IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

ERIC BANKS	:	CIVIL ACTION
	:	NO. 10-5048
Plaintiff	:	
	:	
v.	:	
	:	
COLOPLAST CORP.	:	
	:	
Defendant	:	

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT COLOPLAST CORP.'S MOTION FOR SUMMARY JUDGMENT

I. INTRODUCTION

On August 26, 2011, defendant Coloplast Corp. ("Coloplast") filed its motion for summary judgment on all claims against it. The motion sought dismissal on two related, but distinct grounds. Initially, each of the causes of action asserted against Coloplast is contingent on the premise that the penile prosthesis manufactured by Coloplast and implanted into plaintiff was defective and/or negligently produced in some fashion. Because the design and manufacture of medical devices are matters beyond the scope of knowledge of an ordinary layman, expert witness testimony would be essential to establish a claim under any theory of recovery. Although plaintiff's expert reports were due on or before June 24, 2011, under the scheduling order in this case, no reports were submitted. In the absence of expert testimony, Coloplast argued that there is no set of facts upon which a finder of fact could conclude that Coloplast is liable to plaintiff.

Coloplast also sought relief on the ground that plaintiff's failure to preserve the prosthesis has caused irreparable prejudice. Without the opportunity to inspect the prosthesis, Coloplast would be severely limited in its ability to determine the existence, nature and cause of any alleged performance

deficiencies in the unit in question, and this prejudice can only be rectified by dismissal of the claims against Coloplast.

Plaintiff filed a three-page response (exclusive of exhibits) on September 12, 2011. This response does not contain any type of expert opinion evidence that would be admissible at trial, or indeed anything even remotely close to it. The response also argues, without any plausible basis, that Coloplast has not been prejudiced by Mr. Banks' failure to preserve the prosthesis. For the reasons that follow, plaintiff's response fails to raise a credible basis for the denial of Coloplast's motion, and Coloplast is entitled to judgment in its favor as a matter of law.

II. STATEMENT OF FACTS

Plaintiff Eric Banks initiated the instant products liability litigation against Coloplast in the Court of Common Pleas of Philadelphia County, Pennsylvania. The case was thereafter removed to this court. According to counsel's stipulated set of facts,[1] on or about December 18, 2007, an inflatable penile prosthesis manufactured by defendant Coloplast Corp. was implanted into plaintiff Eric Banks. On or about August 1, 2008, the Coloplast implant was removed, re-sectioned and re-implanted into Mr. Banks. On or about June 1, 2009, the Coloplast implant was removed and replaced with a product supplied by another manufacturer.

It has also been stipulated that the current whereabouts of the extracted prosthesis are unknown to all parties. Plaintiff testified during his deposition on March 2, 2011, that he does not have possession of the prosthesis and sent a written request to Albert Einstein Medical Center ("Einstein") asking that the prosthesis not be discarded following its extraction. *See* plaintiff's deposition at pg. 38, lines 17-24 and

[1] These stipulated facts appear both in Coloplast's initial motion and plaintiff's response.

pgs. 39-40, lines 24, 1-2. A true and correct copy of the pertinent portions of Plaintiff's deposition is attached hereto as Exhibit "A." While plaintiff has produced a copy of what purports to be the aforementioned letter through voluntary disclosures, a true and correct copy of which is attached as Exhibit "B," the letter was notably absent from the records obtained by Coloplast from Einstein via subpoena. Nevertheless, even if Mr. Banks did actually initially request that the prosthesis be preserved, there is no evidence that he ever followed up in any way to obtain possession of it, and Einstein does not have it in its possession. *See* the affidavit of Barbara Eissler, medical secretary, pathology, at Einstein, a true and correct copy of which is attached hereto as Exhibit "C." In light of plaintiff's deposition testimony and Einstein's assertion that it does not have possession of the prosthesis, the most likely scenario is that the prosthesis was discarded following extraction.[2]

Plaintiff contends that Coloplast negligently designed, manufactured, tested, distributed and/or sold the prosthesis at issue resulting in Plaintiff's physical pain, mental anguish and emotional distress (*see*, plaintiff's amended complaint, a true and correct copy of which is attached hereto as Exhibit "G" at ¶¶ 15 and 16) and has brought claims sounding in negligence, negligence per se and strict liability against Coloplast.

