2019 PA Super 287

MARGARET ENGLEMAN	:	IN THE SUPERIOR COURT OF
	:	PENNSYLVANIA
	:	
v.	:	
	:	
	:	
ETHICON, INC., AND JOHNSON AND JOHNSON,	:	
	:	
	:	No. 3320 EDA 2017
Appellants	:	

Appeal from the Judgment Entered September 12, 2017
In the Court of Common Pleas of Philadelphia County Civil Division at
No(s): March Term, 2014 - No. 05384

MARGARET ENGLEMAN	:	IN THE SUPERIOR COURT OF
	:	PENNSYLVANIA
Appellant	:	
	:	
	:	
v.	:	
	:	
	:	
ETHICON, INC. AND JOHNSON & JOHNSON	:	No. 3400 EDA 2017
	:	

Appeal from the Judgment Entered September 12, 2017
In the Court of Common Pleas of Philadelphia County Civil Division at
No(s): 05384

BEFORE: PANELLA, J., DUBOW, J., and KUNSELMAN, J.

DISSENTING STATEMENT BY DUBOW, J.: **FILED SEPTEMBER 20, 2019**

I respectfully dissent from the Majority's decision to affirm the trial court. In light of numerous evidentiary errors that the trial court made, I would reverse the judgment and order a new trial.

In June 2007, Dr. Bolton implanted into Appellee TVT-Secur, a vaginal mesh, to alleviate Appellee's symptoms associated with Stress Urinary

Incontinence. A month after the surgery, Appellee experienced vaginal pain and a return of urinary incontinence. Appellee went back to Dr. Bolton, and three months later, in September 2007, Dr. Bolton surgically removed two pieces of the exposed vaginal mesh.

Appellee continued to suffer pain, and her incontinence increased, so Dr. Bolton referred Appellant to Dr. Joseph Montella. In February 2008, Dr. Montella removed all but approximately three centimeters of the vaginal mesh.

In 2012 and 2013, Appellee's pelvic pain returned, and Appellee's new gynecologist identified additional erosion in Appellee's vaginal wall. In December 2013, Dr. Montella performed another procedure to remove the remaining mesh. Appellee continued to suffer pain and other significant symptoms.

In December 2013, Appellee saw advertisements on television describing the symptoms that she was experiencing. Appellee testified that these commercials connected her symptoms to the vaginal mesh. She filed a Complaint within two years of viewing the commercials, in October 2014.

On April 12, 2017, the parties tried the case before a jury, and on April 28, 2017, the jury awarded Appellee $2,500,000 in compensatory damages and $17,500,000 in punitive damages. Appellants timely filed a Post-Trial Motion, which the trial court denied. The trial court entered judgment, and Appellants appealed.

2008 and 2011 FDA Notices

Seven years elapsed between 2007, when Appellee began to suffer symptoms from the implantation of Appellants' vaginal mesh, and 2014, when Appellee filed her Complaint. As a result, a significant issue in the trial was whether the Discovery Rule tolled the Statute of Limitations.

At trial, Appellants attempted to introduce into evidence FDA Notices that the FDA published on its website in 2008 and 2011. The original notice, in its title, states "Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and **Stress Urinary Incontinence**." Exhibit CTX-D—Exhibits in Support of Defendants' Proffer Regarding FDA Evidence, filed 8/30/17, "FDA Public Health Notification," 10/20/08 (emphasis added). The notice describes the nature of the complications, cautioning that the transvaginal mesh was linked to "pain, urinary problems, and recurrence of prolapse and/or incontinence." ***Id.*** "In some cases," according to the FDA, "vaginal scarring and mesh erosion led to a significant decrease in patient quality of life due to discomfort and pain, including dyspareunia." ***Id.***

In 2011, the FDA updated its findings and continued to identify as its target audience health care providers and patients "who are considering or have received a surgical mesh implant to repair . . . **stress urinary incontinence**." Exhibit CTX-D—Exhibits in Support of Defendants' Proffer Regarding FDA Evidence, filed 8/30/17, "FDA Safety Communication," 7/13/11 (emphasis added).

Appellants argued to the trial court that these two notices were relevant to the jury's determination of the Discovery Rule, *i.e.*, whether a reasonable person using due diligence would have discovered a link between her injury and the cause of the injury earlier than Appellee did in this case. The trial court disagreed and precluded the introduction of the 2008 and 2011 FDA Notices on two grounds. First, the trial court found that the notices were not relevant pursuant to Pa.R.E. 402 and 403 because the notices do not "refer to stress urinary incontinence." Trial Ct. Op., 1/32/18, at 42. The trial court also found that the public notices were inadmissible as hearsay. ***Id.*** Both of the court's findings are incorrect.

As an initial matter, the trial court is incorrect about the topic of the notices. Both notices, in fact, refer to Appellee's condition, Stress Urinary Incontinence. The notices specifically target patients who suffer from Appellee's condition, and they describe the nature and potential severity of side effects associated with vaginal implantation of surgical mesh.

