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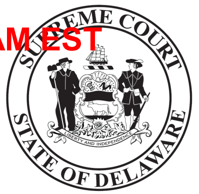

IN THE SUPREME COURT OF THE STATE OF DELAWARE

BARBARA A. MAMMARELLA,	)	
	)	No. 548,2013
Plaintiff Below-Appellant,	)	
	)	
v.	)	Appeal from the Superior Court
	)	of the State of Delaware in
ALAN B. EVANTASH, M.D.,	)	for New Castle County
ALL ABOUT WOMEN OF	)	
CHRISTIANA CARE, INC., and.,	)	
CHRISTINE W. MAYNARD, M.D.	)	
	)	
Defendants Below-Appellees.	)	C.A. No. N11C-12-242 VLR

DEFENDANTS BELOW, APPELLEES, ALL ABOUT WOMEN OF CHRISTIANA CARE, INC.'S AND CHRISTINE W. MAYNARD, M.D.'S

ANSWERING BRIEF ON APPEAL

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Dated: January 22, 2014

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NATURE OF PROCEEDINGS

On December 28, 2011, Plaintiff-below/Appellant Barbara A. Mammarella (hereinafter "Plaintiff" or "Mrs. Mammarella") filed this medical negligence action against Alan B. Evantash, M.D., All About Women of Christiana Care, Inc., and Christine W. Maynard, M.D. (collectively "Defendants").[1] Mrs. Mammarella alleged that Defendants failed to timely diagnose her breast cancer shortly after her October 16, 2009 ultrasound revealed a new 6 mm mass in her right breast. She was diagnosed with breast cancer on May 7, 2010.

Following discovery, Appellant's sole claim for damages was that the alleged seven-month delay caused her to undergo chemotherapy rather than partial breast radiation. (B-6; A-37 at 29:22-30:16; A-116 at 5:19-23; A-118: at 7:12-18; A-138 at 27:6-8; A-147-148 at 36:19- 37:20; A-149-150 at 38:18- 39:4.) According to Mrs. Mammarella, "chemotherapy is more disfiguring, disabling, painful and fatiguing than [radiation]." (B-6.)

On July 18, 2013, Defendants filed a Joint Motion for Summary on the basis

[1] Originally, this action included a loss of consortium claim on behalf of Mrs. Mammarella's husband, Thomas Mammarella. (B-4.) However, his claim was voluntarily dismissed. (A-5.) Plaintiff originally alleged a medical negligence claim against Christiana Care Health Services, Inc., which was later voluntarily dismissed. (B-1-4.) Finally, the Complaint originally identified Pike Creek Associates in Womencare, P.A., as a defendant, subsequently Defendant All About

that Mrs. Mamarella's sole causation expert, Dr. David Biggs, failed to support her claim that the alleged delay in diagnosis caused her treatment to change. (A-21-24.) The trial court denied Defendants' Joint Motion on August 22, 2013, during the Pre-trial conference. (A-29-45.)

Trial was scheduled to begin on September 23, 2013.[2] Dr. Biggs was unable to testify at trial, and presented for a videotaped trial deposition on September 3, 2013. (A-18.)

On September 6, 2013, counsel for Defendants Dr. Maynard and All About Women of Christiana Care, Inc. (hereinafter the "AAW Defendants") asked the trial court for an opportunity to present a Motion for Judgment as a Matter of Law based on Dr. Biggs' trial deposition testimony. (A-46.) That same day, the AAW Defendants provided Plaintiff with a copy of the Motion. (BB-108.)

On September 18, 2013, the trial court held a teleconference to discuss the Motion for Judgment as a Matter of Law, at which time an argument hearing was scheduled for September 19, 2013. (A-113 at 2:7-8.)

During the hearing, the trial court granted the Defendants' Motion for Judgment as a Matter of Law and found that Dr. Biggs' trial testimony failed to

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[2] This matter was originally assigned to the Honorable Jerome O. Herlihy but was reassigned to the Honorable Vivian L. Rapposelli on June 27, 2013, following his retirement.

establish a causal nexus between the alleged medical negligence and a change in Plaintiff's treatment. (A-146-163.) Plaintiff now seeks review of the trial court's September 19, 2013 Order granting the Motion.

Plaintiff filed her Opening Brief on December 23, 2013, and an Amended Brief on December 30, 2013. This is the AAW Defendants' Answering Brief on Appeal.

SUMMARY OF ARGUMENT

I. DENIED. THE SUPERIOR COURT PROPERLY GRANTED THE DEFENDANTS' MOTION FOR JUDGMENT AS A MATTER OF LAW BECAUSE DR. BIGGS' TRIAL TESTIMONY FAILED TO PROVIDE A LEGALLY SUFFICIENT EVIDENTIARY BASIS FOR A REASONABLE JURY TO FIND THAT THE ALLEGED MEDICAL NEGLIGENCE PROXIMATELY CAUSED PLAINTIFF'S TREATMENT TO CHANGE.

STATEMENT OF FACTS

Medical Background

On October 13, 2009, Mrs. Mammarella underwent an annual screening mammogram at the Helen F. Graham Cancer Center ("Helen Graham") in Newark, Delaware. (A-164.) According to the interpreting radiologist, Kristina Siddall, M.D., the mammogram revealed "[a] new 6 mm mammographic mass with ill-defined margins" in Mrs. Mammarella's right breast. (BB-001.) Dr. Siddall recommended that Mrs. Mammarella undergo a follow-up targeted diagnostic ultrasound and digital mammogram for further evaluation of the mass. (BB-001.)

The follow-up imaging study was performed on October 16, 2009, and interpreted by Defendant Dr. Evantash, a board-certified radiologist. (A-165-168.) According to Mrs. Mammarella, before she left Dr. Evantash's practice, a technician told her that the mass in her right breast was "benign," and that she should return in one year for an annual screening mammogram. (A-82.)

