KLINGER, Plaintiffs, vs. DARDICK, M.D., Defendants.	SUPERIOR COURT OF NEW JERSEY LAW DIVISION – CIVIL PART ESSEX COUNTY DOCKET NO.: L-7756-13 Civil Action **OPINION**

Decided: February 2, 2018

By: Stephanie A. Mitterhoff, J.S.C.

I. INTRODUCTION

This matter comes before the court on Plaintiff's motion to bar testimony. For the reasons stated herein, Plaintiff's motion to bar testimony is GRANTED in part.

II. FACTUAL BACKGROUND

This motion arises from two consolidated civil actions. (Pl.'s Br. at 8.) On October 3, 2013, Plaintiff Ilene Klinger filed a Complaint in the Superior Court of New Jersey, initiating a Track III medical malpractice action against Michael Dardik, M.D. and Saint Barnabas Medical Center. (Ibid.) An amended complaint was filed on March 31, 2014 to join Livingston Pathology

Associates as a defendant. (Ibid.) Ms. Klinger filed a separate Complaint against Jonathan F. Lara, M.D., Marietta Kintiroglou, M.D., Livingston Pathology Associates, and St. Barnabas Medical Center. (Ibid.) An order for consolidation was entered on February 6, 2015. (Id. at 8-9.) During the pendency of this case, Dr. Lara died, and an amended complaint was filed in the second action, naming the Estate of Jonathan F. Lara as a defendant. (Id. at 9.) The events leading up to the filing of these actions are summarized below.

Ms. Klinger has undergone twice yearly screening for breast cancer since at least December 1998. (Id. at 3.) In May 2009, Ms. Klinger's doctor, Nancy Elliot, M.D., recommended that she undergo genetic testing for mutations to the BRCA genes. (Ibid.) A test, dated May 12, 2009, revealed that Ms. Klinger had a "6174delT mutation" of the BRCA2 gene. (Ibid.) Ms. Klinger's expert, Steven Narod, M.D., a preeminent epidemiologist widely published on breast cancer risk, observed that a 6174delT mutation of the BRCA2 gene indicates "the risk of developing breast cancer for Ms. Klinger is increased beyond that of women in the general population." (Ibid.) However, the specific mutation that Ms. Klinger has "is associated with a cancer risk that is much lower than that of other BRCA2 mutations." (Ibid.) In the absence of prophylactic therapy, the risk that Ms. Klinger would develop breast cancer is 34% through age 70 and 39% through age 80, including consideration of Ms. Klinger's family history of breast cancer. (Ibid.) This results in an annual risk of developing breast cancer of 1.3% per year at the current time, meaning it is not probable that Ms. Klinger would have developed breast cancer in her life. (Id. at 4.)

After discovery of the BRCA2 gene mutation, Ms. Klinger was counselled regarding her options for risk reduction, which included: prophylactic bilateral mastectomies; chemoprevention with tamoxifen; or enhanced surveillance with mammography, physician visits, and annual MRIs.

(Ibid.) Ms. Klinger felt having mastectomies would be drastic, since she did not actually have cancer, so she chose to undergo enhanced surveillance. (Ibid.)

On October 1, 2012, Ms. Klinger had a bilateral breast MRI, which revealed a "[l]ow level new enhancing nodule within the left breast." (Ibid.) As a result, she had a vacuum-assisted ultrasound-guided left breast biopsy on October 4, 2012 and an MRI-guided needle biopsy of her left breast on December 6, 2012. (Ibid.) The surgical specimen, taken on December 6, was sent to the Department of Pathology at Saint Barnabas Medical Center, where it was interpreted by Defendant Dr. Michael Dardik, who concluded it was cancer. (Id. at 4-5.) At the time of his review, Dr. Dardik was unaware that Ms. Klinger had a BRCA2 gene mutation. (Id. at 5.) Dr. Dardik then showed the specimen to Defendants Dr. Jonathan F. Lara, now deceased, and Dr. Marietta Kintiroglou, who both agreed with Dr. Dardik's diagnosis of invasive ductal carcinoma. (Id. at 5.) On December 10, 2012, Dr. Dardik issued a Surgical Pathology Consultation Report announcing that the biopsy revealed invasive ductal carcinoma. (Ibid.)

