IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF GEORGIA MACON DIVISION

TIMOTHY R. COURSON and LINDA COURSON,	:	
Plaintiffs,	:	
v.	:	**Civil Action No. 5:12-CV-173 (CAR)**
WRIGHT MEDICAL TECHNOLOGY, INC.,	:	
Defendant.	:	

ORDER ON DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

Before the Court in this products liability case is Defendant Wight Medical Technology, Inc.'s ("Wright Medical") Motion for Summary Judgment [Doc. 23]. Having considered the relevant facts, applicable law, and the parties' arguments, Wright Medical's Motion for Summary Judgment [Doc. 23] is hereby **GRANTED in part** and **DENIED in part.**

For the reasons stated in the Court's Oral Order on Defendant's Motion to Exclude the Opinion Testimony of Dr. John D. Jarrell, Ph.D., P.E. [Doc. 25] given on October 11, 2013, the instant Order on Motion for Summary Judgment is in the form of a detailed outline, rather than the typical form issued by this Court.

LEGAL STANDARD

Summary judgment is proper 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."[1] The moving party "always bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, which it believes demonstrate the absence of a genuine issue of material fact" and that entitles it to a judgment as a matter of law.[2] If the moving party discharges this burden, the burden then shifts to the nonmoving party to go beyond the pleadings and present specific evidence showing that there is a genuine issue of material fact.[3]

The Court must view the facts, and any reasonable inferences drawn from those facts, in the light most favorable to the party opposing the motion.[4] "The inferences, however, must be supported by the record, and a genuine dispute of material fact requires more than 'some metaphysical doubt as to the material facts.'"[5] In cases where opposing parties tell different versions of the same events, and one is "blatantly contradicted by the record, so that no reasonable jury could believe it, a court should not adopt that version of

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[1] Fed. R. Civ. P. 56(a); *see Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).
[2] *Catrett,* 477 U.S. at 323 (internal quotation marks omitted).
[3] *See* Fed. R. Civ. P. 56(e); *see also Catrett,* 477 U.S. at 324-26.
[4] *Penley v. Eslinger*, 605 F.3d 843, 848 (11th Cir. 2010); *Welch v. Celotex Corp.*, 951 F.2d 1235, 1237 (11th Cir. 1992).
[5] *Logan v. Smith*, 439 F. App'x 798, 800 (11th Cir. 2011) (quoting *Penley*, 605 F.3d at 848).

the facts."[6] A disputed fact will preclude summary judgment only "if the dispute might affect the outcome of the suit under the governing law."[7] "The court many not resolve any material factual dispute, but must deny the motion and proceed to trial if it finds that such an issue exists."[8]

BACKGROUND

This is a products liability case involving the PROFEMUR® hip replacement system, a prosthetic hip implant manufactured and sold by Defendant Wright Medical. On September 21, 2009, Plaintiff Timothy R. Courson underwent right hip replacement surgery during which a PROFEMUR® prosthetic hip was implanted. The PROFEMUR® hip system is comprised of four separate components that are assembled together during surgery: the acetabular cup, the femoral head, the modular neck, and the femoral stem.

Enclosed with the PROFEMUR® hip replacement were warnings known as Instructions for Use ("IFU"), which indicated that certain factors were critical to the eventual success or failure of the hip replacement procedure. Among other things, the IFU provided:

> Patient's weight. An overweight or obese patient can produce high loads on the prosthesis which can lead to failure of the prosthesis.

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[6] *Pourmoghani-Esfahani v. Gee*, 625 F.2d 1313, 1315 (11th Cir. 2010) (per curiam) (quoting *Scott v. Harris*, 550 U.S. 372, 380 (2007)).

[7] *Id*. (internal quotation marks omitted).

[8] *Envtl. Def. Fund v. Marsh*, 651 F.2d 983, 991 (5th Cir. 1981). In *Bonner v. City of Prichard*, 661 F.2d 1206, 1209 (11th Cir. 1981) (en banc), the Eleventh Circuit adopted as binding precedent all the decisions of the former Fifth Circuit handed down prior to the close of business on September 30, 1981.

