



IN THE SUPREME COURT OF THE STATE OF DELAWARE

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

APPELLANT'S REPLY BRIEF

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RESTATEMENT OF FACTS

Defendants' filings in this litigation have continually failed to provide Dr. Soffer's relevant testimony. Dr. Soffer testified Ms. Norman's injury was caused by the secondary trocar being inserted too forcefully.¹ Dr. Soffer testified his opinion was further reinforced after Dr. Woo, who repaired Ms. Norman's bladder injury, indicated that the perforation was able to be sewn without excising any tissue,² thereby making a thermal injury to the bladder unlikely.

Defendants argue Dr. Soffer could not point to anything in Defendant Maynard's operative records indicating she used improper surgical technique. Since Defendant Maynard failed to appreciate injuring Ms. Norman's bladder, she had no reason to document causing injury to the bladder. Defendant Maynard erroneously thought her surgery was uneventful. Her records do establish that she failed to appreciate and treat the bladder injury her surgical technique caused. Nevertheless, Defendants assert, "There's no information in Dr. Maynard's operative report that leads you to your basis that she used sloppy surgical technique, right?"³ Dr. Soffer answered, "Well, of course not. No one is going to write in their report that they used sloppy surgical technique. That's silly. She is

¹ AR-3.

² AR-3.

³ AR-7.

not going to imply that either.”⁴ Dr. Soffer went on to testify that a surgeon is able to see a patient’s bladder has been perforated because there is a hole, and sometimes bleeding, and sometimes leakage of urine.⁵ “That is the key. You have to look at these structures and look carefully to make sure you are not missing anything after the case is finished.”⁶ “After surgery, as I mentioned in my report, you are supposed to take a very meticulous look at all adjacent structures to make sure there’s no injury. Defendant Maynard’s operative note makes no mention of an inspection of the bladder, though other structures are identified.⁷ Defendant Maynard testified she did not believe she was anywhere near the bladder.⁸

After Dr. Soffer opined Ms. Norman’s bladder injury was the result of too forceful an entry with the secondary trocar⁹, Defendants’ counsel engaged in a game of semantics with Dr. Soffer. Counsel asked, “The sole basis for your opinions that Dr. Maynard used sloppy, to use your words, surgical technique, is the fact that an injury occurred.” Dr. Soffer answered, “Yes.”¹⁰ However, later in the deposition, Dr. Soffer was asked, “So there’s three things Maynard missed. The actual perf itself by looking at it and seeing a hole in the bladder, the blood

⁴ AR-7.

⁵ AR-5.

⁶ AR-5.

⁷ A-20 – A-22.

⁸ A-55.

⁹ AR-3.

¹⁰AR-6.

that would have been secondary to the perforation, and the urine, correct?” Dr. Soffer answered, the perforation occurred with the secondary trocar. Dr. Maynard and anyone doing laparoscopic surgery knows that the secondary trocars are put in under direct visualization. It is the job of the surgeon to watch every centimeter of that entry of that secondary trocar into the abdomen with care not to injure the bladder. That’s why you are doing it under what we call direct visualization. So you can direct that trocar in different directions to avoid bowel and to avoid the bladder.¹¹ At the end of his deposition, Dr. Soffer testified, “...there are certain circumstances where things occur and there’s no malpractice involved. On the other hand, there are injuries that occur like this one, where I believe there was malpractice involved.”¹²

¹¹ AR-8.

¹² AR-9.

ARGUMENT I

DR. SOFFER'S TESTIMONY PROVIDES SUFFICIENT EVIDENCE OF THE STANDARD OF CARE, AND DEFENDANT MAYNARD'S BREACH OF THAT STANDARD, TO CREATE A GENUINE ISSUE OF MATERIAL FACT ON THE QUESTION OF MEDICAL NEGLIGENCE.

Lacking medical evidence of record, the trial court erred when it ruled Dr. Soffer's expert testimony unreliable and inadmissible. Dr. Soffer opined in his deposition testimony, and his expert report, that Dr. Maynard utilized improper surgical technique during a laparoscopic procedure under direct visualization by inserting the left-sided secondary trocar too forcefully¹³, and further, failed to recognize the injury she caused before completion of the surgery.