Dr. Evantash authored a radiology report summarizing his interpretations of the October 16, 2009 imaging studies. In his report, Dr. Evantash concluded that there was "[n]o evidence of malignancy," and recommended that Mrs. Mammrella continue with her annual screening mammogram in one year. (A-165-168.) A

copy of Dr. Evantash's report was sent to Dr. Maynard, Plaintiff's OB/GYN physician.

On October 19, 2009, Dr. Evantash sent a letter to Mrs. Mammarella in which he stated that "[t]he results of your mammogram show no evidence of cancer. A benign (non-cancer) appearing finding was seen." (A-169.)

On October 20, 2009, Dr. Maynard called Mrs. Mammarella to discuss the results of the October 16, 2009 imaging studies. (A-86-87.) During this telephone conversation, Mrs. Mammarella expressed concern over the new mass, and stated that she felt uncomfortable waiting a year for a screening mammogram. (A-86-87.) As a result, Dr. Maynard recommended a six-month repeat diagnostic ultrasound of her right breast, to which Mrs. Mammarella agreed. (A-86-87.)

On April 22, 2010, Mrs. Mammarella underwent a diagnostic ultrasound and digital mammogram as ordered by Dr. Maynard. The reviewing radiologist concluded that the mass in Mrs. Mammarella's right breast measured 8 mm in greatest dimension, and recommended a biopsy. (A-171-172.)

On May 7, 2010, Emily Penman, M.D., a breast surgeon at Helen Graham, performed an ultrasound-guided biopsy of Mrs. Mammarella's breast mass. (A-173.) The biopsy diagnosed the mass as grade III, invasive ductal carcinoma (breast cancer). (A-173.)

On May 13, 2010, Mrs. Mammarella met with several members of the breast cancer multidisciplinary team at Helen Graham to discuss her diagnosis. (A-173-176.) Members of this team included, among others, Dr. Penman (breast surgeon), David Biggs, M.D., (medical oncologist), and Christopher Koprowski, M.D. (radiation oncologist). (A-173-176.)

As of May 13, 2010, Mrs. Mammarella's breast cancer stage was unknown. (B-43-44 at 32:23-33.) Until further testing was completed, the multidisciplinary team was unable to provide Mrs. Mammarella definitive treatment recommendations.[3] (B-44; BB-022 at 13:12-16.)

As the team's surgeon, Dr. Penman recommended to Mrs. Mammarella that she undergo a lumpectomy, a procedure that completely removes the tumor but

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[3] To diagnose breast cancer stage, oncologists use a T-N-M (Tumor-Node-Metastasis) classification system. (BB-031.) The factors include the size of the primary tumor (T), whether or not the cancer has spread to the regional lymph nodes (N), and whether or not the cancer has metastasized to any other organ of the body (M). (BB-031.) As of May 13, 2010, all three factors were unknown. (BB-100.) Although the April 22, 2010 ultrasound demonstrated the tumor was 8 mm in greatest dimension, measurements obtained on imaging are considered inaccurate, and are not used to diagnose breast cancer stage. (B-44 at 35-36; BB-99-100; BB-034.) For purposes of identifying tumor size (T), the tumor is measured under a microscope after it has been removed. (B-44 at 35-36.)

allows for breast conservation. (BB-100.) A lumpectomy serves a therapeutic purpose (removal of the tumor), as well as a diagnostic purpose (allows for pathological measurement of the tumor for staging purposes). (BB-100.)

As the team's radiation oncologist, Dr. Koprowski discussed with Mrs. Mammarella the potential benefits of both partial and whole breast radiation treatment following the lumpectomy. (A-175-176.) At this time, no decision was made with respect to which form of radiation treatment would be used. (B-39-40 at 16:23- 17:10.)

As the team's medical oncologist, Dr. Biggs explained to Mrs. Mammarella the potential benefits of chemotherapy treatment to reduce the risk of undetectable metastatic disease outside of the breast. (A-173-174.) According to Dr. Biggs, he provided no definitive chemotherapy treatment recommendations to Mrs. Mammarella on May 13, 2010. (B-43 at 29:6-11; B-44 at 33:20-24.) Furthermore, Dr. Biggs testified that he does not make treatment recommendations until the patient's cancer stage has been diagnosed. (B-44 at 33.)

According to Mrs. Mammarella, her understanding from this initial consultation with Dr. Biggs was that, following her lumpectomy: (1) she needed chemotherapy and radiation if her tumor, when removed, was larger than 8 mm; and (2) she needed only radiation, and not chemotherapy, if the tumor was 8 mm or

less when it was removed. (BB-005.) Dr. Biggs' testified that Mrs. Mammarella's "understanding" was inaccurate, and explained that: "my goal in that initial meeting [was] to try to provide a general framework for understanding how we make decisions, and so that was my goal. If that came across as being very specific, that was unintentional." (B-43 at 29:6-11.)

On May 27, 2010, Dr. Penman performed a lumpectomy, and sentinel node biopsy. (BB-100.) The tumor measured 1.1 cm in greatest dimension, and Mrs. Mammarella's lymph nodes were negative for cancer. (B-40 at 19.) In addition, imaging studies did not reveal any evidence of metastatic disease. (BB-100.) Based on these findings, Dr. Biggs diagnosed Mrs. Mammarella with Stage I, Grade III, breast cancer and recommended that she undergo twelve weeks of chemotherapy. (BB-100.) Dr. Koprowski also recommended that Mrs. Mammarella undergo localized breast radiation therapy following her chemotherapy treatment. (BB-002.)[4]

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[4] Mrs. Mammarella never received radiation therapy. Following her chemotherapy treatment, Mrs. Mammarella tested positive for a genetic mutation that is believed to significantly increase the risk of breast cancer, including episodes of recurrence. (BB-007.) As a result, Mrs. Mammarella elected to undergo prophylactic bilateral mastectomies (complete removal of both breasts). (BB-007.) Because these procedures removed Mrs. Mammarella's breast tissue, there

Thus, as a result of her breast cancer diagnosis in May 2010, Mrs. Mammarella's treating physicians recommended that she undergo a lumpectomy, sentinel node biopsy, twelve weeks of chemotherapy, and local radiation therapy. (BB-002.)

