief – the experts never factually explained how or why the alleged delay caused the patient to move beyond DCIS, especially where Dr. Brian diagnosed DCIS after Appellants' care ended. The flaw in the expert reports that went unaddressed in Appellees' Brief is the fact that the expert reports factually appear to show that SK suffered no harm from the delayed diagnosis: while a timely diagnosis would allegedly have resulted in a DCIS diagnosis, she had a DCIS diagnosis even after the alleged delay. Looking at the reports from the end of the case, they fail to connect any delay to the purported harm because they appear to show that she had the same diagnosis that would have existed with an earlier diagnosis: DCIS. The trial court abused its discretion in concluding the reports were sufficient on causation.

2. The Experts Provide No Analysis of SK's Lymph Nodes – The Key to Determining Stage IIIC Cancer

Turning the case around and looking at SK's condition at the front end, the reports are also deficient because they never factually explain how the experts conclude that the patient just had DCIS at the time the alleged delay began. In this

second problem, the reports fail to include any discussion of lymph node status – something that is key to the determination of Stage IIIC cancer. Appellants' Brief, pp. 14-17. Instead, the experts appear to assume that the patient had DCIS. But we know that if enough lymph nodes – or even just one in the right location – were cancerous back at the beginning of the claimed delay, then the diagnosis at the end – Stage IIIC – would have remained the same.

While the reports have some vague (and incomprehensible to the lay public) discussion of lymph node status, none of the reports provide sufficient information to say that the lymph nodes were negative back when the alleged delay began. And this is important because positive nodes in correct number or location combined with *any* tumor size, which includes DCIS, is sufficient to trigger the Stage IIIC diagnosis. American Joint Commission on Cancer, Chapter 32: Breast, *Cancer Staging Manual*, 360 (2010). Moreover, the reports contain some evidence suspicious for something going on with the lymph nodes because that is SK's initial complaint on her very first visit for the care at issue in the lawsuit. *See*, *e.g.*, CR 25 ("left axilla pain—feels like swollen lymph nodes [times] several weeks").

In order for the experts to conclude that the patient had DCIS that then became Stage IIIC cancer during the alleged delay in diagnosis, the experts would have to demonstrate that the lymph nodes were not involved at the time the delay began. The experts, however, offered no comment – in the form of an opinion or even just a factual statement – regarding what occurred with the lymph nodes at that

critical time. Instead, the experts just said that the cancer would have been DCIS without providing any analysis. That lack of analysis or explanation does not explain causation "based on the facts presented." *Jelinek*, 328 S.W.3d at 539-540. The trial court abused its discretion in concluding that the reports adequately addressed causation.

3. The Court Should Not Provide Analysis or Explanation that the Experts and Appellees Did Not Give

It is axiomatic in expert-report litigation that a court cannot make inferences from the report. *Collini v. Pustejovsky*, 280 S.W.3d 456, 462 (Tex.App.—Ft. Worth 2009, no pet.). Thus, the Court cannot speculate what explanation of Dr. Brian's finding of DCIS that Appellees' experts would provide. Similarly, the Court cannot hypothesize what the experts think regarding lymph node involvement at the beginning of the care. The job of explaining those issues belonged to the experts.

Additionally, the Court should not fill in the gaps in Appellees' discussion of the case.[1] For example, Appellees make much of the fact that the expert reports should be read together and criticize Appellants' "separate" analysis of the reports. Appellees' Brief, pp. 5, 7. But Appellees never explain how reading the reports together overcomes any of the problems. Appellees only "analysis" of any of the

[1] Appellees actually spend more time (and provide more citations) in their Brief arguing that the experts were qualified than they do arguing that the reports sufficiently addressed causation. Appellees' Brief, pp. 8-9. Appellants never challenged the experts' qualifications in this Court.

reports is to provide details regarding what their surgical oncologist said about "causation" without providing any information about what the experts say. Appellees' Brief, pp. 8-9.

Moreover, Appellees' Brief never even addresses the specific arguments about why the causation element is lacking. Appellees' Brief, pp. 8-9. Instead, Appellees pretend that Dr. Brian's finding of DCIS requires no explanation and that the lymph node issue does not exist. They certainly do not provide any analysis of why either of those issues does not matter to the causation analysis. And the problem is that both issues are germane given the facts presented in this case. In order to say that the cancer would have been just DCIS instead of Stage IIIC cancer at the beginning of the alleged delay, the experts needed to explain that the lymph nodes were not involved, or at least not sufficiently involved, to trigger a different cancer stage. And the experts needed to explain why Dr. Brian's finding of DCIS after this period of alleged delay did not matter to the causation analysis. The experts did neither. So we do not know that the claim has merit because we do not know whether SK could have had Stage IIIC cancer all along and we do not know whether she went from DCIS to Stage IIIC after Appellants' involvement ended.

