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

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

Memorandum Opinion and Order

RUFE, J. **February 28, 2012**

This is an action for personal injuries sustained by Plaintiff Eric Banks, which were allegedly caused by a defect in an inflatable penile prosthesis manufactured by Defendant Coloplast Corp. ("Coloplast"). Plaintiff's Complaint alleges negligence, negligence *per se*, and strict liability. Before the Court is Coloplast's Motion for Summary Judgment. For the reasons set forth below, the Motion will be granted in part and denied in part.

I. BACKGROUND

The parties have stipulated to the following facts:[1]

1. On or about December 18, 2007, an inflatable penile prosthesis manufactured by defendant, Coloplast Corp. was implanted into plaintiff Eric Banks.
2. On or about August 1, 2008, the Coloplast implant was removed, resectioned and re-implanted into Mr. Banks.
3. On or about June 1, 2009, the Coloplast implant was removed and replaced with a product supplied by another manufacturer.

[1] Recited verbatim from Exhibit B to Defendant's Motion for Summary Judgment, Doc. No. 10.

4. The present whereabouts of the Coloplast implant are unknown.

In addition, the record before the Court includes deposition testimony, correspondence, medical records, and affidavits.

During his deposition, Plaintiff testified that after initial implantation the Coloplast implant would not deflate once inflated. He was required to seek medical attention on several occasions due to the device's failure to deflate. A Coloplast representative was present at some of these medical appointments. After several failures, the representative told Plaintiff that the pump on the device was defective, and recommended replacing only the pump, which is one part of the three-part implant. The pump was replaced in a second surgery. Shortly thereafter, Plaintiff experienced a "blowout" or tear in the pump, after which the implant would no longer inflate. The Coloplast representative then recommended replacing the whole unit. A third surgery was performed. This time, however, Plaintiff opted to replace the Coloplast implant with one made by another company. After the prosthesis was removed, Plaintiff's physician photographed the damaged pump.

Plaintiff also provides the affidavit of Dr. Michael J. Metro, the doctor who first surgically implanted the Coloplast device. Dr. Metro offers no opinion or factual information regarding the cause of the first Coloplast pump's deflation problems. He states that he found a hole in the second Coloplast pump after he removed it, which had prevented the device from properly inflating, but he does not opine as to the source or cause of that hole.

After the Coloplast pump was removed, Plaintiff sent a letter to Albert Einstein Hospital ("Einstein"), where the procedure was performed, asking the medical staff to preserve the prosthesis. Einstein has provided an affidavit from its employee, Barbara Eissler, in which she

attests that Einstein does not possess the prosthesis nor does it have any record indicating its whereabouts. A Perioperative Nursing Record indicates that the penile implant was returned to Coloplast.[2] However, Coloplast has no record of receiving it, nor of a request for the return packaging materials the company required due to the biohazards posed by removed medical implants.[3] Therefore, the device at issue is not available for inspection.

Plaintiff has not obtained an expert opinion in support of his claims.

II. STANDARD OF REVIEW

Under Federal Rule of Civil Procedure 56, a court may grant summary judgment only "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law."[4] A fact is "material" if it could affect the outcome of the suit, given the applicable substantive law.[5] A dispute about a material fact is "genuine" if the evidence presented "is such that a reasonable jury could return a verdict for the nonmoving party."[6] In considering a summary judgment motion, the Court does not weigh the evidence or make credibility determinations; "[t]he evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor."[7]

The party opposing summary judgment must support each essential element of the

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[2] Doc. No. 12, Ex. E.

[3] Aff'd of Christine Buckvold, Doc. No. 12, Ex. F.

[4] Fed. R. Civ. P. 56 (2011).

[5] Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).

[6] Id.

[7] Anderson, 477 U.S. at 255.

opposition with concrete evidence in the record.[8] "If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted."[9] This requirement upholds the "underlying purpose of summary judgment [which] is to avoid a pointless trial in cases where it is unnecessary and would only cause delay and expense."[10] Therefore, if, after making all reasonable inferences in favor of the non-moving party, the court determines that there is no genuine dispute as to any material fact, summary judgment is appropriate.[11]

III. DISCUSSION

Strict Liability

To establish a prima facie case of strict liability, a plaintiff must show that the product was defective, that the defect existed at the time the product left the manufacturer's control, and that the defect caused the plaintiff's injury.[12] Plaintiff alleges that Coloplast is strictly liable for his injury because the design or manufacture of the penile prosthesis created a defect which rendered it unreasonably dangerous when used as intended, and Coloplast placed it in the stream of commerce in a dangerous or hazardous condition.

