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Case Number 26,2018

IN THE SUPREME COURT OF THE STATE OF DELAWARE

AMANDA M. NORMAN,	:	
	:	No. 26,2018
Plaintiff Below,	:	
Appellant,	:	
	:	Court Below:
	:	Superior Court State of Delaware
	:	C.A. No. K14C-12-003 WLW
	:	
	:	
ALL ABOUT WOMEN, P.A.	:	
a Delaware Corporation, and	:	
CHRISTINE W. MAYNARD, M.D.	:	
	:	
Defendants Below,	:	
Appellees	:	

DEFENDANTS BELOW, APPELLEES ALL ABOUT WOMEN, P.A. AND CHRISTINE W. MAYNARD, M.D.'S AMENDED ANSWERING BRIEF

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Dated: April 10, 2018

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NATURE OF PROCEEDINGS

Plaintiff-below/Appellant Amanda M. Norman (hereinafter "patient" or "Norman") brought suit against her prior OB/GYN, Christine W. Maynard, M.D., and Dr. Maynard's employer, All About Women, P.A.[1] (collectively "Defendants"). She retained Jeffrey L. Soffer, M.D.[2] to serve as an expert to criticize Dr. Maynard's performance of a laparoscopy, and to support a claim of vicarious liability against All About Women, P.A. for a bladder injury following the laparoscopy on October 22, 2013.[3] Liability, causation, and damages are denied by Defendants and their experts.[4]

Following expert depositions and the close of discovery, Defendants moved for summary judgment due to Plaintiff's failure to establish a *prima facie* case of negligence secondary to inadmissible testimony by her sole expert.[5] Defendants advanced two independent grounds in their Motion: Dr. Soffer's testimony is grounded on the doctrine of *res ipsa loquitur*, contrary to the statutory and caselaw in Delaware governing medical negligence cases; and his opinions lacked the requisite reliability to pass through the *Daubert* filter.[6] The latter basis was fully

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[1] Plaintiff's Complaint designated the wrong entity, subsequently corrected in the First Amended Complaint (Feb. 12, 2015) (B 3).
[2] Plfs' Answr. Form 30 Interrog. 5 (Dec. 4, 2014) (B 2).
[3] First Amended Compl. (B 3-6).
[4] Answer to Amended Compl. (B 7-10). *See also* Pre-Trial Stipulation and Order (B 567-601)(p. 2-4 and 25-26).
[5] Defs. Mot. (Jan. 16, 2017) (B 225-351)
[6] *Id.*

briefed in Defendants' Motion *in Limine* filed on February 7, 2017.[7] Norman opposed both motions and requested oral argument on each. The Court considered arguments by both sides at hearing on Defendants' Motion *in Limine* on September 22, 2017.[8] It deferred ruling on the Summary Judgment Motion but ruled on the Motion *In Limine* on November 16, 2017.[9] The Court, *in limine*, excluded Dr. Soffer's testimony and requested clarification of any relief remaining for Court consideration.[10] Defendants requested a ruling on the pending dispositive motion,[11] and Plaintiff opposed.

Plaintiff took the position the Court's decision only barred Dr. Soffer's testimony in part. This was discussed at the Pre-Trial Conference. Unfortunately, due to limited judicial resources the Court was unable to provide a court reporter for this conference. Defendants filed a brief letter the following day with record cites refuting Plaintiff's position.[12] It was further discussed at the hearing on Defendants' Motion for Summary Judgment.[13] After hearing arguments from both sides on whether Plaintiff's claims failed as

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[7] The transcription of Dr. Soffer's deposition testimony accompanied this Motion as an Exhibit. *See* Discv. Dep. Tr. Of Dr. Soffer (Apr. 5, 2016) (B 150-224).
[8] Excerpt of Hearing Tr. (Sept. 22, 2017) (B1-32).
[9] (B 496-497).
[10] (A 3)
[11] (B 565-566).
[12] Defs.. Suppl. (Dec. 7, 2017)(B 602-605).
[13] Hearing Tr. (Dec. 15, 2017)(B 606-635).

a matter of law, the Superior Court granted judgment for Defendants, prompting this appeal.

SUMMARY OF THE ARGUMENT

1. Appellant's requested relief should be denied. The trial Court did not commit reversible error in granting summary judgment for Defendants when Norman failed to adduce admissible expert testimony on the standard of care controlling Dr. Maynard's performance of a diagnostic laparoscopy and subsequent care under 18 *Del. C.* §6853(e). Dr. Soffer's testimony that the injury speaks for itself stands as the sole basis for his testimony that a deviation from the standard of care occurred. This is both legally erroneous and logically unsound, requiring exclusion of these opinions.

2. Appellant's requested relief should be denied. The reasonableness of the Superior Court's ruling is illustrated by the way in which Norman argues for reversal. Rather than defend the admissibility of Soffer's testimony based on the record that was before the Superior Court when it ruled on the *Daubert* motion and motion for summary judgment, plaintiff relies on the qualifications of her expert together with anecdotal evidence by Defendants experts. Dr. Soffers' expertise never served as the basis for Defendants' position but does not render his opinions presumptively reliable. Despite Appellant's assertion to the contrary, testimony by defense experts which rebuke Dr. Soffer's conclusions as to what the standard of care required, a breach of it by Dr. Maynard, and whether a causal nexus existed does not render Dr. Soffer's opinions reliable nor inform an analysis as to their

admissibility under D.R.E. 702. Rather, the only consensus among the experts was that the procedure involved a known complication and that such an injury can occur in the most diligent and skilled of hands without any negligence. The Superior Court's consideration of each of the D.R.E. 702 factors, the directives of *Daubert* and its Delaware progeny is an analysis free of legal error, supported by the evidence and the testimony of Plaintiffs' expert.

