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

MARGUERITE J. SOUFFLAS,	:	CIVIL ACTION
	:	NO. 04-4753
Plaintiff,	:	
	:	
v.	:	
	:	
ZIMMER, INC.,	:	
	:	
Defendant.	:	

M E M O R A N D U M

EDUARDO C. ROBRENO, J. February 21, 2007

Before the Court is Defendant Zimmer's contemporaneously filed motions to exclude Plaintiff's experts, Drs. Hetzel and Sidor, and its motion for summary judgment. As the ultimate outcome of defendant's motion for summary judgment is dependant upon the Court's ruling regarding the admissibility of Plaintiff's experts' opinions, the Court will address Defendant's motion to exclude plaintiff's experts and Defendant's motion for summary judgment seriatim.

This is a product liability case in which Plaintiff Marguerite J. Soufflas claims that three polyethylene tibial components implanted during two total knee arthroplasties and manufactured by Defendant, Zimmer, Inc. (Zimmer), were defectively designed and manufactured as a result of the method in which they were sterilized. Ms. Soufflas's complaint contains nine counts: (1) defective design and manufacture, (2)

failure to warn, (3) violation of Pennsylvania consumer protection act, (4) fraud, (5) breach of implied warranty of merchantability, (6) breach of implied warranty of fitness for a particular purpose,[1] (7) breach of express warranty, (8) negligent design and manufacture, and (9) punitive damages. Zimmer has moved for summary judgment on all nine counts.

I. BACKGROUND

Ms. Soufflas has a long history of problems in both knees. In 1975, she tore the cartilage in her left knee, causing significant pain and swelling. To repair the damage, Ms. Soufflas underwent three separate left knee surgeries to remove the torn cartilage and "reshape" and "clean" her knee.

In 1998, Plaintiff again experienced problems with both of her knees. After seeking treatment for a "burning" pain in her right knee, she decided to undergo knee replacement surgery, also known as bilateral total knee arthroplasty, on both knees.

On March 30, 1999, Plaintiff underwent bilateral total knee replacement surgery, during which Zimmer's Insall-Burstein II Modular Knee System was implanted into each knee. Each device consisted of a femoral component, tibial tray, tibial insert articular surface (tibial insert) and patella button. The tibial

[1] Count six actually is entitled "Breach of Implied Warranty of Merchantability," but really alleges a breach of the implied warranty of fitness for a particular purpose.

insert, which is at issue in this litigation, is made of a type of plastic called ultra high molecular weight polyethylene (UHMWPE), and is placed in the tibial tray to provide the surface on which the femoral component rotates or articulates.

In September 2002, Ms. Soufflas felt something in her right knee "break." Soufflas Dep. at 110-11. She subsequently had pain and swelling in her right knee and instability when walking. Ms. Soufflas's surgeon fit her knee for a brace and ordered physical therapy, but after a month, neither measure resolved her pain and swelling. Although her surgeon could not definitively determine the cause of Ms. Soufflas's instability, he advised her that she "may have loosened one or more of her parts, and she clearly need[ed] a polyethylene enhancement to restore stability." Soufflas Dep. at 135.

On January 7, 2003, Plaintiff underwent surgery to replace the tibial insert (called "revision surgery") in Plaintiff's right knee with a thicker Insall-Burstein Tibial Insert. Despite receiving a thicker tibial insert, Ms. Soufflas continued to experience instability in both knees.

Within months of the January 2003 surgery, Ms. Soufflas's right knee began "locking."[2] She was treated again

[2] Plaintiff described the locking sensation as follows: "if you went to watch my knee, it would literally go from side to side. It would go sort of – it would hit left, and then hit right, because you could see that the knee was totally not connected." Soufflas Dep. at 178-179.

for instability and swelling in her right knee. As a result, the surgeon informed her that the revision surgery "did not take" and that she needed "to have that [right] knee replaced completely." Soufflas Dep. at 178, 179-180.

In mid-to-late February 2004, Ms. Soufflas's right knee locked again and she fell, landing on her left knee. On March 5, 2004, during a visit related to the upcoming right knee replacement surgery, x-rays revealed that Ms. Soufflas's left knee also needed to be "revised." On March 23, 2004, Ms. Soufflas underwent knee revision surgery on both knees.

On December 21, 2004, she filed her complaint against Zimmer. In the complaint, Plaintiff alleges that Zimmer is liable because Zimmer's method of sterilizing the tibial inserts, by gamma irradiation in air, "caused premature wear and degradation of UHMWPE [and] resulted in artificial joint failure." Compl. ¶ 35.

Whether the tibial insert used in Ms. Souflas's artificial knee was, in fact, sterilized by gamma irradiation in air or by some other sterilization process, and whether that sterilization process caused the ensuing fracture of the insert and the need for further surgeries, remain disputed issues of fact in the case.

Defendant's expert, Dr. Maloney, will testify that both the 2003 tibial insert and the left tibial insert from Ms.

Soufflas's 1999 surgery were packaged and sterilized in nitrogen, as opposed to gamma irradiation in air. On the other hand, Plaintiff's expert, Dr. Hetzel, opines that all three of Plaintiff's tibial inserts were sterilized by gamma irradiation in air. Hetzel Report at 8; see also Hetzel Dep. at 66, 132.

II. DISCUSSION

A. Defendant's Motion to Preclude Plaintiff's Expert Testimony

1. The Court's Gatekeeping Role Under Daubert.

Under Daubert, a "trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 589 (1993). Expert testimony is admissible only where "the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue." Id. at 592.

In order to constitute "scientific knowledge," the expert's proposed opinion "must be derived by scientific method . . . and supported by appropriate validation, i.e., 'good grounds.'" Id. at 590. Expert testimony is deemed to assist the trier of fact to understand or determine a fact in issue where "the expert testimony proffered in the case is sufficiently tied to the facts of the case that it will aid the jury in resolving a

factual dispute." Id. at 591. "The consideration has been aptly described . . . as one of 'fit.'" Id. In other words, Daubert requires a "valid scientific connection to the pertinent inquiry as a precondition to admissibility" of expert testimony. Id. at 592. "This requires a preliminary assessment of whether the reasoning or methodology underlying the [proposed] testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." Id. at 593.

Factors that may guide a district court's preliminary assessment of these requirements include (1) whether the methodology can and has been tested; (2) whether the technique has been subjected to peer review and publication; (3) the known or potential rate of error of the methodology; and (4) whether the technique has been generally accepted in the proper scientific community. Heller v. Shaw Industries, Inc., 167 F.3d 146, 152 (3d Cir. 1999) (citing Daubert, 509 U.S. at 593-94). The district court's role as the gatekeeper is a "flexible one" and "the factors are simply useful signposts, not dispositive hurdles that a party must overcome in order to have expert testimony admitted." Heller, 167 F.3d at 152.

In addition to the factors listed above, the Third Circuit has suggested that the district court consider additional factors, including (1) the existence and maintenance of standards controlling the technique's operation; (2) the relationship of

the technique to methods which have been established to be reliable; (3) the expert witness's qualifications; and (4) the non-judicial uses to which the method has been put. Heller, 167 F.3d at 152 (citing In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 742 n.8 (3d Cir. 1994)); see Johnson v. Vane Line Bunkering, Inc., No. 01-5819, 2003 WL 23162433 at *2-3 (E.D. Pa. Dec. 30, 2003) (Robreno, J.).