Defendants' Answering Brief is written on the premise that Plaintiff wants the Court, and ultimately the jury, to infer negligence without any basis other than an injury occurred. Defendants make this argument by attempting to lock Dr. Soffer into a semantical straight jacket. Viewing Defendants' Statement of Facts and Arguments in their Answering Brief, it is clear they ignore pertinent parts of Dr. Soffer's opinions.

This Court's decision in *Balan v. Horner*¹⁴ rejects the Defendants' arguments. In *Balan* the defendants appealed an unfavorable verdict involving

¹³ AR-3.

¹⁴ 706 A.2d 518 (Del. 1998).

injury caused by a secondary trocar that damaged a major artery. The *Balan* defendant argued legal error occurred when the trial court refused to strike the Plaintiff's standard of care medical expert's testimony regarding the breach of the standard of care since the opinion allegedly was based only on the fact the plaintiff was injured during the surgery. This Court rejected this argument and found Plaintiff's expert provided sufficient evidence of a breach of the standard of care because the defendant was negligent in the way he inserted the secondary trocar.

In particular, the medical expert in *Balan* testified that, '[I do] not know exactly where Balan put [the secondary trocar]. But I can say that he put it in the wrong place.' 'I know it was done incorrectly or we would not be here...' This expert also testified that, on rare occasions, the insertion of the initial trocar causes an injury, but that he has neither experienced nor read about a case where the insertion of a secondary trocar damaged a major artery. On cross-examination, this expert admitted that he did not know where Balan inserted or aimed the secondary trocar.

While this Court noted, "It is settled law that 'a plaintiff cannot use evidence that a medical procedure had an unusual outcome to create an inference that the proper standard of care was not exercised,'" ¹⁵ the Court rejected *Balan's* argument that the Plaintiff's expert was attempting to do just that since he did not know any

¹⁵ *Id.* at 521.

of the details of how or where the secondary trocar was inserted, and he was unable to state how *Balan* purportedly deviated from the applicable standard of care. Thus, the expert was merely opining that *Balan* was negligent simply because of the unusual outcome.

In rejecting this argument, this Court stated:

“In advancing this argument, Balan misconstrues [plaintiff’s expert’s] testimony. While it is true that Levinson did not know exactly where or how the second trocar was inserted, that information was not critical to his analysis.”¹⁶

“[The plaintiff’s expert] opined that, ‘once the first trocar was successfully inserted, Balan was operating under direct vision, and should have been able to control the second trocar as accurately as if Balan were performing open surgery.’ ‘Since a careful surgeon could have avoided puncturing the iliac artery, Balan’s failure to do so constituted a deviation from the applicable standard of care.’ In sum, [the plaintiff’s expert] opinion was based on his analysis of the circumstances of this case, not mere speculation over the cause of a bad result.”¹⁷

The *Balan* defendant’s rejected arguments are basically indistinguishable from the Defendants’ arguments in the present matter. Thus, Ms. Norman seeks a similar ruling in her case. Dr. Soffer’s opinions are based on his analysis of the circumstances of the case, not mere speculation over the cause of a bad result. Dr. Soffer testified that the perforation occurred with the secondary trocar. “Dr. Maynard and anyone doing laparoscopic surgery knows that the secondary trocars are put in under direct visualization. It is the job of the surgeon to watch every

¹⁶ *Id.*

¹⁷ *Id.*

centimeter of that entry of that secondary trocar into the abdomen with care not to injure the bladder. That's why you are doing it under what we call direct visualization. So you can direct that trocar in different directions to avoid bowel and to avoid the bladder.”¹⁸ This testimony supports Dr. Soffer's opinion that Defendant Maynard's breach of the standard of care caused injury to Ms. Norman's bladder.