Plaintiff's Medical Negligence Claim

Plaintiff alleged that the Defendants committed medical negligence in that they failed to timely diagnose her breast cancer. Specifically, she alleged the Defendants: (1) failed to recognize that the mass should have been biopsied; (2) failed to order a biopsy of a mass seen on October 13, 2009; (3) failed to treat, surgically or otherwise, the mass seen on October 13, 2009; and (4) erroneously advised Plaintiff that the mass was benign, that she was cancer free, and that she should be monitored in one (1) year. (B-3-4.)

In her Complaint, Plaintiff alleged that the Defendants' medical negligence proximately caused her to undergo disfiguring surgery, suffer physically and emotionally, and resulted in debilitating and painful treatment.[5] (B-4.)

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was no need for radiation therapy. Mrs. Mammarella concedes that her bilateral mastectomies are unrelated to her medical negligence claim. (A-37 at 29:23- 30:16; B-6.)

[5] Mrs. Mammarella also alleged that the Defendants' medical negligence proximately caused her tumor to metastasize, which never occurred. (B-4.). Plaintiff later acknowledged that this

Expert Discovery

In support of her claim, Plaintiff identified four medical experts:[6] (1) Daniel N. Powers, M.D., an OB/GYN; (2) Dr. Biggs, Mrs. Mammarella's treating medical oncologist; (3) Dr. Penman, Mrs. Mammarella's treating surgeon; and (4) Lawrence Milner, M.D., a board-certified radiologist.[7]

Dr. Powers and Dr. Milner testified solely about the standard of care issues in this case.[8] (B-28-29, 31 at 23-24; BB-094 at 172:1-3.) Dr. Penman testified that Mrs. Mammarella's prognosis, treatment, and cancer stage were unchanged by the

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statement was inaccurate and that there are no claims of metastasis. (A-37 at 29:23- 30:16.)

[6] Plaintiff identified a fifth expert, Gabriella M. D'Andrea, M.D., who was later withdrawn.

[7] Drs. Biggs and Penman, however, were identified as experts without their prior knowledge or consent. (BB-016 at 7:16-20; BB-097 at 5.) In addition, both Drs. Biggs and Penman testified that they had never discussed their opinions of the case with counsel prior to their discovery depositions. (BB-016 at 7:16-20; BB-097 at 5.)

[8] Moreover, Dr. Powers testified that: (1) he was not qualified to provide expert opinions regarding Mrs. Mammarella's treatment or prognosis changes from October 2009 to May 2010; and (2) he would defer to Dr. Biggs regarding all issues of breast cancer treatment and prognosis. (B-28 at 162-165.) Even if qualified to provide causation opinions, which he is not, Dr. Powers lacked foundation to offer any causation opinions because his understanding of Mrs. Mammarella's cancer treatment, stage and grade came solely from Mrs. Mammarella's deposition testimony, not any of the medical records. (B-28 at 165:1-6.) D.R.E. 702, 703.

alleged delay in diagnosis. (B-33 at 14-15; B-34 at 21-23.) Therefore, the only expert who could potentially causally link the alleged negligence to the sole claimed injury (i.e., that the alleged seven-month delay in failing to diagnose the cancer caused her to undergo chemotherapy rather than partial breast radiation) was Dr. Biggs.

At his discovery deposition, Dr. Biggs was unable, however, to support Mrs. Mammarella's claim that her treatment or prognosis changed as a result of the alleged delay in diagnosis:

> Q. Okay. And I just want to clarify and make sure that I understand your opinions, but I believe you have no opinion as to any differences in treatment from October 2009 to May 2010 that the patient may have needed; correct?
>
> A. Yes, I have no -- I can't state that there's any -- I can't state what my opinion would have been at an earlier point in time.
>
> Q. And the same would hold true for prognosis; correct?
>
> A. I can't state what the prognosis would have been at an earlier point in time.[9]

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[9] Dr. Biggs testified that he could only speculate as to whether Mrs. Mammarella's prognosis changed from October 2009 to May 2010. (BB-035-36.) He further testified that he could not say whether or not Mrs. Mammarella's risk of metastatic disease changed from October 2009 to May 2010. (BB-045.)

(BB-072-73.) In response, Plaintiff asked Dr. Biggs to discuss his May 13, 2010 initial consultation with Mrs. Mammarella:

> Q. . . . Did you have any conversation with Barbara Mammarella before you knew what the exact size was, you just had the imaging reports, that if it were over 8 millimeters you would probably recommend chemotherapy and if it were under 8 you would not?
>
> THE WITNESS: I think looking back at our initial consultation note, I indicated that if the tumor was no larger than it appeared on ultrasound, which I think was, what, 8 millimeters, that I would likely feel that she would not take chemotherapy. I would like to underline the word likely, though, because it's really a gray zone.
>
> And when you are in that gray zone, you really have to have a patient who - - you have to suss out, or you have to try to understand the desires of the patient to be aggressive and try to help them understand the risks and potential benefits within the level of uncertainty that we have. So it's not quite as exact as that. Do you know what I am trying to say?