Additional tests were performed on the biopsy sample, reflected in addendums to the pathology report entered by Teresita Redondo, M.D., a Saint Barnabas pathologist, on December 14, 2012. (Ibid.) Dr. Redondo conducted estrogen receptor ("ER") and progesterone receptor ("PR") tests, in order to guide oncologists on how to treat the presumed cancer. (Ibid.) The specimen produced negative ER and PR results, which Dr. Redondo thought unusual because a grade one invasive ductal carcinoma would normally produce positive ER and PR results. (Id. at 5-6.) Due to the unusual results, Dr. Redondo repeated the test, and it produced the same results. (Id. at 6.) Dr. Redondo testified that it was her custom to inform the diagnosing pathologist if she found anything unusual when she did her tests, so the pathologist could take another look. (Ibid.)

On December 13, 2012, Ms. Klinger met with Dr. Elliott to discuss the cancer diagnosis and her treatment options, and she was advised to undergo bilateral mastectomies. (Ibid.) The surgery was done on January 10, 2013. (Ibid.) After the surgery, Dr. Lara reviewed the mastectomy specimen and again concluded there was cancer. (Ibid.) On January 22, 2013, Ms. Klinger saw Dr. Richard A. Michaelson, a Saint Barnabas oncologist, to determine whether she should have chemotherapy. (Id. at 6-7.) Dr. Michaelson noted the unusual ER and PR negative test results previously observed by Dr. Redondo and asked for the test to be repeated. (Ibid.) The test that Dr. Michaelson ordered confirmed the negative ER and PR test results. (Ibid.) Dr. Michaelson testified that he found the results "unusual" because "the tumor seemed to be not a very aggressive looking tumor under the microscope." (Ibid.) Dr. Michaelson recommended "some type of chemo," but Ms. Klinger wanted a second opinion, which Dr. Michaelson "encouraged . . . [and] [o]ffered to help her arrange." (Ibid.)

On February 6, 2013, Ms. Klinger went to Memorial Sloan-Kettering ("MSK") for a second opinion. (Ibid.) The MSK pathology department reviewed the biopsy slides from Saint Barnabas and found no evidence of invasive or in situ carcinoma. (Ibid.) Dr. Teresa Ann Gilewski, a MSK oncologist, and Dr. Melissa P. Murray, a MSK pathologist, concluded that Ms. Klinger had microglandular adenosis, which "may be a precursor to the development of cancer" but was not cancer itself. (Id. at 7-8.) MSK did not recommend further treatment. (Id. at 8.)

III. DISCUSSION

A. Preexisting Condition

1. Definition

When a defendant physician's malpractice aggravates a preexisting condition that has a risk of causing the ultimate harm even if there had been no malpractice, the doctor is responsible only for harm he or she caused and not for the harm caused by the preexisting condition. See, e.g., Lanzet v. Greenberg, 126 N.J. 168 (1991); Scafidi v. Seiler, 119 N.J. 93 (1990). In Scafidi, the Court established a formula to govern this apportionment, under which juries are asked to: (1) determine that the defendant's malpractice increased the risk of an ultimate harm which actually eventuated; (2) determined that the defendant's malpractice was a substantial factor in causing that harm; and (3) establish by a percentage, the total damages which was the natural consequence of the preexisting condition and the total damages for the "lost chance" for which the defendant should be responsible. 119 N.J. at 108-09.

To be eligible to use the allocation formula established in Scafidi, the defendant must prove that the injured plaintiff actually suffers from a preexisting condition or illness and has sustained the "ultimate harm," as opposed to a condition, as of the date of malpractice, that could later develop into a preexisting condition leading to the ultimate harm. A preexisting condition is one for which "the patient [seeks] treatment from a physician with the express purpose to obtain treatment which would alter or delay the outcome attributable to the condition." Golinski v. Hackensack Med. Ctr., 298 N.J. Super. 650, 655 (App. Div. 1997). Preexisting conditions must also be capable of evolving into the ultimate condition suffered by the plaintiff without any negligence by the defendant. See Holdsworth v. Galler, 345 N.J. Super. 294 (App. Div. 2001); Tindal v. Smith, 299 N.J. Super. 123, 135 (App. Div. 1997).

In Tindal, supra, the defendant doctors had performed surgery to remove bunions, which the plaintiff alleged was contraindicated by a vascular condition, Raynaud's disease, with which the plaintiff was afflicted. 299 N.J. Super. at 125. The harm suffered by the plaintiff was Reflex Sympathetic Dystrophy ("RSD"). Id. at 123. The Appellate Division reversed the trial court's holding that Raynaud's disease was a preexisting condition because the disease "could not, without the intervening surgery, have progressed into [RSD]." Id. at 135. The court held that the trial court erred in giving the Scafidi charge. Ibid.