In *Green v. Weiner*,¹⁹ survivors of a deceased patient brought suit against a surgeon after he performed a pacemaker implant procedure. The Green plaintiffs alleged that the surgeon's negligent removal of a guidewire caused the patient's death. The trial court granted the Green defendant's motion for summary judgment because the expert could not testify live at trial. This Court reversed and remanded because Plaintiffs' expert's report and deposition without live testimony provided sufficient evidence to establish a breach of the standard of care, and the plaintiffs were not required to provide uncontradicted evidence.²⁰ Rather, this Court ruled:

“...the *Greens* must provide credible evidence of each of these elements from which a reasonable jury could find in their favor.” “So long as Dr. Kahn's testimony provides this minimal evidence, any inconsistencies in Dr. Kahn's testimony must be resolved by a jury and are thus irrelevant for purposes of ruling on a motion for judgment as a matter of law.”²¹

¹⁸ AR-8.

¹⁹ 766 A.2d 492 (Del. 2001).

²⁰ *Id.* at 495.

²¹ *Id.* at 495-96.

Particularly apt to Ms. Norman’s claim, this Court held:

“During his deposition, Dr. Kahn also testified that he had ‘no other way of explaining [the rip in Green’s vein] other than that an operator dependent vascular injury occurred and in my view should have been recognized or anticipated and as a result possibly and probably avoided.’”²² “Although Dr. Weiner argues that such inferences would amount to impermissible speculation by Dr. Kahn, we find that Dr. Kahn’s ‘opinion was based on his analysis of the circumstances of this case, not mere speculation over the cause of a bad result.’”²³ “Any contention that Dr. Kahn was speculating would go to the weight of the evidence and thus presents a jury question.”²⁴

Again, in rejecting the type of arguments being made by the Defendants, this Court held in *Green* that a jury could reasonably infer the applicable standard of care required applying a degree of force sufficient to remove the wire without seriously damaging the patient’s blood vessel. A jury could reasonably infer that Dr. Weiner breached this standard of care by applying ‘considerable force’ to withdraw the guidewire from Green’s vein.²⁵ Such findings from the expert’s opinion raise an issue of material fact with respect to all of the elements of a medical malpractice claim under 18 *Del. C.* § 6853 for the jury to resolve.²⁶ The *Balan* and *Green* rulings demonstrate that issues of visualization and appropriate

²² *Green*, 766 A.2d at 496.

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.*

force can form the basis for finding one's surgical technique to breach the applicable standard of care which is what Dr. Soffer found in the present matter.

In *McCusker v. Surgical Monitoring Assocs.*,²⁷ the Court held that a medical expert's testimony that a bone was driven into the patient's spinal canal, as a result of back surgery, was sufficient under 18 *Del. C.* § 6853(e) to allow a reasonable jury to conclude that a surgeon had breached the applicable standard of care, even though the expert could not specifically say how the injury occurred. Before the Court was a Motion for Judgment as a Matter of Law, and the Court held, reading both components of an expert's opinion together, it satisfied the minimal evidentiary standards of 18 *Del. C.* § 6853 as the expert identified the standard of care and opined that the medical center deviated from it. "It may have been preferable for [plaintiff's expert] to have concisely summed up her testimony in language akin to that found in the Act and customary to lawyers practicing in the field of medical negligence, but the legal standard 'does not require medical experts to couch their opinions in legal terms or to articulate the standard of care with a high degree of legal precision or with 'magic words.'"²⁸ "There was enough in the record for rational jurors to conclude, as the jury did in this case, that they believed [plaintiff's expert] and disbelieved the defendant's experts as to the cause

²⁷ CA No. 01-891 KAJ, 2005 U.S. Dist. LEXIS 7298 (D. Del. Feb. 7, 2005).

²⁸ *McCusker* at *19, citing *Green* at 495.

of the Plaintiff's injuries."²⁹ "Whether or not I or anyone else disagrees with that assessment is immaterial. It is supported by a sufficient evidentiary basis to withstand both the motion for judgment as a matter of law and the motion for a new trial."³⁰

"Under 18 *Del. C.* § 6853, a party alleging medical malpractice must produce expert medical testimony that specifies (1) the applicable standard of care, (2) the alleged deviation from that standard, and (3) the causal link between the deviation and the alleged injury."³¹ Dr. Soffer's report and deposition satisfy this evidentiary requirement. His opinion supports the premise that, with the exercise of reasonable care and diligence,³² Ms. Norman's outcome could and should have been avoided with the appreciation of the visualized operative field and application of appropriate force in placing a secondary trocar. Defendants ignore the part of Dr. Soffer's deposition where he explicitly states his opinion that the secondary trocar caused injury when it was inserted too forcefully under direct visualization.³³ Instead, Defendants argue there was, "nothing in either the medical records nor deposition testimony to support his contention that Dr. Maynard was inattentive

²⁹ *McCusker* at *19.

