UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

DOLORES DUNN, et. al.,	**:**	**3:00CV1306 (DJS)**
Plaintiffs,	**:**	**[pertains to 3:01cv518 (DJS)]**
-v-	**:**	
	:	
ZIMMER, INC.,	**:**	
Defendant.	**:**	

MEMORANDUM OF DECISION

Defendant, Zimmer, Inc. ("Zimmer"), has moved for summary judgment **[doc. #160]** on all claims brought by plaintiff Joann Lopes ("Lopes"). Plaintiff alleges that her hip prosthesis, the Centralign Precoat, was defective pursuant to Connecticut General Statute §52-572m, et. seq., under theories of design defect, manufacturing defect and failure to warn. Further, Lopes seeks damages under the Connecticut Unfair Trade Practices Act and for common law fraud. The motion for summary judgment is **GRANTED in part**.

Background

Plaintiff, Joann Lopes ("Lopes") consulted Dr. Bruce Moeckel ("Moeckel") in 1993 complaining of pain in her left hip. Lopes has a medical history of hip problems, including a total hip replacement of her right hip in 1992. Lopes was experiencing significant pain and limitation in the function of her left hip by December 1994. Dr. Moeckel discussed hip replacement surgery, informing Lopes of the dangers of loosening and the differences between cemented and cementless implants. Lopes has a cementless stem in her right hip, but Dr. Moeckel did not consider using a cementless stem in the left hip. Dr. Moeckel performed a total hip arthroplasy on Lopes's left hip on March 21, 1995, using a Centralign Precoat Hip Prosthesis Femoral Stem size 2 ("Centralign"), manufactured by the defendant, Zimmer, Inc. ("Zimmer").

Dr. Moeckel does not recall reading the package insert that Zimmer claims accompanied the Centralign prosthesis. The defendant places a package insert in each Centralign container that provides physicians with warnings about the use, care and operation of the Centralign. Specifically, the package insert addresses the risks of the femoral stem loosening inside the patient. According to the insert, loosening is a known problem that occurs for a number of reasons, including defective fixation in the patient (improper cementing of the stem to the body), latent infection, mechanical problems (localized stress on the hip) or other biological complications. The package insert also provides recommendations regarding the appropriate choice of stem size and the proper techniques for implanting and cementing the stem.

Dr. Moeckel performed the surgery using a third-generation cementing technique that optimizes the likelihood of achieving a uniform and consistent cement mantle without voids, although it is difficult, if not impossible, for any surgeon to achieve a uniform cement mantle in every operation. The use of insufficient cement to attach the hip can increase the stress on the femoral stem and increase the risk of loosening. Dr. Moeckel put the prosthesis in the canal to check its fit, causing the prosthesis to become covered in blood. The prosthesis was then stored in a jar of antibiotic solution while the femoral canal was prepared for insertion. The operation was an initial success.

Lopes fell approximately three months after the surgery, injuring her left hip. She began to feel pain and to hear a clicking sound in her left hip sometime in August or September 1996. Lopes returned to Dr. Moeckel in January 1997, complaining of increased pain in her hip. X-rays taken at that time showed signs that the prosthesis was loosening. Dr. Moeckel referred Lopes to a Dr. Schutzer, who then referred her to Dr. John Grady-Benson ("Dr. Grady-Benson").

Dr. Grady-Benson examined Lopes and concluded that she had significant osteolysis near

the prosthesis, putting her at risk of a serious fracture unless a revision surgery was performed. Lopes underwent the revision surgery on March 14, 1997, and the condition of her left hip has improved since that time.

Dr. Richard Berger ("Dr. Berger"), testifying on Zimmer's behalf, stated that the cement mantle surrounding Lopes's stem was inadequate and that this was the most significant cause of the later hip failure. Berger also testified that the blood and antibiotics on the stem prior to insertion interfered with the bonding between the cement and the stem, leading to eventual failure of the stem.

Dr. Robert Rose ("Dr. Rose"), plaintiff's expert witness, testified that the failure of the precoat layer caused the separation of the cement at the stem-cement interface and led to the failure of the hip prosthesis. According to Dr. Rose, the precoat layer and the roughened surface of the stem constitute design defects.

