UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
OCALA DIVISION

JOHN ANDREW PANTAGES, JR.,

Plaintiff,

v. Case No. 5:08-cv-116-Oc-GRJ

CARDINAL HEALTH 200, INC., a foreign for-profit corporation, and ALLEGIANCE HEALTHCARE CORPORATION, a foreign for-profit corporation,

Defendant.
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ORDER

Pending before the Court are: (1) Plaintiff's Second Motion for Partial Summary Judgment (Doc. 77); (2) Plaintiff's Fourth Motion for Partial Summary Judgment (Count III of the Third Amended Complaint – Negligent Failure to Warn) (Doc. 106); and (3) Plaintiff's Fifth Motion for Partial Summary Judgment (Count I of the Third Amended Complaint – Strict Liability). (Doc. 108.) Defendant, Cardinal Health 200, Inc., has filed responses in opposition (Docs. 103, 116 & 117) and, therefore, the motions are ripe for review. For the reasons set discussed below, Plaintiff's Second Motion for Partial Summary Judgment (Doc. 77), Plaintiff's Fourth Motion for Partial Summary Judgment (Doc. 106), and Plaintiff's Fifth Motion for Partial Summary Judgment (Doc. 108) are due to be **DENIED**.

I. BACKGROUND AND FACTS

This is a products liability action arising from personal injuries purportedly resulting from a catheter which broke during a surgical procedure known as a

thoracentesis. Defendant, Cardinal Health 200, Inc. ("Cardinal 200") is in the business of manufacturing, designing, packaging, distributing, supplying and selling medical devices including but not limited to the 4341B Thoracentesis Catheter from Lot #L3N243 at issue here (the "Pantages Catheter"). Plaintiff underwent an elective thoracentesis procedure on February 10, 2006 at Munroe Regional Medical Center ("MRMC") and allegedly suffered personal injuries when, during the procedure, the Pantages Catheter broke into pieces as Plaintiff's surgeon, Dr. Amruth Bapatla was attempting to insert it. As a result, Plaintiff had to undergo additional subsequent surgical procedures to remove pieces of the broken catheter that had lodged into Plaintiff's chest cavity.

Prior to manufacturing and distributing Lot #L3N243 of its 4341B Thoracentesis Catheters, Defendant changed the type of plastic used in a component part of the catheters from PVC to PEBAX. Thereafter, and at some point prior to Plaintiff's surgery, Defendant manufactured and distributed Lot #L3N243 to MRMC. Unlike subsequent Lots, none of the catheters in Lot #L3N243 were packaged in an opaque foil pouch. MRMC allegedly stored the 4341B Thoracentesis Catheters—including the Pantages Catheter—in such a manner that the catheters were periodically exposed to ultraviolet ("UV") light up until the time they were used.

II. DISCUSSION

Plaintiff filed the instant motions seeking partial summary judgment with respect to the issue of the "defectiveness of the PEBAX catheter component" as well as to Counts One and Three of Plaintiff's Third Amended Complaint—which each allege that the product was defective because of Defendant's failure to warn. Thus, central to each

of Plaintiff's motions is whether the evidence of record establishes that the Pantages Catheter was "defective" as a matter of law.

Pursuant to Rule 56(c) of the Federal Rules of Civil Procedure, the entry of summary judgment is appropriate only when the Court is satisfied that "there is no genuine issue as to any material fact and that the movant is entitled to a judgment as a matter of law." In applying this standard, the Court must examine the pleadings, depositions, answers to interrogatories, and admissions on file, together with any affidavits and other evidence in the record " in the light most favorable to the nonmoving party."[1]

According to Plaintiff, there is no genuine issue of material fact that exposure of the PEBAX plastic component part of the Pantages Catheter to UV light caused the plastic to lose its flexibility, become brittle, and break during normal use of the product. Plaintiff also argues that this "defect" gave rise to a duty to warn and it is undisputed that Defendant did not provide any warning with regard to the potential effects of UV light on the catheter.

A. Plaintiff's Second Motion for Partial Summary Judgment

In his Second Motion for Partial Summary Judgment, Plaintiff argues that he is entitled to judgment as a matter of law with respect to the "defectiveness of the PEBAX catheter component part" of the Pantages Catheter because he has established a

[1] Samples v. Atlanta, 846 F.2d 1328, 1330 (11th Cir. 1988).

