CENTRAL DISTRICT OF ILLINOIS
URBANA DIVISION

GLENN D. PANKEY,	)	
	)	
Plaintiff,	)	
v.	)	**Case No. 09-CV-2150**
	)	
WRIGHT MEDICAL GROUP, INC., a corporation, WRIGHT MEDICAL TECHNOLOGY, INC., a corporation, and WRIGHT MEDICAL EUROPE SA, a corporation,	)	
	)	
Defendants.	)	

OPINION

This case is before the court for ruling on the Combined Motion to Dismiss and Motion for Summary Judgment (#79) filed by Defendants, Wright Medical Group, Inc., Wright Medical Technology, Inc. and Wright Medical Europe SA. This court has carefully reviewed the arguments of the parties and the documents filed by the parties. Following this careful and thorough review, Defendants' Combined Motion to Dismiss and Motion for Summary Judgment (#79) is GRANTED in part and DENIED as moot in part.

FACTS[1]

Plaintiff, Glenn D. Pankey, underwent hip replacement surgery on his right hip on February 7, 2007. Plaintiff's doctor, Dr. Milton Smit, placed a Profemur® prosthesis, model PHA0-1254, long neck, 8 Degree Var/Val Long, in Plaintiff's right hip. This prosthesis was

[1] The facts are taken from Defendants' statement of undisputed facts, Plaintiff's statement of additional undisputed facts and the documents submitted by the parties. This court has only included facts which are adequately supported by evidence in the record.

a modular prosthesis which was manufactured by Defendants. The modular prosthesis consists of separate components and is promoted as providing the surgeon with greater flexibility. The neck of the modular prosthesis was made of titanium alloy. It is undisputed that prostheses with a monolithic design, consisting of only one part, were available as an alternative to Dr. Smit, who chose to use the Profemur® modular implant instead. On October 10, 2007, Dr. Smit again performed hip replacement surgery and replaced Plaintiff's left hip. Dr. Smit again used a Profemur® prosthesis, model PHA0-1254, long neck. Dr. Smit's surgical notes stated that the procedure used "allowed for what appeared to be correct geometry and equal leg lengths." It is undisputed that Plaintiff has weighed as much as 265 pounds and is around six feet tall.

The prosthesis package insert, which was available to Plaintiff's doctor, stated that "it must be recognized that [hip replacement prostheses] are manufactured from metal, ceramic, and plastic materials and that any hip replacement system, therefore, cannot be expected to withstand activity levels and loads as would normal healthy bone." The insert also stated that "the system will not be as strong, reliable, or durable as a natural human hip joint." The insert listed the patient's weight as a factor which could be critical to the eventual success of the procedure and explained that "[a]n overweight or obese patient can produce high loads on the prosthesis, which can lead to failure of the prosthesis." The insert stated that the procedure was absolutely contraindicated by "obesity where obesity is defined as three times normal body weight." The insert also stated that the "patient should be warned that the prosthesis does not replace normal healthy bone, that the prosthesis can break or become

damaged as a result of certain activity or trauma, has a finite expected service life, and may need to be replaced at some time in the future."

Plaintiff signed a consent form before both surgeries. Both forms stated:

> My doctor has explained to my satisfaction:
>
> a. The procedure(s) or operation(s) to be performed.
>
> b. The benefits reasonably anticipated by undergoing this procedure, or operation, including the possible consequences and complications and potential problems related to recuperation.
>
> c. The likelihood of achieving the care, treatment or goals.
>
> d. The risks reasonably anticipated by not undergoing this procedure, or operation, including the possible consequences and complications of not receiving care, treatment and services.
>
> e. Any reasonable alternatives to this method of treatment, and that the choice to undergo or not undergo the procedure, or operation is mine alone.
>
> f. I have been informed there are other risks, such as loss of life, loss of blood, infection, cardiac arrest, damage to teeth, etc., that are attendant to the performance of any surgical or anesthetic procedure.

Both forms were also signed by Dr. Smit. By signing the forms, Dr. Smit stated that he had "discussed the above with patient and/or family/legal representative."

On April 16, 2009, the neck of the prosthesis in Plaintiff's left hip failed and it was removed in a revision surgery on April 21, 2009. On October 17, 2010, the neck of the prosthesis in Plaintiff's right hip failed and Plaintiff had it removed in a revision surgery on October 20, 2010. Plaintiff's deposition was taken on August 15, 2011. Plaintiff testified that he was told the implant would last "probably" ten years.

PROCEDURAL HISTORY

Plaintiff filed a Complaint (#1) against Defendants in this court on June 23, 2009. Plaintiff alleged that the prosthesis manufactured by Defendants and placed in Plaintiff's left hip was "unreasonably dangerous for its intended or reasonably foreseeable uses." On August 18, 2009, a Discovery Order (#13) was entered which set a deadline for the amendment of pleadings of April 1, 2010. The Discovery Order also set the case for a jury trial on February 28, 2011. However, various delays have prolonged this case well beyond the original trial date. The discovery order was amended many times and the jury trial has been rescheduled numerous times.

On March 31, 2011, Plaintiff filed an Amended Complaint (#58). Plaintiff added allegations that the prosthesis placed in his right hip failed on October 17, 2010, and "was unreasonably dangerous for its intended or reasonably foreseeable uses."

On June 10, 2011, Plaintiff was allowed to file his Second Amended Complaint (#72). Plaintiff alleged that Defendants designed, manufactured, distributed and sold the hip

prosthesis system in question. Plaintiff alleged that both the left hip prosthesis and the right hip prosthesis were unreasonably dangerous for their intended or reasonably foreseeable uses. Plaintiff focused his allegations on problems with the neck portion of the prostheses and alleged that the prostheses were unreasonably dangerous under the risk-benefit test and under the consumer-expectation test. On August 15, 2011, the jury trial was rescheduled once again and is currently scheduled for June 11, 2012, at 9:00 a.m.