Hip Arthroplasty and the Centralign Prosthesis

The hip joint is a critical joint in the human body. The hip includes the femur, a bone with a ball at one end situated on an angular protrusion known as the femoral neck. The ball sits in a bone socket, called the acetabulum, that is located in the pelvis. Large muscles connect the pelvis to the femur and allow movement and balance during walking, running or climbing. The force generated by these muscles can reach two to five times body weight, resulting in work loads applied across the hip joints that are three to six times body weight. This load is applied to the femoral head and transmitted through the femoral neck into the shaft of the femur. The load path runs through the dense cancellous bone inside the femoral neck and then gradually moves out into the strong cortical shell of the femur.

A total hip arthroplasty involves substituting metal and ultra-high-moleculer-weight-

polyethelene implants for the surfaces of the bones comprising the hip joint. The femoral head (the ball at the end of the femur) is replaced by the femoral component, which consists of a stem implanted into the patient's femur and an artificial femoral head. The hip socket is replaced by a metal shell implanted into the patient's hip, into which is placed a liner. These components are collectively referred to as the acetabular component.

The designer of a total hip joint prosthesis has a number of challenges to overcome. The most important is the transfer of load across the hip. The prosthesis must be capable of transferring load from the ball of the artificial joint to the shaft of the femur through the femoral stem. The connection between the femoral component and the natural bone must be strong enough to facilitate the load transfer over many years. The conventional solution to this need is the use of a stemmed component that consists of a ball end with an off-set neck that replicates the anatomy of the femoral neck and a stem end that is inserted into the hollow inside of the femur. The nature of the prosthetic stem and the method of insertion are critical to the longevity and functionality of the replacement hip.

There are two schools of thought regarding the design of the prosthetic stem. One school proposes that it have a porous surface to allow a bony in-growth between the stem and the inside of the bone shaft, permitting a direct transfer of load from the prosthesis, through the new bone tissue into the bone shaft. This is known as the cementless component. The second school uses a cemented component that requires a filler material to connect the prosthetic stem with the inside of the bone shaft. The filler is a type of grout, known as bone cement. The grout is made from a powdered polymethylmethacrylate ("PMMA") that, when mixed with a liquid methacrylate monomer, forms a thin, doughy material that hardens into a plastic chemically identical to Plexiglas. The doughy material is inserted, prior to hardening, into a femoral canal that is

prepared by removing the femoral head and neck and widening the femoral shaft to permit the insertion of the prosthesis. The cement surrounding the femoral stem serves to transfer the load from the prosthesis to the femur.

The bone cement can loosen at either the interface with the bone or with the prosthesis. The loosening of the cement leads to a loosening of the femoral stem and failure of the artificial hip. Loosening of the cement is a risk for all cemented stem implants. Multiple factors can lead to a loosening of the femoral stem. The most significant factors are generally grouped in two categories: surgeon factors and patient factors. Surgeon factors include the type of implant selected, the cementing technique used, the type of cement used, the quality of the femoral channel and the quality of the cement mantle around the stem. Patient factors include weight, age and activity level, all of which may increase the load placed on the replacement hip.

The record reflects a general consensus in the medical community that the interface between the stem and the cement is weaker than the interface between the bone and the cement. Attempts to strengthen this weak point through the design of the prosthesis have focused on improving the strength of the bond between the stem and the cement by creating a textured surface on the stem to improve the mechanical interlock. This improvement was, in theory, accomplished by creating a roughened surface stem. Similarly, the PMMA pre-coated stem was intended to maximize the strength of the interface between the metal surface of the stem and the cement. Stems are manufactured with smooth, roughened, porous and cement pre-coated surfaces, sometimes with combinations of these features. Stems also come with or without collars around the proximal end to permit or discourage subsidence of the stem. Stems are uni-block (single-piece) or modular and they also may be asymmetric or designed for use specifically in the right or left hip. The four most common head diameters for the femoral stem component

are 22, 26, 28 and 32 millimeters.