"prima facie case of the Thoracentesis Catheter's defectiveness" pursuant to the holding in *Cassisi v. Maytag Co.*[2]

There is a fundamental problem with Plaintiff's reliance upon *Cassisi* at this stage of the proceedings. In *Cassisi* the Court held that an inference of defect sufficient to send the case to the jury could be created by proof of a probable product malfunction during normal usage coupled with refutation of other causes of the accident.[3] The *Cassisi* inference simply frees a plaintiff from having to disprove all alternative causation theories in order for the case to go to the jury. As such, the *Cassisi* inference merely acts as an aid to the Plaintiff in establishing a *prima facie* case for jury consideration. It does not cast the burden of proof nor the burden of producing evidence upon the defendant. Therefore, where a *Cassisi* inference is appropriate, the inference does not establish defectiveness, as a matter of law, but only permits a Plaintiff to submit the case to the jury to consider the inference when determining whether there is a defect in the product. The bottom line is that simply establishing the applicability of a *Cassisi* inference does not entitle a plaintiff to judgment as a matter of law on summary judgment.

In addition to the fact that the application of a *Cassisi* inference does not entitle the Plaintiff to summary judgment there are also numerous disputed issues of fact with regard to whether the PEBAX component part of the Pantages Catheter was defective. In order for Plaintiff to be entitled to summary judgment, he bears the initial burden of

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[2] 396 So. 2d 1140 (Fla. 1st DCA 1981).

[3] Id.

establishing the nonexistence of a triable issue of fact.[4] On summary judgment, it is not the function of the Court to resolve conflicting views of the evidence. And when viewing the evidence on a motion for summary judgment the Court is required to draw all reasonable inferences in favor of the non-moving party.

Whether the catheters manufactured by Defendant were "defective" is hotly disputed by the parties. Further, there are genuine issues of material fact with respect to causation—an element critical to the issues raised in Plaintiff's Second, Fourth, and Fifth Motions for Partial Summary Judgment.

"Defectiveness" of the PEBAX Component Part of the Pantages Catheter

In a products liability suit against a manufacturer, whether sounding in negligence or strict liability, the plaintiff must show that the product is defective, that the defect existed at the time the product left the manufacturer's possession, and that the product's defect caused the injuries of which Plaintiff complains.[5] A product may be defective by virtue of a defect in its design or manufacture. A product may also be "defective" if, during its normal use, the product poses a particular latent risk to consumers and the manufacturer has not adequately warned consumers of the product's dangerous propensities.[6]

Plaintiff argues that the Pantages Catheter was defective because part of the catheter was made with plastic that was susceptible to breaking upon exposure to UV

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[4] Celotex Corp. v. Catrett, 477 U.S. 317 (1986).

[5] West v. Caterpillar Tractor Co., 336 So. 2d 80, 86-87 (Fla. 1976).

[6] West, 336 So. 2d at 86-87; Ferayorni v. Hyundai Motor Co., 711 So. 2d 1167 (Fla. 4th DCA 1998), Brown v. Glade & Grove Supply, Inc., 647 So. 2d 1033, 1036 (Fla. 4th DCA 1994); Cohen v. Gen. Motors Corp., 427 So. 2d 389 (Fla. 4th DCA 1983).

light. However, aside from Plaintiff's argument that the *Cassisi* inference establishes "defectiveness," the evidence is conflicting as to whether the Pantages Catheter was in fact defective.

In support of his argument that UV light degrades the PEBAX plastic rendering it susceptible to breaking Plaintiff selectively points to evidence suggesting that Defendant had determined UV light to be the "most likely 'root cause'" of brittle catheters. There is conflicting evidence of record, however, on this issue because there is evidence suggesting that Defendant was never able to determine the extent to which UV light impacted the PEBAX plastic. For example, James Larson, a former Cardinal Health employee - and the engineer who participated in the failure investigation Defendant conducted in response to consumer complaints regarding malfunctioning catheters - testified that the fact that a particular material is "sensitive" to UV light is not determinative because all materials are sensitive to UV light to some extent. (James Larson Dep. 30:13-14, Dec. 4, 2008, Doc. 94-2.) Mr. Larson also testified that although his investigation revealed that UV light exposure was a potential contributing factor to the catheter breakage, he was unable to rule out the involvement of other potential factors such as contamination, improper heating of the plastic material, and user error. (Larson Dep. 34-36.) Moreover, contrary to Plaintiff's assertion that Defendant never conducted UV light testing on the PEBAX material before using the material in the catheter, there is evidence of record that Defendant did in fact conduct such testing. (Doc. 103-2, pp. 27-31.)

Finally, Plaintiff offers the testimony of Dr. Bapatla, the surgeon who operated on the Plaintiff, in support of his argument that the Pantages Catheter was defective.