On October 3, 2011, Defendants filed their Combined Motion to Dismiss and Motion for Summary Judgment (#79), with an attached Memorandum in Support and Exhibits. Defendants filed additional supporting Exhibits (#80) under seal. On October 27, 2011, Plaintiff filed a Response to Defendants' Combined Motions (#81) with attached exhibits. Plaintiff also filed additional supporting Exhibits (#82) under seal. On November 14, 2011, Defendants filed their Reply (#83) and supporting Exhibits (#84) under seal. On December 9, 2011, Plaintiff filed an additional Response (#85) and asked to present oral argument in response to Defendants' Motion (#79). Defendants' Motion (#79) is fully briefed and ready for ruling and this court concludes that oral argument is not necessary.

The documents provided to this court include expert reports and peer-reviewed articles. Plaintiff also provided documents he received from Defendants which show 184 reported failures of the Profemur® neck of which 173 were failures of a long neck. Defendants have pointed out that the documentation shows that only 67 of these failures involved model PHA0-1254, including the failures of Plaintiff's prostheses.

Plaintiff's expert, James Pugh, a litigation consultant with a Ph.D. in Biomedical

Engineering from Massachusetts Institute of Technology (MIT), issued an expert report on September 2, 2010. Pugh stated that "it is my opinion to a reasonable degree of scientific certainty that the [Profemur®] prosthesis was unreasonably dangerous for its intended or reasonably foreseeable use in an individual such as [Plaintiff] in that the design features whereby the oblong taper of the neck is joined to the stem of the prosthesis by way of an oblong slot in the neck which results in micromovements between the oblong taper and the oblong slot which results in fretting of the materials thereby resulting in stress concentration which causes fatigue failure of the oblong taper portion of the neck inside of the oblong slot." Pugh stated that "the failures were not the result of a manufacturing defect, but rather of the design of the prosthesis where a neck with a tapered oval distal end is joined to the femur stem of the prosthesis through an oblong slot in the proximal end of the stem." Pugh stated that, until 2009, the necks were manufactured from a titanium alloy. He stated that "cobalt chromium alloy assemblies in general showed higher strength when compared to the titanium alloy necks." Pugh expressed the opinion that these "observations raise the possibility that the failures in question may be reduced by changing to cobalt chromium necks, which are stronger and may have reduced fretting." Pugh stated that "the same basic problem of fretting and resulting stress leading to failure remains, but potentially may be at a substantially reduced incidence." Pugh stated:

> The unreasonably dangerous design condition can be eliminated by a one piece stem and neck assembly. The manufacturing of the one piece stem and neck assembly in

> different lengths and angles of the neck may be more costly than using different necks. However, this would eliminate the design defect in question and the suffering disability and expense resulting from failures.

Plaintiff's expert, Carl Alstetter, who also has a degree from MIT and is a professor emeritus in metallurgical engineering at the University of Illinois, issued a written report on September 1, 2010. In his report, Alstetter stated that he had conducted an investigation of the Wright Profemur® prosthesis that fractured in the distal end of the neck after implant into Plaintiff. Alstetter stated that "[b]ased on my investigation, it is my opinion to a reasonable degree of scientific certainty that the prosthesis was unreasonably dangerous for its intended or reasonably foreseeable use in an individual such as [Plaintiff]." Alstetter stated:

> One of the problematic design features is that the oblong taper of the neck is inserted in a tapered, oblong slot in the stem. Under the cyclic stress of normal use micromovements between the oblong taper and the oblong slot could result in fretting of the materials. Such a process would make it difficult to maintain the passive film on the surface that is responsible for the normally excellent corrosion resistance of the material. Under the cyclic stress of normal use and the corrosive environment the damage to the surface could develop into a fatigue crack that propagates into the material. At a critical

> crack depth complete failure of the oblong taper portion of the neck occurs in a single application of load. When this occurs the device can no longer support any tensile load.

Plaintiff has also provided copies of articles written regarding the failure of modular prostheses, including a case study of Ronald Cappellano, the plaintiff in Case No. 08-CV-2265 filed in this court. The case study regarding Cappellano was written by Alstetter and the surgeon who performed Cappellano's revision surgery, Chris J. Dangles, M.D. This article was published in 2010 and stated that the modular design "is a relatively recent design promoted as giving the surgeon more options in controlling leg lengths, offset, and implant stability."[2] The article also stated that "[i]mplant failure is a known occurrence" and the "benefits of modularity must be shown to outweigh the risks of this failure pattern."[3] The article concluded:

> The benefits of modularity allow for intraoperative adjustments to promote optimal positioning of the prosthesis. This should improve stability, decrease the dislocation rate, and assist in equalization of leg length. However, a well-fitting prosthesis that fails within a few years is neither what the patient

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[2] Chris J. Dangles, M.D. and Carl J. Alstetter, ScD, Failure of the Modular Neck in a Total Hip Arthroplasty, The Journal of Arthroplasty 2010, Vol. 25 No. 7 at 1169.e5.

[3] Id. at 1169.e6. Plaintiff stated that this article opined that the advantages provided by a modular system are more than offset by the failures of the modular neck inside the femoral stem and that the "Profemur prosthesis is an unsafe product." No such statements are included in the copy of the article provided by Plaintiff.

> reasonably expects or what is acceptable performance. Although the surgeon is not responsible for the design of a prosthesis, it is urged that surgeons consider potential design flaws when they are published in the literature.[4]

A paper written by faculty of Dalhousie University and published by the Canadian Arthritis Society concluded that the "findings of this study demonstrate that this design of a modular neck total hip arthroplasty component is at a relatively high risk of early catastrophic failure."[5] An article published in 2010 concluded that "[i]t is difficult to extrapolate the results from one patient beyond the case studied," but "[i]t is suggested that long-necked modular stems, particularly when used with offset heads, should be used with caution, especially in heavier patients, who place higher functional demands on the prosthesis."[6] Another article published in 2010 noted that "modularity enables the surgeon to better optimize the patient's biomechanics and anatomy, but additional mechanical junctions can lead to corrosion processes resulting in fracture."[7] This article concluded that "it appears that there is a risk of implant fracture at the stem-neck junction when double-modular devices are

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[4] Id. at 1169.e7.