The Centralign is a femoral stem component of a total hip replacement used in a total hip arthroplasty. The Centralign has a dimpled, blasted finish known as macro-surface texturing and a thin layer of PMMA precoating. The stem is sterilized using a gamma-irradiation technique. The Centralign is offered in different sizes from size 1 (smallest) to size 6 (largest) with increasing stem diameter, length and surface area.

Expert Testimony and Scientific Reports

Plaintiff claims that the failure of her Centralign hip replacement was due to a design defect. The expert reports and medical literature submitted in support of this claim can be summarized, briefly, as follows. The designers of replacement hip components face a variety of difficulties, including the proper size, shape and surfacing of the femoral stem component. Current theory and research postulates that the weakest point in the cemented stem implantation is the interface between the metal stem and the bone cement. A classic femoral stem is smooth and does not have any cement precoating. Theory suggests that the use of a roughened, precoated stem permits a stronger physical and chemical bond between the stem and the cement. No studies have proved this theory in practice, although roughened, precoated stems are now widely used.

The results of various studies conducted on the Centralign Precoat stem suggest that, if the stem moves within the cement mantle, a roughened surface may have the opposite of the intended effect, causing increased breakup of the cement and increasing the rate of osteolysis (the destruction of bone tissue by particulate matter). The effect of the PMMA precoat is indeterminate based on the data. Some research suggests that the precoat has a distinct negative impact on the failure rate of the femoral stems, but the data are inconclusive.

Dr. Rose testified that the PMMA precoat could have a negative effect in three ways.

First, the roughness of the stem could harbor debris or air that would degrade the stem-cement interface, if it was trapped by the precoat layer. Second, the precoat layer itself could be improperly applied or cured. Third, Dr. Rose postulates that the radiation sterilization of the femoral stem could break down the chemical bonds in the PMMA layer and cause it to deteriorate or otherwise to break off the stem, causing separation at the stem-cement interface and a loosening of the stem. Dr. Rose cited to studies and his own observations showing that the precoat layer could be peeled off of the femoral stems that had loosened and required a revision surgery. Dr. Rose also extrapolated the harms caused by radiation from the presence of gas and air bubbles in the precoat layer on certain stems, a result he claims is a sign of radiation-caused debonding. According to Dr. Rose, the bubbles should have been a sign that the stems were defective. Although he implies that a failure of quality control could explain the failed stems, Dr. Rose does not offer any evidence that Zimmer's quality control was inadequate, beyond the existence of the bubbles in the precoat of the failed stems.

The Centralign series has also been criticized for its mechanical design. Dr. Richard Santore ("Dr. Santore") conducted a study that led him to question the design of the Centralign as too small, too short and too round to serve its intended purpose. A study of the effects of femoral stem design on cement strain concluded that the straight, tapered design of the Centralign (described by the study as "commonly used") was less optimal for long-term functioning of the prosthesis than a more angular, 'anatomically shaped' design. Dr. Rose testified that a larger and longer femoral stem with a larger and longer cross-section would reduce the likelihood of stem loosening by reducing critical stresses on the cement-stem interface. According to Dr. Rose, the Centralign is undersized for the patients it is rated for, meaning that it is smaller and shorter than other stems that would be used in the same femoral canal. Dr. Rose posits that the design of the

Centralign increases the stress on the stem-cement interface at critical junctures where the increased stress is more likely to result in stem loosening.

Defendant argues that the Centralign hip is not defectively designed and that it was not the proximal cause of the hip replacement failure in the plaintiff. Defendant's expert, Dr. Albert Burstein ("Dr. Burstein"), reports that the Centralign was not the cause of hip failure. Rather, Dr. Burstein contends that the failure of a replacement hip is multi-factorial, with the age, gender, weight and activity level of the patient as key factors, along with the quality of the cement mantle around the stem. Dr. Berger emphasized the same factors as Dr. Burstein when offering his opinion regarding the prosthesis failure. Dr. Paul Lachiewicz ("Dr. Lachiewicz") provides testimony that he used the Centralign prosthesis in his orthopredics practice and found a relatively low failure rate. Dr. Lachiewicz conducted a study specifically of his Centralign patients after reading the article by Dr. Santore regarding high failure rates, but he reached the opposite conclusion from Dr. Santore. Dr. Rick White ("Dr. White") also reported a good experience with the Centralign. Although Dr. Santore reported a high failure rate with the Centralign hip, he testified that no conclusions regarding the precise causal factor for the hip failures could be drawn from one study using a single design prosthesis. Dr. Santore also testified that his study found no statistical significance to smaller stems failing at a higher rate than larger stems.