2. Dr. Hetzel's opinions

Dr. Hetzel, a scientist in the field of organic chemistry, opines that (1) the tibial insert implanted in Ms. Soufflas's knee was sterilized using gamma irradiation in air, (2) the effect of this sterilization method is to chemically degrade the insert, weakening it over time, (3) this weakening ultimately caused the tibial insert to fracture, (4) based on the polymer literature, Zimmer knew or should have known of the dangers of this sterilization process, (5) alternate sterilization processes were available at the time of manufacture of the tibial insert used in Plaintiff, and (6) the tibial insert contained voids or air bubbles, which are manufacturing defects.

Zimmer attacks Dr. Hetzel's proposed testimony as unreliable and inadmissible under Federal Rule of Evidence 702 and Daubert. Dr. Hetzel will be permitted to offer some but not all of the proposed opinions.

Dr. Hetzel's testimony will be limited to the sterilization methods available at the time Zimmer sterilized the tibial insert used on Ms. Soufflas, the chemical effects caused by gamma irradiation in air on UHMWPE, the indications of these effects and what he examined in the inserts extracted from Ms. Soufflas's knee. This evidence is both relevant and reliable under Daubert's standards.

It is relevant in that it provides one possible explanation for the failure of Ms. Soufflas's tibial inserts - that it was weakened by the chemical effect the sterilization process used had on the particular polymer. As an organic chemist, Dr. Hetzel is experienced in the chemical makeup of polymers, such as the substance used in Ms. Soufflas's tibial insert. Therefore, Dr. Hetzel is qualified to render his opinion as to the effect of the sterilization on the material.[3] That Dr. Hetzel is not medically trained does not bear upon his qualifications to opine as to the chemical affects of gamma irradiation in air on Ultra High Molecular Weight Poyethylene.

[3] That Dr. Hetzel's opinions has been excluded in another case, see Swank v. Zimmer, Inc., No. 03-CV-60-B (D. Wyo. Apr. 20, 2004) (motion in limine excluding Dr. Hetzel's opinions of design defect because "he has no experience or education in designing hip implants."), is not binding on this Court. Moreover, this Court does not agree that Dr. Hetzel's opinions regarding the sterilization method chosen by Zimmer should be excluded merely because he has not designed artificial knees. Dr. Hetzel has considerable experience in the chemical effect of sterilization methods on plastics, a fact relevant to the issues of this case.

Additionally, Dr. Hetzel's opinions with respect to the effect on gamma irradiation in air are reliable because they are based on generally accepted literature in the field. Many of defendant's arguments to support its motion to preclude Dr. Hetzel's opinion, such as the argument that the tibial inserts were actually sterilized by a method other than gamma irradiation in air, are appropriate to raise in its cross examination of Dr. Hetzel. At most, the shortcomings alleged by Defendant render Dr. Hetzel's opinion "shaky", but nonetheless admissible. "'[V]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence . . . .'" Johnson, 2003 WL 23162433, at *8 (quoting Daubert, 509 U.S. at 596).

While Dr. Hetzel may testify as to the chemical effects of certain sterilization processes on the tibial insert used on Ms. Soufflas's knee, he may not opine as to any manufacturing defect, as this testimony does not satisfy the standards for reliability set out in Daubert and its progeny.

In concluding that sterilization of the insert using gamma irradiation in air constitutes a manufacturing defect, Dr. Hetzel used "little, if no methodology beyond his own intuition". Oddi v. Ford Motor Co., 234 F.3d 136, 158 (3d Cir. 2000). He neither examined other tibial inserts nor verified that the

insert used in Ms. Soufflas deviated from Zimmer's specifications.

On the contrary, during his deposition, Dr. Hetzel admits that the insert used in Ms. Soufflas's knee conformed to Zimmer's specifications. Hetzel Dep. 110, 112, 156. The blanket conclusion that the tibial insert suffered from a manufacturing defect by virtue of the sterilization process does not meet the standards set out in Daubert as it is not supported by appropriate validation and does not assist the trier of fact. The Court is not satisfied that this opinion testimony reliably flows from the facts known to Dr. Hetzel. General Elec. Co. v. Joiner et ux., 522 U.S. 136, 146 (1997).

Additionally, Dr. Hetzel is not qualified to opine about the alleged inadequacies of Zimmer's warnings. He is not a surgeon and has had no experience implanting the such devices, nor does he have any qualifications by way of training or experience related to medical considerations when implanting an artificial knee.

Finally, Dr. Hetzel may not opine as to the customary practices of manufacturers of medical devices. As he has no experience in the manufacturing of prescription medical devices or the common practices of those in the industry, he is not qualified as an expert to opine on such customary practices.

3. Dr. Sidor's opinions

Dr. Sidor proposes to testify that Dr. Booth, Ms. Soufflas's surgeon, correctly aligned the prostheses and performed the total knee replacements in accordance with medically proper techniques.

Defendant offers three reasons for the exclusion of Dr. Sidor's expert opinion: (1) Plaintiff did not timely disclose Dr. Sidor as an expert, (2) Plaintiff failed to provide a written report that complies with the requirements of Rule 26(a)(2)(B), Rule 702 and Daubert, and (3) Dr. Sidor's opinions are irrelevant in that they fail to address medical causation. Dr. Sidor's opinions will be permitted.

a. Failure of Plaintiff to timely disclose Dr. Sidor

Defendant's first argument is unpersuasive. While the Court may prohibit the admission of evidence, including testimony by an expert witness, when offered by a party in violation of a pre-trial order, this is an extreme sanction and is not justified in this case.[4] One, the report of Dr. Sidor is in the nature of

[4] The Federal Rules of Civil Procedure authorize the district court, where appropriate, to prohibit the admission of evidence, including testimony by expert witnesses, offered by a party in violation of a pre-trial order. Fed. R. Civ. P. 37(b)(2); United States v. 68.94 Acres of Land, 918 F.2d 389, 396 (3d Cir. 1990). Under Rule 37(c)(1), however, untimely evidence – that is evidence which was disclosed after initial expert reports were due under the pretrial order – may be admitted if the party proffering the evidence shows substantial justification

a rebuttal report. As Zimmer's expert attributed the tibial insert's fracture to Plaintiff's own "ligament instability," it appears that the issue of the medical cause of the tibial insert's fracture was raised by Zimmer in its own expert report. Once the issue surfaced, Plaintiff acted diligently to obtain a rebuttal report. Two, the case has not yet been listed for trial and Defendant will be afforded ample time to procure an expert in rebuttal or to have its experts supplement their reports.

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for its failure to disclose or if the failure to disclose is harmless.

There are four factors the Court should consider when determining whether the untimely expert opinion should be excluded: (1) the prejudice or surprise of the party against whom the excluded evidence is offered; (2) the ability of that party to cure the prejudice; (3) the extent to which allowing the evidence would disrupt the orderly and efficient trial of the case; and (4) bad faith or willfulness in failing to make a required disclosure or comply with a court order. Myers v. Pennypack Woods Home Ownership Ass'n, 559 F.2d 894, 904 (3d Cir. 1977), overruled on other grounds by Goodman v. Lukens Steel Co., 777 F.2d 113 (3d Cir. 1985).