(Amruth Bapatla Dep. 20:15-17, Aug. 14, 2008, Doc. 55-2.) While the deposition testimony of Dr. Bapatal addresses the Pantages Catheter, Dr. Bapatla's testimony cannot be considered expert testimony on the issue of defectiveness for the simple reason that Dr. Bapatal is not an engineer nor did he perform any testing on the catheter. While a treating physician may testify as a lay witness regarding his observations and decisions during treatment of a patient, the treating physician cannot provide lay witness testimony concerning his hypothesis about the cause of an injury.[7] Thus, where a treating doctor expresses an opinion unrelated to his treatment of the patient and which concerns scientific, technical, or other specialized knowledge unrelated to the physician's area of expertise, the testimony must satisfy the requirements of Rule 702 and *Daubert* before it may be considered. Accordingly, because Dr. Bapatal is not identified as an expert witness in this case and his opinion concerning the "defectiveness" of the catheter is well outside the bounds of permissible lay testimony, his testimony cannot be considered evidence of defectiveness.

Causation

In addition to the material issues of fact concerning the question of whether UV light degradation establishes a defect in the PEBAX plastic component part of Defendant's catheters, there are also genuine issues of material fact concerning what actually caused the Pantages Catheter to break. In the absence of a causal connection between the product defect and plaintiff's injuries, there is no basis for imposing product

[7] *See* United States v. Henderson, 409 F.3d 1293, 1300 (11th Cir. 2005).

liability upon the manufacturer.[8] "It is not contemplated that a manufacturer should be made the insurer for *all* physical injuries caused by his products."[9] As such, while Plaintiff advances several legal theories as to *why* the catheter is defective, there, nonetheless, remains a disputed issue of fact as to whether the Pantages Catheter actually broke *as a result of* a product defect or broke as a result of use of the product during the procedure.

According to Plaintiff, testimony from Dr. Bapatla that the Pantages Catheter was "very friable" and that it "crumbled" into several small pieces in his hands (Bapatla Dep. 14:9-12, Aug. 14, 2008) suggests that the Catheter was defective. Plaintiff also points to testimony from Dr. Bapatla that the catheter broke while he was using it in the manner it was intended to be used and that Dr. Bapatla denied having any role in causing the catheter to break (Bapatla Dep. 30:2-7, 15:1-16, Aug. 14, 2008) as testimony negating any argument that there was product misuse.

However, there is other testimony from Dr. Bapatal, which is in conflict with his own testimony. Later in his deposition, Dr. Bapatla testified that only one piece broke off of the catheter (Amruth Bapatla Dep. 37:20-25, 38:1-3, 53:14-19, 54:7-9, Feb. 18, 2009, Doc. 109-2), testimony which is in conflict with his own testimony that the catheter "crumbled into several little pieces.

Further, there is other evidence of record which calls into question whether the catheter broke because of a product defect. One of Plaintiff's treating physicians noted

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[8] West v. Caterpillar Tractor Co., 336 So. 2d 80, 86-87 (Fla. 1976).

[9] West, 336 So. 2d at 86 (quoting Royal v. Black & Decker Mfg. Co., 205 So. 2d 307 (Fla. 3d DCA 1967)).

that Plaintiff's thoracentesis procedure "was complicated by shearing of the end of the catheter"—a description consistent with breakage due to misuse. (Doc. 103-2, p. 3.)

Additionally, James Larson testified that his investigation could not rule out misuse of the product as a potential factor causing the catheters to break. (Larson Dep. 26:6-11, 81:22, 82:7.) "[Defendant] never found an exact causation agent. So that, . . . could still be debated." (Larson Dep. 36:11-13.) In fact, according to the testimony of Joseph Hutson, Director of Quality for Interventional Specialties for Cardinal Health, it is not uncommon for a catheter to break as a result of user error. Hutson testified that "Misadvancing the needle" is a common error and occurs when a physician accidentally pierces the catheter with the needle. Another way that misuse can cause a catheter to break is the use of too much force when inserting the catheter into the patient. (Joseph Hutson Dep. 72:24, 73:1-13, 82:2, Aug. 21, 2008, Doc. 82-2.) Whether the handling of the catheter caused the breakage or contributed to the breakage of the catheter or whether the exposure of the PEBAX plastic component part of Defendant's catheters to UV light caused the breakage are issues best suited for resolution by a jury and not by the Court on this record on a motion for summary judgment. Accordingly, Plaintiff's Second Motion for Partial Summary Judgment (Doc. 77) is due to be **DENIED**.

