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

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

MOTION FOR RECONSIDERATION OF DEFENDANT COLOPLAST CORP.

For the reasons set forth more fully in the attached memorandum of law, defendant Coloplast Corp. ("Coloplast") respectfully requests that the court reconsider its order and opinion of February 28, 2012 denying its motion for summary judgment with respect to plaintiff's strict liability claim. Reconsideration is appropriate because the motion was denied on the malfunction theory, a theory of law not advanced by plaintiff in opposition, and Coloplast was never given notice or the opportunity to respond as required under F.R.C.P. 56(f). As a result, Coloplast had no opportunity to present the evidence and arguments which follow in the memorandum. Coloplast also requests that, upon reconsideration, the court reverse its decision and grant summary judgment in its favor on all counts.

Respectfully submitted,

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By: */s/ Jonathan Dryer*

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Dated: March 7, 2012

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ERIC BANKS	:	CIVIL ACTION
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DEFENDANT COLOPLAST CORP'S MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR RECONSIDERATION

This is an action for damages allegedly sustained by plaintiff as a result of an alleged defect or defects in a penile prosthesis manufactured by defendant Coloplast Corp. ("Coloplast") and implanted into plaintiff. On February 28, 2012, this court entered an order and opinion granting in part and denying in part Coloplast's Motion for Summary Judgment.[1] The essence of the opinion is that plaintiff's failure to produce an expert witness report is fatal to his negligence claims, but that he could potentially establish a strict liability claim under the "malfunction" theory without the benefit of expert witness testimony. For the reasons that follow, Coloplast respectfully requests that the reconsider its decision to allow this medical device products liability action to go forward without expert testimony and, upon reconsideration, to reverse that decision.

I. RECONSIDERATION IS APPROPRIATE IN THIS CASE

"The purpose of a motion for reconsideration...is to correct manifest errors of law or fact or to present newly discovered evidence." *Max's Seafood Cafe v. Quinteros, 176 F.3d 669, 677 (3d Cir. 1999) (quoting Harsco Corp. v. Zlotnicki, 779 F.2d 906, 909 (3d Cir. 1985)).* "Accordingly, a judgment may be altered or amended if the party seeking reconsideration shows

[1] A true and correct copy of the opinion is attached hereto as Exhibit "A."

at least one of the following grounds: (1) an intervening change in the controlling law; (2) the availability of new evidence that was not available when the court granted the motion for summary judgment; or (3) the need to correct a clear error of law or fact or to prevent manifest injustice." *Id.* (citing *North River Ins. Co. v. CIGNA Reinsurance Co., 52 F.3d 1194, 1218 (3d Cir. 1995)).* "A motion for reconsideration is not to be used as a means to reargue matters already argued and disposed of or as an attempt to re-litigate a point of disagreement between the Court and the litigant." *Abu-Jamal v. Horn, 2001 U.S. Dist. LEXIS 20813, No. CIV. A. 99-5089, 2001 WL 1609671, at *9 (E.D. Pa. December 18, 2001) (citations and internal quotation marks omitted).*

Although the court ruled that plaintiff's strict liability claim could be established without expert testimony by virtue of the "malfunction" theory (an inferential process recognized under Pennsylvania law), this was not an argument raised by plaintiff himself, but rather by the court *sua sponte*. While such a determination is well within the court's authority, that authority is not unbridled. Federal Rule of Civil Procedure 56(f) provides:

> Judgment Independent of the Motion.
> After giving notice and a reasonable time to respond, the court may:
>
> ...
>
> (2) grant the motion on grounds not raised by a party; or
>
> ...

Since Coloplast did not receive notice that the court was considering the malfunction theory even though plaintiff had not raised it, reconsideration is warranted under criteria two and three, above. Available evidence was not presented because Coloplast had no notice and no reason to believe that the only theory to which it was relevant was being considered by the court. In addition, Coloplast had no opportunity to present the arguments that follow herein, and was therefore deprived of the opportunity to prevent what it respectfully submits is both a clear error

of law and a manifest injustice to it. Coloplast therefore respectfully requests that the court reconsider its February 28, 2012 order and opinion.

II. UPON RECONSIDERATION, THE COURT SHOULD REVERSE ITS DECISION OF FEBRUARY 28, 2012 AND GRANT SUMMARY JUDGMENT IN FAVOR OF COLOPLAST ON ALL COUNTS

Pursuant the court's alternative summary judgment motion procedure, on August 26, 2011, Coloplast filed its motion for summary judgment seeking the dismissal of all claims against it because (1) plaintiff had not produced an expert report and could not establish a claim against Coloplast on any theory without expert testimony; and (2) plaintiff's failure to take adequate steps to preserve the subject prosthesis had irreparably prejudiced Coloplast by depriving it of the opportunity to inspect the unit and determine the cause of the alleged malfunction. Plaintiff's response did not mention the malfunction theory or in fact cite any legal authority. Rather, Mr. Banks argued that his own hearsay testimony was sufficient to establish that the unit was defective.[2]