Appellant fails to explain how Soffer's reasoning was reliable or how the Court misapplied settled law. Instead, she claims that Soffer's opinions are immune from *Daubert* review altogether. This argument was not raised below, and should be deemed waived. Plaintiff cites to no persuasive authority in advancing this proposition, and fails to address the statute controlling this issue. Moreover, she offers no authority or evidence that supports an inference that bladder a perforation can only occur with negligence, either due to a failure in technique or inspection, a fact conceded by Appellant's expert. Moreover, Norman fails to articulate why the trial court erred in excluding her expert's opinions when her expert conceded that this injury can occur absent negligence, but failed to articulate what distinguished the instant case where be believed negligence had occurred.

Given Dr. Soffer's opinion that this injury can occur absent negligence and it can go undetected absent negligence, the trial court correctly concluded that some

rationale must be given for the expert's belief that negligence occurred in this case. The court properly concluded that Dr. Soffer's belief that negligence occurred because the patient was injured, was insufficient as a matter of law given the aforementioned concessions that this can occur without negligence by the physician. As such the court properly granted Defendants Motion for Summary Judgment.

STATEMENT OF FACTS

Norman hired Jeffrey Soffer, M.D. to opine that Dr. Maynard committed two (2) standard of care violations: 1) a perforation of the Plaintiff's bladder; and, 2) a failure to timely recognize this.[14]

Dr. Soffer was deposed on April 5, 2016. At his deposition he testified that these two situations can occur absent negligence.[15] He was specifically asked whether anything existed in the medical records to support his opinion that there was negligence in this case, thereby distinguishing it from the instances where this occurs in the absence of negligence. He responded that there was nothing in the medical records to infer negligence by Dr. Maynard.[16] He further testified that there was nothing in the deposition testimony to infer negligence by Dr. Maynard.[17]

He summarized by testifying that the sole basis for his opinion that Dr. Maynard breached the standard of care was the fact that an injury occurred during the procedure she performed on Norman.[18] Thus, Dr. Soffer believed there were two standard of care violations and these criticisms were based entirely on the fact that there was a bad outcome:

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[14] Report of Dr. Soffer (Jan. 30, 2016) (A 65-66).
[15] Deposition of Dr. Soffer (p. 19)(B 168) and (p. 69-71) (B 218-220)
[16] Deposition of Soffer (p. 20-11)(B 169-170) and p. 44-46 (B 193-195)
[17] Id.
[18] Id.

> Q: The sole basis for your opinion that Dr. Maynard used sloppy, to use your words, surgical technique is the fact that an injury occurred, Correct?
>
> A: Yes.
>
> Q: And the sole basis for your opinion that she missed the bladder injury during the operation is the fact that a bladder injury occurred?
>
> A: Yes.

(B 183-184) (Depo. of Dr. Soffer)(pp. 34-35).[19]

Dr. Soffer, when pressed for the basis of his opinions, went so far as to assert that the fact that the injury was missed means there was inadequate inspection "[s]o that speaks for itself." (B 182)(Depo. Of Dr. Soffer) (P. 33).

When asked directly what distinguished those cases of non-negligent conduct from Dr. Maynard's conduct in this case, the only basis he could provide was the singular fact an injury occurred. He was specifically and repeatedly questioned about the factual predicate informing his opinions and agreed that neither the operative report, nor the records of any healthcare providers involved in Norman's care, nor the deposition testimony of any

[19] *See also* (B 192-193) (Depo. Dr. Soffer) (43-44) (agreeing that "the only" basis for all his opinions Dr. Maynard missed the perforation is that the patient had a bladder injury); and (B 194-195)(45-46)(same).

witness supported his belief there was a negligent inspection by Dr. Maynard during the procedure.[20]

Based on this testimony Defendants filed a Motion for Summary Judgment on January 16, 2017.[21] Since the issues were evidentiary in nature and also involved questions governed under Delaware Rule of Evidence 702, Defendants elected to also file a Motion *in Limine* to Exclude Dr. Soffer's Testimony as inadmissible.[22]

The trial court, understanding the two motions were linked, deferred ruling on the Motion for Summary Judgment until after the Motion in Limine was ruled upon.[23] On November 16, 2017 the Court issued a decision regarding Dr. Soffer's testimony.[24] Dr. Soffer's testimony was excluded because Ms. Norman was unable to demonstrate that his opinion was based on information reasonably relied upon by experts in the field.[25] The Court further requested Defendants to inform the Court whether the Motion for Summary Judgment needed to be decided as well.[26]

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[20] (B 193-194) (Depo. of Dr. Soffer) (p. 44-45). *See also* (B 169-170) (p. 20-21) (same for improper surgical technique); (B 187-188)(38-39) (same).
[21] (B 225-351).
[22] (B 389-437).
[23] (B 496-497).
[24] *Norman v. All About Women, P.A.* 2017 WL 5624303 (Del. Super. Nov. 16, 2017).
[25] Id. at *2.
[26] Id.

Defendants responded that the Motion for Summary Judgment was ripe for consideration and following additional briefing, the trial Court held oral arguments on December 15, 2017.[27] On December 19, 2017 the trial Court granted Defendants' Motion for Summary Judgment and this appeal followed.[28]

[27] (B 606-635)(Transcript of Oral Argument on Motion for Summary Judgment).
[28] (B 636-650) (Order Granting Summary Judgment).