Also, the trial court erred in concluding that the FDA Notices were inadmissible hearsay. Appellants were not attempting to introduce them for substantive purposes, but rather as evidence that in the public domain was notice of a link between Appellee's symptoms and Appellants' product. In other words, Appellants were attempting to introduce them for purposes of applying the Discovery Rule, *i.e.*, as notice to a reasonable person that there was a link between her symptoms and the vaginal mesh. Because Appellants were attempting to use the FDA Notices to establish "notice," not the facts

contained therein, the trial court erred in concluding that the FDA Notices constituted inadmissible hearsay.

The Majority in this case agrees that the trial court erred in finding that the FDA Notices were hearsay but finds that they were not relevant. The Majority bases its analysis on the conclusion that Appellee "is not expected to self-diagnosis [sic]." Maj. Op. at 14. The Majority relies on ***Nicolaou v. Martin***, 195 A.3d 880 (Pa. 2018), for the proposition that when applying the Discovery Rule, Appellee is "only charged with the knowledge communicated to her by the medical professionals who provided treatment and diagnosis." Maj. Op. at 14. In other words, the Majority concludes that the FDA notices are irrelevant because the statute of limitations does not begin to run until a medical professional provides a plaintiff with information that links the plaintiff's injury to the medical cause of that injury.

To accept the Majority's interpretation of ***Nicolaou*** would result in the limitations period commencing, in any case involving medical causation, only when a medical professional informs a patient of a link between the patient's condition and the cause of the condition. However, the Supreme Court in ***Nicolaou*** specifically rejects the Majority's expansive interpretation of the Discovery Rule. 195 A.3d at 892 ("This Court has recognized that Pennsylvania's formulation of the discovery rule represents a more narrow approach and places a greater burden on plaintiffs[.]"). The Supreme Court notes further that triggering the limitations period only upon "specific medical evidence supporting a cause of action" would represent a "groundbreaking

transformation" in our law. ***Id.*** at 892 n. 14 (deferring any reevaluation of the Discovery Rule to a future case in which the issue is properly preserved).

Moreover, the nature of the claims pursued in ***Nicolaou*** are rather different from this case. ***Nicolaou*** was a medical malpractice case in which several doctors for many years misdiagnosed the plaintiff's condition. In July 2009, a nurse practitioner tentatively gave the plaintiff the correct diagnosis of Lyme Disease and encouraged the plaintiff to undergo a particular test to confirm the diagnosis. The plaintiff waited seven months to undergo the test, receiving confirmation that she had Lyme Disease in February 2010. She filed her malpractice suit within two years of the February 2010 date. The trial court granted the defendants' Motion for Summary Judgment on the grounds that the statute of limitations began to run in July 2009, when the nurse practitioner gave her a tentative diagnosis of Lyme Disease, and had expired by the time the plaintiff filed a Complaint in February 2012.

The issue before the Supreme Court was whether the limitations period commenced when the nurse provided the plaintiff with a tentative diagnosis or when the plaintiff received the test results confirming that diagnosis. The Supreme Court concluded that the commencement of the limitations period and application of the Discovery Rule were questions for the jury and that, therefore, the trial court had erred in granting the defendants summary judgment. ***Id.*** at 894-95.

In this case, Appellee does not assert that doctors misdiagnosed her condition or erred by failing to link Appellee's symptoms to the vaginal mesh.

Further, unlike ***Nicolaou***, no question arises that requires a fact finder to weigh the impact of a tentative medical diagnosis. Therefore, there is no legal basis to defer commencement of the limitations period until a medical professional gave Appellee information linking the vaginal mesh to her symptoms.

In fact, it was a television commercial, publicly-disseminated information, that influenced Appellee to consider a link between the vaginal mesh and her symptoms. Similarly, the FDA Notices were publicly-disseminated information suggesting a link and, thus, relevant for the jury to consider when applying the Discovery Rule.

The Majority also rejects Appellants' argument on the relevancy of the FDA Notices by finding that Appellants are disingenuously arguing that the FDA notices are relevant for the application of the Discovery Rule, but not relevant to establish a product defect. Maj. Op. at 15. The issue, however, is not whether Appellants are disingenuous, but rather whether the trial court erred in precluding the jury from considering the FDA notices when applying the Discovery Rule. The fact that the notices contain information that the jury might also (inappropriately) consider in determining whether the vaginal mesh was defective is irrelevant to the analysis of whether a reasonable person would have discovered the link before Appellee discovered it from the television commercial.

In sum, I conclude that the FDA Notices were relevant evidence for purposes of applying the Discovery Rule and the trial court erred in precluding

them from evidence. The notices caution about a linkage between Appellants' product and symptoms that Appellee suffered. Like the television commercial that informed Appellee about the linkage, the FDA Notices were publicly available. The trial court erred in not allowing the jury to consider them.