In Holdsworth, supra, the defendant doctor mistakenly removed a portion of the right side of the plaintiff decedent's colon, when the patient actually had a tumor on the left side of the colon. 345 N.J. Super. at 297. To correct the mistake, the defendant performed a second surgery to remove a portion of the left side of the colon. Id. at 297-98. The patient died six weeks later from complications caused by the loss of so much of his colon. Ibid. The defendant argued that the risks associated with the proper surgery constituted a preexisting condition, so the trial court gave a Scafidi charge. The Appellate Division defined a preexisting condition as something that is treated to "alter or delay the outcome attributable to that condition." Id. at 300. The need for a Scafidi charge only arises where "there is a likelihood of adverse consequences based on the preexisting condition alone, and the physician's negligence hastens or otherwise fails to stem the patient's downward course caused by the preexisting condition. Ibid. The court observed:

> Every preexisting condition that has been thus far recognized as warranting Scafidi's application has had a probable adverse consequence inherent in the condition and has been present in the patient's body. In addition, the condition has constituted at least one of the reasons that brought the patient to the doctor or has manifested itself during the patient's treatment.

Id. at 301-02. The court reversed the trial court's decision, finding the Scafidi charge to have been improperly applied, as it could not "logically be said that the surgery risks combined with the

surgeon's negligence to cause the ultimate harm." Id. at 300. No preexisting condition could have, "without the unnecessary first surgery, caused any of plaintiff's injuries or his death." Ibid.

A review of several New Jersey cases demonstrates that only conditions which themselves can cause the ultimate harm, independent of the defendant's negligence, may be considered preexisting conditions. The courts have found preexisting conditions to exist and have applied the Scafidi charge in the following cases:

a. In Scafidi, supra, 119 N.J. at 97-100, the plaintiff mother sued the defendant physician for the death of her child at birth, after she presented to the defendant experiencing premature labor and bleeding, which alone, could have caused the death. The defendant had failed to diagnose the premature labor.

b. In Gardner v. Pawliw, 150 N.J. 359, 367, 388-89 (1997), the death of an infant was caused by preexisting "umbilical cord and placenta abnormalities," which the defendant failed to properly detect. The Court found that the plaintiffs satisfied their burden of proving that the failure to perform needed tests increased the risk posed by the preexisting condition that the fetus would die *in utero*.

c. In Fischer v. Canario, 143 N.J. 235, 239 (1996), the Court found that the tumor in the plaintiff's chest constituted a preexisting condition, triggering a Scafidi charge. The plaintiff had claimed that the defendant doctor had failed to properly find the tumor and diagnose cancer, leading to death.

d. In Lanzet, supra, 126 N.J. at 170, the court applied the Scafidi analysis where the plaintiff decedent died during cataract surgery, after the doctors failed to detect that she was experiencing a cardiac episode (the preexisting condition), which caused her death.

e. In Velazquez ex rel. v. Jiminez, 336 N.J. Super. 10, 23, 36-37 (App. Div. 2000), aff'd 172 N.J. 240 (2002), the Appellate Division held that the condition with which the plaintiff mother presented (loss of fetal heart rate, umbilical cord wrapped around the infant's neck, and shoulder dystocia), and which caused hypoxia and death of the infant, was a preexisting condition under Scafidi.

f. In Hutchinson By and Through Hutchinson v. Atlantic City Medical Center-Mainland, 314 N.J. Super. 468, 485 (App. Div. 1998), the Appellate Division held that an E-coli infection that caused permanent injuries, that existed at the time the defendant doctor examined the plaintiff, but which the defendant failed to diagnose, clearly constituted a preexisting condition under Scafidi.

g. In Arenas v. Gari, 309 N.J. Super. 1, 24-25 (App. Div. 1998), the court held that obstructive pneumonia, which the defendant failed to diagnose, and which caused the child's death, was considered a preexisting condition.

h. In Greene v. Memorial Hosp. of Burlington County, 299 N.J. Super. 372 (App. Div. 1997), the Appellate Division considered myocarditis (inflammation of the heart) a preexisting condition that caused the death of the patient. The patient had claimed that the defendants failed to properly examine and treat her when she presented to the emergency room with chest pain and worsening vital signs.

i. In Ginsberg v. St. Michael's Hosp., 292 N.J. Super. 21, 30 (App. Div. 1996), the Appellate Division held that the Scafidi charge was appropriate where both the plaintiff and the defendants "conceded that [plaintiff's] underlying condition[,] [congestive heart failure,] would ultimately cause his death." The plaintiff claimed that the defendants negligently gave plaintiff a fatal overdose of insulin, while in the hospital

for weakness and shortness of breath associated with congestive heart failure. The defendants claimed that, "while the overdose increased the risk of premature death, Ginsberg actually died from his underlying congestive heart failure, and that the overdose was not sufficiently significant." Id. The court noted that the question for the jury—"whether the overdose of insulin combined with Ginsberg's pre-existing condition to bring about his premature death, or whether it was his pre-existing condition alone that caused it"—fit "squarely within the Scafidi construct of increased risk of harm causation." Id.