ARGUMENT

I. THE TRIAL COURT CORRECTLY DETERMINED THAT DR. SOFFER'S OPINION THAT THERE WAS NEGLIGENCE BASED ON THE MERE FACT THAT AN INJURY OCCURRED WAS INSUFFICIENT AS A MATTER OF LAW

A. Question Presented

Whether the Court committed reversible error when it granted judgment in Defendants' favor because Plaintiff was unable to produce reliable evidence to support a fundamental element of her Complaint?

Defendants preserved this issue in their Motion for Summary Judgment (B 225-351), Motion *in Limine*, (B 389-437), supplemental briefing (B 565-566), in the Pre-Trial Stipulation and Order (B 567-601) and at oral argument (B 606-635).

B. Scope of Review

This Court reviews a grant of summary judgment de novo.[29] "Viewing the facts and reasonable inferences in the light most favorable to the non-moving party, if an essential element of the non-movant's claim is unsupported by sufficient evidence for a reasonable juror to find in that party's favor, then summary judgment is appropriate." *Edminsten v. Greyhound Lines*, 49 A.3d 1192, 2012 WL 3264925, at * 2 (Del. Aug. 13, 2012).

[29] *Cleotox Corp. v. Catrett,* 477 U.S. 317 (1986).

Where the Appellant fails to include all portions of the record relevant to the claims on appeal, this Court is precluded from undergoing appellate review and must affirm the lower Court's ruling.[30]

C. Merits of Argument

1. Plaintiff's failure to include all relevant portions of the record necessary for appellate review warrants affirmation of the trial judge's grant of summary judgment for Defendant.

Plaintiff failed to include "the complete docket entries in the trial Court arranged chronologically in a single column" required by Supreme Court Civil Rule 14 (e) as follows:

1. Amended Complaint dated January 26, 2015;
2. Defendants' Answer dated February 12, 2015;
3. Plaintiff's expert designation dated December 8, 2015;
4. Defendants' Rule 26(b)(4) expert designation dated February 8, 2016;
5. Discovery deposition transcript for Dr. Soffer dated April 5, 2016;
6. Defendants' Motion for Summary Judgment dated January 16, 2017;
7. Defendants' Motion in Limine to exclude testimony by Dr. Soffer on the standard of care dated February 7, 2017;
8. Hearing transcript on Oral Argument on Defendants' Motion in *Limine* regarding Dr. Soffer dated September 22, 2017.

[30] *Trioche v. State*, 525 A2d 151, 154 (Del. 1987); Super. Ct. R. 9 (e)(ii) and 14 (e).

9. Defendants' response to Plaintiff's letter supplement regarding Plaintiff's expert designations dated October 13, 2017;

10. Defendants' response to the Court Order regarding testimony of Dr. Soffer dated November 17, 2017;

11. Defendants' supplement to its Motion for Summary Judgment dated December 7, 2017; and

12. Hearing transcript for Oral Argument on Defendants' Motion for Summary Judgment dated December 15, 2017.

These materials are necessary for appellate review to determine whether (1) the claimed error was preserved on the record which included any exhibits attached to the pre-trial motions and statements made at oral argument; (2) because Plaintiff's appeal is premised on the arguments raised in the papers as well as at oral argument; and (3) to properly evaluate whether the record supported the Court's determination that Dr. Soffer's testimony was inadmissible under 18 Del. C. §6853(e), *Daubert* and Delaware Rule of Evidence 702.[31]

The failure to include relevant portions of the record necessary to consider the context of the claimed error precludes appellate review and prompts affirmance of the lower Court's decision.[32]

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[31] Defendant's inclusion of the relevant materials in their Appendix does not cure Plaintiff's defect or satisfy her obligation to furnish the necessary documents for appellate review.

[32] *Trioche*, 525 A.2d at 154.

2. Dr. Soffer's standard of care opinions were legally insufficient and unreliable.

Defendants took Dr. Soffers' deposition to explore the bases for his opinions. Once that deposition was completed, all the evidence about standard of care Plaintiff was relying on was available to the Superior Court, which could therefore determine as a matter of law whether Norman had established a legally sufficient basis for a reasonable jury to find that her injury was caused by a breach in the standard of care by Dr. Maynard. If any "good grounds" existed, it was incumbent on Norman to present it in order to preclude summary judgment.

The Superior Court properly found that Dr. Soffer's testimony did not provide a sufficient evidentiary basis, as required by § 6853(e)(3) *et seq.,* for the jury to find that Dr. Maynard failed to adequately inspect the surrounding structures operated on or used poor surgical technique during the procedure. To the contrary, Dr. Soffer repeatedly testified that his basis for concluding that there was a breach in the standard of care was the fact that an injury occurred in this case, although it could occur absent negligence. (B 169-170) (B 193-195).

Reading the testimony in the most favorable light to Plaintiff, Dr. Soffer agreed that there was nothing in either the medical record nor deposition testimony to support his contention that Dr. Maynard was inattentive during the surgery or used poor technique. Further, was unable to reconcile his

opinions in this case with the peer reviewed literature which demonstrated these injuries can occur when there is no negligence. Moreover, he could not articulate the specifics of what the standard of care required of Dr. Maynard as far as surgical technique or how she failed to follow it in this case. He simply relied on the premise that negligence must have occurred due to the fact that the patient suffered an injury, an injury which he concedes can occur absent negligence.

In short:

> "...No presumption of medical negligence arises from the mere fact that the patient's treatment had an undesirable result. Medical negligence is never presumed. The fact that a patient has suffered an injury while in the care of a healthcare provider does not mean that the healthcare provider committed medical negligence."

Del. P.J.I Civ. § 7.1A (rev'd 2003).