While in some circumstances the exclusion of an expert witness may be an appropriate sanction for a party's violation of a discovery or pre-trial order, 68.94 Acres of Land, 918 F.2d at 396, "it is an extreme sanction" and, if the evidence is critical, one "not normally to be imposed absent a showing of willful deception or 'flagrant disregard' of the court order by the proponent." Myers, 559 F.2d at 905; see also Montgomery v. Mitsubishi Motors Corp., No. 04-3234, 2006 WL 2460563, *10 (E.D. Pa. July 12, 2006) (Pratter, J.) (noting that exclusion of expert testimony as a sanction for violating a court's scheduling order is extreme and rarely imposed).

In essence, exclusion is disfavored unless the opposing party has shown that there is no reasonable explanation for delay, or its legal position is irreparably prejudiced ,or the administration of justice will be greatly burdened.

Therefore, Defendant has not shown that Plaintiff's explanation of the delay is unreasonable, that its legal position will be irreparably prejudiced or that the administration of justice will be unduly burdened.

b. Plaintiff failed to provide a written report that complies with the requirements of Rule 26(a)(2)(B), Rule 702 or Daubert

Defendant argues that Dr. Sidor's opinions must be excluded because his curriculum vitae did not reveal his experience vis-a-vis knee revision surgery and therefore does not provide "a reasonable opportunity to prepare for effective cross examination" in accordance with Rule 26(a)(2)(B). Upon reviewing Dr. Sidor's curriculum vitae, the Court concludes that Defendant's argument fails in this respect.

Dr. Sidor's qualifications are readily apparent from his curriculum vitae. It is clear that he is an orthopaedic surgeon specializing in the knee and shoulder. He has completed numerous training courses regarding knee surgical techniques and knee replacements. In addition, he has instructed courses on orthopaedic surgery generally and knee replacement surgery specifically. Finally, he currently is in private practice focusing on knee and shoulder surgery. Dr. Sidor's curriculum

vitae satisfies the purpose of Rule 26(a)(2)(B).[5]

Finally, Zimmer does not state any justification for its statement that Dr. Sidor has failed to meet the qualification requirement of Daubert and Rule 702. In the absence of some specificity, the Court need not address this blanket conclusion.

c. Dr. Sidor's opinions are irrelevant.

Finally, Zimmer argues that Dr. Sidor's opinions are irrelevant and that his testimony will not aid the jury. It contends that Plaintiff is offering Dr. Sidor in order to show that her surgeon did not fall below the standard of care when implanting or revising the tibial inserts.

Defendant misses the point of Dr. Sidor's testimony. The purpose of his expert opinion is not to relieve Ms. Soufflas's surgeon of liability, but to rule out one possible cause for the tibial insert's ultimate failure. The cause of the tibial insert's failure is highly relevant to the issue of the case and will assist the trier of fact. Therefore, Defendant's motion to exclude the expert testimony of Dr. Sidor will be

[5] To the extent not already provided, at least 20 days prior to the deposition of Dr. Sidor or at least 20 days prior to trial, whichever is later, and in accordance with Rule 26(a)(2)(B), plaintiff shall provide a list of all publications authored by Dr. Sidor within the previous 10 years, the compensation to be paid for his study and testimony, and a listing of any other cases in which Dr. Sidor has testified as an expert at trial or by deposition within the preceding 4 years.

denied.

With the admissibility of Plaintiffs' proffered experts decided, the Court will now turn to Defendant's motion for summary judgment.

B. Motion for Summary Judgment

1. Legal standard

A court may grant summary judgment when "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). A fact is "material" if its existence or non-existence would affect the outcome of the suit under governing law. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). An issue of fact is "genuine" when there is sufficient evidence from which a reasonable jury could find in favor of the non-moving party regarding the existence of that fact. Id. at 248-49. In determining whether any genuine issues of material fact exist, all inferences must be drawn, and all doubts must be resolved, in favor of the non-moving party. Coregis Ins. Co. v. Baratta & Fenerty, Ltd., 264 F.3d 302, 305-06 (3d Cir. 2001).

The non-moving party will not defeat a motion for summary judgment merely by relying on bare assertions, conclusory

allegations or suspicions. Fireman's Ins. Co. of Newark v. DuFresne, 676 F.2d 965, 969 (3d Cir. 1982). Instead, the non-moving party must "make a showing sufficient to establish the existence of every element essential to his case, based on the affidavits or by the depositions and admissions on file." Harter v. GAF Corp., 967 F.2d 846, 852 (3d Cir. 1992).

2. Application

Zimmer moves for summary judgment on a number of grounds: (1) all of Plaintiff's claims fail because there is a lack of evidence of medical causation or defect; (2) Plaintiff's strict liability claim fails as a matter of law because Pennsylvania law excludes prescription medical devices from strict liability; (3) Plaintiff's implied warranty claims are barred as a matter of law; (4) Plaintiff's negligence claim fails as a matter of law; (5) Plaintiff's failure to warn claim is barred as a matter of law; (6) Plaintiff's fraud and consumer protection claims fail as a matter of law; (7) Plaintiff's express warranty claim fails as a matter of law; and (8) Plaintiff's punitive damages claim fails as a matter of law.[6]

[6] Although it is not clear from the parties' submissions, depending on the Food and Drug Administration (FDA) approval process in which Zimmer engaged in order to sell its artificial knees, later there may be an issue of whether some of Plaintiff's claims, including her design defect, failure to warn, breach of warranty and negligent design and manufacture claims, are preempted by the Medical Devices Amendments (MDA). The MDA, 21

U.S.C. § 360c, et seq., regulates the sale of medical devices and gives the FDA comprehensive jurisdiction over all "devices intended for human use." 21 U.S.C. § 360c(a)(1); see Metrodic, Inc. v. Lohr, 518 U.S. 470, 477 (1996) (providing overview of MDA).

The MDA classifies medical devices as Class I, Class II and Class III, depending on their potential danger to humans. Class I devices pose little or no threat to humans, i.e. bandages, while Class III devices are intended "for use in supporting or sustaining human life or . . . [are] of substantial importance in preventing unreasonable risk of illness of injury." 21 U.S.C. § 360c(a)(1)(C). Class III devices include replacement joints, such as the artificial knee and the tibial insert used in Ms. Soufflas. See Green v. Dolsky, 685 A.2d 110, 114 (Pa. 1996) (noting that replacement joints are included in Class III devices).

One of two possible avenues must be taken in order to for a Class III medical device to be approved for sale under the MDA.

> The first is the premarket approval process, in which the manufacturer must submit a detailed premarket approval application to the FDA that presents all available information concerning investigations of the device's safety and effectiveness; detailed information regarding its design, components, ingredients, properties, and principles of its operation; a full description of manufacturing methods and controls. 21 U.S.C. § 360e(c)(1). This premarket application must be approved before the device can be sold. 21 U.S.C. § 360c(a)(1)(C).
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> The second method of approval for the sale of a Class III Medical Device is to establish that it is substantially equivalent to a device that is already on the market. See 21 U.S.C. § 360e(b)(1)(A). If this can be established, the premarket approval process, which is somewhat lengthy, can be avoided.