Fraudulent Concealment Jury Instruction

The trial court included in its jury instruction about the statute of limitations that "[a]n exception to this also applies if you find that the plaintiff did not file suit within two years because she was intentionally or mistakenly misled by the defendant or the defendant's agents." Trial Ct. Op. at 15. The trial court supports its decision to charge the jury on fraudulent concealment based on the following evidence: "During trial, testimony was elicited that Plaintiff relied upon Defendants' statements in the TVT-Secur brochure, Dr. Bolton's consent form (wherein he documented his discussion of the risks and benefits of the procedure) and Dr. Bolton himself as Plaintiff's learned intermediary. Specifically, Plaintiff testified that Defendants' brochure did not mention erosions or possible need for surgeries to treat complications such as eroded mesh." ***Id.***

A defendant must have committed an affirmative, independent act of concealment upon which the plaintiff justifiably relied for the doctrine of fraudulent concealment to apply. ***Kingston Coal Co. v. Felton Mining Co.***, 690 A.2d 284, 291 (Pa. Super. 1997). "Where, through fraud or concealment, the defendant causes the plaintiff to relax his vigilance or deviate from his right of inquiry, the defendant is estopped from invoking the bar of the statute

of limitations." **Molineux v. Reed,** 532 A.2d 792, 794 (Pa. 1987) (internal quotation marks, citation omitted). The plaintiff must establish fraud or concealment with evidence that is clear, precise, and controlling. ***Id.*** Additionally, "a statute of limitations that is tolled by virtue of fraudulent concealment begins to run when the injured party knows or reasonably should know of his injury and its cause." ***Fine v. Checcio***, 870 A.2d 850, 861 (Pa. 2005).

Generally, this fraudulent act occurs subsequent to the allegedly tortious act claimed by the plaintiff, as it is the defendant's effort to conceal the alleged tort that will toll the limitations period. ***See, e.g.***, ***Kingston Coal Co.***, 690 A.2d at 291 (deeming the fraudulent concealment doctrine irrelevant where defendants took no subsequent actions to dissuade plaintiffs from their right of inquiry). In my view, however, none of the evidence cited by the trial court constitutes subsequent, independent acts by Appellants to conceal their allegedly tortious behavior such that Appellee would relax her vigilance in the face of ongoing post-surgical complications. Moreover, although the trial court suggests that Appellants concealed the risk of erosion from Dr. Bolton, the court fails to identify any specific information known to Appellants at the time of Appellee's surgery that Appellants concealed.[1]

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[1] The Majority, *sua sponte*, argues that Appellants waived this issue because Appellant fails to reference to or quote from any authority. Maj. Op. at 30. I disagree with the Majority's conclusion that Appellants waived the issue. The Appellants sufficiently briefed the issue on pages 26-34 of their appellate Brief.

Admissibility of Studies from Australia

The trial court permitted Appellee to introduce into evidence complaints that Appellants began to receive in Australia about the vaginal mesh, as well as a "quality block" that Appellants placed on the product in September 2007, three months **after** Appellee's doctor implanted the vaginal mesh. Trial Ct. Op. at 45.

The trial court found the evidence relevant to support Appellee's failure to warn and design defect claims under the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1. ***Id*.** In particular, the trial court found that "evidence of the complaints in Australia is relevant to show that [Appellants] were aware of the risks associated with the TVT-Secur, but failed to take action and adequately warn [Appellants'] physicians of these issues." ***Id*** at 46. The trial court fails to consider, however, that physicians in Australia did not complain about the vaginal mesh until September 2007, three months after Dr. Bolton implanted the vaginal mesh. Because this evidence does not imply that Appellants knew about the problems when Appellee had the surgery, this evidence is not relevant to establish Appellee's claims.

Feasability of Alternative Design

I also disagree with the Majority's analysis that Appellants are precluded from challenging the jury's verdict on a design defect claim because Appellants did not challenge the jury's verdict on the failure to warn claim. The Majority concludes that even if the trial court erred regarding its decisions on the design

defect claim, Appellants have not challenged any of the trial court's decisions on Appellee's failure to warn claim, and this claim supports the jury verdict. Maj. Op. at 32.

Appellants, however, challenged the trial court's decision regarding the failure to warn claim. In particular, Appellants challenged the trial court's decision to admit the evidence of the complaints from doctors in Australia even though the doctors did not complain until after Appellee's doctor implanted the vaginal mesh. Statement of Questions Involved, paragraph 4. The trial court found this evidence to be relevant because "evidence of complaints is relevant to [Appellee's] failure to warn and design defect claims under the NJPLA, 2A:58C. Tr. Ct. Op. at p.45-46. Thus, Appellants have challenged an evidentiary ruling of the trial court on Appellee's failure to warn claim, and we must address Appellants' challenges to the trial court's decisions on the design defect claim.

Conclusion

As a result of these erroneous evidentiary rulings, I would reverse the decision of the trial court.