In this case, the court finds that neither the BRCA2 gene mutation nor the microglandular adenosis is a preexisting condition within the meaning of Scafidi. Both concern unrealized risks, not conditions, and neither mandates the performance of bilateral mastectomies.

2. Ms. Klinger's BRCA2 Gene Mutation

Ms. Klinger's BRCA2 gene mutation is not a preexisting condition. (Pl.'s Br. at 16.) Rather, it is a pre-preexisting condition: a genetic indicator that she is more likely to develop an actual preexisting condition, at a future date, than someone without the trait. (Ibid.) The 1674delT mutation of the BRCA2 gene is a genetic indicator that "the risk of developing breast cancer for Ms. Klinger is increased beyond that of a woman in the general population." (Ibid.) Ms. Klinger's risk of developing breast cancer, in the absence of preventative surgery or tamoxifen, was 34% through age 70 and 39% through age 80. (Ibid.)

Unlike the cases cited above, where New Jersey courts have found preexisting conditions, the BRCA2 gene mutation alone could not have caused the ultimate harm suffered by Ms. Klinger: bilateral mastectomies. (Ibid.) By itself, this mutation is not a condition that actually will cause harm, as would an existing tumor, infection, or congestive heart failure, all of which are preexisting

conditions. (Id. at 16-17.) Alone, the mutation merely indicates that a person is statistically more at risk than the average person for the future development of breast cancer. (Id. at 17.) The mutation is not a guarantee that the disease will develop and is not the disease itself. (Ibid.)

A person's genetic makeup is not a preexisting condition, and to hold so would effectively open a Pandora's Box, through which an endless number of DNA combinations could be considered preexisting conditions under Scafidi. (Ibid.) With the expanding capabilities of genetic testing, such as with the genetic testing firm "23andMe," companies can offer direct-to-consumer at-home genetic testing that can show the specific percentages of the consumer's lifetime risks of developing certain diseases based solely on DNA from the consumer's saliva sample. (Id. at 17-18.) If defendants were allowed to use a plaintiff's DNA, as opposed to an actual, existing physical condition or illness, to offset liability for negligent acts, courts would be required to engage in the grim calculus of what type of genetic predisposition and what percentage of risk would constitute a "preexisting condition." (Id.) There is no clear answer as to how to make such a determination. (Id. at 18.) Further, this result is contrary to the existing cases interpreting Scafidi, which require that for a condition to be preexisting, it must have "a probable adverse consequence inherent in the condition" and "[be] present in the patient's body," and to have been one of the reasons that the patient went to that doctor. (Id. at 19; see Holdsworth, supra, 345 N.J. Super. at 301-02). None of those requirements are satisfied in this case because a genetic predisposition is not an existing physical condition, and Dr. Dardik, who did not know of Ms. Klinger's BRCA2 gene mutation, was not treating her for that mutation. (Pl.'s Br. at 19.) In that regard, Defendant's argument that in this case "it is alleged that **a misdiagnosis of the plaintiff's pathology slides accelerated plaintiff's BRCA2 genetic condition** so that a certain percentage chance of having bilateral

mastectomies became a certainty" is unfounded. Ms. Klinger's gene mutation was not accelerated; rather, the misdiagnosis was the but for cause of her decision to undergo bilateral mastectomies

Additionally, any argument that Ms. Klinger's BRCA2 gene mutation constitutes a preexisting condition, because it could have led to the prophylactic performance of bilateral mastectomies, ignores Ms. Klinger's decision after she discovered the mutation. (Ibid.) Although bilateral mastectomy is an option for treatment of the BRCA2 gene mutation, it is not the only accepted form of treatment, as "[s]creening MRI and mammography [are] considered a valid accepted alternative to [bilateral prophylactic mastectomies] by all respected cancer societies and organizations." (Ibid.) Ms. Klinger chose to undergo the enhanced screening procedures to avoid removal of her breasts unless there was confirmation that she actually had cancer. (Id. at 19-20.)

Ms. Klinger's BRCA2 gene mutation cannot, as a matter of law, constitute a preexisting condition under Scafidi, so the defendant physicians and medical centers are not entitled to present any defense that the ultimate harm suffered by Ms. Klinger, the unnecessary bilateral mastectomies, was in any way caused by or attributable to the gene mutation.