[5] Wilson, Dunbar, Amirault, Farhat, Catastrophic Early Failure of a Modular Total Hip Arthroplasty Component, The Canadian Arthritis Society (undated).

[6] David A.J. Wilson, Michael J. Dunbar, John D. Amirault and Zoheir Farhat, Early Failure of a Modular Femoral Neck Total Hip Arthroplasty Component, The Journal of Bone and Joint Surgery, 2010; Vol. 92, at 1517.

[7] Sara A. Atwood, Eli W. Patten, Kevin J. Bozic, Lisa A. Pruitt and Michael D. Ries, Corrosion-Induced Fracture of a Double-Modular Hip Prosthesis: A Case Report, The Journal of Bone and Joint Surgery, 2010; Vol. 92, at 1525.

used, particularly when those with a long neck are implanted in heavy patients."[8] Yet another article published in 2010 focused on the use of titanium alloy for the neck of the modular prosthesis and concluded that a cobalt-based alloy "increases the safety of the cone connection significantly."[9] A paper presented in 2009 stated that modular necks were a relatively new innovation in total hip arthroplasty, with several companies offering modular neck options. The paper stated that the "proposed advantages of reduced impingement, reduced dislocation rate, and better reconstitution of leg length and offset are compelling."[10] The paper noted that few reports in the literature address the outcomes of these devices and that those that are published "at best demonstrate equivalence to conventional" total hip arthroplasty.[11] The paper stated that there were numerous disadvantages to the new technology, with a fracture rate reported of 1.4%.[12] The paper also stated that fractures occurred "more frequently in heavy men" and "with the preponderance of fractures occurring around the 2-year mark."[13] This paper concluded that more research is required and stated that "[g]iven the lack of literature to support the proposed benefits of proximal neck

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[8] Id. at 1525.

[9] Thomas M. Grupp, Thomas Weik, Wilheim Bloemer, Hanns-Peter Knaebel, Modular Titanium alloy neck adapter failures in hip replacement - failure mode analysis and influence of implant material, BioMedical Central Musculoskeletal Disorders 2010, Vol. 11.

[10] Michael J. Dunbar, The Proximal Modular Neck in THA: A Bridge Too Far: Affirms, The Ortho Supersite, at 1. (A copy of this paper was filed by Plaintiff as Ex. J (#81-7).)

[11] Id. at 1.

[12] Id. at 1.

[13] Id. at 1.

modularity, and the published theoretical and known complications with significantly increased costs, the available evidence would suggest that the proximal modular neck in [total hip arthroplasty] is a bridge too far."[14]

Defendants have also provided expert reports in this case. Brad James, Ph.D., P.E., of Exponent Failure Analysis Associates, issued a report dated October 15, 2010. James stated that the findings in his report were "made to a reasonable degree of engineering certainty." James stated that no manufacturing defects were observed and that "[d]evice history records indicate the subject device conformed to Wright Medical's specified dimensional and surface finish requirements." James stated that "[f]retting is a very well-known issue in modular orthopedic implants, such as the subject device." James stated:

> Although modular orthopedic implants are well known to be susceptible to fretting, modular systems allow distinct advantages in terms of fitting patient anatomy. The continued extensive use of various modular hip prostheses indicates the medical community generally believes the benefits outweigh the disadvantages . . . . Thus, the presence of fretting or fatigue fracture in a modular implant does not necessarily indicate the presence of a design or manufacturing defect.

James stated that "studies have shown a clear trend of patient weight with time-to-implant

[14] Id. at 4.

fracture time or fracture rate." James concluded that Plaintiff's "weight contributed to the stresses placed upon his implant, and its eventual fatigue failure." James also concluded:

> The subject implant neck design has been on the market for more than ten years. In fact, a similar neck design has been in use as an implant in Europe since 1986. Wright Medical observed a fracture rate of approximately 0.0059% for long necks from 2002 through 2008. The fracture rate for all necks was reported to be 0.027%. These fracture rates for the Wright Medical PROFEMUR® device compare favorably with published literature, which includes most designs on the market. For example, the Swedish Hip Arthroplasty register reported that between 1979 and 2007 1.4% of hip revisions in Sweden were necessary because of hip implant fractures (475 out of 34,195 cases). The National Joint Registry for England and Wales stated 1% of all indications for hip revision surgeries in 2008 were because of implant fractures. Others have reported [total hip replacement] fracture rates between 0.23 to 91%. It is important to note these numbers include both monoblock and modular devices made by several different manufacturers. Thus, the PROFEMUR® fracture rates appear to be substantially lower than the rest of the hip replacement industry.

> Given the long service experience, the validation testing conducted by Wright Medical, and the low reported fracture rates, it can be concluded that the design of the subject neck is appropriate for its intended function. (Citations omitted.)[15]

James noted that Pugh had commented that changing to chromium alloy necks may reduce device failures. James acknowledged that it was true that cobalt chromium alloys have better fatigue resistance and are less susceptible to fretting than titanium alloys. However, James stated that other important design factors must be considered before simply switching alloys. James stated that the most common cause of total hip replacement prosthesis failure is aseptic loosening. James stated that, in fact, aseptic loosening failure rates in hip implants dwarf the rate of fatigue fracture. James pointed out that one factor in implant loosening is implant stiffness and cobalt chromium alloys "have a significantly higher elastic modulus (stiffness)" than titanium alloys. James stated that "Pugh apparently only considered fretting and fatigue performance when he suggested switching alloys may reduce 'failures;' such a statement is simplistic and does not consider the larger issues involved." James noted that, in addition, titanium alloys are typically considered to have superior biocompatibility compared to cobalt chromium alloys. He stated that "just switching alloys is not a simple process; gains in one design area are typically balanced by reduction(s) in another."