(BB-064.) Dr. Biggs rejected Mrs. Mammarella's claim that 8 mm, or any other measurement served as a bright line cut-off for determining whether chemotherapy treatment is appropriate. (BB-042-043.)

Dr. Biggs also explained that the discussions he had with Mrs. Mammarella on May 13, 2010, prior to her lumpectomy, were "hypothetical" since he did not know Plaintiff's cancer stage. (BB-069.) In fact, Dr. Biggs testified that he cannot give an opinion on cancer treatment based only on imaging studies, which is all that is available from October 2009:

> Q. And if you had been dealing with this situation when the tumor was on imaging studies, showing 6 millimeters as its largest dimension, would you then have had a discussion about what I'm calling gray zone chemotherapy?
>
> A. I try- - it's dangerous to make definitive statements about what you would or wouldn't do based on imaging. We really need to know what it is. And so the consultation that we had prior to her surgery was - -
>
> Q. Tentative?
>
> A. - - hypothetical.

(BB-068-069.)

Pre-trial Motion Practice

Upon the completion of discovery, Defendants filed a Joint Motion for Summary Judgment on the basis that Mrs. Mammarella failed to present any expert testimony to support the element of causation. (A-21-24.) Plaintiff opposed Defendants' Motion for Summary Judgment on the basis that Dr. Biggs' deposition testimony supported her claim that she "lost the option of radiation and had to undergo chemotherapy." (A-28.)[10] Plaintiff argued that Dr. Biggs' discovery deposition testimony supported her theory that the delay in diagnosis caused her to

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[10] Appellant's claim that she lost the "option of radiation" is factually inaccurate. When she was diagnosed with breast cancer in May 2010, her treatment plan included radiation therapy. (BB-002.)

require chemotherapy because her tumor was greater than 8 mm when removed (despite Dr. Biggs' testimony to the contrary). Missing from Plaintiff's argument, among other things, was any expert testimony that Mrs. Mammarella's tumor was in fact 8 mm or less in October 2009.[11] Nonetheless, the trial court denied Defendants' Joint Motion for Summary Judgment based on counsel's representations that Dr. Biggs' trial testimony would demonstrate a change in treatment. (A-37; A148-149 at 37:21- 38:6.)

Thereafter, Plaintiff repeatedly confirmed that the sole causation issue to be presented at trial was whether or not the alleged delay in diagnosis proximately caused Mrs. Mammarella's treatment options to change. (B-6; A-37 at 29:22-30:16; A-116 at 5:19-23; A-118: at 7:12-18; A-138 at 27:6-8; A-147-148 at 36:19-37:20; A-149-150 at 38:18- 39:4.) Plaintiff also represented to the trial court and parties on multiple occasions that Dr. Biggs was her only causation expert. (A37 at 31-32; A-117 at 6:5-11; A-136 at 25:5-11.) In the Pre-trial stipulation, Plaintiff described her damages as follows:

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[11] Defendants have not filed a cross-appeal regarding the trial court's denial of their Motion for Summary Judgment as the issues involved in both Motions are similar in nature, although the testimony to be evaluated is different (discovery versus trial). Nonetheless, given the identical nature of the issues, Plaintiff was on notice before Dr. Biggs' trial testimony as to the testimony she needed to establish her *prima facie* causation case.

> [b]ecause of the increase in size [of the tumor] Plaintiff had to undergo chemotherapy treatment and lost the option of partial breast irradiation [sic] treatment which would have been available to her in October 2009. The side effects of chemotherapy were more disfiguring, disabling, painful and fatiguing than irradiation [sic].

(B-6.)

During the August 22, 2013 Pre-Trial Conference, Plaintiff's counsel stated:

> [t]he only issue in the case is that she had to undergo chemotherapy and lost the option of radiation. We're not talking about any prognosis on [sic] life expectancy or metastases or anything like that. It's never come up. From our standpoint, the only place it ever can [sic] came up that I can recall was probably in the pleadings. But in the discovery was when they started deposing the plaintiff's daughter. They got into the issue about mastectomies and metastases and so forth, but I'm not going to present any evidence on that.
>
> THE COURT: Well, I think that the issue, as I understand it, is that the basis of the harm, or what you're going to present or wish to present to a jury about the alleged injury is that she had to undergo chemotherapy instead of radiation and that she suffered emotional distress as a result of the delay.
>
> MR. CASTLE: Exactly.

(A-37 at 29:23- 30:16.) Furthermore, the trial court granted (BB-106-107.), as unopposed, the AAW Defendants' motion *in Limine* precluding Mrs. Mammarella from introducing any evidence to support a claim that her prognosis changed as a

result of the alleged delay in diagnosis. (BB-103-105.)[12] Thus, at trial, Mrs. Mammarella's claim for damages was limited to the effects of chemotherapy treatment, which was to be supported only by the expert testimony of Dr. Biggs.

Trial Deposition of Dr. Biggs

Dr. Biggs was unavailable to testify at trial. His videotaped trial deposition took place on September 3, 2013.

During direct examination, Plaintiff never asked Dr. Biggs: (1) what Mrs. Mammarella's treatment would have been in October 2009; (2) whether or not Mrs. Mammarella's treatment in October 2009 would have included chemotherapy; (3) how big Mrs. Mammarella's tumor was in October 2009; or (4) whether Mrs. Mammarella's treatment changed as a result of the alleged delay from October 2009 to May 2010. (B-36-43.) Instead, Plaintiff asked Dr. Biggs about his initial consultation with Mrs. Mammarella on May 13, 2010:

> Q. There has -- there will be testimony in trial, and we talked about it then, that Mrs. Mammarella was under the impression that if the tumor on biopsy turned out to be less than 8 -- 8 centimeters [sic] or less in size, that she was a candidate for radiation treatment instead of chemotherapy first. Is that a correct statement?
>
> A. You'd have to ask her what her impression was. My goal in that initial meeting is to try to provide a general framework for

[12] Plaintiff has not sought review of this Order.