Plaintiff attempts to salvage Dr. Soffer's lack of any deductive process through statements by Dr. Maynard at her deposition, which were properly considered and rejected by the lower Court. Plaintiff on appeal similarly directs this court to Dr. Maynard's testimony about her thought process on how the bladder could have been injured.[33] Dr. Maynard's speculation on a causation issue is irrelevant to the inquiry before this Court. Dr. Soffer was asked, and admitted at his deposition, he could point to no testimony by Dr. Maynard suggesting she used

[33] Opening Brief, at 15.

poor technique or failed to diligently inspect the visual field. Plaintiff's reliance on her testimony on appeal is irrelevant.[34] The only reliance that matters is that of her expert who conceded it did not inform his opinions on this case. Plaintiff's characterization of other portions of the record in an attempt to connect them to his expert's opinions is likewise unpersuasive on the reliability of his methodology under *Daubert* since he was directly asked and conceded he did not rely on these materials.

Her characterization of this case on appeal, as one involving a basic surgical technique[35] used during a standard, common procedure cannot be reconciled with the vast decisional law treating medicine as specialized subject matter requiring competent medical testimony or clear legislative intent allowing for limited exceptions where the jury could infer negligence.[36] Even if that was an accurate premise and characterization of the medicine involved, it does not make Soffer's testimony reliable or remove the gatekeeping function of the trial court.[37] On the

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[34] *See e.g. In Re Asbestos Litigation (Helm)*, 2007 WL 1651968, at * 16 (Del. Super. Ct. May 31, 2007) *rev and corr* ("The Court must decline to draw an inference for the non-moving party if the record is devoid of facts upon which the inference can reasonably be based. In other words, there is no "precedent fact" to give rise to a "logical inference.").

[35] Opening Brief, at 12.

[36] *See, e.g., Wendenberg v. Williams*, 784 S.W.2d 705, 707 (Tex. App. 14th Dist. 1990)(use of a pituitary roenguer to grip tissue during back surgery required extensive training and not within common knowledge of a lay person), *writ denied.*

[37] *See e.g. Kuhmo Tire Co. v. Carmichael* (judge's gatekeeping function identified in Daubert applies to all expert testimony, including that which is non-scientific).

contrary, it makes her expert's inability to articulate how such a technique was improper or point to any medical literature supportive of his deductive process all the more suspect.

Counsel's opinion of what portions of the record collaborate an expert's conclusions are immaterial to a *Daubert* inquiry, as a matter of law, and on the specifics of this case when the expert himself concedes there is nothing in the record to inform his opinions. Statue mandates that the standard of care governing Defendants conduct at issue be established at trial through competent, admissible expert testimony.[38] No such evidence has been proffered in this case, thus summary judgment was appropriate.[39]

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[38] *Hornbeck v. Homeopathic Hospital Association of Del.*, 197 A.2d 461 (Del. 1964).
[39] *See Froio v. DuPont Hosp. for Children*, 816 A.2d 784 (Del. 2003).

II. THE COURT'S DETERMINATION THAT PLAINTIFF HAD TO PROVE ALL ELEMENTS OF HER CLAIM WITH EXPERT TESTIMONY IS FREE FROM LEGAL ERROR.

A. Question Presented

Whether inference or anecdotal evidence that Dr. Maynard breached the standard of care based on the mere fact that an injury occurred satisfies the Plaintiff's burden of proof under 18 *Del. C.* 6853(e)?

Defendants preserved this issue in their Motion for Summary Judgment (B 225-351), Motion *in Limine*, (B 389-437), supplemental briefing (B 565-566), in the Pre-Trial Stipulation and Order (B 567-601) and at oral argument (B 606-635).

B. Scope of Review

The Court's consideration of evidence as unreliable is reviewed for an abuse of discretion.[40] The standard of review for consideration of arguments not raised on the record below is plain error.[41]

C. Merits of the Argument

1. Plaintiff failed to proffer admissible expert evidence to establish negligence by Defendants, as required by 18 *Del. C.* § 6853(e) to survive summary dismissal.

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[40] *Tumlinson v. Advanced Micro Devices, Inc.*, 81 A.3d 1264 (Del. 2013).
[41] *See* Super. Ct. R. 8; *Sullivan v. State*, 636 A.2d 931, 937 (Del. 1994); *Culver v. Bennett*, 588 A.2d 1094, 1096 (Del.1991); *Stoltz v. Mngmt. Co. v. Consumer Affairs Bd.*, 616 A.2d 1205, 1212 (Del. 1992).

Plaintiff's burden of proof is controlled by clear statute and she fails to reconcile its language prohibiting any inference of negligence outside three circumstances and expressly requiring affirmative evidence on each element of her claim through an expert.[42] Where a plaintiff's expert cannot give a legally sufficient opinion on the standard of care or a breach of it by a defendant, the Court must enter judgment for Defendant as a matter of law.[43]

Appellant argues that negligence can be inferred from the facts of this case and/or rational inferences taken from the medical records or deposition testimony. This argument has two fatal flaws. First, it is undisputed that in a medical negligence case, absent a statutory exception, the Plaintiff must prove his/her case through expert testimony. 18 *Del. C.* 6853(e), *et. seq.*. Dr. Soffer testified he did not rely on any of the materials in which Appellant's counsel is indicating such an inference can be made.

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[42] *Burkhart v. Davies*, 602 A.2d 56, 59 (Del. 1991), *certiorari denied*, 112 S. Ct. 1946, 504 U.S. 912 (1992)("the production of expert medical testimony is an essential element of a plaintiff's medical malpractice case, and, as such, is an element on which he or she bears the burden of proof.").

[43] *Dickenson v. Sopa*, 2013 WL 3482014 (Del. Super. June 30, 2013), *aff'd*, 2013 WL 6726884 (Del. 2013) (TABLE) (rejecting Plaintiff's proposition that expert opinions were sufficient for jury inference as insufficient to satisfy evidentiary requirements imposed by statute and affirming Court's award of summary judgment in favor of Defendant).