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[15] This court notes that Defendants provided this court with James' report only and did not include James' resume or the list of documents he relied upon.

James also questioned Pugh's conclusion that a monolithic or one-piece design would eliminate the defect in question. James stated:

> Over 200 different one-piece implant variations would be required to replace the possible neck-stem combinations that exist because of the modularity of the PROFEMUR® Z-line. Further, one-piece implants are available from Wright Medical for surgeons to choose.
>
> Much of the literature cited in this report discusses failure of one-piece implants. As stated earlier, other factors, such as aseptic-loosening, result in far more hip implant revisions than do fractures. Stiffer, one-piece implants can be more prone to aseptic loosening than modular devices. Further, the flexibility provided by modularity can provide better patient fit and biomechanics. The subject Wright Medical PROFEMUR® device is state of the art. There is no alternative hip implant design that would have eliminated the possibility of fracture in [Plaintiff].

Defendants' expert, Jorge A. Ochoa, Ph.D. P.E., of Exponent Failure Analysis Associates, issued a report dated October 15, 2010. This report set out information about Ochoa's qualifications, including a Ph.D. in Mechanical Engineering from Purdue University, and included citations to the sources he relied upon. Ochoa stated that his report

was "based on [his] education and experience as a biomechanical engineer and [his] experience designing, testing, and commercializing medical devices." In his lengthy report, Ochoa stated that the titanium alloy used in the Profemur® modular necks "has a long history of clinical success in orthopaedic surgery due to its superior biocompatibility, fatigue properties, and strength" and "has a modulus of elasticity closer to that of bone than other alloys commonly used in orthopaedic implants." Ochoa stated that designing modular necks with a tapered junction out of alternative materials such as cobalt chromium alloys "may increase the strength of the neck components themselves, but a simultaneous reduction in disassembly strength may be a resulting performance byproduct." Ochoa also stated:

> The benefits as well as the potential pitfalls of modularity are well understood and accepted by the orthopaedic community. Tradeoffs between strength and biomechanical performance are explicit with the use of modular transplants. Modularity enables the surgeon to optimize the patient's biomechanics by accommodating anatomic variability, but the addition of junctions can lead to increased stresses, micromotion, fretting and corrosion at the modular interfaces, resulting in mechanical failure. (Citations omitted.)

Ochoa stated that the fact that Plaintiff "is a heavy individual would further exacerbate the incremental loading resulting from microseparation, even during activities of daily living." Ochoa summarized:

> As with any mechanical structure, there is always some risk of failure with an orthopaedic implant. While total hip replacement is largely successful in attaining the clinical goals of patients, it must be recognized that hip prostheses are manufactured from metal, ceramic, and polymeric materials. Therefore, no hip replacement component can be expected to withstand activity levels and loads similar to that of normal healthy bone for the lifetime of the patient. It is understood that artificial hip components will not be as strong, reliable, or durable as a natural human hip joint.

Ochoa concluded that "the subject PROFEMUR modular neck met its intended design and functional requirements, provided end user functionality and patient safety, and was not designed or manufactured in a defective manner."

ANALYSIS

I. MOTION TO DISMISS

Defendants have argued that, to the extent that Plaintiff sought to state a claim based on a failure to warn theory, the lack of factual allegations on this theory requires dismissal of the claim. In his response to Defendants' Motion, Plaintiff has conceded that no failure to warn claim has been asserted. Therefore, Defendants' request for dismissal of any failure

to warn claim is GRANTED.[16]

Defendants also argued that, to the extent that Plaintiff sought to state a claim for a manufacturing defect, he has failed to do so and dismissal is warranted. In addition, Defendants argued, in the alternative, that they are entitled to summary judgment on any manufacturing defect claim brought by Plaintiff. This court concludes that, at this stage of the proceedings, it is more appropriate to consider whether Defendants are entitled to summary judgment on this claim. Therefore, Defendants' request for dismissal of Plaintiff's manufacturing defect claim is DENIED as moot.

II. MOTION FOR SUMMARY JUDGMENT

A. SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); see also Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986). In ruling on a motion for summary judgment, a district court "has one task and one task only: to decide, based on the evidence of record, whether there is any material dispute of fact that requires a trial." Waldridge v. Am. Hoechst Corp., 24 F.3d 918, 920 (7th Cir. 1994). In making this determination, the court must construe the evidence in the light most favorable to the nonmoving party and draw all reasonable inferences in favor of that party. See

[16] This court notes that Plaintiff stated in a footnote that "based on the defendants' fallacious arguments, it has become apparent that there may be a failure to warn claim which plaintiff may ask leave to assert." This court reminds Plaintiff that the deadline for amending pleadings in this case passed long ago. Therefore, any such request would be untimely and would be denied.

Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986); Singer v. Raemisch, 593 F.3d 529, 533 (7th Cir. 2010). However, a court's favor toward the nonmoving party does not extend to drawing inferences which are only supported by speculation or conjecture. See Singer, 593 F.3d at 533.