B. Plaintiff's Fourth and Fifth Motions for Partial Summary Judgment

In his Fourth and Fifth Motions for Partial Summary Judgment Plaintiff also argues that the Pantages Catheter was defective as a result of Defendant's failure to warn consumers of the risk posed by exposure of the catheters to UV light. Plaintiff is not entitled to summary judgment under this theory because there are disputed material

issues of fact as to whether UV light poses a "risk" triggering a duty to warn, and if so, whether Defendant had the requisite knowledge of the "risk" thus triggering a duty to warn.

Under Florida law, a manufacturer of a product has a duty to warn of the inherent dangers associated with a product when the product has "dangerous propensities."[10] A product is considered to have a "dangerous propensity" if the manufacturer knows or has reason to know that the product is likely to be dangerous during normal use. Whether the failure to warn claim is based upon a theory of strict liability or negligence, a manufacturer must take reasonable precautions to avoid reasonably foreseeable injuries to the users of its products and as such assumes a duty to convey to the users of that product an adequate warning of potential risks associated with normal use of the product of which the manufacturer is or should be aware.[11] Whether a product has dangerous propensities, and whether a duty to warn exists under the circumstances are generally questions of fact for the jury.[12]

According to Plaintiff, Defendant had a duty to warn consumers of the potential that their catheters would become brittle and break due to UV light exposure. The determination of whether a manufacturer has a duty to warn involves assessment of the

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[10] West v. Caterpillar Tractor Co., 336 So. 2d 80, 86-87 (Fla. 1976); Ferayorni v. Hyundai Motor Co., 711 So. 2d 1167 (Fla. 4th DCA 1998), Brown v. Glade & Grove Supply, Inc., 647 So. 2d 1033, 1036 (Fla. 4th DCA 1994); Cohen v. Gen. Motors Corp., 427 So. 2d 389 (Fla. 4th DCA 1983).

[11] Pinchinat v. Graco Children's Prods., Inc., 390 F. Supp. 2d 1141 (M.D. Fla. 2005).

[12] Advance Chem. Co. v. Harter, 478 So. 2d 444, 447-48 (Fla. 1st DCA 1985).

foreseeability of the harm encountered by the consumer – and that is a question of fact.[13]

Plaintiff points to the testimony of Tracy Horst, formerly a Quality Manager for Defendant, who purportedly opined that the catheter posed a risk to patient safety. A closer and full examination of the complete testimony of Ms. Horst discloses, however, that she later testified that she did not know what caused the catheters to break and thus could not say whether the catheters posed a risk to patient safety. Therefore, contrary to Plaintiff's characterization of Tracy Horst's testimony as constituting "indisputable proof that Cardinal Health was actually aware of the dangerous propensities" of the catheter due to degradation caused by exposure to UV light, Ms. Horst testified that she did not know whether the catheter caused a risk to patient safety or whether UV light was the cause of the incidents. (Tracy Horst Dep. 10:7-11, 29:4-5, 29:12, 42:9-12, 42:14-15 **,** 42:18-19**,** 43:19-21**,** 45:1-3**,** 47:1-4**,** 47:10-20, 48:2-4, 49:21-23, Dec. 5, 2008, Doc. 95-2.)

Additionally, Mr. Larson testified that Defendant "never found a specific causation agent in the field where complaints were coming from that would tell us what conditions exactly were brought to bear on a catheter to duplicate [Defendant's] testing." (Larson Dep. 77:8-12.) Mr. Larson also testified that Defendant's catheters—whether exposed to UV light or not—did not pose a risk to patient safety. (Larson Dep. 78:10-17.)

[13] Id.

These deposition excerpts demonstrate that there is sharply divergent evidence with regard to whether Defendant had the requisite knowledge of a defect to trigger a duty to warn. "Manufacturers are not required to warn of every risk which might be remotely suggested by any obscure tidbit of available knowledge, but only of those risks which are discoverable in light of the generally recognized and prevailing best knowledge available."

Accordingly, because there are genuine issues of material fact as to whether the risk posed by UV light exposure was sufficient to give rise to a duty to warn in this case, Plaintiff is not entitled to the entry of partial summary judgment and thus Plaintiff's Fourth, and Fifth Motions for Partial Summary Judgment are due to be **DENIED**.

IT IS SO ORDERED.

DONE AND ORDERED in Ocala, Florida, on July 27, 2009.

GARY R. JONES
United States Magistrate Judge

Copies to:
All Counsel