Green, 685 A.2d at 114 (citing Medtronic, Inc. v. Lohr, 518 U.S. 470, 477–78 (1996)).

Whether or not the MDA, which itself does not provide a private right of action, preempts state law action based on

injuries received as a result of a medical device, depends upon which of these two avenues Zimmer pursued when obtaining FDA approval of its Insall-Burstein II Modular Knee System. Two possible scenarios exist, one that leads to express preemption under MDA's § 360k, and one that would allow Ms. Soufflas's claims.

If Zimmer gained FDA approval by the rigorous premarket approval (PMA) procedures of § 360c(a)(1)(C), then Ms. Soufflas's claims for defective design, breach of warranties, strict liability and negligent design and manufacture are all preempted by the MDA. To hold otherwise would be to impose an additional requirement different from, or in addition to, the FDA's requirements. When approval is sought through premarket approval, the FDA independently determines that the product is neither dangerous nor defectively designed before approving the device for sale. See Horn v. Thoratec Corp., 376 F.3d 163, 169 (3d Cir. 2004) (finding that the PMA process is a specific federal interest defined in the MDA's preemption clause and holding that PMA is federal "requirement" which triggers MDA preemption); Green, 685 A.2d at 118 ("To allow a strict liability claim for a product specifically approved by the FDA would be to impose 'requirements' which are different from those of the FDA and which affect the safety of the device, in violation of § 360k.").

On the other hand, if Zimmer gained FDA approval through the second approval method, § 510(k), her causes of action would not be preempted by the MDA's § 360k. When addressing whether a plaintiff's negligent and strict liability claims were preempted by the MDA when the manufacturer of a pacemaker obtained FDA approval using the "substantially similar" process of § 510(k), the Supreme Court in Medtronic, Inc., 518 U.S. at 493-94, concluded that § 510(k) does not trigger preemption. Under this process, which merely confirms that pre-1976 and post-1976 devices are substantially equivalent, and does not independently determine the potential danger or possible defects of the device, preemption is not an issue, as the claims do not seek to impose requirements that are different from, or in addition to, the requirements of federal law. See id.

As Defendant has not raised the issue of preemption, and based on the fact that most Class III products do not undergo the rigorous premarket approval process, the Court will assume, unless the parties state otherwise, that Zimmer's insert obtained FDA approval through the "substantially similar" procedure set

Each ground Zimmer offers as a basis of summary judgment will be addressed seriatim.

a. Evidence of medical causation and defect

Two essential elements of any products liability claim in Pennsylvania are (1) proof of an actual defect in the product and that (2) the defect was the proximate cause of the plaintiff's injuries. Davis v. Berwind Corp., 690 A.2d 186, 190 (Pa. 1997). Generally, defect must be proven through expert testimony. Oddi v. Ford Motor Co., 234 F.3d 136, 160 (3d Cir. 2000).

Zimmer argues that all Plaintiff's claims fail as she has no admissible evidence of medical causation, established by an expert witness, and no evidence of a defect of the tibial insert. In essence, Zimmer contends that Ms. Soufflas has failed to offer a medically qualified expert to state that a defect in the insert proximately caused her injuries. This argument, however, is dependant upon the its motion to exclude Plaintiff's experts, Drs. Hetzel and Sidor. After the Court's ruling on Zimmer's motion to exclude, it is evident that Ms. Soufflas, through the combined testimony of Drs. Hetzel and Sidor, has offered evidence to show that the sterilization method used by

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out in § 510(k) and preemption does not bar plaintiff's claims.

Zimmer had the chemical effect of weakening the plastic of the tibial component, causing it to ultimately fail in her leg, and that its failure was due to no fault of Ms. Soufflas or the performing surgeon. Therefore, she has raised a genuine issue of material fact concerning the cause of the tibial insert's failure and, in turn, the ultimate cause of her injuries.

b. Applicability of strict liability to the tibial insert

Three types of defective conditions can give rise to strict liability in Pennsylvania: design defect, manufacturing defect and failure to warn defect. Phillips v. A-Best Prods. Co., 665 A.2d 1167, 1170 (Pa. 1995); Parkinson v. Guidant Corp., 315 F. Supp. 2d 741, 746 (W.D. Pa. 2004) (Diamond, J.). Plaintiff is advancing all three theories of strict liability.[7]

Under Pennsylvania law, a plaintiff alleging a product design or manufacturing defect based on a theory of strict

[7] While Plaintiff's complaint appears to advance a failure to warn claim based on strict liability, Plaintiff's response to Zimmer's motion for summary judgment compares its claim to a negligent failure to warn claim advanced by a plaintiff in another case. Specifically, plaintiff's response to Zimmer's motion for summary judgment cites Stranger v. Smith & Nephew, Inc., 401 F. Supp. 2d 974 (E.D. Mo. 2005), where the district court for the Eastern District of Missouri granted plaintiff's partial summary judgment motion on plaintiff's negligent failure to warn claim against a manufacturer of a tibial insert. To the extent that plaintiff is advancing a negligent failure to warn claim, it will be addressed in section II.B.2(c).

liability must show that (1) the product was defective; (2) the defect was the proximate cause of the plaintiff's injuries; and (3) the defect causing the injury existed when the product left the seller's hands. Pavlik v. Lane Limited/Tobacco Exporters Int'l, 135 F.3d 876, 881 (3d Cir. 1998).

In addition, Pennsylvania has adopted Section 402A of the Restatement (Second) of Torts, which imposes strict liability on manufacturers of products sold "in a defective condition unreasonably dangerous to the user or consumer." Mazur v. Merck & Co., 964 F.2d 1348, 1353 (3d Cir. 1992); See also Moyer et al v. United Dominion Indus., Inc., 473 F.3d 532, 538 (3d Cir. 2007); Phillips, 665 A.2d at 1170 (quoting Restatement (Second) of Torts). Despite § 402A's general imposition of strict liability for unreasonably dangerous products, comment k of § 402A denies application of strict liability to products considered "unavoidably unsafe."[8] These products include

[8] Note that apparently not all jurisdictions adopting The Restatement (Second) of Torts § 402A and comment k provide a blanket exclusion to manufacturers of prescription drugs from strict liability. For example, under New Jersey law, despite comment k, whether or not strict liability is excluded in prescription drug cases depends on a case-by-case review. See Perez v. Wyeth Labs., Inc., 734 A.2d 1245, 1250 (N.J. 1999) ("Drugs, like any other products, may contain defects that could have been avoided by better manufacturing or design. Whether a drug is unavoidably unsafe should be decided on a case-by-case basis; we perceive no justification for giving all prescription drug manufacturers a blanket immunity from strict liability manufacturing and design defect claims under [Restatement (Second) Torts § 402A] comment k [(1965)].").

"prescription drugs, which, although dangerous in that they are not without medical risks, are not deemed defective and unreasonably dangerous when marketed with proper warnings." Hahn v. Richter, 673 A.2d 888, 889-90 (Pa. 1996). In Hahn, the Pennsylvania Supreme Court made clear that § 402A is inapplicable to prescription drugs. Id. The reasoning behind comment k is that some products, such as prescription drugs, present a unique set of risks and benefits that may be harmful to one person and beneficial to another. Taylor v. Danek Medical, Inc., No. 95-7232, 1998 WL 96062, at *7 (E.D. Pa. Dec. 29, 1998) (Broderick, J.).