The party opposing summary judgment may not rely on the allegations contained in the pleadings. Waldridge, 24 F.3d at 920. "[I]nstead, the nonmovant must present definite, competent evidence in rebuttal." Butts v. Aurora Health Care, Inc., 387 F.3d 921, 924 (7th Cir. 2004). Summary judgment "is the 'put up or shut up' moment in a lawsuit, when a party must show what evidence it has that would convince a trier of fact to accept its version of events." Koszola v. Bd. of Educ. of City of Chicago, 385 F.3d 1104, 1111 (7th Cir. 2004), quoting Johnson v. Cambridge Indus., Inc., 325 F.3d 892, 901 (7th Cir. 2003). Specifically, to survive summary judgment, the nonmoving party "must make a sufficient showing of evidence for each essential element of its case on which it bears the burden at trial." Kampmier v. Emeritus Corp., 472 F.3d 930, 936 (7th Cir. 2007), citing Celotex Corp., 477 U.S. at 322-23. Conclusory allegations not supported by the record are not enough to withstand summary judgment. See Basith v. Cook County, 241 F.3d 919, 928 (7th Cir. 2001).

B. STRICT PRODUCT LIABILITY

Plaintiff's claim is based upon strict product liability under Illinois law. "Under this doctrine, strict liability is imposed upon a seller of 'any product in a defective condition unreasonably dangerous to the user or consumer or to his property.'" Calles v. Scripto-Tokai Corp., 864 N.E.2d 249, 254 (Ill. 2007), quoting Restatement (Second) of Torts § 402A, at

347-48 (1965). It is "well established that to recover in a strict product liability action, a plaintiff must plead and prove that the injury complained of resulted from a condition of the product, that the condition was unreasonably dangerous, and that it existed at the time the product left the manufacturer's control." Mikolajczyk v. Ford Motor Co., 901 N.E.2d 329, 335 (Ill. 2008). A product may be found to be unreasonably dangerous based on proof of any one of three conditions: (1) a physical defect in the product itself (manufacturing defect); (2) a defect in the product's design (design defect); or (3) a failure of the manufacturer to warn of the danger or to instruct on the proper use of the product. Mikolajczyk, 901 N.E.2d at 335. This court has already dismissed any claim based upon the failure to warn.

1. PLAINTIFF'S MANUFACTURING DEFECT CLAIM

"A manufacturing defect occurs when one unit in a product line is defective, whereas a design defect occurs when the specific unit conforms to the intended design but the intended design itself renders the product unreasonably dangerous." Salerno v. Innovative Surveillance Tech., Inc., 932 N.E.2d 101, 108 (Ill. App. Ct. 2010), citing Blue v. Envtl. Eng'g, Inc., 828 N.E.2d 1128, 1137 (Ill. 2005). "Generally speaking, manufacturing defects result from qualities of a product not intended by the manufacturer." Mech. Rubber & Supply Co. v. Caterpillar Tractor Co., 399 N.E.2d 722, 723 (Ill. App. Ct. 1980).

Defendants have argued that they are entitled to summary judgment on any claim included in Plaintiff's Second Amended Complaint alleging a manufacturing defect because there is no evidence which supports such a claim. Defendants pointed out that Plaintiff's own expert, Pugh, conceded that Plaintiff's injuries were not caused by a manufacturing

defect.

In his response, Plaintiff has provided the supplemental opinions of Alstetter and Pugh. In his supplemental opinion, dated August 31, 2011, Pugh stated that "the only rational conclusion is that there is either a design defect and/or a manufacturing defect," contradicting his original report, which stated that "the failures were not the result of a manufacturing defect." Pugh explained that "the extremely small design tolerances may result in manufacturing defects that is the distal end of the neck may be smaller than design tolerances and the oval slot of the stem may be larger than designed tolerances (emphasis added)." Alstetter's supplemental expert report, dated July 27, 2011, stated that he had reviewed additional information, including the list of failures provided by Defendants and photographs of Plaintiff's right hip that failed in October 2010. Alstetter stated, in pertinent part, that:

> All information supports the conclusion that these failures are a result of fatigue crack propagation, possibly initiated by fretting in a corrosive environment caused by micromovements between the neck and the tapered slot in the stem. This uniform pattern means there is either a design defect or a manufacturer defect or a combination that results in the degree of micro-movements necessary to accelerate fretting and failure.

This court agrees with Defendants that Plaintiff has not come forward with any evidence that the hip prosthesis deviated in any way from Defendants' intended design.

Plaintiff's experts' supplemental reports have provided only speculative opinions that there may be a manufacturing defect. In addition, these opinions contradict Pugh's original opinion regarding a manufacturing defect with little explanation. "An expert who supplies nothing but a bottom line supplies nothing of value in the judicial process" and does not save a party from summary judgment. Mid-State Fertilizer Co. v. Exchange Nat'l Bank of Chicago, 877 F.2d 1333, 1339 (7th Cir. 1989); see also Weigel v. Target Stores, 122 F.3d 461, 468-69 (7th Cir. 1997). This court concludes that Plaintiff has provided no evidence showing the existence of a manufacturing defect and that Defendants are therefore entitled to summary judgment on Plaintiff's manufacturing defect claim.

2. PLAINTIFF'S DESIGN DEFECT CLAIM

A plaintiff may demonstrate that a product has been defectively designed in one of two ways. Calles, 864 N.E.2d at 255, citing Lamkin v. Towner, 563 N.E.2d 449, 457 (Ill. 1990). One way is to present evidence that the product fails to satisfy the consumer-expectation test. Calles, 864 N.E.2d at 255. "Alternatively, a plaintiff may demonstrate a design defect by presenting evidence that the risk of danger inherent in the challenged design outweighs the benefits of such design." Calles, 864 N.E.2d at 255. The latter test, which added the balancing of risks and benefits to the alternative design and feasibility inquiries, has come to be known as the risk-utility or risk-benefit test. Mikolajczyk, 901 N.E.2d at 336.