Although Coloplast is well aware of the malfunction theory, it was not addressed in its motion papers because it had not been raised by plaintiff. Instead, Coloplast argued that the absence of expert testimony precluded plaintiff from establishing a *prima facie* case under any legal theory. Approximately one month after receipt of Coloplast's memorandum of law, plaintiff submitted an untimely reply which included an affidavit from his treating physician. Again, there is no mention of the malfunction theory. Instead, plaintiff argues at Section IV of his reply that the affidavit of his surgeon constitutes an expert report sufficient to show that the device was defective.[3]

[2] True and correct copies of plaintiff's response and initial memorandum of law are attached hereto as Exhibit "B."
[3] A true and correct copy of plaintiff's reply is attached hereto as Exhibit "C."

Because plaintiff's reply again made no mention of the malfunction theory, there was again no reason for Coloplast to address it in its surreply. Instead, Coloplast focused on the numerous inadequacies of the affidavit as a surrogate for the type of expert report necessary to satisfy the disclosure requirements of the Federal Rules of Civil Procedure and defeat a summary judgment motion, an argument apparently accepted by the court to the extent it granted Coloplast's motion in part. However, Coloplast had no notice and no reason to believe that the malfunction theory was in play in this case until it received the court's opinion. Had it been made aware of this issue earlier, it would have demonstrated that the malfunction theory does not rescue plaintiff's case from summary judgment for the reasons set forth below.

As the court recognizes at Pages 5 and 6 of its opinion, the Pennsylvania Supreme Court has set forth the appropriate procedure under the malfunction theory, *Barnish v. KWI Bld. Co., 980 A.2d 535, 541 (Pa. 2009).* The "malfunction theory requirements correlate with the first three elements of a standard 402A claim." *Id.* To prove a malfunction theory of liability, the plaintiff must show the following elements:

> 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 . . . [B]y 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.

Although the malfunction theory offers a plaintiff the opportunity to present a *prima facie* products liability case without identifying a specific defect, the leeway it affords is not without bounds. While the plaintiff need not demonstrate the actual product defect, he cannot depend

upon conjecture or guesswork, Id., at 542. The malfunction theory provides a means of proving a product defect; it does not alter the basic requirements of Section 402A of the Restatement (Second) of Torts, *Sochanski v. Sears, Roebuck and Company, 689 F. 2d 45, 50 (3d. Cir. 1982).*

Plaintiff's case cannot succeed under the malfunction theory for a number of reasons. First and foremost, the malfunction theory is factually and legally inapplicable to this case. As set forth earlier, under the malfunction theory, the "occurrence of a malfunction" is circumstantial evidence to assist the plaintiff in establishing that the product had a defect, **even though the defect cannot be identified**. In other words, the theory allows the finder of fact to infer the existence of an unspecified product defect from the accident circumstances. This is plainly not the case herein; plaintiff (through his testimony and the affidavit of his doctor) has alleged that the pump had a hole in it when it was removed the second time, and that the device failed to inflate because of the hole. Since plaintiff has identified a specific alleged defect, there is no need for an inference. There is no mystery as to why the pump did not work; the mystery is how and why the hole originated. The malfunction theory only enables a plaintiff to infer that a defect exists in the absence of improper use or reasonable secondary causes; it does not entitle him to an inference that a demonstrable deficiency in a product is the fault of the manufacturer. See, e.g., *Sochanski, supra.*

Even if the malfunction theory was applicable to this case, plaintiff could not successfully establish a claim in the absence of expert testimony. Although the Pennsylvania decisions regarding the malfunction theory vacillate as to whether a plaintiff must negate both abnormal use and reasonable secondary causes, *Schroeder v. Com. Dept of Transp., 710 A. 2d 23 (Pa. 1998)* or merely one of them, *Barnish, supra,* it is indisputable that there must be affirmative

evidence to establish at least one of them. Absent expert testimony, plaintiff cannot sustain this burden.

The court opines, at Pages 6-7 of the opinion, that "[t]here is no evidence indicating that abnormal or unintended use led to the malfunction. Plaintiff testified that he knew the proper mechanism for deflating the device. Plaintiff further testified that his doctor and a Coloplast representative also experienced difficulty deflating the implant, indicating that this was not "operator error." With all due respect, this analysis simply does not go far enough, as plaintiff cannot show that the device was not *used* improperly unless he can show that it was not *implanted* improperly. As the court also noted at Footnote 23 of its opinion, certain aspects of the malfunction theory can be established without the benefit of expert testimony. However, whether or not the device was implanted properly is not one of them. Coloplast also agrees that the question before the court "is only whether the plaintiff can establish that the penile prosthetic was defective when it left Coloplast's control without an expert opinion." In this case, however, he simply cannot.[4]

The court recognizes at Page 6 of its opinion that there are two separate malfunctions alleged, first a failure to deflate, and then later an inability to inflate. An analysis of the medical records for first occasion shows just why expert testimony is necessary. According to these records,[5] plaintiff appeared in surgery on August 1, 2008 to correct a problem with his prosthesis, which had been implanted in December of 2007. The records further reveal that the prosthesis is a multi-component device consisting of a pump, a reservoir, a valve and connective tubing, and that all of the components were removed by way of a 3 centimeter incision that

[4] Coloplast concedes that this might be possible in the case of a simple product that did not require installation or implantation.