The parties agree that Plaintiff cannot produce direct evidence of the product's defective condition, as the product is unavailable. Coloplast argues that its defense has been irreparably prejudiced by Plaintiff's failure to preserve the prosthetic device. As Coloplast cannot examine

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[8] Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986).

[9] Anderson, 477 U.S. at 249-50 (citations omitted).

[10] Walden v. Saint Gobain Corp., 323 F. Supp. 2d 637, 641 (E.D. Pa. 2004) (citing Goodman v. Mead Johnson & Co., 534 F.2d 566, 573 (3d Cir. 1976)).

[11] Celotex, 477 U.S. at 322; Wisniewski v. Johns–Manville Corp., 812 F.2d 81, 83 (3d Cir. 1987).

[12] Barnish v. KWI Bldg. Co., 980 A.2d 535, 541 (Pa. 2009).

the device, it cannot determine the nature and cause of any defects in the device. Therefore, it asserts, summary judgment should be entered in its favor.

However, courts in Pennsylvania have held that when the device or product at issue is unavailable, circumstantial evidence may be used to prove strict liability.[13] A case in which a plaintiff has only circumstantial evidence to support his strict liability claim may proceed under the "malfunction theory." Some potential sources of circumstantial evidence are:

> (1) the malfunction of the product; (2) expert testimony as to a variety of *possible* causes; (3) the timing of the malfunction in relation to when the plaintiff first obtained the product; (4) similar accidents involving the same product; (5) elimination of other possible causes of the accident; and (6) proof tending to establish that the accident does not occur absent a manufacturing defect.[14]

As Plaintiff has asserted some circumstantial evidence in support of his strict liability claim, including the malfunction of the product, the timing of the malfunction, and the elimination of certain other possible causes, the Court will not enter summary judgment simply because Plaintiff has failed to preserve the implant. Rather, the Court will assess the merits of the claim.

The Pennsylvania Supreme Court provides the Court with guidance regarding the requirements for proceeding under the malfunction theory:

> First, the "occurrence of a malfunction" is merely circumstantial evidence that the product had a defect, even though the defect cannot be identified. The second element in the proof of a malfunction theory case, which is evidence eliminating abnormal use or reasonable, secondary causes, also helps to establish the first element of a standard strict liability case, the existence of a defect. By demonstrating the absence of other potential causes for the malfunction, the plaintiff allows the jury to infer the existence of defect from the fact of a

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[13] Barnish, 980 A.2d at 541.

[14] Id. at 542-43.

> malfunction. For example, by presenting a case free of abnormal uses, such as using the product for an unintended purpose, the plaintiff can demonstrate that the product failed to perform as a reasonable customer would expect; thus, that it malfunctioned. Similarly, by eliminating other reasonable secondary causes, a plaintiff allows the jury to infer that a defect in the product caused the malfunction, as opposed, for example, to operator error or failure to service the equipment. Similarly, by presenting a case free of "abnormal uses" by the plaintiff and free of "other reasonable secondary causes," a plaintiff can establish through inference from circumstantial evidence the second and third elements of a § 402A case, that the alleged defect caused the injury (as opposed to another cause) and that the defect existed when it left the manufacturer's control (as opposed to developing after the product left the manufacturer's control).[15]

Here, Plaintiff has proffered evidence demonstrating that malfunctions in the penile prosthesis occurred, necessitating multiple visits to his doctor and two additional surgeries. After the first surgery, the implant failed to deflate once inflated. Shortly after the second surgery, the replacement pump stopped inflating the prosthesis altogether.

A reasonable jury could conclude that the timing of both problems gives rise to the inference that the device was defective when it left Coloplast's control. According to Plaintiff's testimony, the first malfunction (failure to deflate) occurred the very first time he used the implant.[16] The second malfunction (failure to inflate) occurred only a couple of weeks after Plaintiff began using the prosthesis again after healing from the surgical pump replacement.[17]

There is no record evidence indicating that abnormal or unintended use led to the malfunction. Plaintiff testified that he knew the proper mechanism for deflating the device.[18] He

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[15] Id. at 541-42.