Zimmer provides studies that show no negative impact on PMMA bonding from the use of gamma irradiation in the sterilization process. Laboratory testing shows that the PMMA precoat creates a stronger bond between the metal of the stem and the cement. Again, it is important for any analyst of the record in this case to note that no study clearly concludes that the precoat layer causes early failure of the replacement hip.

Defendant also relies on the expert testimony of Rik Huiskes ("Huiskes"), a professor of biomedical engineering in the Netherlands. According to Huiskes, other products comparable in size and surface finish to the Centralign have performed well in testing and in service. Huiskes testified that studies have shown good results for stems that are shorter and rougher than the Centralign, and he can find no basis in design for any criticism of the Centralign. Husikes emphasized that the failure of a replacement hip is multifactorial– the interplay of patient factors, surgical factors and product factors are too complex to permit identification of a single causal force.

Zimmer's Warnings and Packaging

Zimmer provided extensive warnings to purchasers of the Centralign hip. The warnings identified the dangers and methods of implanting the hip, precautions and safe care requirements for the hip components and recommendations for choosing recipients of a Centralign hip. Zimmer also mailed, in early 1998, a letter to all distributors and doctors, outlining studies of the Centralign hip and evidence that the hips were not appropriate for a certain class of recipients, including younger, heavier or more active patients. Zimmer recommended alternate replacement hips that are described as longer and wider than the Centralign within each size category. Zimmer specifically warned that size 1 and 2 Centralign hips were recommended only for very small patients. The weight limits for some of the Centralign sizes were reduced from Zimmer's original recommendations, approximately two years after the Centralign was placed on the market. It is not clear from the record if weight limits for certain sizes of Centralign stems were published during the first two years of sales. There is a question as to the availability of Zimmer's package insert for doctors and surgeons. According to testimony from Dr. Grady-Benson, hospitals purchase, unpackage and store the hips, not doctors, thus preventing doctors from reading the

package insert instructions and warnings.

Standard of Review

Summary judgment may be granted "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue of material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c).

Summary judgment is appropriate if, after discovery, the nonmoving party "has failed to make a sufficient showing on an essential element of [its] case with respect to which [it] has the burden of proof." Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). "The burden is on the moving party 'to demonstrate the absence of any material factual issue genuinely in dispute.'" American Int'l Group, Inc. v. London Am. Int'l Corp., 664 F.2d 348, 351 (2d Cir. 1981) (quoting Heyman v. Commerce & Indus. Ins. Co., 524 F.2d 1317, 1319-20 (2d Cir. 1975)).

A dispute concerning a material fact is genuine "'if evidence is such that a reasonable jury could return a verdict for the nonmoving party.'" Aldrich v. Randolph Cent. Sch. Dist., 963 F.2d 520, 523 (2d Cir. 1992) (quoting Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986)). The court must view all inferences and ambiguities in a light most favorable to the nonmoving party. See Bryant v. Maffucci, 923 F.2d 979, 982 (2d Cir. 1991). "Only when reasonable minds could not differ as to the import of the evidence is summary judgment proper." Id.

Discussion

Plaintiff Joann Lopes brings the present cause of action alleging violations of: (a) the Connecticut Products Liability Act, Conn.Gen.Stat. §52-572m, et. seq., ("CPLA"); (b) the Connecticut Unfair Trade Practices Act, §42-110b, et. seq., ("CUTPA"); and (c) common law

fraud. Lopes seeks compensatory and punitive damages. Zimmer seeks summary judgment on each of Lopes's claims. According to the defendant, Lopes cannot show that the design of the Centralign was defective, that its manufacture was defective or that Zimmer failed to properly warn of dangers involved in the use of its replacement hip. Zimmer also argues that claims under CUTPA are preempted by claims under the CPLA, that there is no evidence of fraud and that the punitive damage claim fails as a matter of law.