Defendants have argued that they are entitled to summary judgment on Plaintiff's design defect claim because the evidence does not support Plaintiff's claim. In his Response, Plaintiff argued that there are genuine disputes of material fact as to his design defect claim

under the risk-utility test and under the consumer-expectation test.

a. CONSUMER-EXPECTATION TEST

To prevail under the consumer-expectation test, a plaintiff must demonstrate that "the product failed to perform as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner." Calles, 864 N.E.2d at 256. However, Plaintiff has correctly recognized that "if the evidence is sufficient to implicate the risk-utility test, a broader test which incorporates the factor of consumer-expectation is applied by the trier of fact." See Mikolajczyk, 901 N.E.2d at 352-53. Under the formulation set out in Mikolajczyk, "consumer expectations are included within the scope of the broader risk-utility test." Show v. Ford Motor Co., 659 F.3d 584, 587 (7th Cir. 2011), quoting Mikolajczyk, 901 N.E.2d at 352. In this case, Plaintiff has presented evidence and argument regarding the risk-utility test, so the consumer-expectation test is simply one factor incorporated into the risk-utility test. See Mikolajcyzk, 901 N.E.2d at 352-53. Therefore, this court will consider this factor in its discussion of the risk-utility test.

b. RISK-UTILITY TEST

Under the risk-utility test, the plaintiff must offer proof that the risk of danger inherent in the product design outweighs its benefits. Calles, 864 N.E.2d at 255. "When the risk of harm outweighs the utility of a particular design, there is a determination that the manufacturer exposed the consumer to a greater risk of danger than is acceptable to society." Jablonski v. Ford Motor Co., 955 N.E.2d 1138, 1154 (Ill. 2011). Plaintiff bears the burden of proving that the risks outweigh the benefits. See Calles, 864 N.E.2d at 255.

Plaintiff has asked this court to consider the factors set out by the Illinois Supreme Court in Jablonski in analyzing whether there is sufficient evidence to go to the jury based upon the risk-utility test. In Jablonski, the court set forth a nonexhaustive list of factors which may be relevant to the risk-utility analysis. Jablonski, 955 N.E.2d at 1154. "These factors include evidence of (1) the availability and feasibility of alternate designs at the time of the product's manufacture; or (2) that the design used did not conform to the design standards in the industry, design guidelines provided by an authoritative voluntary organization, or design criteria set by legislation or governmental regulation." Jablonski, 955 N.E.2d at 1154, citing Calles, 864 N.E.2d at 260. "Other factors that may be relevant include the utility of the product to the user and to the public as a whole, the safety aspects of the product including the likelihood that it will cause injury and the probable seriousness of the injury, and the manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility." Jablonski, 955 N.E.2d at 1154.

The court in Jablonski noted that there are a myriad of factors that may be relevant to the balance of risk and benefits, which may vary depending upon the unique facts and circumstances of each case. Jablonski, 955 N.E.2d at 1155. "In applying the balancing test, the court must initially balance factors it finds relevant to determine if the case is a proper one to submit to the jury." Jablonski, 955 N.E.2d at 1155. This court notes that Jablonski was a negligence case rather than a strict product liability case. However, the court stated that "the balancing test developed for strict liability claims, which examines whether a

product is unreasonably dangerous, is essentially identical to the test applied in determining whether a defendant's conduct in designing a product is unreasonable." Jablonski, 955 N.E.2d at 1155.

Plaintiff has argued that, based upon Jablonski, he must only submit enough facts so that this court may initially balance relevant factors to determine if the jury should decide this matter. Plaintiff suggested that the relevant factors in this case are: (1) the availability and feasibility of an alternate design; (2) the ability to eliminate the unsafe character without impairing its usefulness; and (3) the seriousness of the potential injury.

As far as the first suggested factor, Plaintiff argued that Defendants could have used an alternate, monolithic, design at the time of manufacture to prevent the failure of Plaintiff's prosthesis. Plaintiff argued that he had established through the testimony of both of his experts that the modular design of the Profemur® prosthesis was a major cause of the failures. Plaintiff stated that his experts "are not suggesting that a monolithic design would eliminate *all* failures" but were testifying that "a monolithic design would eliminate the particular design defect in this case." Plaintiff argued, citing Jablonski, he "need not prove that an alternative design would eliminate any and all failures as the defendants suggest." Plaintiff also contended that the same argument holds true in relation to his assertion that the use of a Morse taper and chromium-cobalt necks was an alternative design that was available and feasible. Plaintiff noted that Pugh's report stated that by changing the taper and metallurgical composition of the prosthesis neck, fretting and failures may be reduced.

As to the second suggested factor, Plaintiff argued that he had shown that the

alternative design is not overly costly to Defendants and would not impair the usefulness of the Profemur® prosthesis. Plaintiff stated that Defendants "admit as much in their Motion for Summary Judgment by stating that Wright Medical already had over 200 monolithic options available on the market at the time of the implantation of the Profemur® prostheses in the plaintiff."[17]

In addition, Plaintiff argued that the third suggested factor, the potential seriousness of the injuries resulting from a failure, is important in this case. Plaintiff argued that, when the neck of the prosthesis fails, the entire prosthesis must be removed, including the femoral component which must be extricated from the femur. Plaintiff argued that this "is a difficult procedure that frequently results in fractures of the proximal end of the femur." Plaintiff contended that "in almost every case a full revision surgery is necessitated." Plaintiff noted that, in his case, he was still recovering from the first revision surgery when his second prosthesis failed. As support for his arguments, Plaintiff referred to the information provided by Defendants regarding the failures of the Profemur® prosthesis.

As far as the availability and feasibility of an alternate design factor, this court agrees with Plaintiff that a monolithic design was available at the time the Profemur® prosthesis was manufactured. However, based upon the expert reports and the published articles

[17] This court notes that Plaintiff is correct that Defendants made this argument in their Motion for Summary Judgment. Defendants cited to James' report. However, James stated in his report that "[o]ver 200 different one-piece implant variations would be required to replace the possible neck-stem combinations that exist because of the modularity of the PROFEMUR® Z-line." Therefore, this court reads James' report to state that over 200 different monolithic variations would be needed to replace the modular design of the Profemur® prosthesis, not that over 200 monolithic options are available. In any case, there is no dispute that many monolithic options are available, including monolithic prostheses manufactured by Defendants.

provided by Plaintiff, it is also clear that there are some advantages to the modular design over the monolithic design in the area of flexibility and providing more options in controlling leg lengths, offset, and implant stability. These reports and articles also show that there have been problems with failure of the modular necks, especially when a long neck is used and the prosthesis is implanted in an overweight individual. Plaintiff has provided evidence of 184 failures of the Profemur® prosthesis and that 173 of these failures involved the failure of a long neck.