[16] Banks Dep. at 30: 15-17, March 2, 2011.

[17] Banks Dep. at 38: 4-7, March 2, 2011.

[18] Banks Dep. at 32: 23-24, 34:4-7, March 2, 2011.

further testified that his doctor and a Coloplast representative also experienced difficulty deflating the implant, indicating that this was not "operator error."[19] Ultimately, according to Plaintiff's testimony, his doctor and the Coloplast representative determined that it was necessary to replace the pump.[20] After the "blowout" in the second pump, the doctor and the Coloplast representative determined it was necessary to remove and replace the entire device.[21]

The Court finds that the circumstantial evidence presented by Plaintiff is sufficient to make a prima facie case under the malfunction theory of liability.

Coloplast argues that because the prosthetic device was implanted by a surgical team, it is possible that the device was implanted incorrectly or that the device was damaged during implantation, causing the malfunctions. Coloplast's argument merely raises a genuine issue of material fact as to when and how the defect occurred; it does not support an entry of summary judgment in Coloplast's favor.[22] However, Coloplast argues that this issue of fact should not be put to a jury because, as a matter of law, Plaintiff cannot prove that the product was defective when it left Coloplast's control without an expert opinion to that effect, which he has not produced.[23] The Court disagrees. A reasonable jury could determine, without an expert opinion,

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[19] Banks Dep. at 34: 8-10, 36: 5-8, March 2, 2011.

[20] Banks Dep. at 36: 5-8, March 2, 2011.

[21] Banks Dep. at 40:16-41:3, March 2, 2011.

[22] Barnish, 980 A.2d at 542 (citing Rogers, 565 A.2d at 755) (where plaintiff presents a prima facie case and the defense counters with a different theory of causation, a jury must resolve the question of fact).

[23] Plaintiff need not establish that the defective product caused his injuries through an expert opinion. If he can show that there was a defect and an injury and eliminate other reasonable causes of the injury, a reasonable jury could infer that a defect in the product caused the injury without an expert opinion. Wiggins v. Synthes (U.S.A), 29 A.3d 9, 17 (Pa. Super. Ct. 2011). The question, then, is only whether Plaintiff can establish that the penile prosthetic was defective when it left Coloplast's control without an expert opinion.

whether the defect was preexisting or caused by the medical provider. Accordingly, Coloplast's Motion for Summary Judgment on the count of strict liability will be denied.

Negligence

While a strict liability claim focuses on the product itself, a negligence claim targets a manufacturer's compliance with its duties. A cause of action in negligence requires proof of four elements: 1) the defendant had a duty; 2) the defendant breached that duty; 3) the breach caused the injury in question; and 4) the plaintiff incurred an injury.[24] Because the first and fourth elements are not disputed here, the Court need only examine whether Coloplast breached its duties to doctors and consumers and whether that breach caused Plaintiff's injury.

Plaintiff alleges that Coloplast was negligent in designing, manufacturing, inspecting, testing, and/or marketing of the prosthesis. However, Plaintiff has not put forth any evidence from which a reasonable jury could infer that Coloplast negligently designed, manufacted, inspected, or sold its products. Although an expert opinion is not necessarily required to establish this claim, Plaintiff must proffer specific evidence of Coloplast's negligence. He simply has not done so. Plaintiff has not provided a single document obtained from Coloplast during discovery, nor has he provided the Court with deposition testimony from Coloplast employees. The affidavit obtained from his own physician does not offer any opinion regarding the cause of the malfunctions. The only information we have about Coloplast's conduct comes from Plaintiff's deposition testimony about his interactions with one of Coloplast's representatives. However, nothing in that testimony is sufficient to support an inference that

[24] Pyeritz v. Com., 32 A.3d 687, 692 (Pa. 2011).

Coloplast acted negligently in designing, manufacturing, testing, or marketing its product. The evidentiary record is simply insufficient to support such this claim.

Plaintiff also alleges that Coloplast deviated from the industry's standard of care. To proceed on this claim, Plaintiff would need to produce an expert opinion, as the penile prosthetic industry's standard of care is beyond the knowledge and experience of a lay juror. As he has failed to do so, he cannot proceed on this theory of negligence.