> Patient's occupation or activity. If the patient is involved in an occupation or activity which includes substantial walking, running, lifting, or muscle strain, the resulting forces can cause failure of the fixation, the device, or both. The prosthesis will not resort to the level expected with normal healthy bone, and the patient should not have unrealistic functional expectations.
>
> Absolute Contraindications include:
> 8. Obesity where obesity is defined as three times normal body weight.

The IFU also includes a section under CONTRAINDICATIONS that lists five conditions "presenting increased risk of failure." A patient's weight is not listed as one of the conditions.

On the date of the implantation surgery, Plaintiff was 6' ½" tall and weighed 296 pounds. Dr. Shane Smith, Plaintiff's orthopedic surgeon, knew of the warnings. He acknowledged that if Plaintiff had a body mass index of over 30 at the time of surgery, he would be classified as clinically obese. However, Dr. Smith believed that "[Plaintiff] had no contraindications to surgery for the hip replacement."[9] Moreover, Dr. Smith stated that "[Plaintiff's] body habitus was more muscular in nature. He's a big guy with large shoulders, large thighs, large muscular hips, and so he was an active gentleman that – in my mind there were really no indications to have a significant amount of weight loss. I didn't think that that was a limitation to him to the point that it would prevent him from having the surgery or doing well with the surgery."[10] Moreover, "[b]ecause 'normal weight' for a six foot tall male is 145-185 pounds, the contraindication as provided in the

[9] Smith Depo., p. 15.
[10] *Id.* at pp. 16-17.

packet insert [of the implant] only applied to patients of [Plaintiff's] height if they weighed at least 435 pounds."[11] Plaintiff clearly did not weigh that much.

Prior to performing the implantation surgery, Dr. Smith discussed the pre-operative plan with Wright Medical's representative, Jaime Harris. Harris "gave no indication that the Hip-Joint Implant would have a greater propensity of failure given [Plaintiff's] size."[12] Dr. Smith recalls that nothing was a major concern, and he and Harris would "template" the hip implant together, based on Plaintiff's x-rays.[13]

Approximately one year and nine months after receiving the implant, on June 13, 2011, Plaintiff was transported to the emergency room after he felt a snap in his hip, pain, and then was unable to walk while he was at work. Two days later, on June 15, 2011, Plaintiff had revision surgery on his right hip after it was discovered the PROFEMUR® neck component had fractured.

Dr. Smith performed the revision surgery. Prior to the surgery, Dr. Smith talked with Wright Medical distributor Shawn Fobas who told Dr. Smith that Wright Medical had developed an extraction tool that could remove the neck remnant. Mr. Fobas reviewed the "protocol" for the device with Dr. Smith – the "[t]echnique, the pictures, the drills."[14] Dr. Smith understood that if the extraction device successfully removed the neck remnant, "[t]hat would have meant less surgery for [Plaintiff], [and a] quicker recovery

[11] Smith Affidavit, ¶ 6.
[12] *Id.* at ¶ 7.
[13] Smith Depo., p. 34.
[14] *Id.* at p. 59.

versus the trochanteric osteotomy."[15] The engineers who designed the extraction tool flew down and instructed Dr. Smith how to use the device. Dr. Smith specifically asked, "What happens if this thing breaks," to which one of the engineers responded that the device was made "from the same metal that's used for the space shuttles and it's the strongest metal that man can make."[16] However, Dr. Smith recognized that the tool could break. Indeed, after several hours attempting to remove the neck remnant, the center bolt of the extraction device broke. Thus, Dr. Smith had to proceed with the extension trochanteric osteotomy (ETO).

Dr. Smith testifies that had he not used the extraction device, the ETO would have taken 2-3 hours.[17] However, because he used the extraction device, "[t]here was an additional couple of hours of surgery."[18] Following the surgery, Plaintiff has had a series of problems, including suffering from blood clots in his lungs and a pulmonary embolism.[19] Dr. Smith testifies that "[i]n my opinion, [the blood clot in his lungs is] a result of the prolonged surgery."[20] Dr. Smith further states that the increased time Plaintiff underwent surgery increased his risk for blood clots "significantly."[21]

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[15] *Id.* at pp. 44-45.
[16] *Id.* at p. 63.
[17] *Id.* at p. 46.
[18] *Id.* at p. 47.
[19] *Id.* at p. 48.
[20] *Id.*
[21] *Id.* at pp. 49-50.