On April 21, 2011, this court entered a Revised Scheduling Order, extending the fact discovery deadline to June 24, 2011 and requiring plaintiff to submit any and all expert reports by June 24, 2011. No reports have been provided even as of the date of this response.

[2] Although the Einstein records did not contain Mr. Banks' alleged request that the prosthesis be preserved, they did contain notations that it was alternatively "discarded" or "returned to company." *See* Exhibits "D" and "E." As set forth in the affidavit of Christine Buckvold, a true and correct copy of which is attached as Exhibit "F," Coloplast has very specific methods and channels by which its products may be returned and keeps detailed records regarding any return activities. Coloplast has no record of receiving a request to authorize a return or provide return packaging, and no record of ever having the prosthesis in its possession. Nor do the Einstein records contain a request for return packaging or any type of transmittal documentation with respect to shipment of the prosthesis.

III. LEGAL STANDARD

A. Summary Judgment Standard

Pursuant to Rule 56 of the Federal Rules of Civil Procedure, summary judgment is appropriate if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). This rule is a procedural device which enables the court to facilitate the resolution of a matter without the expense and delay of conducting a trial when the critical facts of the case are not in dispute. *Acevedo v. Start Plastics, Inc.*, 834 F. Supp. 808 (E.D. Pa. 1993) (emphasis added). The United States Supreme Court has recognized that the moving party "bears the initial responsibility of informing the District Court of the basis for its motion, and identifying those portions ... which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986).

After the moving party has filed a properly supported motion, the burden shifts to the non-moving party to "set forth specific facts showing that there is a genuine issue for trial." *See* Fed. R. Civ. P. 56(e). The non-moving party may not rest upon the mere allegations or denials of its pleadings. If the record taken as a whole in a light most favorable to the non-moving party, "could not lead a rational trier of fact to find for the non-moving party, there is no genuine issue for trial." *Matsushita Elec. Company v. Zenith Radio,* 475 U.S. 574, 587 (1986). If the evidence for the non-moving party is merely colorable, or if it is not significantly probative, summary judgment should be granted. *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 249-50 (1986).

If a moving party satisfies their burden of proving a *prima facie* case for summary judgment, the opposing party "must do more than simply show there is some metaphysical doubt as to material facts." *Boyle v. County of Allegheny, PA,* 139 F.3d 386, 393 (3d Cir. 1990). Rather, there must be sufficient evidence for a jury to render a verdict in favor of the non-moving party. *Id.* at 393. In other words, Rule 56 does not allow the non-moving party to rely upon their assertions, conclusory accusations or suspicions. *Soriero v. F.D.I.C.*, 887 F. Supp. 103, 106 (E.D. Pa. 1995). The non-moving party must offer specific facts, contradicting the facts averred by the movant which indicate that there is a genuine issue for trial. *Id.* at 106.

IV. ARGUMENT

A. Plaintiff's amended complaint should be dismissed as plaintiff has failed to produce an expert report regarding the alleged defective condition of the prosthesis and cannot present a case without expert testimony.

The cornerstone to plaintiff's recovery in this medical products liability action is a finding that the product involved is defective in some manner, or that the defendant was negligent in some fashion in its design or manufacture. Since either of these conclusions is beyond the knowledge of a layman, expert witness testimony is necessary. This court recognized in *Jones v. Toyota Motor Sales, USA, Inc.* that "[u]nder Pennsylvania law… it is clear that 'a plaintiff must present expert testimony when laymen would lack the necessary knowledge and experience to render a just and proper decision.'" *Jones v. Toyota Motor Sales, USA, Inc.*, 282 F. Supp. 2d 274, 276 (E.D. Pa. 2003) (citing *Raysely v. Zanders,* 22 Pa. D. & C. 4th 566, 567 (Lehigh Co. 1993)). The primary purpose of expert testimony is to assist the trier of fact to understand, evaluate and decide complex evidentiary material. See *United States v. Perez,* 280 F.3d 318 (3d Cir. 2002). When a topic requires special experience and forms a main issue in a case, the evidence on that issue *must* contain expert testimony or it will not suffice. *National Cash Register*

Co. v. Haak, 335 A.2d 407, 410 (Pa. 1975) (emphasis added, citations omitted). The inner workings, design and alleged failure mechanism of an inflatable penile prosthesis certainly fall outside the common knowledge of a layperson.