Second, presumptions of negligence in a medical negligence action is strictly a creature of statute. A rebuttable inference of negligence by a healthcare provider arises in only three circumstances, (1) a foreign object was left inside a patient following surgery; (2) an explosion or fire occurs during the course of treatment; or (3) a surgical procedure was performed on the wrong patient, organ or part of a patient's body. 18 *Del. C.* 6853(e). These statutory bases are exclusive and negligence may not otherwise be presumed. Therefore, the doctrine of *res ipsa loquitur* may not be used for any set of circumstances aside from those codified. *See e.g., Lacy v. G.D. Searle & Co.*, 484 A.2d 527, 530 (Del. Super. 1984).

Plaintiff designated one expert witness during discovery, Jeffrey Soffer, M.D. Fairly read, Dr. Soffer's testimony is clear that he concluded there was negligence based solely on the outcome of the procedure. (B 169-170) (B192-195). He repeatedly confirmed that the fact of Norman's injury was the basis for his opinion that Dr. Maynard breached the standard of care. However, Delaware juries are instructed that no negligence should be presumed from the fact there is an injury.[44] As a result, there was no legally sufficient expert evidence under which the Plaintiff could carry her burden of proof for a *prima facie* claim for medical negligence.[45]

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[44] *Ciociola v. Del. Coca-Cola Bottling Co.*, 172 A.2d 252, 257 (Del. 1961).
[45] *O'Donald v. McConnell*, 858 A.2d 960, 2004 WL 1965034, at * 2 (Del. Aug. 19, 2004) (summary judgment properly granted when medical malpractice plaintiff

Dr. Soffer's testimony was also improper under Delaware Rule of Evidence 702 because it did not provide any factual basis for the jury to decide the issue of standard of care or a breach by Dr. Maynard.[46] In other words, it would have been an impermissible basis for inference of negligence on the part of Defendants.[47] Thus, the Superior Court properly deemed Soffer's standard of care testimony insufficiently reliable and fundamentally fatal to Plaintiff's case.[48]

2. Plaintiff provided no basis to find Soffer's methodology reliable.

Norman was free to choose her expert witness, and she chose Dr. Soffer, who did not provide testimony legally sufficient to support her claims. She bore the burden of showing that Soffer's testimony satisfied the admissibility requirements of Rule 702 and *Daubert*. Given Soffer's outcome-dependent methodology, his deposition testimony, and the undisputed peer review literature establishing this

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failed to satisfy the statutory requirement through expert causation evidence) (citing 18 *Del. C.* § 6853(e)).

[46] *See e.g. Timblin v. Kent General Hosp. (Inc.),* 640 A.2d 1021, n. 2 (Del.1991) (discussing in dicta improper expert statistical data testimony was inadmissible under 403 in addition to 702 because it gave no fact basis for jury to decide causation and did not aid to understanding of facts or issues).

[47] *In Re Asbestos Litigation (Helm)*, 2007 WL 1651968, at * 16 (Del. Super. Ct. May 31, 2007) *rev and corr* (" . . . 'Where there is no precedent fact, there can be no inference; an inference cannot flow from the nonexistence of a fact, or from a complete absence of evidence as to the particular fact.'").

[48] *See Mammarella v. Evantosh,* 93 A.3d 629, 636 (Del. 2014)(discussing that a plaintiff's decision to rely on one expert who would not carry her evidentiary burden or inability to find one who could, would not excuse the inability to satisfy her evidentiary requirements imposed by statute).

outcome can and does occur with reasonable care, a fact conceded by Appellant's expert, the lower Court did not abuse its discretion in concluding that Norman failed to carry that burden.

As the Court noted, Soffer provided no explanation of an analytical basis for his standard of care opinions other than connecting an outcome to a breach. The Court correctly concluded that he did nothing to tie his opinions to the medical literature known to him or to distinguish the occasions discussed in scientific literature that involved non-negligent conduct from the the conduct of Dr. Maynard in this case. He simply asserted that there was inadequate technique and attention to the visual field because there was an injury, and it went undetected. As asserted by Defendants in their briefs, Soffer's methodology had nothing to do with an analytical process grounded in the record or in the generally accepted practices of the obstetrics and gynecological community. Thus, it was reasonable for the Court to factor Soffer's inability to proffer research or peer review information to support his opinions in reaching its conclusion that it was inadmissible and unreliable.

On appeal, she argues that testimony of defendants' expert is evidence helpful on the limited issue for this Court's consideration. Her reliance on Defendants' experts is fatally flawed because both experts testified Dr. Maynard's conduct was reasonable and met the standard of care. Moreover, personal experience of Defendants' experts (whether they ever perforated the bladder)

would not have been admissible at trial to prove liability or a proper basis for the jury to predicate a finding of negligence by Defendants.[49]

Appellant argues that her expert is a qualified physician with experience performing these procedures. However, the qualifications of Dr. Soffer were never attacked. It was the opinion of this expert, the logic behind that opinion and the lack of support in the record or scientific community that served as the basis for Defendants' attack. "Just because an expert is qualified in a field does not automatically make the [expert's] opinion reliable." *State v. Wright*, 2009 WL 3111047 (Del. Super. Ct. Sept. 14, 2009) (citing *Eskin v. Carden*, 842 A.2d 1222 at 1228). But this is precisely the approach taken by Norman in explaining the basis for Dr. Soffer's opinions having good grounds or the hallmarks of reliability. In essence, Plaintiff argues that Dr. Soffer's personal experience (in not ever perforating the bladder during a laparoscopy) and Dr. Stepp's personal experience (in appreciating that an injury occurred before the surgery was over) further bolster's Dr. Soffer's *res ipsa* reasoning and renders it more reliable.[50] This

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[49] *See Timblin v. Kent General Hosp.*, 640 A.2d 1021 (Del. 1994) (Statistical probability evidence cannot be used to show compliance with the standard of care); *see generally* David Faigman, Legal Alchemy: The Use and Misuse of Science in the Law 69 (1999)("Although juries may generally use their common sense in reaching a verdict, they may not make unguided empirical assumptions on issues that are outside the common knowledge of laymen.")(citing *Mazda Motor Corp. v. Lindahl*, 706 A.2d 526, 533 (Del. 1998).