Zimmer argues that comment k should be extended to apply not only to prescription drugs, which are explicitly mentioned in the comment, but also to prescription medical devices, such as the tibial insert. If so extended, then prescription medical devices, like the tibial insert manufactured by Zimmer and used in Ms. Soufflas's leg, would be deemed "unavoidably unsafe" and manufacturers of medical devices would be effectively immune from strict liability suit in Pennsylvania.

The Pennsylvania Supreme Court has not addressed the issue of whether prescription medical devices are included in §

Under Pennsylvania law, however, strict liability and § 402A are inapplicable to prescription drugs. Hahn v. Richter, 673 A.2d 888, 889-90 (Pa. 1996); Murray v. Synthes U.S.A., Inc. et al., No. 95-7796, 1999 WL 672937 *6 (E.D. Pa. Aug. 23, 1999) (Hutton, J.).

402A comment k's "unavoidably unsafe" characterization. Recently, however, the Pennsylvania Superior Court in Creazzo v. Medtronic, Inc., 903 A.2d 24, 31 (Pa. Super. Ct. 2006), affirmed the Northampton County Court of Common Pleas's decision granting the defendant's motion for summary judgment. Concluding that comment k applied to medical devices, the court found "no reason why the same rational applicable to prescription drugs may not be applied to medical devices." Id. at 31; see also Lawrence v. Synthes, Inc., No. 94-7627, 2002 WL 32747667 (Chester Co. Ct. C.P. July 25, 2002) (dismissing plaintiff's strict liability claim due to lack of causation, but noting that it would nonetheless be barred by the reasoning of Murray extending the Pennsylvania Supreme Court's reasoning in Hahn and 402A comment k to prescription medical devices).

In addition, several federal district courts predicting Pennsylvania law have extended comment k's reach to prescription medical devices. The first case to do so was Taylor v. Danek Medical, Inc., No. 95-7232, 1998 WL 962062, at *7 (E.D. Pa. Dec. 29, 1998) (Broderick, J.). Taylor was one of many bone screw cases, where the plaintiff sued a manufacturer of spinal bone screws for, inter alia, strict liability after the screws implanted in her spine caused increased pain in her back. Id. In addressing the defendant's motion for summary judgment with respect to the plaintiff's strict liability claim, Judge

Broderick noted that the reasoning behind comment k, and the Pennsylvania Supreme Court's reasoning in Hahn, supports its application to prescription medical devices. Id. In so deciding, the court granted the defendant's motion for summary judgment on the plaintiff's design defect claim based on strict liability. Id.

Other federal courts predicting the Pennsylvania Supreme Court's decision on the issue have followed Judge Broderick's reasoning in Taylor. For example, Burton v. Danek Medical, Inc., et al., No. 95-5565, 1999 WL 118020 * 7 (E.D. Pa. Mar. 1, 1999) (Kelly, J.), was another bone screw case where the plaintiff alleged design defect, manufacturing defects and failure to warn claims based on a theory of strict liability. Citing Judge Broderick's opinion in Taylor, the court found "the same reasoning underlying Comment k that excludes prescription drugs from Section 402A should also apply to prescription medical devices. Id. "Therefore, prescription medical devices are not covered by Section 402A and Plaintiffs' strict liability claims must fail." Id. See also Murray v. Synthes, No. 95-7796, 1999 WL 672937, at *6-8 (E.D. Pa. Aug. 23, 1999) (Hutton, J.) ("This Court also agrees with the reasoning of Judge Broderick in Taylor and finds that the same reasoning underlying Comment k that excludes prescription drugs from Section 40A should also apply to prescription medical devices."); Davenport v. Medronic, Inc., 302

F. Supp. 2d 419, 422 (E.D. Pa. 2004) (Kelly, J.) ("This Court agrees with the reasoning of these cases [Murray, Burton, Taylor] and finds that Comment k precludes application of Section 402A to prescription medical devices."); Parkinson v. Guidant Corp., 315 F. Supp. 2d 714, 747 (W.D. Pa. 2004) ("Accordingly, this court predicts that the Pennsylvania Supreme likely would find that comment K to § 402A applies as equally to prescription medical devices as it does to prescription drugs.").

This Court will follow the other federal courts in predicting, based on its reasoning in Hahn, that Pennsylvania Supreme Court would extend § 402A's comment k to exclude prescription medical devices from strict liability. Accordingly, Zimmer's motion for summary judgment will be granted with respect to Plaintiff's strict liability claims.

c. Failure to warn

Defendant's motion for summary judgment contends that Plaintiff has failed to show any evidence that Zimmer improperly warned physicians. Zimmer's argument has merit.

Based on the same reasoning as applied above in the strict liability section, a strict liability claim for failure to warn is not cognizable under Pennsylvania law. Burton, 1999 WL 118020, at *8. Accordingly, negligence is the only possible basis for recovery based upon the adequacy of warnings associated

with prescription medical devices. Hahn, 673 A.2d at 891. To the extent that Plaintiff advanced a failure to warn claim grounded in a theory of negligence, Defendant's motion for summary judgment will be granted.[9]

To establish a claim for failure to warn based on negligence, Plaintiff must show that Zimmer failed to exercise reasonable care in warning of the dangers of its prescription medical device. Burton, 1999 WL 118020, at *8. Under the learned intermediary doctrine, applicable in Pennsylvania, a manufacturer will only be held liable where it fails to exercise reasonable care to inform the one for whose use the product is supplied of the facts that make the product likely to be dangerous. Rosci v. AcroMed, Inc., 669 A.2d 959, 969 (Pa. Super. 1995). In a case involving a prescription medical device, the intended user is the prescribing physician. Id. Whether a warning was adequate depends on whether a learned intermediary, having considered the "the data supplied to him by the manufacturer, other medical literature, and any other source available to him, and weighing that knowledge against the personal medical history of his patient," would use his

[9] As previously stated, it is unclear whether Plaintiff's failure to warn claim is one based on a theory of negligence or strict liability. To the extent that it is based on strict liability, it must be dismissed as comment k to § 402A excludes prescription medical devices from suit based on a theory of strict liability. See, supra section II.B.2(b) and accompanying text.

independent judgment to prescribe a medical device. Coyle v. Richardson-Merrell, Inc., 584 A.2d 1383, 1386 (Pa. 1991).

Generally, the adequacy of a warning in prescription medical device cases must be proven by expert testimony. Demmler v. SmithKline Beecham Corp., 671 A.2d 1151, 1154 (Pa. Super. Ct. 1996). This case is no different. While Plaintiff has proffered the expert testimony of Dr. Sidor, who proposes to rebut Zimmer's evidence that the tibial insert fractured as a result of Ms. Soufflas's ligament instability, she has not produced any expert to testify that Zimmer's warnings in place at the time the artificial knee system was implanted provided the surgeon with inadequate warning of the possible dangers of the device. As previously mentioned, Dr. Hetzel is not qualified to render such an opinion. In addition, nowhere in Dr. Sidor's report did he address the adequacies of the warnings given by Zimmer. Therefore, to the extent Plaintiff's failure to warn claim sounds in negligence, summary judgment is granted in favor of Defendant.[10]

d. Implied Warranties of Merchantability and Fitness for a Particular Purpose

Like Plaintiff's strict liability claims, summary

[10] Again, to the extent that plaintiff's failure to warn claim is based on a theory of strict liability, it is barred.

judgment in favor of Defendant is also warranted with respect to Plaintiff's implied warranty of merchantability and fitness for a particular purpose claims.