It is undisputed that the extraction device was a prototype. Dr. Smith states that he does not recall being told it was a prototype;[22] he "knew that it had been used on a couple of other different cases."[23] However, had he been told it was a prototype, Dr. Smith testified he still would have used the device: "Q: Had it been brought up, had you been told this is a prototype tool, would you have done anything differently? A: "No, probably not."[24]

Plaintiffs Timothy Courson and his wife Linda filed this products liability action alleging that Wright Medical defectively designed and manufactured both the hip-joint implant and the extraction tool, and that Wright Medical failed to adequately warn of the dangers of both the hip-joint implant and the extraction tool. Plaintiffs engaged Dr. John D. Jarrell, Ph.D., P.E., as their expert on each of these claims. Wright Medical has filed a Motion to Exclude the opinions of Dr. Jarrell and a Motion for Summary Judgment.

On October 11, 2013, the Court issued its Oral Order granting in part and denying in part Defendant's Motion to Exclude the Opinions of Dr. John D. Jarrell. In issuing the instant Order, the Court relies on the admissible testimony of Dr. Jarrell as explained in the Oral Order.

[22] *Id.* at p. 59.
[23] *Id.*, p. 44.
[24] *Id.* at p. 59

DISCUSSION

I. INTRODUCTION:

- **Plaintiffs' Claims**: Plaintiffs allege strict liability design, manufacture, and failure to warn claims as to both the hip-joint implant and the extraction device. To establish strict liability, Plaintiffs must show "the property when sold by the manufacturer was not merchantable and reasonably suited to the use intended, and its condition when sold is the proximate cause of the injury sustained." O.C.G.A. § 51-1-11(b)(1).
    - **General Law on Strict Liability Claims**: Under Georgia law, "a manufacturer has a duty to exercise reasonable care in manufacturing its products so as to make products that are reasonably safe for intended or foreseeable uses." *Chrysler Corp. v. Batten*, 264 Ga. 723, 724 (1994).

II. DESIGN DEFECT CLAIMS

A. RULING:

- **Summary Judgment DENIED as to BOTH the hip-joint implant and the extraction device claims.** Genuine issues of material fact exist as to both claims.

B. GENERAL TEST: 2 PRONGS

1. Risk-Utility Analysis: To establish a defective design claim, Plaintiffs must first prove the risks inherent in the design outweigh the utility or benefit derived from the product. *Dean v. Toyota Indus. Equip. Mfg., Inc.*, 246 Ga. App. 255, 259 (2000).

2. Causation: Once it is established the product has a defect, Plaintiffs must establish causation – both general and specific. *Guinn v. AstraZeneca Pharms. LP*, 602 F.3d 1245, 1249 n.1 (11th Cir. 2010).

3. The Court analyzes both the hip-joint implant and the extraction device under each prong.

C. RISK UTILITY ANALYSIS:

1. LAW ON RISK-UTILITY

a. Expert Testimony Required for Risk-Utility Analysis: Plaintiffs "have the burden to demonstrate a genuine issue of material fact that the product is defectively designed; to do this, they must produce evidence from an expert who is qualified to conduct the risk-utility analysis and to opine that the risks inherent in [the product's] design outweigh the utility or benefit derived from the product." *In re Mentor Crop. ObTape Transobturator Sling Products Liab. Litig.*, 711 F. Supp. 2d 1348, 1365 (M.D. Ga. 2010); *see also Dean*, 246 Ga. App. at 259.

b. Important Factor—Reasonable Alternative Design: There are many relevant factors to consider. Most important factor: "whether the design chosen was a reasonable one from among the feasible choices of which the manufacturer was aware or should have been aware" – this factor is "heart" of design defect cases. *Banks v. ICI Ams., Inc.*, 264 Ga. 732, 736 (1994).