I. Lopes's CPLA Claim

Connecticut law recognizes a statutory action for damages grounded in strict liability for a product defect. Conn.Gen.Stat. §52-572n. "A product may be defective due to a flaw in the manufacturing process, a design defect or because of inadequate warnings or instructions." Vitanza v. Upjohn Co., 257 Conn. 365, 373 (Conn. 2001). Connecticut courts have adopted the strict liability test established at §402A of the Restatement (Second) of Torts.[1] Garthwait v. Burgio, 153 Conn. 284, 289-290 (Conn. 1965). Section 402A imposes liability only when the product is unreasonably dangerous to "the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics." Potter v. Chicago Pneumatic Tool Co., 241 Conn. 199, 211 (Conn. 1997)(quoting 2 Restatement (Second) Torts §402A, comment (i) (1965)). "Under this formulation, known as the 'consumer expectation' test, a manufacturer is strictly liable for any condition not contemplated by the ultimate consumer that will be unreasonably dangerous to the consumer." Id. at 212.

A 'modified consumer expectation' test exists in Connecticut for application whenever

[1]Zimmer argues that the court should adopt, as an additional standard of law applied to medical devices, the product liability rule found at §6(c) of the Restatement (Third) of Torts, Product Liability (1998). No Connecticut court has applied §6(c) and this court will not do so in the absence of some evidence that the Connecticut Supreme Court, considering this issue, would adopt Zimmer's position.

the product involves complex designs "in which an ordinary consumer may not be able to form expectations of safety." Potter, 241 Conn. at 219. Under the modified expectation test the fact-finder will use a risk-utility analysis[2] as the basis for determining whether a reasonable consumer would consider the product unreasonably dangerous. Id. at 220. The fact-finder may consider a variety of factors, including but not limited to, the usefulness of the product, the likelihood and severity of the danger posed by the design, the feasibility of alternative designs, the cost of improvements, the ability to alter the design without harming the product's usefulness or price, and the possibility of spreading potential loss by increasing the product's price. Id. at 221. The plaintiff may show the availability of a feasible design alternative to establish that the risks outweigh the utility, but this showing is not necessary to prove the claim of design defect. Id.

Although no Connecticut court has yet adopted the 'modified consumer expectation' test in a case involving a hip prosthesis, it seems apparent that such devices are highly complex and it is unlikely that the average consumer would be reasonably capable of determining product safety. An assessment of the Centralign's alleged defect requires knowledge of chemistry, biomechanical engineering, materials science and engineering, statistics and medicine. At best, a reasonable, ordinary consumer could choose a prosthesis based on a simplified explanation of pros and cons delivered by an educated medical professional, but the ultimate source of safety expectations would be the doctor, not the consumer. This court will therefore apply the modified consumer expectation test when analyzing the motion for summary judgment.[3]

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[2]The risk-utility analysis considers whether the risks of the product as designed outweigh its utility.

[3]Zimmer argues that the Centralign should be treated as an unavoidably unsafe product within the meaning of §402A, comment k of the Restatement (Second) of Torts. The Connecticut Supreme Court has adopted the reasoning of comment k, which protects manufacturers from strict liability when the product is a) properly manufactured and b) proper warnings are given.

Plaintiff claims that the Centralign was defective because it was designed improperly, manufactured defectively and lacked the proper warnings. Summary judgment must be denied on the issue of design defect. The record is filled with competing studies and testimony regarding the effect of a precoated, roughened surface femoral stem on the loosening of the artificial hip. Defendant has failed to meet its burden of showing that no issue of fact exists and the plaintiff is entitled to present her case to a fact-finder. Ultimately, the fact-finder will weigh the evidence and determine if the risks posed by the design of the Centralign outweigh the benefits.