The implied warranty of merchantability and fitness for particular purpose arise by operation of law and were created to protected buyers from products sold below commercial standards or unfit for the buyer's purposes. Altronics of Bethlehem, Inc. v. Repco, Inc., 957 F.2d 1102, 1105 (3d Cir. 1992). In order to meet the definition of "merchantable," products must, inter alia, be "fit for the ordinary purpose for which such goods are used". 13 Pa. Cons. Stat. Ann. § 2314(b)(3). More exacting than the implied warranty of merchantability, the implied warranty of fitness for a particular purpose requires the seller to know the particular purpose for which the goods are required and the buyer to rely on the skill or judgment of the seller to select or furnish suitable goods. Id. at § 23145.

Both warranties are inapplicable to prescription medical devices in Pennsylvania. "The very nature of prescription medical products which are considered 'unavoidably unsafe products' precludes the imposition of a warranty of fitness for 'ordinary purposes.'" Taylor, 1998 WL 962062, at *14 (predicting that the Pennsylvania Supreme Court would exclude a cause of action based on implied warranty of merchantability for prescription medical devices, and citing Makripodis v. Merrell-

Dow Pharm, Inc., 523 A.2d 374 (Pa. Super. Ct. 1987)); see also Murray, 1999 WL 672937, at *9 (predicting that the nature of prescription medical devices precludes claims for breach of the implied warranty of merchantability under Pennsylvania law). Likewise, Plaintiff's breach of implied warranty of fitness for a particular purpose is also excluded as a matter of Pennsylvania law. See Parkinson, 315 F. Supp. 2d at 753 (granting defendant's motion for summary judgment with respect to plaintiff's breach of implied warranties of merchantability and fitness for particular purpose claims as precluded claims under Pennsylvania law).

e. Fraud, Pennsylvania consumer protection and breach of express warranty

As to Plaintiff's fraud, Pennsylvania consumer protection and breach of express warranty claims, summary judgment is granted in favor of defendant. Defendant has pointed to an absence of genuine issue of material fact with respect to each of these claims and Plaintiff has failed to point to the existence of a genuine issue of material fact on these issues.[11]

With respect to the fraud claim, Defendant has pointed to an absence of genuine issue of material fact in that Plaintiff has not produced any evidence that shows that Zimmer engaged in

[11] In fact, from plaintiff's silence on these claims in her opposition to defendant's motion for summary judgment, it appears that plaintiff has conceded these claims.

any material misrepresentation, or that such a misrepresentation was justifiably relied upon.

Likewise, Plaintiff has failed to show a genuine issue of material fact regarding any fraudulent or deceptive conduct on the part of Zimmer.[12]

Finally, no genuine issue of material exists as to Plaintiff's express warranty claim as there is no evidence that Plaintiff relied upon an express statement by Zimmer and that the reliance caused her injury.

f. Negligent Design and Manufacture[13]

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[12] Pennsylvania's Unfair Trade Practices Act and Consumer Protection Law provides a statutory remedy to consumers that are victims of unfair, fraudulent and deceptive acts or practices. 73 Pa.Cons. Stat. Ann. §§ 201-2, 202-3. The UTPCPL's Catchall Provision prohibits "[e]ngaging in any other fraudulent or deceptive conduct which creates a likelihood of confusion or of misunderstanding." 73 Pa. Cons. Stat. Ann. 201-2(4)(xxi) (emphasis added). A plaintiff alleging fraudulent conduct must prove all of the elements of common law fraud. Prime Meats, Inc. v. Yochim, 619 A.2d 769, 773-74 (Pa. Super. 1993). In the alternative, a plaintiff claiming deceptive conduct must only "demonstrate that he/she detrimentally relied upon the deceptive practice of the defendant and that the plaintiff suffered harm as a result of this reliance.") Toy v. Metropolitan Life Ins. Co., 863 A.2d 1, 9 (Pa. 2004). As Plaintiff has shown neither fraudulent nor deceptive conduct on the part of Zimmer, Defendant's motion for summary judgment is granted in this respect.

[13] At the outset, it is important to note that a negligent design claim is not foreclosed merely because summary judgment is granted in favor of Defendant on Plaintiff's strict liability claim. See Phillips v. Cricket Lighters ("Phillips I"), 841 A.2d 1000, 1008 (Pa. 2003) (overruling Dambacher v. Mallis, 485 A.2d 408 (Pa. Super. Ct. 1984), and holding that the failure of a

strict liability claim is not fatal to a negligence claim because the two legal theories are distinct). See also Moroney v. General Motors Corp., 850 A.2d 629, 634-35 (Pa. Super. 2004).

Moreover, although it may be clouded by the frequent muddying of the strict liability waters with concepts of negligence, a products liability action based on negligence does not require proof of a defect. To the extent that the Third Circuit in Oddi, 234 F.3d at 144, held that evidence of a defective condition is required to maintain a products liability claim based in negligence, this interpretation of Pennsylvania law has been specifically overruled by the Pennsylvania Supreme Court in Phillips I, 841 A.2d at 1008.

In Phillips I, where the relatives of a family killed in a fire started by a child playing with a butane lighter brought strict liability and negligence claims against the manufacturer, the Pennsylvania Supreme Court held that the plaintiff did not show the product to be defective and the strict liability claim could not be sustained pursuant to § 402A. Regardless, the court stressed that the negligence and strict liability claims are distinct legal theories and held that the plaintiff's negligence claim could survive independently of the determination that product defect strict liability claim. In addressing the plaintiff's negligence action, the court did not import the § 402A's requirement of defect into the analysis, but rather analyzed the traditional elements of negligence, namely whether there was a duty, breach of duty and causation. Id. at 1006-1010.

In Defendant's summary judgment briefing, it states that Plaintiff must produce evidence of a defect even in the negligence claim. Def. Mot. Summary Judgment at 13 ("Thus, regardless of whether a plaintiff is proceeding under a theory of negligence, strict liability, or breach of warranty, proof of a defective condition in the product is an essential element of the claim."). For this proposition, Defendant cites Taylor, 1998 WL 962062, at *7 and Petrucelli v. Bohringer & Ratzinger, 46 F.3d 1298, 1310 (3d Cir. 1995). Defendant's reliance on these cases in this context is misplaced, however, as neither case stands for the proposition that in order to defeat a motion for summary judgment in a negligence action a plaintiff must prove defect. In fact, the portion of Taylor, cited by Defendant speaks to the necessity of proving defect in strict liability action. Later in the opinion, the court addresses the plaintiff's negligence action. Taylor, 1998 WL 962062, at *11. The court does not

In order to show negligent design and negligent manufacture under Pennsylvania law, plaintiff must show that (1) the manufacturer owned a duty to the plaintiff, (2) the duty was breached and (3) such a breach was the proximate cause of plaintiff's injuries. Phillips v. Cricket Lighters, 841 A.2d 1000, 1008 (Pa. 2003); Dauphin Deposit Bank & Trust v. Toyota, 596 A.2d 845, 849-50 (Pa. Super. 1991); Oddi, 234 F.3d at 144.