> understanding how we make decisions, and so that was my goal. If that came across as being very specific, that was unintentional.

(B-42-43 at 28:23- 29:11.)

Plaintiff's counsel then asked Dr. Biggs to read a portion of his discovery deposition into the record where he discussed the initial consultation further:

> A. Okay. "I think looking back at our initial consultation note, I indicated that if the tumor was no larger than it appeared on ultrasound, which I think was, what, 8 millimeters, that I would likely feel that she would not take chemotherapy. **I would like to underline the word likely, though, because it's really a gray zone**. "And when you are in that gray zone, you really have to have a patient who" – and then I said "you have to suss out," what I meant was "you have to try to understand the desires of the patient to be aggressive **and try to help them understand the risks and potential benefits within the level of uncertainty that we have. So it's not quite as exact as that**. Do you know what I'm trying to say?"
>
> Q. And is that still your testimony?
>
> A. Yes. I mean, I would stand by this. I can try to elaborate, but...

(B-43 at 30:9- 31:4.) (emphasis added).

Conversely, on cross-examination, Dr. Biggs was directly asked whether he could support Mrs. Mammarella's causation theory:

> Q. Okay. And so if one were to ask you what this patient's treatment would have been or what treatment she would have required in October 2009, you couldn't state that, correct?
>
> A. Correct.

> Q. Okay. You would be speculating if you gave that information, correct?
>
> A. Correct.
>
> *   *   *   *
>
> Q. I just want to make sure that we all understand your testimony today. You can't tell the jury to a reasonable degree of medical probability what Mrs. Mammarella's treatment would have been in October 2009. Is that correct?
>
> A. Correct.

(B-44 at 35:12-19; B-46 at 41:6-12.)

One of the many reasons Dr. Biggs could not support Mrs. Mammarella's theory that her treatment changed from October 2009 to May 2010, is that he cannot say how big Mrs. Mammarella's tumor was in October 2009 based on imaging studies:

> Q. And do you have any opinion as to how big Mrs. Mammarella's tumor would have been in October 2009 based on the imaging studies alone?
>
> A. The- no.
>
> Q. And so you can't tell the jury how big Mrs. Mammarella's tumor was in October 2009, correct?
>
> A. Correct.[13]

---

[13] In her Opening Brief, Plaintiff claims that her tumor grew 33% from October 2009 to May 2010 without any expert testimony to support this claim. (Appellant's Op. Br. at 10.)

(B-44 at 36:10-18.)

<u>Defendants' Motion for Judgment as a Matter of Law</u>

On September 6, 2013, before filing their Motion for Judgment as a Matter of Law based on Dr. Biggs' trial deposition testimony, Defendants provided Plaintiff's counsel a copy. (BB-108.) That same day, Defendants then asked the trial court for an opportunity to present their Motion prior to trial on September 23, 2013. (A-46.)[14] Therefore, Plaintiff's counsel knew Defendants' position and argument more than two (2) weeks before the motion was heard.

On September 18, 2013, the Superior Court held a teleconference with counsel to discuss Defendants' Joint Motion for Judgment as a Matter of law.

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[14] As noted in Appellant's Opening Brief, the trial court initially rejected Defendants' request to present their Motion for Judgment as a Matter of Law on the basis that the dispositive motion deadline had passed (despite the fact that no dispositive motion deadline was identified in the applicable trial scheduling order). Regardless, pursuant to Superior Court Civil Rule 50(a)(2), a motion for judgment as a matter of law "may be made at any time before submission of the case to the jury." Thus, Defendants' <u>trial</u> Motion was timely under the Rules and not barred by the discovery motion deadline. In Plaintiff's Abbreviated Response to the Motion for Judgment as a Matter of Law, she characterizes the trial court's denial of the hearing request as an Order. This is inaccurate, as this was communicated to counsel from the trial judge's assistant by way of e-mail.

During the teleconference, Plaintiff's counsel again confirmed that Mrs. Mammarella's sole causation expert was Dr. Biggs, and that the alleged harm was a change in treatment. (A-117 at 6:5-11; A- 136 at 25:5-11.) The trial court scheduled an argument hearing for the following day and permitted Defendants to file their Motion on September 18, 2013. Appellant filed an Abbreviated Response on September 19, 2013. (A-110-111.)

At the September 19, 2013 hearing, the Superior Court granted Defendants' Joint Motion for Judgment as a Matter of Law:

> THE COURT: … The Plaintiff indicated that Dr. Biggs would state that plaintiff had undergone a different treatment plan but for the delay in diagnosis. And that was - - that's what's stated in the pretrial stipulation and that [sic] those are the representations that had previously been made. So a timely diagnosis in October of 2009 after the first ultrasound, therefore, would have resulted in a treatment plan that would have been different than the chemotherapy that she ultimately underwent. Again, partial breast radiation versus chemotherapy.
>
> The deposition, however, of Dr. Biggs was taken September the 3rd. This testimony doesn't appear to comport with what was anticipated. And it's very much like the Kardos versus Harrison decision and what happened in that particular care.
>
> *　　*　　*　　*
>
> Dr. Biggs' trial deposition completed the record Mrs. Mammarella could present at trial with respect to the issue of causation.
>
> *　　*　　*　　*

> . . . At no point is the doctor ever able to say within a reasonable degree of medical probability that the prognosis [sic] for treatment would have changed had she been diagnosed in October 2009. He indicates that the call would have been speculative, at least from what – my reading of his deposition. I don't think this is sufficient for plaintiff to establish proximate cause.
>
> . . . [P]laintiff's only evidence on causation by Dr. Biggs is speculative and I think plaintiff fails to make a *prima facie* case on the issue of causation.