[50] On the opposite end of the spectrum, Dr. Soffer does not have any first-hand experience with injuring the bladder (or ureter) during the procedure Dr. Maynard

argument ignores the purpose of medical expert testimony, as recognized by the General Assembly, which is that, subject to the exceptions in the statute, the standard of good practice and reasonable care applicable to a healthcare provider are not within the common knowledge of a layperson.

Moreover, such evidence would be impermissible if used at trial in an attempt to establish liability against Defendants. D.R.E. 702. It invites an inappropriate inference that just because two experts in this case have not encountered this particular complication, Dr. Maynard must have deviated from the standard of care because this surgery ended in a bad result. This would be an improper measure for the standard of care or basis for a jury to determine any breach of it in this case by Dr. Maynard.[51] Nor does it cure the failure of Dr. Soffer to articulate, as an expert, what standards are required and how those were not met in this case, using accepted practices and data in the medical community.

Under the same rationale, it is equally improper and irrelevant to infer that because Dr. Stepp (Defendants other expert) intraoperatively discovered the injury he caused, Dr. Maynard would be required to do the same.[52] The question

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performed, and thus, no personal experience with detecting it or not. (B 195) (Discv. Dep. Tr. of Dr. Soffer) (46).

[51] *See Timblin* at 1026 (improper statistical evidence offered through testimony of Defendants' medical expert reversible error).

[52] Opening Br., at 16 (Obron) and 18 (Stepp).

confronted by the Court below was whether the Plaintiff proffered admissible evidence from her expert, Dr. Soffer, as to the standard of care applicable to Defendant for the procedure and a deviation of it by the Defendant.[53] As the Plaintiff proffered no admissible expert evidence on these fundamental elements of her cause of action, she could not prove negligence by Defendants, as a matter of law.[54]

3. The Delaware Medical Negligence Act requires that, in the absence of several exceptions which are not applicable to this case, a plaintiff's claim for medical negligence ***must*** be supported by medical expert testimony.

Plaintiffs' attempts to circumvent the evidentiary requirements of *Daubert* as one involving "basic surgical technique" is an attempt to carve out an exception contrary to clear legislative intent. *See Robinson v. Mroz*, 433 A.2d 1051, 1056 (Del. 1981) ("The need for expert medical testimony upon which to posit liability in a medical malpractice action had been clearly established under Delaware case law prior to the [enactment of the Act]") (citing *Christian v. Wilmington Gen. Hosp. Ass'n*, 135 A.2d 727) (Del. 1957). In *Robinson*, this Court aptly found that the Act "particularized the need for expert medical testimony and defined those

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[53] *Timblin v. Kent Gen. Hosp.*, 640 A.2d 1021, (Del. 1994) ("a plaintiff cannot use evidence that a medical procedure has an unusual outcome to create an inference that the proper standard of care was not exercised").

[54] *O'Donald*, 2004 WL 1965034, at * 2 ("Without expert medical testimony as to breach of standard of care and causation, the plaintiff cannot prevail." *Id.*) (citing *Burkhart v. Davies*, 602 A.2d 56; 18 *Del C.* § 6853).

cases in which a rebuttable inference of negligence could arise without it." *Robinson*, 433 A.2d at 1057. It also runs counter to settled precedent.[55]

Plaintiff fails to offer any authoritative support or point to any textual ambiguity for the Court to read in a "common knowledge" or "basic technique" exception under the plain language of the Act.[56] Moreover, the General Assembly was capable of providing a mechanism for "obvious liability" where no expert testimony is required and the jury may infer negligence as it did for three limited scenarios.[57]

Under recognized principles of statutory construction, the legislature's silence on an exception for surgical technique must be deemed purposeful.[58]

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[55] *See, e.g., Thomas v. St. Francis Hosp., Inc.*, 447 A.2d 435, 438 (Del 1982) (an inference of negligent medical treatment isn't warranted simply because the patient's care ended with highly unusual results).

[56] *See Coastal Barge Corp. v. Coastal Zone Indus. Control Board*, 492 A.2d 1242 (if a statute is unambiguous, the court's role is "limited to an application of the literal meaning of the words." *Id.* at 1246).

[57] Title 18, Section 6853(e) provides in pertinent part that: a rebuttable inference that personal injury or death was caused by negligence shall arise where evidence is presented that the personal injury or death occurred in any 1 or more of the following circumstances: (1) A foreign object was unintentionally left within the body of the patient following surgery; (2) an explosion or fire originating in substance used in treatment occurred in the course of treatment; or (3) a surgical procedure was performed on the wrong patient or the wrong organ, limb or part of the patient's body. Except as otherwise provided herein, there shall be no inference or presumption of negligence on the part of the health care provider. 18 *Del. C.* § 6853(e).