The first element can be addressed with virtually no discussion. It is undisputed that Defendant, the manufacturer of a knee replacement system, owed a duty of care to a recipient of its knee replacement.

Second, in order to raise a genuine issue of material fact with respect to the negligent design and negligent manufacture claim, Plaintiff must offer evidence that Zimmer breached its duty. This requires a showing that the Defendant

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impose on the plaintiff a burden of proving defect, but rather explores the traditional elements of negligence, that the defendant deviated from the standard of care, and that the deviation proximately caused the plaintiff's injuries. Id.

Likewise, Defendant's reliance on Petrucelli is misplaced. Petrucelli refers to a defective condition solely in the context of strict liability action. 46 F.3d at 1308. Moreover, in the negligence context, the Petrucelli court cited its decision in Griggs v. BIC Corp., 981 F.2d 1429, 1439 (3d Cir. 1992), overruled on other grounds by Surace v. Caterpillar, Inc., 111 F.3d 1039, 1046 n.6 (3d Cir. 1997), wherein the court predicted that the Pennsylvania Supreme Court, pre-Phillips I, would recognize that proof of negligence may be possible without a finding of strict liability.

failed to exercise due care in manufacturing or supplying the product. Put another way, Plaintiff must come forward with evidence that Zimmer's method of sterilization deviated from the general standard of care expected under the circumstances. Taylor, 1998 WL 96062, at * 11.

Plaintiff has proffered the expert opinion of Dr. Hetzel, who intends to opine that it is customary in the medical device manufacturing industry to assess the role of irradiation and other sterilization techniques on the product function over a period of time, and that Zimmer has not produced any such studies. As the Court has concluded that Dr. Hetzel is not qualified to render expert opinion concerning customary practices of the medical device manufacturing industry, Plaintiff has failed to produce any admissible evidence that Zimmer's method of sterilization fell below the general standard of care expected under the circumstances. Therefore, Plaintiff is unable to meet the second element of negligence – that Zimmer breached its duty.

As Plaintiff has not shown that Zimmer breached its duty, it is unnecessary, and in fact would be illogical, to analyze the third element – that is whether Plaintiff's injury were proximately caused by Defendant's negligence.

When the evidence is insufficient to establish the foregoing elements of negligence, a party still may be able to establish a negligence claim using the doctrine of res ipsa

loquitur, which Plaintiff advances in this case.

Under a theory of res ipsa loquitur, instead of directly proving the elements of ordinary negligence, the plaintiff proceeds by providing facts and circumstances surrounding the injury that make an inference of the defendant's negligence reasonable. Toogood v. Owen J. Rogal, DDS, P.C., 824 A.2d 1140, 1146 (Pa. 2003). The defendant's negligence can be inferred under the doctrine of res ipsa loquitur when "(1) the event is of a kind which ordinarily does not occur in the absence of negligence; (2) other responsible causes, including the conduct of the plaintiff and third persons, are sufficiently eliminated by the evidence; and (3) the negligence is within the scope of the defendant's duty to the plaintiff." Parkinson, 315 F. Supp. 2d at 750 (citing Gilbert v. Korvette's, Inc., 327 A.2d 94 (Pa. 1974)).

While the doctrine of res ipsa loquitur is typically invoked as an inference which the jury can draw, some courts have applied it in analyzing motions for summary judgment. For example in Parkinson, the court noted that res ipsa loquitur "normally arises in the context of whether a plaintiff is entitled to such a jury instruction after the evidence has been offered," but proceeded to apply it at the summary judgment stage. 315 F. Supp. 2d at 750. After addressing the elements of res ipsa loquitur as applied to the facts of the case, the court

concluded that while it was for the jury to decide whether the inference is to be drawn, the plaintiffs nevertheless proffered sufficient evidence to survive the defendant's summary judgment motion. Id.

Since at the summary judgment stage it is appropriate to draw reasonable inferences in favor of the non-movant, the Court agrees that Plaintiff may rely upon the benefit of a res ipsa loquitur inference to defeat summary judgment.

As to the first element necessary for a res ipsa loquitur inference to apply, under Pennsylvania law "in order to show an accident was the type which ordinarily does not occur in the absence of negligence, a plaintiff need not prove that an accident could not occur in the absence of negligence, but must only show that it is more probable than not that the plaintiff's injuries were caused by defendant's negligence." Parkinson, 315 F. Supp. 2d at 751 (emphasis in original) (citing Micciche v. E. Elevator Co., 645 A.2d 278, 281 (Pa. Super. Ct. 1994)).

In this case, Plaintiff relies upon Defendant's experts' disclosed report and deposition, both of which state that a fracture of tibial insert is rare. Merely because an incident is rare, however, does not mean that it does not ordinarily occur in the absence of negligence. However, the Court recognizes that it is "for the jury to determine whether the inference is to be drawn in any case where different

conclusions reasonably may be reached." Parkinson, 315 F. Supp. 2d at 751 (citing Smick v. City of Phila., 638 A.2d 287, 290 (Pa. Commw. Ct. 1994)). For this reason, the Court will conclude that Plaintiff has raised a genuine issue of material fact as to her negligent design and manufacture claim.

In support of the second element – that is whether other responsible causes of the injury are sufficiently eliminated by the evidence – the plaintiff has proffered the expert opinion of Dr. Sidor. Through Dr. Sidor's testimony, Plaintiff will show that the failure of the tibial insert was not as result of her performing surgeon's insertion of the insert, or her own ligament instability.

Finally, as mentioned, it is clear that negligence is within the scope of the defendant's duty to the Plaintiff as manufacturer's of medical devices clearly have a duty to the recipients of their devices.

Therefore, at this stage of the proceedings, drawing the res ipsa loquitur inference in favor of Plaintiff, the non-moving party, the Court concludes that Plaintiff has raised a genuine issue of material fact as to her negligent design and manufacture claim.

g. Punitive damages

Finally Defendant also moves for summary judgment with

respect for to plaintiff's demand for punitive damages. Def.'s Mot. Summary Judgment at 25. Zimmer contends that punitive damages are an extreme measure and not appropriate in this case because the record is completely devoid of any evidence that indicates Zimmer had an evil motive.

In response, Plaintiff argues that the question of punitive damages should be decided by the jury. She insists that Zimmer knew of the harmful effects of gamma irradiation in air sterilization on the plastics and the potential harm it could cause to recipients of its devices, but nevertheless ignored concerns for public safety in an effort to increase its bottom line.

In diversity actions, based upon state causes of actions, state law applies when discerning the appropriateness of punitive damages. See Griffiths v. CIGNA Corp., 857 F. Supp. 399, 409-10 (E.D. Pa. 1994) (citation omitted), aff'd, 60 F.3d 814 (3d Cir. 1995). State law, however, must not be inconsistent with principles of due process found in federal law. See World-Wide Volkswagen Corp. v. Woodson, 444 U.S. 286, 292; Pacific Mut. Life Ins. v. Haslip, 499 U.S. 1 (1991).