(A-149-150 at 38: 18- 39:9; A-161 at 50:12-18, 50:23- 51:2.)

Plaintiff now seeks review of the September 19, 2013 Order granting Defendants' Motion for Judgment as a Matter of Law.

ARGUMENT

I. DENIED. THE SUPERIOR COURT PROPERLY GRANTED THE DEFENDANTS' MOTION FOR JUDGMENT AS A MATTER OF LAW BECAUSE DR. BIGGS' TRIAL TESTIMONY FAILED TO PROVIDE A LEGALLY SUFFICIENT EVIDENTIARY BASIS FOR A REASONABLE JURY TO FIND THAT THE ALLEGED MEDICAL NEGLIGENCE PROXIMATELY CAUSED PLAINTIFF'S TREATMENT TO CHANGE.

A. Question Presented

Did the Superior Court err as a matter of law when it granted Defendants' Motion for Judgment as a Matter of Law where Plaintiff's sole causation expert, Dr. David Biggs, testified at trial that he could not offer any opinion as to whether the alleged negligent delay in treating Ms. Mammarella's cancer caused the sole claimed injury?

The AAW Defendants preserved this issue when they filed Defendants' Motion for Judgment as a Matter of Law (A-104-109.) and argued the motion on September 19, 2013. (A-112-163.)

B. Scope of Review

This Court reviews a trial court's decision to grant judgment as a matter of law *de novo*. *Kardos v. Harrison*, 980 A.2d 1014, 1016 (Del. 2009). Judgment as a matter of law may be granted when "a party has been fully heard on an issue and there is no legally sufficient evidentiary basis for a reasonable jury to find for that

party on that issue." Del. Super. Ct. Civ. R. 50(a)(1). This Court "must determine 'whether the evidence and all reasonable inferences that can be drawn therefrom, taken in the light most favorable to the nonmoving party, raise an issue of material fact for consideration by the jury." *Kardos*, 980 A.2d at 1016 (citing *Russell v. Kanaga*, 571 A.2d 724, 731 (Del. 1990)).

C. Merits of Argument

1. The only issue before the Court is whether Dr. Biggs' trial testimony establishes a legally sufficient evidentiary basis for a reasonable jury to find that the alleged medical negligence caused her treatment to change.

In her Opening Brief, Mrs. Mammarella asserts, for the very first time, that the alleged delay in diagnosis caused her to suffer, *inter alia*, the following injuries:

(1) risk of death over the next years [sic] at 17% based on the size and characteristics of the tumor;[15]

(2) increased risk of harm (or death); and

(3) loss of chance.

[15] Risk of death alone is not a compensable injury. *U.S. v. Cumberbatch*, 647 A.2d 1098, 1100, n. 3 (Del. 1994). Rather, expert testimony must demonstrate that the risk of death increased as a result of the alleged medical negligence. *Id*.

(Appellant's Op. Br. at 10-11). For several reasons, Plaintiff is precluded from raising these claims on appeal.

The aforementioned injuries require a showing that Mrs. Mammarella's expected outcome/prognosis changed as a result of the alleged medical negligence. *See Kardos*, 980 A.2d at 1017 (the loss of chance "doctrine allows a plaintiff to recover damages for the diminution of that person's chance of survival, where that dimunition was caused by the negligence of a defendant, even though the person already had a greater than fifty percent probability of not surviving."); *Cumberbatch*, 647 A.2d at 1100 n. 3 (the increased risk of harm doctrine allows a plaintiff to recover damages if their "risk of suffering a negative medical condition is increased because of medical malpractice.").

However, claims of a "loss of chance" or "increased risk of harm" were excluded by the trial court when it granted, **as unopposed**, AAW Defendants' motion *in limine* precluding evidence of a change in prognosis at trial. (BB-106-107.)[16] By not opposing this motion, Plaintiff failed to raise, or fairly present, these claims to the Superior Court, and is therefore precluded from doing so now.

[16] During the pre-trial conference, Plaintiff stated that the motion was unopposed since there was no evidence to suggest that her prognosis ever changed. (A-36-37 at 27:13- 30:16.)

Supr. Ct. R. 8; *Culver v. Bennett*, 588 A.2d 1094, 1096 (Del. 1991).[17] Furthermore, Plaintiff did not appeal the trial court's Order granting the motion *in limine*, and thus, she is procedurally barred from revisiting the scope of damages claimed on appeal. Supr. Ct. R. 8.

Additionally, during multiple judicial proceedings, Plaintiff represented to the trial court and Defendants that the claimed damages were limited to a change in treatment:

> MR. CASTLE: ….**The only issue in the case is that she had to undergo chemotherapy and lost the option of radiation. We're not talking about any prognosis on [sic] life expectancy or metastases or anything like that. It's never come up.** From our standpoint, the only place it ever can came[sic] up that I can recall was probably in the pleadings.[18]

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[17] During the hearing on Defendants' Motion for Judgment as a Matter of Law, Plaintiff noted that Dr. Biggs testified that Mrs. Mammarella's estimated risk of death in June 2010 was approximately 17% over the next ten (10) years. (A131-132 at 20:20- 21:7.) This fact alone in legally inconsequential since Dr. Biggs never testified that Mrs. Mammarella's risk of death was different in October 2009. *Cumberbatch*, 647 A.2d at 1100 n. 3.

[18] In fact, Mrs. Mammarella's Complaint never alleged that she suffered a "loss of chance," "increased risk of harm," or any change to her prognosis. (B-1-5.) This omission also precludes her from asserting these claims at trial or on appeal. *VLIW Technology, LLC v. Hewlett-Packard Co.*, 840 A.2d 606, 611 (Del. 2003) (complaint must include allegations to put the opposing party on notice of the claims).