[58] *Leatherbury v. Greenspun*, 939 A.2d 1284, 1291 (Del. 2007) (applying the maxim expression unius est exclusion alterius and noting that "when provisions are

Rather than address the enumerated exceptions in the Delaware statute governing her cause of action, Plaintiff advances irrelevant arguments about Dr. Soffer's qualifications. Plaintiff cites to no decisional case law or precedent in this State, procedural rule or textual ambiguous language in arguing that this Court should treat the standard of care as one unhinged from the evidentiary burden imposed by statute and encapsulated in the common knowledge of a layperson, i.e. as a "non-expert matter".

Because Plaintiff could not proffer any evidence to define the standard of care, or articulate how it was breached by Dr. Maynard, no reasonable jury could find in favor of Plaintiff on negligence under a fair reading of the record as Plaintiff failed to adduce any expert testimony that Dr. Maynard deviated from the standard of care in performing surgery on Norman.[59]

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expressly included in one statute but omitted from another, we must conclude that the General Assembly intended to make these omissions").

[59] *Carney v. Preston*, 683 A.2d 47, 55-56 (Del. Super. Ct. 1996) ("A factual determination beyond the limits of reasonable judgment is at law a question of law.").

III. THE COURT REASONABLY CONCLUDED THAT SOFFER'S TESTIMONY FAILED TO SATISFY D.R.E. 702 AND *DAUBERT.*

A. Question Presented

Was the Court's decision barring Dr. Soffer under D.R.E. 702 from giving expert testimony after considering the record briefs, and argument of the parties arbitrary or capricious?

Defendants preserved this issue in their Motion for Summary Judgment (B 225-351), Motion *in Limine*, (B 389-437), supplemental briefing (B 565-566), in the Pre-Trial Stipulation and Order (B 567-601) and at oral argument (B 606-635).

B. Scope of Review

Appellate review of the decision to exclude expert testimony concerns a determination committed to the trial judge's sound discretion.[60] The trial judge's decision must stand unless appellant demonstrates that it was arbitrary or capricious.[61]

C. Merits of Argument

As the gatekeeper, the trial judge sits in the best position to decide whether an expert's testimony should be admitted. Appellant provides no evidence that

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[60] *Chavin v. Cope,* 243 A.2d 694, 695 (Del. 1968); *M.G. Bancorporation, Inc. v. LeBeu,* 737 A.2d 513 (Del 1999).

[61] *Levine v. Smith,* 591 A.2d 194, 203 (Del. 1991); *Goodridge v. Hyster Co.*, 845 A.2d 498 (Del. 2004).

supports an inference that bladder perforations occur only through negligence, nor that the perforation would have been apparent upon reasonable and careful inspection of the visual filed.

1. The standard of care testimony was properly subject to *Daubert* review.

In order for Dr. Soffer's testimony to be admitted, D.R.E. 702 requires that the expert's "testimony is based upon sufficient facts or data, the testimony is the product of reliable principles and methods, and the witness has applied the principles and methods reliably to the facts of the case." Without an articulable reason explaining why, Appellant claims the trial judge erred in excluding this expert testimony. We must, on appeal, defer to the expertise of the trial judge as gatekeeper.[62] Moreover, Dr. Soffer could not explain how he knew Dr. Maynard used bad technique or was not paying attention during the procedure other than the circuitous argument that she must have been, given that she injured the bladder.[63]

2. Plaintiff failed to proffer any proof of a reliable methodology.

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[62] *See M.G. Bankcorporation v. LeBeau*, 737 A.2d 513, 522 (Del 1999) (both an expert's methodology and ultimate conclusion must be reliable).

[63] *In re TMI Litigation*, 193 F.3d 613, 669 (3d Cir. 1999) (to be reliable, proffered testimony "must be based on the methods and procedures of science, rather than subjective belief or speculation."). *See, e.g., Anderson v. ATMI, Inc.*, 2014 WL 603254 (Del. Super. Ct. Feb. 5, 2014) (experts' opinions that patient experienced excessive oxidative stress because she developed preeclampsia, which itself is a demonstration of excessive oxidative stress are inadmissible).

The proponent of the proffered expert testimony has the burden of showing its relevance, reliability and admissibility by a preponderance of the evidence.[64] Delaware Rule of Evidence 702 imposes a special obligation upon a trial judge to ensure both the relevance and reliability of expert testimony.[65] The Superior Court must therefore decide if a preferred expert's testimony "has a reliable basis in the knowledge and experience of [the relevant] discipline." *Id.* at 523. An expert's analysis must be reliable at every step and "any step that renders the analysis unreliable under the *Daubert* factors *renders the experts testimony inadmissible.*" *Amorgianos Nat'l R.R. Passenger Corp.*, 303 F.3d 256 at 267 (2002) (emphasis in original) (quoting *In re Paola R.R. Yard PCB Litig.*, 35 F.3d 717, at 745) (10th Cir (Kan) 1994). Moreover, the Court would be within its discretion to consider some factors of reliability pertinent, and others not applicable. [66]

The lower Court's rationale was appropriately guided by the settled directives of *Daubert v. Merrell Dow Pharm, Inc.*, [67] *Kuhmo Tire v. Carmichael* [68]

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[64] *Hart v. Resort Investigation & Patrol*, 2004 WL 2050511 (Del. Super. Sept. 9, 2004).
[65] *See M.G. Bancorporation, Inc.*, 737 A.2d at 521.
[66] *Daubert* identified several factors that the trial court should consider, including "testing, peer review, error rates, and 'acceptability' in the relevant scientific community . . .". 509 U.S. 579 (1993). A trial court has "broad latitude" to determine whether any or all of the Daubert factors are "reasonable measures of reliability . . ." in a particular case. *Id.* at 589.
[67] 509 U.S. 579 (1993) (hereinafter "Daubert")
[68] 526 U.S. 137 (1999)

and its progeny in this state. The Court's scrutiny of the proffered testimony included a thoughtful review of his deposition testimony in its entirety, his report, Plaintiffs' expert designation statement and disclosures, extensive briefing by both sides, arguments and law advanced at oral argument at two separate hearings, and positions advanced by counsel at the Pre-Trial Conference, and letter supplements thereafter.