[5] A true and correct copy of the operative notes for plaintiff's August 1, 2008 surgery is attached hereto as Exhibit "D."

"continued toward the previous pump," which was then exposed and delivered. Each of the devices was then tested, including the pump. Finally, and most significantly, all of the parts of the device were re-implanted. As such, while Mr. Banks may believe and have testified that his original device was replaced during his second surgery, the records show unequivocally that it was not.

If there was anything wrong with any component of the prosthesis apart from the manner in which it had been implanted, it is difficult to believe that this would not have been noted in the records and impossible to imagine that a defective unit would have been re-implanted. Yet there is no indication whatsoever of any type of problem with any part of the device itself, and each and every one of its components was re-implanted. Clearly, the overwhelming inference is that the problem arose from the manner of implantation (whether culpable or not) and not from a product problem. As such, since the implantation of a device of this nature is clearly a part of its use, regardless of how Mr. Banks may have used the device once it was initially implanted, he cannot negate the issue of abnormal use without affirmative expert testimony showing how it was implanted.

Viewed in the light of the 2008 records, the inference with respect to the failure to inflate is equally suspect. The "blowout" did not occur "only a couple of weeks after Plaintiff began using the prosthesis again after healing from the surgical pump replacement," Opinion at Page 6. It occurred in late 2008, after the original pump (which had been implanted in 2007) was surgically removed from plaintiff due to issues unrelated to any defect with the prosthesis, inspected and found to be in working order and re-implanted.

As noted above, the prosthesis in question is a multi-component unit which must be implanted by a skilled surgeon. Clearly the possibility exists for an imperfect implantation; one

need look no further for proof than the June, 2008 records. Proof of a case under the malfunction theory requires more than a showing that the product failed to perform as expected. Plaintiff cannot establish a *prima facie* case under the malfunction theory by simply standing up, saying he used his device properly and it didn't work and asking for damages. At a minimum, he bears the burden of producing **affirmative** evidence of at least one of the following: that the product was not used improperly or that there are no secondary explanations for the malfunction. In the case of an implantable medical device such as this, either one of these elements requires expert testimony[6]. Since the device cannot be used until it is implanted, freedom from abnormal use cannot be established without proof of proper implantation. Plaintiff is not qualified to give this testimony and has identified no expert who is prepared to do so. Similarly, while anyone can observe a picture of a hole, plaintiff is not qualified to opine as to the origin or cause of the hole, and Dr. Metro has not done so. As such, the court's conclusion that Coloplast is arguing 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" only paints half the picture. In the absence of negating the possibility of secondary causes, plaintiff must show that the device was properly used (including implantation), which would also require expert testimony.

Reconsideration is appropriate whenever it is necessary to correct a clear error of law or prevent manifest injustice. Coloplast respectfully submits that it is necessary in this case for both of these reasons. As the case sits under the existing decision, plaintiff would be able to get his case to a jury on nothing more than the fact that he received an implant that did not work. He has no evidence to show that the implantation was performed correctly (and, therefore that the

[6] *See, e.g. Rogers v. Johnson & Johnson Products, Inc., et al., 523 Pa. 176, 565 A. 2d 751 (Pa. 1988); Wiggins v. Synthes(U.S.A.), 29 A. 3d 9 (Pa. Super 2011).*

device was not used abnormally) and no evidence to show that the hole in the pump (which did not manifest itself until shortly after the second surgery, but which was verified to be in working order during it) was not caused by secondary factors unattributable to Coloplast. As such, no reasonable jury could determine, absent speculation, "whether the defect was pre-existing or caused by a medical provider," and it would be a manifest injustice to require Coloplast to continue to defend a case plaintiff cannot win. For these reasons and those set forth in previous submissions, Coloplast is entitled to, and hereby respectfully requests, that summary judgment be entered in its favor.

Respectfully submitted,

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Dated: March 7, 2012

CERTIFICATE OF SERVICE

I, Jonathan Dryer, attorney for defendant, Coloplast Corp., hereby certify that on March 7, 2012, a true and correct copy of the foregoing Motion for Reconsideration and Supporting Memorandum of Law filed electronically and is available to all parties through the court's ECF filing system.

/s/Jonathan Dryer
Jonathan Dryer, Esquire