The problem with the evidence provided by Plaintiff is the complete lack of information from which this court could compare the risks of the modular design of the Profemur® prosthesis with the risks of the proposed alternate monolithic design. Defendants have challenged Plaintiff's contention that he only needs to show that the alternative design resolves the one specific defect alleged by Plaintiff and need not come forward with any evidence that the alternative design is generally safer or better. Defendants' expert, James, stated in his report that the failure rate is approximately 0.0059% for long necks from 2002 through 2008. James stated that the fracture rate for all necks was reported to be 0.027% and the fracture rates for the Profemur® device compare favorably with the failure rate of other types of prostheses, including monolithic prostheses. Plaintiff has not countered this statement in James' report and has provided no information regarding failure rates of monolithic prostheses. James stated that "other factors, such as aseptic-loosening, result in far more hip implant revisions than do fractures" and that "[s]tiffer, one-piece implants can be more prone to aseptic loosening than modular devices." Therefore, while it may well be

that a monolithic design would reduce or eliminate fretting and the resulting failure of the neck, there is evidence in this case that the use of the monolithic design could result in failure caused by aseptic loosening and other factors. Plaintiff has not directly disputed this and has provided no information from which this court can assess which design would result in the smallest percentage of failures.

Plaintiff has asserted that he does not need to prove that the alternative, monolithic design "would eliminate any and all failures." That may be true. However, the court stated in Jablonski, "[i]t is not sufficient that the alternative design would have reduced or prevented the harm suffered by the plaintiff if it would also introduce into the product other dangers of equal or greater magnitude." Jablonski, 955 N.E.2d at 1158, quoting Restatement (Third) of Torts: Products Liability § 2, cmt. f, at 23 (1998). Based upon Jablonski, Defendants are correct that Plaintiff is required to show that the monolithic design did not have dangers of equal or greater magnitude. Plaintiff has not done so.

The same is true regarding Plaintiff's proposed alternative design regarding a different taper and a chromium cobalt neck. Plaintiff has not addressed the evidence that, while a chromium cobalt neck may be stronger that a titanium alloy neck, titanium alloy has other advantages. Plaintiff has provided no basis for determining whether the risk of the titanium alloy neck (less strength) outweighs the benefits of the titanium alloy neck (superior biocompatibility and elasticity closer to that of bone). Further, Pugh's report stated that "the same basic problem of fretting and resulting stress leading to failure remains, but potentially may be at a substantially reduced incidence (emphasis added)." This equivocal opinion is

not sufficient to show that the proposed alternative design would actually be better.

As far as Plaintiff's second suggested factor, Plaintiff has provided no comparison of the cost of the modular design as opposed to the monolithic design. Plaintiff's own expert, Pugh, stated that the "manufacturing of the one piece stem and neck assembly in different lengths and angles of the neck may be more costly than using different necks." James stated that "[o]ver 200 different one-piece implant variations would be required to replace the possible neck-stem combinations that exist because of the modularity of the PROFEMUR® Z-line." Therefore, this court concludes that Plaintiff has not shown that the alternative design is not overly costly to Defendants and would not impair the usefulness of the Profemur® prosthesis. In addition, Plaintiff has provided no evidence regarding the cost of using chromium cobalt alloy as compared to the cost of titanium alloy.

In his discussion of his third suggested factor, Plaintiff has argued that the risk of harm is greater with the modular design. Again, however, Plaintiff has provided no evidence from which this court can analyze the harm caused by a failure of a modular prosthesis in comparison to the harm caused by a failure of a monolithic prosthesis.

This court must also consider the consumer-expectation test as a factor in the risk-utility analysis. Plaintiff testified at his deposition that he was told by his doctor that his hip implant would last "probably" ten years. However, Defendants have provided evidence that the product insert provided to Plaintiff's doctor stated that the "patient should be warned that the prosthesis does not replace normal healthy bone, that the prosthesis can break or become damaged as a result of certain activity or trauma, has a finite expected service life, and may

need to be replaced at some time in the future." Plaintiff and his doctor signed consent forms before the implantation of the Profemur® prostheses. Both forms stated:

> My doctor has explained to my satisfaction:
>
> a. The procedure(s) or operation(s) to be performed.
>
> b. The benefits reasonably anticipated by undergoing this procedure, or operation, including the possible consequences and complications and potential problems related to recuperation.
>
> c. The likelihood of achieving the care, treatment or goals.
>
> d. The risks reasonably anticipated by not undergoing this procedure, or operation, including the possible consequences and complications of not receiving care, treatment and services.
>
> e. Any reasonable alternatives to this method of treatment, and that the choice to undergo or not undergo the procedure, or operation is mine alone.
>
> f. I have been informed there are other risks, such as loss of life, loss of blood, infection, cardiac arrest, damage to teeth, etc., that are attendant to the performance of any surgical or anesthetic procedure.