Plaintiff alleges in his amended complaint that the prosthesis was sold, "...in a defective, dangerous and/or hazardous condition due to the negligent packing, design, manufacture, distribution and/or sale by the Defendant," and that, "[t]he Defendant is strictly liable to the Plaintiff because it designed, manufactured, distributed and/or sold the Prosthesis which was defective, dangerous and, hazardous." *See* Exhibit "A" at ¶ ¶ 27 and 28. Furthermore, plaintiff alleges that "[t]he Prosthesis was unsafe and unfit for implantation into the human body." *See* Exhibit "A" at ¶ 29.

In order to prevail in a products liability action under Pennsylvania law, a plaintiff must establish that: (1) a product was defective; (2) that the defect existed at the time the product left the manufacturer's control; and (3) that the defect was a substantial factor in causing the plaintiff's injury. *Giorgini v. Ford Motor Co.*, 2008 U.S. Dist. LEXIS 25344, at *38 (E.D. Pa. 2008) (Citing *Marino v. Maytag Corp.*, 2005 U.S. Dist. LEXIS 22377, at *8 (W.D. Pa. Sept. 29, 2005)).

When a topic requires special experience and forms a main issue in a case, the evidence on that issue must contain expert testimony or it will not suffice. *Haak*, 335 A.2d at 410. At his deposition, and again in the affidavit he submitted in opposition to Coloplast's motion, plaintiff attributed his repeat surgeries to a deficiency in the prosthesis. However, the mechanical workings, design and alleged cause for failure (if indeed a failure actually occurred) of a pump located inside of an inflatable penile prosthesis that was surgically implanted into a human being fall well outside the common knowledge of a layperson, thus requiring the special knowledge and experience of an expert.

Pursuant to Federal Rule of Civil Procedure 26(a)(2), when ordered by the court to do so, a party must disclose the identities of all expert witnesses the party will be using at trial. In addition, the party must provide a written report signed by the expert and disclosing, among other things, (i) a complete statement of all the opinions the witness will express and the basis and reasons for them; (ii) the data or other information considered by the witness in forming them; and (iv) the witness' qualifications. *See* Fed. R. Civ. P. 26(a)(2). In this case, the court's April 21, 2011 Revised Scheduling Order set the deadline for plaintiff's expert disclosure as June 24, 2011.

To this date, nothing even remotely resembling an expert witness report has been forthcoming from plaintiff. Indeed, the only opposition at all consists of plaintiff's own affidavit and some specks of hearsay contained in excerpts from his own deposition. Even if he is trying to belatedly and untimely offer his own treating physician as an expert witness in the field of prosthesis design and manufacture, plaintiff has not provided anything signed by the doctor, a statement of the opinions held, the reasons for them, the facts considered in reaching them or anything to indicate who this individual even is. Not to mention, plaintiff has not indicated why this individual would be qualified to opine as to the presence or absence of a product defect or due care in its design and production. Without expert testimony, plaintiff cannot establish that the prosthesis contained any defective or hazardous condition(s) and cannot satisfy the elements for a claim of strict products liability as set forth by this Court in *Giorgini*. Nor can he establish that the design and manufacturing process of the prosthesis fell short any recognized standard, i.e. that Coloplast was negligent. Since plaintiff cannot establish a claim of any nature absent expert witness testimony, and since he does not have any expert testimony, Coloplast is entitled to judgment in its favor as a matter of law.