³⁰ *McCusker* at *19.

³¹ *Green v. Weiner*, 766 A.2d 492, 494-95 (Del. 2001).

³² 18 *Del. C.* § 6801 (7).

³³ AR-3.

during the surgery or used poor technique.”³⁴ Defendants’ medical records argument lacks credibility. Dr. Maynard had no knowledge that she injured Ms. Norman’s bladder. Without such knowledge, no reasonable person would expect her records to reflect an injury to the bladder. Further, with visualization, the unknowing striking and injuring the bladder at a minimum constitutes inattentiveness.

After Dr. Soffer opined the injury was the result of too forceful an entry with the secondary trocar³⁵, a semantical skirmish ensued with defense counsel. Defendants asked, “The sole basis for your opinions that Dr. Maynard used sloppy, to use your words, surgical technique, is the fact that an injury occurred.” Dr. Soffer answered, “Yes.”³⁶ Later in the deposition, Dr. Soffer was asked, “So there’s three things Maynard missed. The actual perf itself by looking at it and seeing a hole in the bladder, the blood that would have been secondary to the perforation, and the urine, correct?” Dr. Soffer answered, the perforation occurred with the secondary trocar. Dr. Maynard and anyone doing laparoscopic surgery knows that the secondary trocars are put in under direct visualization. It is the job of the surgeon to watch every centimeter of that entry of that secondary trocar into the abdomen with care not to injure the bladder. That’s why you are doing it under

³⁴ See Ans. Br. p. 14.

³⁵ AR-3.

³⁶ AR-7.

what we call direct visualization. So you can direct that trocar in different directions to avoid bowel and to avoid the bladder.³⁷ At the end of the deposition, Dr. Soffer testified that ...”there are certain circumstances where things occur and there’s no malpractice involved. On the other hand, there are injuries that occur like this one, where I believe there was malpractice involved.”³⁸ Looking at the deposition in its entirety, it is clear that Dr. Soffer’s opinion is reliable and meets the applicable expert witness testimony threshold of admissibility to establish a *prima facie* claim of medical negligence.

Defendants allege that Plaintiff wants this Court and ultimately a jury, to ‘infer negligence’ without any basis other than the occurrence of an injury. This assertion is unfounded. Rather, a review of Dr. Soffer’s opinion establishes, consistent with the holdings in *Balan* and *Green*, that it meets the requirements of 18 *Del. C.* § 6853 in establishing a reliable breach of the standard of care by Defendant Maynard which caused injury to Ms. Norman. Defendants utilize case law stating that jurors are instructed that no negligence should be presumed from the fact that there is an injury. However, Dr. Soffer’s opinion is not so limited. Dr. Soffer opined that Dr. Maynard inserted the secondary trocar under direct visualization and too forcefully, causing Ms. Norman’s bladder injury. This is

³⁷ AR-8.

³⁸ AR-9.

sufficient evidence for a jury to find Defendant Maynard breached the applicable standard of care which caused injury to Ms. Norman.

Defendants argue that Dr. Soffer's opinions are inherently unreliable due to a lack of deductive process. Yet, Defendants ignore Dr. Soffer's opinion that secondary "trocars are directly in the line of the dome of the bladder. If you push the trocars in too far and you are a little too forceful with your entry, the trocar will go directly into the dome of the bladder,³⁹ the region of Ms. Norman's injury.⁴⁰ "And I believe, unfortunately, that is what happened here. Most likely the left-sided trocar that was introduced."⁴¹ Dr. Soffer further noted, "I think what reinforces that even more, this being a trocar injury, as opposed a laser or cautery injury, is that Dr. Woo does not describe any cautery like effects in the perforations. He closed it directly without excising tissue.⁴² Usually if you go in and see a cautery effect or laser effect, like a burn, you excise the burned tissue and put together fresh, clean edges."⁴³ Dr. Woo said he didn't do that. He said we went in, we identified the perforation and directly sewed them doing so without

³⁹ AR-3.