> But in the discovery was when they started deposing the plaintiff's daughter. They got into the issue about mastectomies and metastases and so forth, **but I'm not going to present any evidence on that.**
>
> * * * *
>
> THE COURT: Well, I think that the issue, as I understand it, is that the basis of the harm, or what you're going to present or wish to present to a jury about **the alleged injury is that she had to undergo chemotherapy instead of radiation and that she suffered emotional distress as a result of the delay**.
>
> MR. CASTLE: **Exactly**.

(A-37 at 29:23- 30:16.) (emphasis added).

Plaintiff made the same representation during the September 18, 2013 teleconference that the only alleged injury she suffered was a change in her medical treatment. (A-116: 5:19-23; A-149-150 at 38:18- 39:4.) Counsel's statements constitute judicial admissions, and limit her damages claim to the sole issue of whether the alleged negligence caused a change in treatment. *Merritt v. United Parcel Service*, 856 A.2d 1196, 1201 (Del. 2008). But even if those representations were not binding (which they are), Plaintiff's experts never supported an "increased risk of harm" or "loss of chance" claim during discovery. As these experts would have been precluded from offering new opinions at trial, any "new" testimony cannot not serve as a basis to defeat Defendants' Motion Judgment as a Matter of Law. *Turner v. Delaware Surgical Group*, P.A., 67 A.3d

426, 429 (Del. 2013) (*citing Bush v. HMO of Delaware, Inc.,* 702 A.2d 921 (Del. 1997)) (parties must comply with discovery directed at the identification of experts and the "substance of their expected opinion" as prerequisites for the introduction of their expert testimony at trial).

It should be emphasized that, even if Plaintiff was not procedurally barred from asserting a "loss of chance" or "increased risk of harm" claim, Dr. Biggs' trial testimony[19] fails to support these theories. For example, Plaintiff inaccurately states:

> …. in Dr. Biggs' view, the Plaintiff's risk of death, based on the size and characteristics of the tumor, was 17%. This testimony fits the increased risk of harm doctrine and defeats the Defendants' argument.

(Appellant's Op. Br. at 14). What Plaintiff fails to appreciate, however, is that Dr. Biggs never testified that Mrs. Mammarella's risk of death changed from October 2009 to May 2010. (B-35-57.) Plaintiff seeks to take Dr. Bigg's speculative discussion with Mrs. Mammarella as to potential treatment options to support a case where Dr. Biggs himself testified on multiple occasions that he has no opinion

[19] In her Opening Brief, Plaintiff has relied solely upon the testimony of Dr. Biggs to assert her new claim that her prognosis changed as a result of the alleged delay in diagnosis. (Appellant's Op. Br. at 10 -18). Thus, any attempt by Plaintiff to rely on others' testimony to support this claim is waived. Supr. Ct. R.14(b)(A)(3).

as to the change in prognosis. Dr. Biggs testified that he could not say whether Mrs. Mammarella's prognosis changed, and characterized his opinion on that issue as "speculative," rendering his testimony inadmissible. (App.). *O'Riley v. Rogers*, 69 A.3d 1007, 1011 (Del. 2013) (*citing Floray v. State*, 720 A.2d 1132, 1136 (Del. 1998)). Thus, Dr. Biggs' testimony, even when viewed in a light most favorable to Plaintiff, fails to support a claim that Mrs. Mammarella suffered an "increased risk of harm." *Cumberbatch*, 647 A.2d at 1100 n. 3.

In sum, the sole issue before the Court is whether Dr. Biggs' trial testimony establishes a legally sufficient evidentiary basis for a reasonable jury to find that the alleged medical negligence proximately caused her treatment regimen to change.

2. Dr. Biggs' trial testimony fails to establish a legally sufficient evidentiary basis for a reasonable jury to find that the alleged medical negligence caused her treatment to change.

To support her claim that the Defendants' medical negligence proximately caused her to undergo a different form of treatment, Mrs. Mammarella is required to present expert testimony at trial. 18 *Del. C.* § 6853; *Kardos*, 980 A.2d at 1017. To satisfy this requirement, Mrs. Mammarella relied exclusively upon the trial testimony of Dr. David Biggs. (A-117 at 6:5-11; A- 136 at 25:5-11.) Thus, following Dr. Biggs' trial deposition, the trial court could determine as a matter of

law whether or not Plaintiff had a "legally sufficient evidentiary basis for a reasonable jury to find" that the Defendants' conduct proximately caused an injury. *Kardos*, 980 A.2d at 1017.

Under Delaware law, "when an expert offers a medical opinion it should be stated in terms of 'a reasonable medical probability' or 'reasonable medical certainty." *O'Riley*, 69 A.3d at 1011 (*citing Floray v. State*, 720 A.2d 1132, 1136 (Del. 1998)). This is because

> "[A] doctor cannot base his expert medical opinion on speculation or conjecture. '[A] doctor's testimony that a certain thing is possible is no evidence at all.' A doctor's opinion about 'what is possible is no more valid than the jury's own speculation as to what is or is not possible."

Id. *(citing Oxendine v. State*, 528 A.2d 870, 873 (Del. 1987)).

Thus, to defeat a motion for judgment as a matter of law, Dr. Biggs' trial testimony must demonstrate that, to a "reasonable degree of medical probability," or "reasonable medical certainty," the alleged medical negligence proximately caused Mrs. Mammarella's treatment to change from radiation to chemotherapy. *Id.* Dr. Biggs' trial testimony failed to do so.