B. Plaintiff's spoliation of the evidence has irreparably prejudiced Coloplast, and the only appropriate remedy is dismissal of the action.

As set forth above, plaintiff has failed to take the necessary steps to preserve the prosthesis for trial. This court has previously addressed the issue of whether a plaintiff's failure to produce an allegedly defective product for inspection by defendant results in prejudice to the defendant in *Prudential-LMI Commercial Ins. Co. v. Windmere Corp.*, 1994 U.S. Dist. LEXIS 15492 at *2 (E.D. Pa. 1994). In *Windmere*, the court recognized that, "[a] products liability case focuses on the product itself. Often, such trials involve competing expert testimony that juries must evaluate. To allow a plaintiff to go forward with a case in which the defendant's expert would not be able to examine the very product at issue would be unfairly prejudicial." *Id.* This holding applies directly to the instant matter. At his deposition, plaintiff testified that he requested that the prosthesis be preserved following extraction. As such, whether he actually sent the letter or not, there is no plausible explanation for such a request unless he was contemplating litigation at that time. Coloplast, by contrast, did not learn of the possibility of litigation until it was served with process. Even if plaintiff took the initial step of asking that the prosthesis be preserved, it was incumbent on him to take all reasonable steps to be certain Coloplast had a fair opportunity to defend itself if plaintiff intended to bring a lawsuit. He could have gone to Einstein or asked his doctor to get the device for him. He could have requested that the prosthesis be returned to him following extraction for preservation in anticipation of initiating litigation. Instead, it appears he did nothing.

The issue of whether a plaintiff can prevail in a cause of action against a manufacturer without producing the allegedly defective product was addressed by the Superior Court of Pennsylvania in *Creazzo v. Medtronic, Inc.* 903 A.2d 24 (Pa. Super. Ct. 2006). In *Creazzo*, plaintiffs brought suit against the manufacturer of a pain control device ("device") following an alleged malfunction of the device. As

a result of the malfunction, the device was subsequently extracted nearly four years after its initial implantation. *Id.* at 26. The device was ultimately lost by the third-party hospital where the extraction procedure was performed. *Id.* at 29. As a result, plaintiffs and defendant-manufacturer were denied the opportunity to examine the device for a defective condition. *Id.* at 29. The plaintiffs' failure to preserve the evidence coupled with the nature of their asserted claim grounded the court's holding that summary judgment for defendant-manufacturer was proper. *Id.* Notwithstanding the actual loss of the device by a third-party, the court held that plaintiffs were responsible for the device's preservation and faulted them for failing to take "active steps" to preserve the device despite the fact that plaintiffs commenced litigation nearly ten months prior to the extraction procedure. *Id.* at 29-30.

The issue currently before this court is nearly identical to that in *Creazzo*. Like the plaintiffs in *Creazzo*, Mr. Banks clearly contemplated litigation at the time of the extraction procedure. By not following up with Einstein, plaintiff failed to take active steps to ensure the preservation of the prosthesis. This court has also recognized in *Travelers Prop. Cas. Co. of America v. Cooper Crouse-Hind,* that "a party that reasonably anticipates ensuing litigation has an affirmative duty to preserve evidence that may be relevant, and failing to do so constitutes spoliation." *Travelers Prop. Cas. Co. of America v. Cooper Crouse-Hinds*, 2007 U.S. Dist. LEXIS 64572, at *12 (E.D. Pa. 2007).

In *Travelers*, plaintiff initiated a subrogation action against defendant-manufacturer in relation to a fire that severely damaged a building insured by plaintiff. *Id* at *1. Plaintiff's expert determined that a light fixture manufactured by defendant caused the fire, but did not allow defendants to examine it until

more than two years elapsed after the incident. *Id.* at *4-*5. Because the allegedly defective fixture was furnished to defendant in a substantially different condition from when plaintiff examined it, defendant moved for summary judgment based on plaintiff's spoliation of evidence. *Id.* at *1.