1) Factors re: Reasonable Alternative Design: "Alternative safe design factors include: the feasibility of an alternative design; the availability of an effective substitute for the product which meets the same need but is safer; the financial cost of the improved design; and the adverse effects from the alterative." *Banks v. ICI Americas, Inc.*, 264 Ga. 723, 726 n. 6 (1994).

c. Risk-Utility Generally a Jury Question: In general, weighing the risk-utility factors is left to the jury. *See Dean*, 246 Ga. App. at 259. Indeed, judgment as a matter of law "will rarely be granted in design defect cases where any of [the] elements is disputed." *Ogletree v. Navistar Int'l Transp. Corp.*, 271 Ga. 644, 646 (1999). To prevail at summary judgment, a defendant must "show plainly and indisputably an absence of any evidence that a product as designed is defective." *Id.*

2. Risk-Utility Analysis for HIP PROSTHESIS Design Defect Claim:

a. Plaintiffs' Claim: Plaintiffs claim the hip-joint implant was not designed to withstand the forces placed on it by a 296 pound man engaging in normal activity.

b. Dr. Jarrell's Opinions Create Issues of Fact: Opinions of Dr. Jarrell create genuine issues of material fact as to whether the risks of the implant outweigh the benefits.

c. Wright Medical's Argument Goes to Weight of Evidence: The Court is not persuaded by Wright Medical's argument that even with the admission of Dr. Jarrell's opinions, Wright Medical is still entitled to summary judgment because the benefits outweigh the risks as a matter of law. Wright Medical's analysis of each of the factors is "merely illustrative." *Mims v. Wright Medical Technology*, Case No. 1:11-CV-213-TWT, 2012 WL 1681810 at *3 (N.D. Ga. May 11, 2012). The law is clear that when there is a jury question to even just one of the factors, weighing the risks and benefits should be left to the jury.

3. Risk-Benefit Analysis for EXTRACTION DEVICE Design Defect Claim:

a. Plaintiffs' Claim: Plaintiffs claim the design and materials selection of the extraction tool's center bolt (which broke during Plaintiff's revision surgery) was inadequate for the intended purpose – to remove the broken neck fragment.

b. Dr. Jarrell's Opinions Create Issues of Fact: As with the hip implant, Dr. Jarrell's opinions regarding the defects in the extraction tool create genuine issues of material fact as to whether the risks of the extraction tool outweigh the benefits.

c. Wright Medical's Arguments Go to Weight of Evidence: The Court is unpersuaded by Wright Medical's argument that the

claim should be dismissed because conducting the risk/benefit analysis shows the benefits outweigh the risks as a matter of law.

1) Dr. Jarrell on Utility of Threads Used. Wright Medical contends Dr. Jarrell does not give an opinion as to any utility to using the UNF (fine) threads that the design drawing specified or the UNC (course) threads that were actually used in the device. However, Dr. Jarrell in fact says there is no benefit to using those threads. The jury can evaluate his testimony.

2) Dr. Smith's Testimony He Would Have Used Device: Wright Medical also points to Dr. Smith's testimony in which he states would have used the extraction device whether it was a prototype or not. Again, this is evidence to be weighed by the jury.

3) ETO Surgery May Still be required: Finally, Wright Medical also points out that even where the device is successful in extracting broken remnant, it is uncontested that the more complex ETO surgery may still be required because of ingrowth of implant in the femur. Again, this must be weighed by the jury.

D. CAUSATION FOR DESIGN DEFECT CLAIMS:

1. Causation Law:

a. Expert Testimony Required to Prove Causation on Design Defect Claims: Proof of causation generally requires reliable expert testimony which is "based, at the least, on the determination that there was a reasonable probability that the negligence caused the injury." *Rodrigues v. Ga.-Pac. Corp.*, 290 Ga. App. 442, 444 (2008).

b. Causation Generally a Jury Question: "As a general rule, issues of causation are for the jury to resolve and should not be determined by a trial court as a matter of law except in plain and undisputed cases." *Ogletree*, 245 Ga. App. at 3.

2. Causation Analysis as to HIP PROSTHESIS Design Defect Claim:

a. Dr. Jarrell's Opinions Create Issues of Fact: Dr. Jarrell opines that that the defective design of the hip implant caused Plaintiff's injury. These opinions create a genuine issue of material fact on causation for the jury.

b. Wright Medical Has No Other Argument Regarding Causation other than Exclusion of Dr. Jarrell's Opinions: Wright Medical does not have alternate argument (other than the argument that Dr. Jarrell's opinions should be excluded) regarding causation.