During direct examination, Plaintiff <u>never</u> asked Dr. Biggs the single question necessary to establish her *prima facie* case: whether Mrs. Mammarella's

treatment changed from October 2009 to May 2010.[20] On cross-examination, Dr. Biggs testified that he could not state what Mrs. Mamamrella's treatment would have been in October 2009:

> Q. Okay. And so if one were to ask you what this patient's treatment would have been or what treatment she would have required in October 2009, you couldn't state that, correct?
>
> A. Correct.
>
> Q. Okay. You would be speculating if you gave that information, correct?
>
> A. Correct.
>
> * * * * *
>
> Q. I just want to make sure that we all understand your testimony today. You can't tell the jury to a reasonable degree of medical probability what Mrs. Mammarella's treatment would have been in October 2009. Is that correct?
>
> A. Correct.

(B-44 at 35:12-19; B-46 at 41:6-12.) Thus, Dr. Biggs' trial testimony fails to support Plaintiff's claim that her treatment changed from October 2009 to May 2010, and as a result, Defendants are entitled to judgment as a matter of law.

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[20] Since Plaintiff bears the burden of proof, Defendants would have been entitled to judgment as a matter of law without asking a single question on cross-examination. *Delmarva Power & Light v. Stout*, 380 A.2d 1365, 1367 (Del. 1977).

Kardos, 980 A.2d at 1019.

Moreover, Dr. Biggs testified that he could not say whether Mrs. Mammarella's tumor was 8 mm or less in October 2009.[21] (B-44 at 36:10-18.) Therefore, it is irrelevant whether Dr. Biggs' trial testimony supports Plaintiff's claim, which he does not, that she did not need chemotherapy if her tumor was 8 mm or smaller because he admitted that he lacked the proper foundation (i.e., the knowledge of the size of the tumor) to offer any treatment recommendations. D.R.E. 702.

In sum, even when viewed in a light most favorable to Plaintiff, Dr. Biggs' trial testimony fails to establish a legally sufficient evidentiary basis for a reasonable jury to find that the Defendants' conduct proximately caused Mrs. Mammarella to undergo chemotherapy. Therefore, this Court should affirm the trial court's September 19, 2013 Order granting Defendants' Motion for Judgment as a Matter of Law.

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[21] Plaintiff claims that the growth of her tumor constitutes an injury. (Appellent's Op. Br. at 10). Dr. Biggs' trial testimony fails to support this theory. (B-35-57.) This Court has previously held that delayed cancer treatment by itself is insufficient to establish a *prima facie* case; rather, per statute, medical expert testimony is required. *W. O'Donald v. McConnell*, 858 A.2d 960 (Del. 2004).

3. An Affidavit of Merit cannot defeat an otherwise proper motion for judgment as a matter of law.

Plaintiff argues that an affidavit of merit "precludes a judgment as a matter of law in a medical negligence lawsuit when the Affidavit of Merit has been held to comply with 18 *Del. C.* § 6853." (Appellant's Op. Br. at 15). This argument conflicts with the clear language of the Delaware medical negligence statute.

Title 18, Section 6853(d) provides, in pertinent part, that:

> [t]he affidavit of merit itself, and the fact that an expert has signed the affidavit of merit, **shall not be admissible nor may the expert be questioned in any respect about the existence of said affidavit in the underlying medical negligence action** or any subsequent unrelated medical negligence action in which that expert is a witness. (Emphasis added).

Thus, even assuming the substance of Plaintiff's Affidavit of Merit established the element of causation, that document, and any testimony referring to it, is inadmissible at trial. 18 *Del. C.* § 6853(d). Therefore, an affidavit of merit, as a matter of law, cannot defeat an otherwise proper motion for judgment as a matter of law, because it cannot establish a legally sufficient evidentiary basis for a reasonable jury to find in plaintiff's favor on any element of her claim. Super. Ct. Civ. R. 50(a)(1).

Even if an affidavit of merit were admissible, Plaintiff's position ignores the purpose of the affidavit of merit. The affidavit of merit requirement is designed to

prevent the filing of frivolous medical negligence lawsuits, which is why the procedural requirements are "purposefully minimal." *Dishmon v. Fucci*, 32 A.3d 338, 343 (Del. 2011). The affidavit of merit is filed before any discovery has been conducted, or defenses have been asserted. 18 *Del. C.* § 6853. The trial court's review is limited to the affidavit, and the expert's *curriculum vitae*. *Id*. The court does not review the basis of the affiant's opinions, and is to "assume that statements in affidavits of merit are reliable without additional evidentiary support." *Dishmon v. Fucci*, 32 A.3d 338, 343. Furthermore, a defendant cannot challenge the substance or credibility of the expert's opinions at this stage of litigation. 18 *Del. C.* § 6853. The unchallenged opinions set forth in the affidavit of merit establish nothing more than the fact that the plaintiff has retained a supporting expert.

To establish liability, a plaintiff must, as a matter of law, present "expert medical testimony" that demonstrates the defendant deviated from the applicable standard of care, and that the defendant's deviation caused her to suffer an injury. 18 *Del. C.* § 6853(e).

Therefore, to defeat a motion for judgment as a matter of law, Plaintiff must present "expert medical testimony" that provides a legally sufficient evidentiary basis for a reasonable jury to conclude that the Defendants' conduct caused her to

suffer an injury. 18 *Del. C.* § 6853(e); *Kardos v. Harrison, D.O.*, 980 A.2d 1014, 1017; Super. Ct. Civ. R. 50(a)(1). Plaintiff has failed to do so, and therefore, this Court should affirm the trial court's September 19, 2013 Order.

CONCLUSION

Plaintiff's sole causation expert, Dr. David Biggs, testified at trial that he could not offer any opinion as to whether the alleged medical negligence caused the only claimed injury. Therefore, this Court should affirm the Superior Court's September 19, 2013 Order granting Defendants' Motion for Judgment as a Matter of Law.

Respectfully submitted,

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