Both forms were also signed by Dr. Smit. By signing the forms, Dr. Smit stated that he had

"discussed the above with patient and/or family/legal representative." Plaintiff therefore was informed about the procedure and acknowledged there were risks involved. In addition, the evidence indicates that the potential for prosthesis failure was somewhat greater for Plaintiff because of his weight.[18]

Defendants have also pointed out that Plaintiff's experts, Pugh and Alstetter, made no reference to the consumer-expectation test. Expert testimony is not required in all cases to demonstrate that a product was unreasonably dangerous under the consumer-expectation test; however, expert testimony regarding the product's unreasonable dangerousness is required if the product is complex and beyond a lay jury's understanding. See Show, 659 F.3d at 587-88; Gray v. Ford Motor Co., 2011 WL 4859995, at *6 (C.D. Ill. 2011). This court concludes that the evidence presented shows that the product at issue, a hip prosthesis, is a complex device which can fail for many reasons. Therefore, this is a product beyond a lay jury's understanding and expert testimony would be necessary for the consumer-expectation test to be considered as a factor favorable to Plaintiff under the risk-utility test. In arguing the consumer-expectation test, Plaintiff relied on a Supplemental Rule 26(a) Disclosure as to Dr. Chris J. Dangles, who Plaintiff stated is not a retained expert. According to the Disclosure, it is Dangles' "opinion, as a physician, that the advantages provided by a modular system are more than offset by the failures of the modular neck inside the femoral stem and accordingly, in his opinion as an orthopedic surgeon, the Profemur prosthesis is an unsafe

[18] It is possible that Plaintiff's doctor should not have chosen a modular prosthesis because of Plaintiff's weight and activity level. That is not an issue before this court.

product." This court concludes that Dangles' conclusory opinion is not adequate expert testimony to allow the consumer-expectation test to be considered as a factor favorable to Plaintiff under the risk-utility test.

Plaintiff has argued that "the jury should assess the dangers of the [hip] prosthesis from the standpoint of an ordinary implantee," relying on Mele v. Howmedica, Inc., 808 N.E.2d 1026 (Ill. App. Ct. 2004). Plaintiff argued that "[c]learly a reasonably jury can find that an ordinary consumer (implantee) could expect a hip prosthesis would last many years longer than two to three years and was thus unreasonably dangerous."

This court is not persuaded. In Mele, the plaintiff claimed that a device, the D-M system, used as part of his hip replacement was defective and, at trial, relied solely on the consumer-expectation test. Mele, 808 N.E.2d at 1032. Therefore, evidence regarding the risk-benefit test was not allowed at trial. Mele, 808 N.E.2d at 1032. The jury found the D-M system was unreasonably dangerous and awarded damages. Mele, 808 N.E.2d at 1035. The defendant appealed. Mele, 808 N.E.2d at 1035. The Illinois appellate court concluded that the plaintiff "presented sufficient evidence to support the finding that an ordinary implantee would not anticipate this kind of danger from the D-M system." Mele, 808 N.E.2d at 1037. However, the appellate court also concluded that the "artificial hip here, and the D-M system implanted as part of the hip surgery, is not a particularly simple device" and "[c]onsumers do not have an especially clear understanding of all the dangers inherent in the device or the level of safety they can reasonably expect from a product that performs the function of the D-M system." Mele, 808 N.E.2d at 1041. The court concluded that the case did not fall

within the "simple product" exception to the application of the risk-utility test and therefore held that the trial court "should have permitted defendant to present evidence that the product design cannot be considered unreasonably dangerous because its benefits outweighed its risks." Mele, 808 N.E.2d at 1041-42. The judgment was therefore reversed and the case was remanded for a retrial. Mele, 808 N.E.2d at 1042.[19]

Because the jury's verdict in Mele was reversed, this court concludes that Mele does not support Plaintiff's argument that this case should be submitted to the jury for an assessment of the dangers of the hip prosthesis under the consumer-expectation test.

The court in Jablonski stated that it is the plaintiff's burden to present evidence "that the risk was foreseeable and that the risks inherent in the product design outweighed the benefits." Jablonski, 955 N.E.2d at 1157. Plaintiff has presented evidence that the risks of the modular design include the possibility of fracture of the neck of the prosthesis. The evidence in this case also shows that the benefits of the modular design include flexibility and providing more options in controlling leg lengths, offset, and implant stability. The modular design was developed to improve the fit of the prosthesis and to provide a prosthesis which is not as stiff as the monolithic design in order to reduce the failures of monolithic prostheses, including failures caused by aseptic loosening. In order to meet his burden under Jablonski, Plaintiff was required to provide evidence that the risk of the modular prosthesis design (neck failure) outweighed or was greater than the benefits of the modular design

[19] Subsequently, in Calles, the Illinois supreme court disagreed with Mele and other courts and determined that there was no "simple product" exception to the risk-utility test. Calles, 864 N.E.2d at 260-63.

(flexibility and better fit in order to reduce the possibility of the types of failures which have occurred in monolithic prostheses). Because Plaintiff has provided this court with no basis for comparing the risk and the benefits, he has not met his burden. In other words, in order to perform the initial balancing under the risk-utility test to determine it the case should go to the jury, this court must have something to balance. It cannot be enough to show that there is a risk without providing any way to balance the risk against the benefits.

Because Plaintiff has not provided this court with evidence from which it can conduct a threshold risk-utility analysis, this court concludes that Plaintiff has not adequately shown that the risks of the modular design used in the Profemur® prosthesis outweigh the benefits of the design. This court therefore agrees with Defendants that they are entitled to summary judgment on Plaintiff's design defect claim.

IT IS THEREFORE ORDERED THAT:

(1) Defendants' Combined Motion to Dismiss and Motion for Summary Judgment (#79) is GRANTED in part and DENIED as moot in part. Judgment is entered in favor of Defendants and against Plaintiff on all of Plaintiff's claims.

(2) The final pretrial conference scheduled on June 1, 2012, at 2:30 p.m. and the jury trial scheduled on June 11, 2012, at 9:00 a.m. are hereby VACATED.

(3) This case is terminated.

ENTERED this 7th day of February, 2012

s/ Michael P. McCuskey
MICHAEL P. McCUSKEY
CHIEF U.S. DISTRICT JUDGE