The claim for defect by reason of insufficient warning also survives summary judgment. A plaintiff must show, by a preponderance of the evidence, that adequate warnings were not provided and that if such warnings had been provided, the harm would have been avoided. Conn.Gen.Stat. §52-572q. The parties to this action admit that the ultimate harm, failure of the replacement hip, was unavoidable for Lopes. No warning would have prevented her injury. The claim for damages is based, however, not on the fact of failure but on the time of failure–on whether the failure to warn sped the process of prosthesis failure. Plaintiff alleges that Zimmer did not provide adequate information to doctors and patients regarding the uses and limitations of the Centralign. The facts are very much in dispute regarding the adequacy of Zimmer's warnings and the access that medical practitioners had to those warnings prior to 1998. Even if a fact-finder concluded that the Centralign was not defectively designed, she could reasonably find, based on the record, that Zimmer did not adequately warn doctors about the impact of various factors–weight and size of the patient, expected levels of activity–on the durability of the

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Vitanza, 257 Conn. at 375. Presently, no test exists in Connecticut law for determining when a product is unavoidably unsafe within the meaning of comment k. Absent a defined legal standard there is an insufficient basis in the record for resolving the question of whether an artificial hip prosthesis is an unavoidably unsafe product within the meaning of comment k.

Centralign. Such information might have led Dr. Moeckel to use a cementless stem, or to choose a different product entirely, thus reducing or eliminating the harm caused by the alleged early failure of Lopes's hip.[4]

Summary judgment is granted on the alleged defect in the manufacturing process. There is nothing in the record to support the contention that Zimmer's manufacturing efforts were substandard in any respect. The only hint of a flaw in the manufacturing process is the assertion by Dr. Rose that the presence of air and gas bubbles in the precoat layer could be the result of a manufacturing problem. This hint is offset by both Dr. Rose's testimony offering a host of other possible causes for the bubbles, besides a manufacturing defect, and his testimony that there was no observable manufacturing defect or quality control problem in Zimmer's process. Plaintiff relies heavily on claims that the choice of manufacturing process–the decision to engage in grit-blasting and precoating–created a defect, but this is not evidence of a manufacturing defect; rather, it is possible evidence of a design defect. A product can be manufactured correctly, according to all designs and regulations, and yet be defective–but the defect would not be the result of a manufacturing failure. At best, Lopes has provided evidence of a flawed product, excellently made.

Zimmer has raised as a blanket defense the issue of causation, specifically the asserted inability of Lopes ever to prove that her hip failure was caused by the design of the hip or the

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[4]Zimmer argues that the failure to warn claim is barred by the defense of the learned intermediary. Connecticut recognizes the learned intermediary defense for prescription medical devices. Hurley v. The Heart Physicians, P.C., No. X05 CV-00-0177475-S, 2005 WL 20463, *3 (Conn.Super.Ct. Jan. 4, 2005). The doctrine provides that so long as adequate warnings are provided to the prescribing physician, the warning requirement is satisfied even if the warnings are not conveyed to the ultimate consumer. Vitanza, 257 Conn. at 376. The disputed issues of fact in this case involve the warnings that were provided to the physicians and so the court cannot rule on the learned intermediary defense at this time. The defense, of course, may be raised at trial.

failure to warn. Zimmer contends that the law requires, for proof of causation, the production of expert medical testimony, and none is here provided. Zimmer is correct that "[o]rdinarily, expert medical opinion evidence…is required, when the subject-matter to be inquired about is presumed not to be within common knowledge and experience and when legal inference predominates over statement of fact." Fane v. Zimmer, Inc., 927 F.2d 124, 131 (2d Cir. 1991). The Fane case presented the fact-finder with questions of causation that required medical judgment to resolve–similar questions are not present in this case.

Unlike in Fane, where there was no link between the harm, a broken femur, and the broken medical implant device, there is no doubt here about the tie between the plaintiff's injury and the failure of the prosthesis. The record is sufficient to show that Lopes's hip failed and that it caused her pain and required a revision surgery. The record contains adequate evidence and expert testimony from not only the treating physicians but also various biomechanical engineering and design specialists to permit a reasonable fact-finder to resolve the question of causation even in the absence of testimony from a medical doctor that clearly eliminates all factors other than design as the cause of the prosthesis failure.