The court ultimately found plaintiff guilty of spoliation because of plaintiff's failure "to ensure the preservation of integral evidence after litigation became reasonably foreseeable." *Id.* at *14. However, in that case, dismissal was denied because an alternative sanction was proper considering plaintiff asserted a defective design as its singular theory of liability as opposed to a manufacturing defect. Citing *Schmid v. Milwaukee Elec. Tool Corp.*, 13 F.3d 76 (3d Cir. 1994), the court concluded that the prejudice suffered by the adverse party was "much less in a design defect case" because the adverse party is able to assess this theory of liability "as well or better by inspecting and testing multiple [fixtures] of the same design than by inspecting the particular [fixture] involved in the [fire]." *Id.* at *18 (citations omitted).

While plaintiff's amended complaint does contain generic design defect allegations, there are critical points of distinction between *Travelers* and this case. First, plaintiff has produced nothing in the way of specificity or support for his design claim. More importantly, while the defendant in *Travelers* received an altered product to inspect, Coloplast received no product at all. As a result, the prejudice to Coloplast is far more severe.

Plaintiff offers no explanation for his failure to preserve the prosthesis. Instead, he suggests at Page 3 of his response that "[t]he fact that the prosthesis cannot be located does not prejudice the Defendant as it possesses all the medical records and reports related to this incident" and that the Defendant "could have deposed the surgeon who deposed the performed the implantation … or its representative who inspected the prosthesis." With all due respect, this argument simply makes no

sense. Since plaintiff never identified his treating physician as an expert witness in the field of device design, there was no reason to depose him as a fact witness. No one is contesting that Mr. Banks underwent three surgeries, and no one is contesting the nature of the surgeries. On the other hand, if Mr. Banks had identified the surgeon as a liability expert, he would have provided a report in conformity with the rules and there would still be no need to depose him.

The argument concerning plaintiff's uncertain recollections of conversations with an alleged representative of Coloplast is equally unavailing. As evidenced by the records excerpts from the three procedures undergone by plaintiff, copies of which are attached hereto as Exhibits "H," "I" and "J," a Coloplast representative (Marcus Zone) was present when the prosthesis was first implanted in December of 2007 (Exhibit "H") and in August of 2008 (Exhibit "I") when it was removed, adjusted and re-implanted, but was not in attendance in June of 2009 (Exhibit "J"), when it was removed permanently and replaced with a device manufactured by one of Coloplast's competitors, AMS. Matt Esplin, a representative of AMS, attended the June, 2009 procedure. Coloplast would therefore gain nothing (and in fact did gain nothing) by talking to its representative, since he had no opportunity to inspect the prosthesis after it was removed.

While the prejudice to the defendant in the *Schmid* case may have been tempered because of the availability of exemplars to test against plaintiff's design defect claims, the same cannot be said here. Plaintiff has not even specified the manner in which he believes the prosthesis design to be defective. What would Coloplast be looking for by way of comparison? More critically, the product involved is a medical device surgically implanted into plaintiff with the use of scalpels and sewed into place with the use of needles. One obvious possible alternative cause of a deflation, or "blowout" as plaintiff puts it, would be improper implantation. Another would be a cut or nick from a scalpel or needle during the

implantation process. Without the opportunity to examine the prosthesis, Coloplast has been deprived of the opportunity to assert the most basic of defenses. Under the circumstances, the only sanction that is appropriate is dismissal.

V. CONCLUSION

For the foregoing reasons, and in the absence of a genuine issue of any material fact shown by the pleadings and discovery, Coloplast Corp. respectfully requests that this Honorable Court grant its Motion for Summary Judgment and dismiss plaintiff's claims against Coloplast Corp. with prejudice.

Respectfully submitted,

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Dated: September 26, 2011

CERTIFICATE OF SERVICE

I, Jonathan Dryer, attorney for defendant, Coloplast Corp., hereby certify that on September 26, 2011, a true and correct copy of the foregoing Memorandum of Law in Support of Motion for Summary Judgment was filed electronically and is available to all parties through the court's ECF filing system.

/s/Jonathan Dryer
Jonathan Dryer, Esquire