3. Causation Analysis as to EXTRACTION DEVICE Design Defect Claim:

a. Dr. Jarrell's Opinions Create Issue of Fact: Dr. Jarrell opines that the defects he identifies in the extraction device "reduce[] the factor of safety for this application, leading to a high potential for

failure." (Expert report p. 6). Moreover, in his supplemental affidavit, he states, "Had the superior [] UNJ-type threads been both specified and manufactured for this device, the center extraction bolt would have been significantly more resistant to the breakage which resulted in further injuries to the patient." (Affidavit, p. 29, ¶ 11).

b. Dr. Smith's Testimony Creates Issues of Fact: Moreover, Dr. Smith testifies that as result of extraction device breaking, he had to perform trochanteric osteotomy (Smith Depo. p. 45); the surgical procedure was significantly longer than it would have been had the extraction device worked properly or if there had been no attempt to use the device (*Id. at* p. 46); and longer surgery time increased Pl's risk of serious complications from which he later suffered (*Id.* at pp. 49-50), including blood clots and a pulmonary embolism (*Id.* at pp. 46-50). Plaintiff continues to suffer.

III. MANUFACTURING DEFECT CLAIMS

A. RULING:

1. **Summary Judgment GRANTED as to the hip-joint implant.** It appears Plaintiffs have abandoned this claims. Even if they have not, no evidence exists in the record supporting such a claim. The Court will not discuss this claim any further.

2. **Summary Judgment DENIED as to the extraction device.** Jury question as to whether the extraction device when sold caused Plaintiff's injuries.

B. EXTRACTION DEVICE HAS A MANUFACTURING DEFECT:

1. Law: "[I]t is assumed that the design of the product is safe and had the product been manufactured in accordance with the design it would have been safe for consumer use." *Banks*, 264 Ga. at 733.

a. Always a Manufacturing Defect when Product Not Made in Accordance with Specifications: "[B]y definition, a manufacturing defect will always be identifiable as a . . . departure from the manufacturer's specifications established for the creation of the product." *Jones*, 231 F. Supp. 2d at 1236.

2. Dr. Jarrell Finds Threads Used NOT Threads Specified: Because the device used in Plaintiff's surgery was destroyed, Dr. Jarrell examined an exemplar. Upon examination, Dr. Jarrell found that the design drawing specified UNC (course) threads, but the actual threads used were UNF (fine) threads.

3. Wright Medical's Argument is Without Merit: There is no merit to Wright Medical's argument that Plaintiffs cannot maintain their claim because Dr. Jarrell only examined an exemplar.

a. Where Product is Destroyed Can Rely on Exemplar: A party may rely on circumstantial evidence to establish a manufacturing defect where the product has been destroyed. *See Firestone Tire v. King*, 145 Ga. App. 840, 842 (1978).

b. To Accept Wright Medical's Argument Would be Untenable: To accept Wright Medical's argument that not having the original device prevents Plaintiffs "from establishing a prima facie case would be to insulate manufacturers from liability for defective products in any case where the defect causes its own destruction. Such a result would be totally untenable." *Id.*

C. CAUSATION

1. Jury Question: For the same reasons discussed above in the causation section on Plaintiffs' extraction device defective design claim, there exists a jury question as to whether the extraction device, when sold, caused Plaintiff's injuries. The Court adopts the same analysis as the design defect causation prong.

IV. FAILURE TO WARN CLAIMS

A. RULING

1. **Summary Judgment DENIED as to Hip Implant**

2. **Summary Judgment GRANTED as to Extraction Device**

B. LAW:

1. Duty, Breach, Causation: Plaintiffs must show (1) Wright Medical had a duty to warn, (2) it breached that duty, and (3) breach was the proximate cause of Plaintiffs' injuries. It appears unquestioned that Wright Medical had a duty to warn. Thus, the issues as to both the hip implant and the extraction device are breach and causation.
2. Learned Intermediary Doctrine Applies: Both parties agree Georgia's learned intermediary doctrine applies to this case. Under the learned intermediary doctrine, a medical device manufacturer "does not have a duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and the manufacturer." *See Dietz v. Smithkline Beecham Corp*., 598 F.3d 812, 815 (11th Cir. 2010) (applying Georgia law).
    a. First Step of Inquiry: Whether the manufacturer provided the learned intermediary with an **adequate warning**.
    b. Second Step: If the warning was inadequate, Plaintiff must show that the deficient warning **proximately caused** the alleged injury.
        1) Knowledge and Same Course of Action Breaks Causation: If the learned intermediary "has actual knowledge of the substance of the alleged warning and would have taken the same course of action even with

the information the plaintiff contends should have been provided," then the plaintiff cannot establish causation. *See Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1283, n. 8 (11th Cir. 2002).