3. Microglandular Adenosis

Microglandular adenosis, with which Ms. Klinger was diagnosed by MSK doctors, also does not constitute a preexisting condition under Scafidi. (Id. at 20.) Despite being a "known mimicker of invasive carcinoma," microglandular adenosis is physically distinguishable from cancer and does not require the performance of mastectomies. (Ibid.) Instead, it may be treated using a less extensive surgery that preserves the breast. (Id. at 20-21.) Treatment for the microglandular adenosis, which was only present in Ms. Klinger's left breast, would only have necessitated the removal of the lesion itself in the breast, a significantly less drastic procedure than what was actually performed on Ms. Klinger. (Id. at 22.)

While two of the defendants' experts have opined that the microglandular adenosis in Ms. Klinger may have been transitioning to a malignant cancer at the time of Dr. Dardik's interpretation, this still falls short of qualifying as a preexisting condition. (Id. at 21.) Dr. David J. Dabbs, a defense pathologist, stated that the findings were "indicative of a lesion which is in transition, from a benign to a malignant finding" and that there was a "heightened risk" that the lesion would become malignant. (Ibid.) Dr. Arnold M. Baskies, defendants' expert surgical oncologist, opined that "breast cancer has been reported in association with microglandular adenosis in up to 27% of cases" and that "[t]he common presence of atypical microglandular adenosis in areas of transition between microglandular adenosis and carcinoma suggest that microglandular adenosis increases the risk of developing carcinoma by serving as a precursor lesion." (Ibid.)

Defendants' experts can only say that the microglandular adenosis had a risk of becoming cancer at some future time and cannot say that it was actually cancer when Dr. Dardik treated Ms. Klinger. (Id. at 22.) Through his report, Dr. Baskies speaks in terms of "increased risk" of future development of cancer and not of cancer that actually existed. (Ibid.) In his deposition, Dr. Baskies admitted that Ms. Klinger did not have cancer, but she was "on the road" to developing cancer at some point in the future, based on her family history. (Ibid.) He was unable to say exactly when he believed that Ms. Klinger would develop cancer. (Ibid.) Dr. Dabbs' opinion is similarly ambivalent, as he can only say that the microglandular adenosis "is showing progression toward an invasive cancer," meaning that the lesion "was at a heightened risk" of becoming malignant. (Ibid.) His opinion does not dispute that the sample was microglandular adenosis and not cancer, and he later testified that he cannot say without question that the microglandular adenosis would progress into invasive cancer. (Id. at 22-23.)

Although the microglandular adenosis mass was at a "heightened risk" of becoming malignant, it was not cancer at the time that Dr. Dardik treated Ms. Klinger. (Id. at 23.) Even accepting the defense experts' opinions, all the opinions have proved is that the lesion had the possibility of becoming cancer at a later date. (Ibid.) This uncertainty does not constitute a preexisting condition sufficient to invoke Scafidi. (Ibid.)

B. Evidence Concerning Ms. Klinger's BRCA2 Gene Mutation

The court should bar a party from introducing into evidence information that is immaterial to the issues in the case and that is likely to unduly prejudice the opposing party and confuse the jury. See N.J.R.E. 403. Although the court has found that Scafidi does not apply to the facts of this case, the court finds that the fact that Ms. Klinger had the BRCA2 gene mutation is relevant to the decisions she made, including her decision to opt for enhanced screening rather than undergo bilateral mastectomies. That said, any statistical analysis of her likelihood of developing cancer in the future of which Ms. Klinger was not aware of and relied on at the time she formed her decisions is irrelevant and inadmissible. To hold otherwise would impermissibly allow an allocation of causation to what the court has already found is not a pre-existing condition within the meaning of Scafidi.

IV. CONCLUSION

Upon careful review of Plaintiff's motion to bar testimony and in accordance with N.J.R.E. 403, and for the aforementioned reasons, Plaintiff's motion to bar testimony is GRANTED in part. Defendants shall not be entitled to argue a pre-existing condition based on Plaintiff's BRCA2 gene mutation or micrograndular adenosis and will not be entitled to a Scafidi charge at the time of trial. The fact that Plaintiff had the gene mutation is admissible for the purpose of explaining Plaintiff's medical choices. To the extent Plaintiff was not advised of the statistical probability of her

developing cancer in the future, however, such statistics could not form the basis of Plaintiff's choices at the time and thus will be irrelevant and inadmissible. IT IS SO ORDERED.