Finally, Plaintiff alleges negligent failure to adequately warn doctors and consumers of the risks or dangers of the penile prosthesis. Pennsylvania has adopted the "learned intermediary" rule, which requires manufacturers of medications and medical devices to direct their warnings at physicians rather than patients.[25] Thus, the issue in an inadequate warning case involving a medical device such as the penile prosthesis is whether the information provided to the prescribing physicians was adequate.[26] The adequacy of a warning is determined based on what a manufacturer knew or should have known about a given risk at the time the cause of action arose, and whether the label sufficiently warned of that risk.[27] Expert testimony is generally required to determine the adequacy of warnings provided to the medical community by the manufacturer of a medical product.[28] Plaintiff has provided no expert report. Furthermore, although Plaintiff certainly had the opportunity to request copies of the product labels during

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[25] Baldino v. Castagna, 478 A.2d 807, 812 (Pa. 1984); Mazur, 964 F.2d at 1355.

[26] Id.

[27] See, e.g., Mazur, 964 F.2d at 1366; Lance v. Wyeth, 4 A.3d 160, 167 (Pa. Super. Ct. 2010) ("[A] manufacturer has a post-sale duty to warn of any dangerous side effects produced by its drugs of which it knows or has reason to know as long as its drugs are sold on the market.") (citation and internal quotations omitted).

[28] Burton v. Danek Med., Inc., 1999 WL 118020, at *8 (E.D. Pa. Mar. 1, 1999); Demmler v. SmithKline Beecham Corp., 671 A.2d 1151, 1154 (Pa. Super. Ct. 1996), appeal denied, 684 A.2d 557 (Pa. 1996).

discovery, he has failed to provide them to the Court as part of the summary judgment record. Without the opportunity to review these labels, the Court simply cannot find an issue of material fact as to whether the labels were adequate.

As Plaintiff has failed to meet his burden of proof with regard to each of his theories of negligence, his negligence claim will be dismissed.

Negligence Per Se

Finally, Plaintiff alleges negligence *per se*. Negligence *per se* occurs when the duty breached is one established by a statute, ordinance or regulation designed to prevent a public harm.[29] To recover on a negligence *per se* claim, a plaintiff must show that the negligence alleged is the proximate cause of the plaintiff's injury.[30]

Here, Plaintiff alleges that Coloplast violated duties imposed by the Pennsylvania Controlled Substances, Drug, Device and Cosmetic Act ("the Act"),[31] which prohibits, *inter alia*, false or misleading marketing of medical devices, labels with inadequate directions for use, and labels with inadequate warnings regarding hazards.[32] Specifically, Plaintiff alleges that Coloplast labeled the product in a false and misleading manner which failed to warn physicians and the public of the dangers of using the prosthesis, and falsely advertised the efficacy, fitness and safety of its product.

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[29] Cabiroy v. Scipione, 767 A.2d 1078, 1079 (Pa. Super. Ct. 2001).

[30] Id.; Congini v. Portersville Valve Co., 470 A.2d 515, 518, n.4 (Pa. 1983).

[31] 35 P.S. § 780-101, *et seq.*

[32] 35 P.S. § 780-108.

As stated above, Plaintiff has not provided a copy of the label for his prosthesis, nor does he point to particular statements on that label which were false or misleading. He has not offered examples of advertising which contained false statements regarding the efficacy, fitness or safety of the product, nor has he alleged that he or his doctors viewed or heard such advertising. Plaintiff also fails to offer evidence that Coloplast knew or should have known of a defect in or hazard posed by the implant but failed to disclose it. In short, while the Act does create statutory duties, Plaintiff has not raised a genuine issue of fact as to whether Coloplast breached those statutory duties, much less that any breach of Coloplast's labeling and marketing duties under the Act caused Plaintiff's injuries.

IV. CONCLUSION

For the foregoing reasons, the Court will grant Coloplast's Motion for Summary Judgment on the claims of negligence and negligence *per se*, and deny its Motion on the strict liability claim.

An appropriate Order follows.

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

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

ORDER

AND NOW, this 27th day of February, 2012, upon review of Defendant's Motion for Summary Judgment [Doc. No. 10] and all responses and replies thereto, and for the reasons set forth in the attached memorandum opinion, it is hereby **ORDERED** that the Motion is **GRANTED** as to Plaintiff's negligence and negligence *per se* claims, and **DENIED** as to Plaintiff's strict liability claims.

It is so **ORDERED.**

BY THE COURT:

/s/ Cynthia M. Rufe

CYNTHIA M. RUFE, J.