In Pennsylvania jurisprudence, punitive damages are considered an "extreme remedy" that are only available in the most exceptional matters. See Phillips v. Cricket Lighters, ("Phillips II") 883 A.2d 439, 445 (Pa. 2005). They are only

appropriately awarded when the plaintiff has shown that the defendant acted in an outrageous manner, either because of his "evil motive or reckless indifference to the rights of others." Id.; see also Hutchinson v. Luddy, 870 A.2d 766, 770 (Pa. 2005)).

"A defendant acts recklessly when 'his conduct creates an unreasonable risk of physical harm to another [and] such risk is substantially greater than that which is necessary to make his conduct negligent.'" Id. (citing Hutchinson, 870 A.2d at 771). Therefore, a showing of mere negligence, or even gross negligence, will not warrant an award of punitive damages. Id.; see also SHV Coal, Inc. v. Continental Grain Co., 587 A.2d 702, 705 (Pa. 1991). Instead, Plaintiff must set forth evidence to establish that Defendant's conduct was "intentional, willful, wanton or reckless." Phillips II, 883 A.2d at 446 (citing Hutchinson, 870 A.2d at 704).

The determination of whether a defendant's conduct rises to the level of outrageousness is the role of the finder of fact. SHV Coal Inc., 587 A.2d at 705 (Pa. 1991). Accordingly, the Court should decide the viability of a punitive damages claim under Pennsylvania law "only when no reasonable inference from the facts alleged supports a punitive award." Anderson v. Nationwide Ins. Enter., 187 F. Supp. 2d 447, 460 (W.D. Pa. 2002); Eagle Traffic Control v. Addco, 889 F. Supp. 200, 201 (E.D. Pa. 1995).

This issue was addressed by the Pennsylvania Supreme Court in Phillips II. There, a young child ignited a fire after playing with his mother's butane lighter. 883 A.2d at 446. The child, his mother and a sibling perished in the fire. Id. The family's relatives brought suit against the manufacturer of the lighter, claiming that it was defectively designed as it was not equipped with child-proof safety features. Id. Even when faced with testimony of a company employee that the defendant knew of the dangers posed by young children playing with the lighters and that the defendant could have placed resistant features on its butane lighters, the Supreme Court of Pennsylvania nevertheless concluded that the plaintiff did not sufficiently establish that the defendant's conduct was "so outrageous so as to support an award of punitive damages." Id. at 447. Accordingly, the court reversed the superior court's denial of summary judgment with respect to this claim. Id.

Similarly, Plaintiff in this case has not established that Defendant's conduct was outrageous. There is simply no evidence of any evil motive on behalf of Zimmer when manufacturing and storing its knee replacements and components.

Moreover, there is not sufficient evidence from which a reasonable fact finder could conclude that Defendant's conduct was reckless in that it created an unreasonable risk of physical harm to another and such risk is substantially greater than that

which is necessary to make its conduct negligent. Accepting as true Plaintiff's allegations and drawing all reasonable inferences in favor of the Plaintiff and assuming that Zimmer knew the risks of its conduct,[14] as the defendant did in Phillips II, Plaintiff has still failed to point to the requisite outrageous conduct which would to warrant punitive damages in this case.

Given that the facts alleged could not support a punitive award, summary judgment in favor of Defendant is appropriate as to the claim for punitive damages.

III. CONCLUSION

Based on the foregoing reasons, Defendant's motion to exclude Plaintiff's experts will be granted in part and denied in part as follows:

1. Dr. Hetzel's testimony will be limited to the sterilization methods available at the time Zimmer sterilized the tibial insert used in Plaintiff, the chemical effects caused by gamma irradiation

[14] Plaintiff's expert, Dr. Hetzel, a chemist, claimed in his expert report that literature existed prior to the sterilization of Mrs. Zimmer's tibial insert that either put Zimmer on notice or should have put Zimmer on notice of the degrading effect of gamma irradiation in air sterilization. Hetzel Report at 9. Also, Dr. Spiegelberg, expert for defendant, stated at his deposition that he was aware of articles that stand for the proposition that wear increases with gamma in air sterilized parts. Spiegelberg Dep. at 25-26.

in air on UHMWPE, the indication of these effects, and his observations when examining the inserts extracted from Plaintiff's knee. He may not testify as to the existence of any manufacturing defects, the adequacies of Defendant's warnings or the customary practices of manufacturers of medical devices.

2. Dr. Sidor's opinions will be permitted.

Defendant's motion for summary judgment will be granted in part and denied in part as follows:

1. Defendant's motion for summary judgment is **GRANTED** with respect to Plaintiff's (1) defective design and manufacture, (2) failure to warn, (3) violation of Pennsylvania consumer protection act, (4) fraud, (5) breach of implied warranty of merchantability, (6) breach of implied warranty of fitness for a particular purpose,[15] (7) breach of express warranty, and (8) punitive damages claims.

2. Defendant's motion for summary judgment is **DENIED** with respect to Plaintiff's negligent design and manufacture claim.

An appropriate order follows.

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[15] Count six actually is entitled "Breach of Implied Warranty of Merchantability," but really alleges a breach of the implied warranty of fitness for a particular purpose.

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

MARGUERITE J. SOUFFLAS,	:	CIVIL ACTION
	:	NO. 04-4753
Plaintiff,	:	
	:	
v.	:	
	:	
ZIMMER, INC.,	:	
	:	
Defendant.	:	

O R D E R

AND NOW, this **21st** day of **February, 2007**, it is hereby **ORDERED** that Defendant's Motion to Exclude Plaintiff's Expert Witnesses (doc. no. 34) is **GRANTED in part** and **DENIED in part** as follows:

1. Dr. Hetzel's testimony will be limited to the sterilization methods available at the time Zimmer sterilized the tibial insert used in Plaintiff, the chemical effects caused by gamma irradiation in air on UHMWPE, the indication of these effects, and his observations when examining the inserts extracted from Plaintiff's knee. He may not testify as to the existence of any manufacturing defects, the adequacies of Defendant's warnings or the customary practices of manufacturers of medical devices.

2. Dr. Sidor's opinions will be permitted.

IT IS FURTHER ORDERED that Defendant's Motion for Summary Judgment (doc. no. 32) is **GRANTED in part** and **DENIED in part** as follows:

1. Defendant's motion for summary judgment is **GRANTED** with respect to Plaintiff's (1) defective design and manufacture, (2) failure to warn, (3) violation of Pennsylvania consumer protection act, (4) fraud, (5) breach of implied warranty of merchantability, (6) breach of implied warranty of fitness for a particular purpose,[16] (7) breach of express warranty, and (8) punitive damages claims.
2. Defendant's motion for summary judgment is **DENIED** with respect to Plaintiff's negligent design and manufacture claim.

IT IS FURTHER ORDERED that Defendant's Motion to Strike Inadmissible Evidence (doc. no. 61) is **DENIED as moot**.[17]

IT IS FURTHER ORDERED that Defendant's Motion for Leave to File Reply in Support of Motion to Strike Inadmissible Evidence (doc. no. 64) is **GRANTED.**

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[16] Count six actually is entitled "Breach of Implied Warranty of Merchantability," but really alleges a breach of the implied warranty of fitness for a particular purpose.

[17] The Court was careful to consider only admissible evidence when deciding Defendant's motion for summary judgment.

AND IT IS SO ORDERED.

S/Eduardo C. Robreno

EDUARDO C. ROBRENO, J.