II. Plaintiff's CUTPA Claim

A claim brought pursuant to the CPLA is brought exclusive of "all other claims against product sellers, including actions for negligence, strict liability and warranty, for harm caused by a product." Conn.Gen.Stat. §52-572n(a). Product liability claims are defined as all claims for "personal injury, death or property damage caused by the manufacture, construction, design, formula, preparation, assembly, installation, testing, warnings, instructions, marketing, packaging or labeling of any product." Conn.Gen.Stat. §52-572m(b). The Connecticut Supreme Court has

held that claims under CUTPA are not necessarily excluded by §52-572n(a) if the CUTPA claim is "either for an injury not caused by the defective product, or if the party is not pursuing a claim for personal injury, death or property damage." Gerrity v. R.J. Reynolds Tobacco Co., 263 Conn. 120, 128 (Conn. 2003). Claims based on statutory provisions such as CUTPA are not per se excluded under CPLA unless "the claim is, in reality, one falling within the scope of the product liability act." Id. at 129.

The Gerrity court held that a claim for fiscal damages under CUTPA was not excluded by the provisions of the CPLA. "[T]he financial injury…for which the plaintiff seeks to use CUTPA to provide a remedy, cannot reasonably be construed" as one falling within the scope of the CPLA. Gerrity, 263 Conn. at 130-131. The facts of this case do not present the same distinction. Lopes seeks damages arising out of the injuries caused by the failure of her hip prosthesis. She asserts that the marketing of the Centralign violated CUTPA and as a result of the alleged unlawful marketing she was injured by the defective hip. The stated claim is very clearly one for personal injuries caused by the warnings, instructions, marketing or packaging of the Centralign and is therefore excluded by the CPLA. Summary judgment is granted to Zimmer on this issue.

III. Plaintiff's Common Law Fraud Claim

Lopes also seeks damages under a theory of common law fraud. A claim for fraud requires proof of four elements: "(1) a false representation was made as a statement of fact; (2) it was untrue and known to be untrue by the party making it; (3) it was made to induce the other party to act upon it; and (4) the other party did so act upon that false representation to his injury." Suffield Development Associates Ltd. Partnership v. National Loan Investors, L.P., 260 Conn. 766, 777 (Conn. 2002). "The failure to prove any one of the essential elements precludes recovery." Omega Engineering, Inc. v. Eastman Kodak Co., 30 F.Supp.2d 226, 251 (D.Conn.

1998).

Plaintiff's claim specifically alleges that Zimmer misrepresented the quality of stress-distribution in the Centralign as well as the potential effect of the precoated, roughened stem surface on the cement-stem bond. Plaintiff's claims are excluded by the CPLA and otherwise fail due to insufficient evidence. As noted, the CPLA excludes all claims for personal injury caused by the "warnings, instructions, marketing, packaging or labeling of any product." Conn.Gen.Stat. §52-572m(b)–§52-572n(a). Plaintiff's fraud claim is explicitly one arising out of her personal injuries as allegedly caused by inaccurate or fraudulent marketing, packaging or labeling. The common law fraud claim is excluded and summary judgment is granted to Zimmer.

The court is aware that certain post-sale common law claims have been allowed under the CPLA, but the possibility that the fraud claim rests on Zimmer's actions after the sale of the Centralign does not save the claim. See, Densberger v. United Technology Corp., 297 F.3d 66, 71 (2d Cir. 2002). The record does not contain sufficient evidence to meet the legal standard for fraud. "A fraudulent representation in law is one that is knowingly untrue, or made without belief in its truth, or recklessly made and for the purpose of inducing action upon it." Orsini Imports, Inc. v. Marciano, No. CV000434094S, 2001 WL 822279, *2 (Conn.Super.Ct. June 21, 2001). There is no evidence in the record that Zimmer recklessly or knowingly made untrue statements or made statements that it did not believe to be true.