⁴⁰ AR-11 (Pg. 29).

⁴¹ AR-3.

⁴² AR-12 – AR-13.

⁴³ AR-3.

excising any tissue. This reinforces that this was a trocar injury and not related to one of the other instruments.⁴⁴

Defendants brought a *Daubert* challenge basically on the issue of reliability, yet they failed to present any accepted medical findings that reject the opinion of Dr. Soffer as a matter of medical science. For example, Defendants did not challenge Dr. Soffer's experience in more than 200 laparoscopic procedures in which a bladder injury never occurred. Indeed, Defendants could not contradict Dr. Soffer's experience since Defendants' own experts, Dr. Obron and Dr. Stepp had similar experiences in over a thousand laparoscopic procedures.⁴⁵ Defendants did not bring their experts' similar experiences to the trial court's attention.

Defendants allege in their Answering Brief that Dr. Soffer testified that an injury can occur absent negligence.⁴⁶ Defendants asked this as a generalized statement, without relating it to Defendant Maynard's procedure or any hypothetical medical condition. Yet, Dr. Soffer's acceptance of this generalized statement is consistent with the law which recognizes an injury can occur during medical treatment without medically negligent conduct being involved.

Regarding Defendant Maynard's failure to detect the bladder injury she caused, Dr. Soffer testified that a surgeon is able to detect a perforation to a

⁴⁴ AR-4.

⁴⁵ A-43; A-46.

⁴⁶ Ans. Br. p.5.

patient's bladder because there is a hole, and sometimes bleeding, and sometimes leakage of urine.⁴⁷ "That is the key. You have to look at these structures and look carefully to make sure you are not missing anything after the case is finished."⁴⁸ "After surgery, as I mentioned in my report, you are supposed to take a very meticulous look at all adjacent structures to make sure there's no injury." It is undisputed that Defendant Maynard failed to discover the bladder injury she caused which Dr. Soffer opined was also a breach of the applicable standard of care. Dr. Soffer opined that Dr. Maynard did not carefully look at the operative field before concluding the surgery. This is supported by Defendant Maynard's operative report which makes no mention of examining the bladder while it does identify other examined anatomical structures.⁴⁹ It is also supported by Maynard's admission that she believed the bladder was nowhere near the operative field.⁵⁰

Defendants assert that Dr. Soffer's testimony is not reliable because he stated that because there was an injury, there was negligence, this is inaccurate. Rather, Dr. Soffer testified, similar to the doctors' testimony in *Balan* and *Green*, that Defendant Maynard was able to visualize the surgical field during Ms. Norman's diagnostic laparoscopy, it was not a blind procedure and he opined that the injury was likely caused by Dr. Maynard inserting the left-sided secondary

⁴⁷ AR-5.

⁴⁸ AR-5.

⁴⁹ A-20 – A-22.

⁵⁰ A-55.

trocar too forcefully. Dr. Soffer's opinion was based on the circumstances of the procedure. Dr. Maynard had visualization of the surgical field, should have appreciated the bladder's location, should not have perforated it with a secondary trocar and should have discovered the injury she caused. Under these circumstances, Defendant Maynard's surgical techniques deviated from the applicable standard of care as stated by Dr. Soffer. Dr. Soffer's opinion is admissible, as his opinion is reliable and is a reasonable explanation of the applicable standard of care and how Defendant Maynard breached this standard of care which caused injury to Ms. Norman. The trial court's decision to exclude Dr. Soffer's testimony was legally erroneous and should be reversed. Such a reversal also renders the trial court's Summary Judgment of Dismissal erroneous and reversible.

CONCLUSION

For the aforesaid reasons, and the reasons set forth in Plaintiff's Opening Brief, the Superior Court's Order precluding the testimony of Dr. Soffer at trial should be reversed and the Superior Court's Order granting summary judgment to Defendants also should be reversed.

Respectfully submitted,

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