C. Hip Implant Failure to Warn Claim

1. **Jury Question as to Adequacy of Warning**: There is a jury question as to whether Wright Medical breached its duty to adequately warn Plaintiff's doctor of increased risk of failure in the implant in patients of Plaintiff's weight:

    a. Dr. Jarrell's Opinion is Admissible: Wright Medical's argument that Plaintiffs' failure to warn claim fails for lack of admissible expert testimony is moot – Dr. Jarrell's opinion on the inadequacy of the warning on the hip implant is admissible.

    b. Other Evidence Creates Genuine Issues of Material Fact:

        1) IFU only Contraindicated 3X Normal Body Weight: Wright Medical's warning only contraindicated use of device for obese patients as "three times normal body weight."

            i. Plaintiff's Weight Not Contraindicated: As Dr. Smith opines, Plaintiff's height at the time of surgery in September 2009 was 6' ½". The "normal body weight" for a 6 foot tall male is 145-

185 lbs. Thus, the contraindication in the IFU only applied to patients of Plaintiff's height if they weighed at least 435 lbs. (Smith Aff. ¶ 6).

2) IFU's Only Other Mention of Weight Very General: Under "GENERAL PRODUCT INFORMATION" it states: "In selecting patients for total joint replacement, the following factors can be critical to the eventual success of the procedure. 1. Patient's weight. An overweight or obese patient can produce high loads on the prosthesis, which can lead to failure of the prosthesis. This becomes a major consideration when the patient is small boned and a small sized prosthesis must be used." (2009 IFU).

3) Weight Not Listed in IFU as a Condition Presenting Increased Risk of Failure: The IFU also includes a section under "CONTRAINDICATIONS" that lists five conditions "presenting increased risk of failure." None of those five conditions mentions the patient's weight.

4) Dr. Smith's Opinion that the Warning is Inadequate: Additionally, Dr. Shane Smith, Plaintiff's orthopedic surgeon, opines that the warnings issued by Wright Medical with the implant were "insufficient to

reasonably convey a significant increased risk of femoral neck fractures in its hip implant when such implant was being used in an active male weighing 296 pounds." (Smith Aff., ¶ 10). *See Bryant v. Hoffmann-La Roche, Inc.*, 262 Ga. App. 401, 410 (2003) (testimony of board certified cardiologist that drug package insert was inadequate to fully warn physicians of potential dangers of prescribing drug was evidence requiring reversal of summary judgment to manufacturer).

5) Wright Medical's Knowledge of Increased Risk of Failure: Evidence also reveals Wright Medical knew the hip-joint implant for people of Plaintiff's weight had increased rate of failure prior to Plaintiff's surgery:

    i. CAPA initiated in August 2008: By August 15, 2008, a year before Plaintiff's surgery, Wright Medical initiated a Corrective Action/Preventative Action process, "CAPA" #172, related to its titanium PROFEMUR® modular necks (like the one ultimately used in Pl's surgery) due to number of modular neck complaints that had been made. (McDaniel Depo., p. 72).

ii. Number of Fractured Necks: Wright Medical's records reveal over 65 titanium modular necks were reported to have fractured between April 2005 and Sept 21, 2009 (date of surgery).

iii. Testing on Cobalt Chromium: In connection with CAPA #172, testing completed by Oct. 22, 2008, showed that cobalt chromium (CoCr) necks displayed higher strength than titanium alloy necks.

iv. McDaniel's Testimony: Mr. Christopher McDaniel, senior director of ortho recon product development at Wright Medical, stated that Wright Medical continued to provide titanium necks while it investigated CoCr because Wright Medical believed its fracture rates were low and "the ones that had been fractured and coming back in were typically found in overweight males with, you know, long necks with a high offset, which was somewhat contradictory to what the package insert." (McDaniel Depo., p. 75).

v. Health Canada's Request for Information: August 9, 2009, Wright Medical received Request for

Information from medical device division of Health Canada which raised concern that the PROFEMUR® hip system may not meet the safety and effectiveness requirements of Canada's regulations. The letter expressed concerns with the failure rate of the modular femoral necks.