Plaintiff points to Zimmer's marketing materials and representations regarding the benefits of both roughened-stem implants and precoated stems as proof of fraud. The record, however, is clear that the theoretical benefits of such products were widely known and accepted within the medical community until approximately 1997, when certain studies were published that cast doubt on the results achieved with patients. Zimmer believed in every representation

made concerning the Centralign Option during the entire period from 1990 until 1997, and there is no basis in the record for inferring recklessness or a knowing disregard of the truth. After the relevant studies were published in 1997, the record shows that Zimmer conducted its own investigation, a process that included meetings with Dr. Santore and a review of the results achieved by numerous doctors. That process led Zimmer, in early 1998, to revise the information it provided to customers to reflect the then-available knowledge about the Centralign's effectiveness.

Plaintiff paints the revised information provided to doctors as an attempt to hide past wrongdoing, but there is nothing to substantiate this assertion. The record shows that Zimmer had a belief in the accuracy of its statements about the Centralign, supported by both testing and theory, and that it corrected any errors as soon as corrective information was available and could be verified. There is no evidence of statements made without the requisite belief or in reckless disregard of the truth. Absent proof of the knowledge element of fraud, the claim must fail.

IV. Plaintiff's Claim for Punitive Damages

A plaintiff may be awarded punitive damages in a products liability action if "the harm suffered was the result of the product seller's reckless disregard for the safety of product users, consumers or others who were injured by the product." Conn.Gen.Stat. §52-240b. Punitive damages require showing of reckless disregard for the rights of others and intentional and wanton violations of those rights. Ames v. Sears, Roebuck and Co., 8 Conn.App. 642, 654 (Conn.App.Ct. 1986)(quoting Collens v. New Canaan Water Co., 155 Conn. 477, 489 (Conn. 1967)). An award of punitive damages is usually justified in terms of wanton and malicious injury, evil motive and violence. Ames, 8 Conn.App. at 655.

Plaintiff's evidence in support of punitive damages consists of the assertion that Zimmer

failed to properly comply with federal Food and Drug Administration regulations. There is no evidence of such a failure in the record. Further, there is no evidence that Zimmer manufactured, marketed or sold the Centralign hip prosthesis with disregard for the dangers it posed to consumers. The record clearly shows that the primary danger is posed by the potential failure of the prosthesis and that the danger cannot be avoided by currently available technology. There is absolutely no evidence that Zimmer was unaware of this problem, that it ignored the problem or that it acted recklessly or with wanton indifference to the problem of prosthesis failure. Zimmer's sole focus, based on the record, was the manufacture of a hip prosthesis that would provide increased durability and delay the unavoidable failure. The Centralign was manufactured specifically with the safety of product users in mind, and there is no evidence that Zimmer ever ceased to be concerned for the safety and health of hip prosthesis users. There is no evidence to support a charge of punitive damages in this case.

Conclusion

The pending action, Joann Lopes v. Zimmer, Inc, No. 3:01cv518 (DJS), was consolidated with the matter of Dunn v. Zimmer, No. 3:00cv1306 (DJS), for the purpose of conducting discovery. The pending motion for summary judgment was filed in the lead case. This decision concerns only the claims brought by Joann Lopes.

The motion for summary judgment **[doc. #160]** is **GRANTED in part**. The claims for damages under CUTPA and for common law fraud are dismissed as barred by the CPLA. The fraud claim, to the extent it is not barred, fails for lack of evidence. The claim based on manufacturing defect also fails for lack of evidence. Finally, there is no evidence to support an award of punitive damages in this case. Summary judgment is denied as to the remaining claims for design defect and failure to warn.

This case is referred to the Hon. Thomas P. Smith, United States Magistrate Judge, for a settlement conference. The parties are **ORDERED** to submit a joint trial memorandum on or before September 1, 2005.

IT IS SO ORDERED at Hartford, Connecticut, this 31st day of March, 2005.

/s/DJS
DOMINIC J. SQUATRITO
UNITED STATES DISTRICT JUDGE