Thus, notwithstanding his own clinical inexperience with a perforation to the bladder (B 195), or any organ, during laparoscopy, his knowledge of literature on other medical providers performing the same procedure leading to a bladder perforation that is not detected intraoperatively (B 218) and his agreement at least some of these providers were not negligent, (B 219-220) Dr. Soffer concludes causing a perforation and not detecting it is negligence in this case. In the absence of any supportive data or literature in the medical community and in the case of a known complication occurring, it was all the more incumbent on Dr. Soffer to articulate a logical, and deductive process as to how Dr. Maynard breached the standard of care.

In other words, once he concedes that an injury can occur and go undetected absent negligence, it was incumbent on him to distinguish why he believes it was negligent in this case. In attempting to do so, he failed to cite to any medical record, deposition testimony, scientific support or any tangible/intangible basis for

his belief. Rather, he falls back on the proposition that a deviation occurred because there was an injury. "[S]o that speaks for itself." (B 182). Such opinions were appropriately found by the trial Court insufficiently reliable to pass through the *Daubert* filter.

3. Dr. Soffer's *ipse dixit* rationale was insufficient to allow it into evidence under D.R.E. 702.

Dr. Soffer could not identify any supportable facts in the record whether it was Mrs. Norman's medical records, the parties' deposition testimony or documents procured during discovery. His proffered testimony that Dr. Maynard had sloppy technique and didn't give due attention prior to suturing the patient is based on his subjective belief due to his own personal experience in never causing any injury during this procedure, rather than a methodology, peer reviewed publications or data.[69] Conclusory opinions such as Dr. Soffer's are too speculative to meet the evidentiary standard set by *Daubert* and its Delaware progeny.

Although repeatedly pressed to do so at his deposition, Dr. Soffer was unable to articulate a reliable methodology or principles employed to reach his

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[69] See, e.g. *State v. Wright*, 2009 WL 3111047(Del. Super. Sept. 14, 2009) (proposed expert opinion in sufficiently reliable); *Sturgis v. Bayside Health Assoc. Chartered*, 942 A.2d 579 (Del. 2007) (affirming ruling there was insufficient support in the peer reviewed literature for opinion of mother's expert where mother proffered no verifiable scientific evidence supporting the conclusion of her expert).

opinion on how Dr. Maynard breached the standard of care. His rationale stated at his deposition was mere *ipse dixit* based on an injury occurring, which is insufficient under *Daubert*.[70] As in *Tumlinson v. Advanced Micro Devices, Inc.*, 81 A.3d 1264 (Del. 2013), the trial Court excluded the medical witness opinion as unreliable because it (1) lacked the specificity required under *Daubert's* "testability" factor; (2) was without indicia of reliability because it was formed solely for litigation; and (3) could not be explained or expounded upon with any detail as to what methodology was employed, if any.[71] Defendants were entitled to summary dismissal of Plaintiffs medical negligence claims because she could not reliably establish a breach in the standard of care or causation through the testimony of her proffered expert, which was a prerequisite to proving her case pursuant 18 *Del. C.* § 6853.

Counterstatement

Appellant does not attack the sufficiency, comprehensiveness or care with which the lower court analyzed Plaintiff's proffer of evidence nor Defendants' application to exclude her expert opinions on the standard of care. Appellant likewise takes no issue with the Court's consideration of the record in concluding

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[70] See *Jones v. Astra Zeneca, LP*, 2010 WL 1267114 (Del. Super. Ct. Mar. 31, 2010).

[71] *Id.* at 1272 (affirming trial Court's exclusion of epidemiologist testimony as unreliable under *Daubert*).

the evidence was inadmissible. Rather, Appellant argues the trial court committed legal error because *Daubert* does not apply to this case and as a result, the unchallenged qualifications of Dr. Soffer mandate that his standard of care opinions be put before the jury.

Appellant offers no legal authority for the proposition that *Daubert* applies only to junk science cases.[72] The caselaw is legion that *Daubert* is the standard governing admissibility of expert evidence in Delaware and should guide the courts analysis of whether the expert's testimony D.R.E. 702. In essence, Appellant asks this Court to hold that an expert's qualifications renders his testimony inherently reliable, without exception and proper consideration for a jury. Not only does this outcome shift the burden of proof on to a non-proffering party (in challenging the evidence on some other grounds), it is manifestly unjust given the deference and weight jurors afford to testimony from someone who is an expert. Settled precedent requires this Court reject Appellant's request to carve out an exception for her burden of affirmative proof and lower the threshold for admissible expert evidence.

[72] Moreover, such a position is at odds with the authority Appellant advances in this appeal. *See, e.g.* Opening Br. at 14, citing to *Seifert v. Balink*, 372 Wis.2d 525 (Wis. 2007) (addressing Daubert for the first time on physician's appeal of lower courts denial of request to exclude expert).

CONCLUSION

In conclusion, the Superior Court's well considered exclusion of Plaintiff's proffered expert upon application of the framework of *Daubert v. Merrell Pharmaceuticals, Inc.* 509 U.S. 579 (1993) and analysis of D.R.E. 702 with the complete record before it, was free from legal error and supported by the evidence. Dr. Soffer's anecdotal opinions were inherently unreliable due to a lack of deductive process, inability to articulate methods for distinguishing his conclusions on this case from admitted non-negligence cases with the same outcome, or offer any support for his conclusions with data or literature that are generally accepted in the medical community.

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