vi. Wright Medical's Testing: Wright Medical's basic fatigue testing showed normal activities for a person with a body weight of 230 lbs or greater resulted in load demands on the titanium modular necks that exceeded the peak fatigue strength for the product. Dr. Jarrell states this scientific testing was readily available well before implantation of Plaintiff's hip-joint implant.

c. Law Favors Issue of Adequacy of Warning be Determined by Jury: "Whether adequate efforts were made to communicate a warning to the ultimate user and whether the warning is communicated was adequate are uniformly held questions for the jury." *Watson v. Uniden Corp. of America*, 775 F.2d 1514, 1516 (11th Cir. 1985).

2. **Jury Question as to Causation**: If the jury finds the warning inadequate, there is clearly a jury question as to whether the inadequate warning caused Plaintiff's injuries.

   a. Dr. Smith's Testimony in Affidavit Creates Issues of Fact: Dr. Smith testifies he reasonably relied upon the contraindication in the 2009 IFU (Smith Aff. ¶ 10), and says if he would have been warned of increased failure in heavyweight patients, he would not have used the implant. (*Id.* at ¶ 11).

   b. Wright Medical's Sham Affidavit Argument Unpersuasive: The Court is not persuaded by Wright Medical's argument that this is a sham affidavit contradicted by Dr. Smith's prior deposition testimony.

      1) Sham Affidavit Law: "A district court may find an affidavit which contradicts testimony on deposition a sham when the party merely contradicts its prior testimony without giving any valid explanation." *Van T. Junkins and Assoc. v. U.S. Indus.*, 736 F.2d 656 (11th Cir. 1984). However, an affidavit may only be disregarded as a sham "when a party has given clear answers to unambiguous questions which negate the existence of any genuine issue of material fact." *Id.* at 657. Clearly this is not such a case.

2) Dr. Smith's Affidavit Testimony: In his affidavit, Dr. Smith testifies that he "would not have used the same Hip-Joint Implant in Mr. Courson's case in September 2009, had packet insert numbered 136288-0001 contained a warning stating the following: "Higher than normal rates of early failure of the long offset PROFEMUR® Titanium Modular Necks have been observed for heavyweight (>230 lbs) patients. This should be considered in patient selection when using these implants. Other patient selection factors such as activity level cannot be dismissed as potential factors in these failures. Alternative devices, such as cobalt chrome modular necks and monoblock hip stems, may also be considered for these patients." (Smith Aff.)

3) Nothing Contradictory in Dr. Smith's Deposition: Defendant does NOT point to prior deposition testimony that has allegedly been altered by the testimony in the affidavit. Moreover, the Court could find no contradictory testimony.

D. FAILURE TO WARN CLAIM FOR EXTRACTION TOOL

1. The Court can assume the warning was not adequate:

    a. No evidence of any warning: There is no evidence Dr. Smith was provided any warning as to the extraction tool. Moreover, Dr. Smith denies he was told the extraction device was a prototype.

    b. Dr. Jarrell's Opinion: Dr. Jarrell opines that the physician was entitled to be warned the device was experimental in nature.

2. **Plaintiffs, However, FAIL to Establish Causation:** Even though the warning was inadequate, Plaintiffs FAIL to establish causation:

    a. Law: If the learned intermediary "has actual knowledge of the substance of the alleged warning and would have taken the same course of action even with the information the plaintiff contends should have been provided," then the plaintiff cannot establish causation. *See Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1283, n. 8 (11th Cir. 2002).

    b. Dr. Smith's Testimony: Dr. Smith states that even if he was warned that the extraction device was a prototype, he would have proceeded with the same course of action. (Had he been told it was a prototype, would "no, probably not" have done anything differently. Smith Depo., p. 59.)

CONCLUSION

Defendant's Motion for Summary [Doc. 23] is **GRANTED** as to Plaintiff's manufacturing defect claim on the hip implant and failure to warn claim on the extraction device; the Motion is **DENIED** as to Plaintiff's design defect claims on both the hip implant and the extraction device; the manufacturing defect claim on the extraction device; and the failure to warn claim on the hip implant.

SO ORDERED, this 11th day of October, 2013.

S/ C. Ashley Royal
C. ASHLEY ROYAL
UNITED STATES DISTRICT JUDGE