"The purpose of briefs is to help [the appellate court] and conserve judicial resources…." *King-Mays v. Nationwide Mut. Ins. Co.*, 194 S.W.3d 143, 145 (Tex.App.—Dallas 2006, pet. denied). "An appellate court is not required to search the appellate record, with no guidance from the briefing party, to determine if the record supports

the party's argument." *Citizens Nat'l Bank v. Allen Rae Invs., Inc.*, 142 S.W.3d 459, 490 (Tex.App.—Ft. Worth 2004, no pet.). Appellees' Statement of Facts and Argument sections provide no citations to the record and, in fact, do not even purport to recite what the experts say regarding causation other than their summary (with no citation) of what Dr. DeIpolyi says. Appellees' Brief, pp. 3, 8-9. Appellees did not satisfy their briefing requirement to provide a clear and concise argument, including appropriate citations to authority and the record "by merely uttering brief conclusory statements unsupported by legal citations." *Ward v. Ladner*, 322 S.W.3d 692, 697 (Tex.App.—Tyler 2010, pet. denied). A lack of substantive analysis is usually a waiver. *Id.* Appellees do not raise any affirmative issues, and thus waiver is inappropriate in this instance. The Court should not provide the explanations that Appellees did not in light of the lack of substantive analysis of the arguments, citations to the record, and citations to case law.

B. *Polone* Is Not Like This Case

Appellees argue that this case has more causation analysis than *Polone*. Appellee's Brief, p. 9. Appellees are correct in one respect – the litany of events listed by Dr. DeIpolyi is longer and more involved. But Appellees again miss the point that the initial link to that litany is missing in this case (in light of Dr. Brian's finding of DCIS after the alleged delay ended), making this case much weaker than *Polone*.

In *Polone*, the data about the cancer was much more limited: a 22-month delay resulted in "progressive growth and development of breast cancer,…increase[ing] [the

patient's] risk of metastatic breast cancer and subsequent morbidity and mortality…." *Polone v. Shearer*, 287 S.W.3d 229, 236 (Tex.App.—Ft. Worth 2009, no pet.). But because that was sufficient in that case – due to the limited facts presented – does not mean that the reports are sufficient in light of the *facts presented in this case.* In particular, the facts recited in the report in *Polone* do not appear to include the subsequent treating physician's finding of the disease state claimed to have been lost by the delay. *Id.* Here, Dr. Brian found DCIS after the alleged delay was complete – the exact disease state the experts claim was lost. And in this case, again unlike *Polone*, the stage of cancer ultimately claimed by the experts turned on the status of lymph nodes, yet the experts provided no data regarding lymph node status. Based on the facts presented by the experts, this case is not at all like *Palone* because the facts presented demonstrate the two holes in the experts' causation analysis. And the facts presented by the expert in *Polone* did not demonstrate any hole with respect causation.

C. A Remand for Consideration of a 30-Day Extension Would Be an Appropriate Remedy

Appellants agree that a remand for the trial court to determine whether to grant a 30-day extension is appropriate because the reports are "deficient" and not "absent." That is why they prayed for that exact relief. Appellants' Brief, pp. 38-39.

Wherefore, Appellants Consultants in Radiology, P.A., Jason W. Skiles, D.O., David W. Simonak, D.O., Fossil Creek Family Medical Center, P.A. pray that this Court reverse the trial court's orders denying their motions to dismiss and overruling

their objections and remand this case to the trial court for a determination of whether an extension of the expert report deadline is appropriate. Appellants Consultants in Radiology, P.A., Jason W. Skiles, D.O., David W. Simonak, D.O., Fossil Creek Family Medical Center, P.A. pray for recovery of their appellate costs and for such other relief to which they may be entitled.

Respectfully submitted,

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CERTIFICATE OF SERVICE

On May 28, 2014, I served a true and correct copy of Appellants' Brief Appellee's counsel, Mr. James E. Girards, by email and then subsequently served a paper copy on May 29, 2014, by certified mail, return receipt requested.

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