UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

RICARDO DIAZ-GRANADOS and MARIA DIAZ-GRANADOS,

Plaintiffs,

v. **Case No: 6:14-cv-1953-Orl-28TBS**

WRIGHT MEDICAL TECHNOLOGY, INC.,

Defendant.

ORDER

In this products liability case, Plaintiff Ricardo Diaz-Granados brings three claims arising from a failed prosthetic hip joint that was designed and manufactured by Defendant Wright Medical Technology, Inc. (Am. Compl., Doc. 29).[1] A trial is set to begin on April 1, 2016. Defendant filed two Daubert[2] motions to exclude opinion testimony of Plaintiff's experts, Dr. Reed Ayers and Ms. Mari Truman. (Docs. 59 & 60). Defendant also filed a Motion for Summary Judgment that, in part, depends on the outcome of the Daubert motions. (Doc. 61). I held a hearing to address Defendant's motions on March 10, 2016. (Mins., Doc. 98). After considering Defendant's motions, Plaintiff's responses (Docs. 69, 70 & 71), Defendant's reply (Doc. 72), and oral argument, I denied Defendant's motions. This Order explains those rulings.

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[1] Mr. Diaz-Granados's wife, Maria, also brought a claim for loss of consortium (Count IV) that is derivative of the claims alleged by her husband, (Counts I, II & III). As discussed below, Maria dropped her sole claim and is due to be dismissed from the case. Therefore, I will refer only to Ricardo Diaz-Granados as Plaintiff, unless noted otherwise.

[2] Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993).

I. Background

Defendant is in the business of designing and manufacturing prosthetic implant devices, including the Profemur® Total Hip System implanted in Plaintiff.[3] On September 27, 2004, Plaintiff underwent a right side total hip arthroplasty, during which he was implanted with Defendant's hip system by George D. Markovich, M.D. When Plaintiff was implanted with the device, he weighed 190 pounds and worked as an air conditioning mechanic. (Pl. Dep., Doc. 71-7, at 63–64).[4] Seven years later, when Plaintiff was exiting his vehicle in December 2011, the Profemur® Neck implanted in his hip broke in half at the junction where it joined the femoral stem. (Id. at 21). Plaintiff underwent emergency surgery to remove and replace the femoral stem along with the neck and ball components. (Id. at 26–27). After the emergency replacement procedure—which required cutting Plaintiff's femur open and tying it back together—Plaintiff developed heterotopic ossification on his hip joint—i.e., improper bone growth in soft tissue. (Ryan Dep., Doc. 95-13, at 23–26 & 68).

Plaintiff alleges that the device's failure was due to a defect in its design. Specifically, he alleges that (1) the neck component of the device is comprised of an inferior titanium material known as "Ti6A14V" that was improperly coupled with a cobalt-chromium alloy utilized in other Profemur® component parts, and (2) there was a faulty metal-on-metal arrangement of the components—the femoral head is in direct contact with the metal acetabular cup. (Am. Compl. at 6). As a result of these defects, among others, the device

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[3] Defendant manufactures several brands of hip replacement components. The names of the components implanted in Plaintiff are: Profemur® Plasma Z Femoral Stem; Profemur® Long Neck; Conserve® Total Femoral Head; and Conserve® Plus Cup. (Am. Compl. at 21–22).

[4] The page numbers of the depositions refer to the individual pages of the deposition transcript rather than the pages of the document in the docket.

was allegedly susceptible to micromotion and fretting—a process in which two surfaces move in contact with each other at very small displacements that over time remove a layer on the titanium. (Id. at 6, 22–23; Ayers Report, Doc. 59-1, at 2–3). This process allegedly causes fatigue and stress-crack corrosion from the torque and forces placed on the device. (Am. Compl. at 14, 22–23; Ayers Report, at 3). Plaintiff ultimately contends that fretting of the implanted modular neck led to stress-crack corrosion and eventually caused the device to catastrophically break in half. (Am. Compl. at 6). Plaintiff alleges that Defendant was aware in 2004 of the availability of a superior design made of cobalt-chromium alloy but did not employ that design until 2009. (Id. at 13–14).

Plaintiff also claims that Defendant failed to adequately warn orthopedic surgeons—including Plaintiff's surgeon, Dr. Markovich—of the significant risks involved when the device is used in overweight and active patients and indeed marketed the device for use in patients with active lifestyles. (Id. at 14–15, 42–46). Plaintiff further alleges that Defendant failed to disclose to surgeons reported fractures of the device prior to Plaintiff's initial implant. (Am. Compl. 42–47). Four years after Plaintiff's initial implant, in 2008, Defendant sent out a "Safety Alert" to healthcare professionals stating in relevant part, "[f]rom more than 130,000 units sold worldwide since 2002, we have received reports of 35 modular neck failures as of November 21, 2008. Initial investigations have revealed some commonalities in these failures: heavy-weight males, long modular necks, and patient activities such as heavy lifting and impact sports." (Safety Alert, Ex. G to Mot. Summ. J., Doc. 61-7, at 1).

Based on the device's failure, Plaintiff allege three claims against Defendant: (i) strict products liability for defective design (Count I); strict products liability for failure to

warn (Count II); and negligence[5] (Count III). Additionally, his wife, Maria Diaz-Granados brings a claim of loss of consortium (Count IV). (Am. Compl.). During a hearing on the instant motions, Plaintiff states that he is no longer pursuing claims of manufacturing or metal-on-metal defects, nor is he pursuing damages for lost wages, income, or capacity to work. Additionally, Maria Diaz-Granados is no longer pursuing her sole claim of loss of consortium.

II. Daubert Motions

A. Standard

Federal Rule of Evidence 702 governs expert testimony and provides that if a witness is qualified as an expert, the witness can provide opinion testimony if: "(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702. The proponent of the opinion testimony has the burden of establishing each precondition to admissibility by a preponderance of the evidence. Rink v. Cheminova Inc., 400 F.3d 1286, 1292 (11th Cir. 2005). Scientific expert testimony must be both relevant and reliable. Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 589 (1993). The requirement of Rule 702(a) that the evidence "will help the trier of fact to understand the evidence or to determine a fact in issue" "goes primarily to relevance." Id. at 591.

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[5] The negligence claim is based on Defendant's alleged failure to exercise reasonable care in the "design, formulation, manufacture, testing, quality assurance, quality control, labeling, marketing, warning, sale and/or distribution" of the device; to "assure that its products did not pose a significantly increased risk of bodily harm and adverse events;" and "to comply with federal requirements." (Am. Compl. at 47–48).

Trial courts function as gatekeepers with regard to the admission of expert evidence. United States v. Frazier, 387 F.3d 1244, 1260 (11th Cir. 2004). "District courts are charged with this gatekeeping function 'to ensure that speculative, unreliable expert testimony does not reach the jury' under the mantle of reliability that accompanies the appellation 'expert testimony.'" Rink, 400 F.3d at 1291 (quoting McCorvey v. Baxter Healthcare Corp., 298 F.3d 1253, 1256 (11th Cir. 2002)). In carrying out this charge, trial courts are given substantial discretion. Id.

B. Reed Ayers

Defendant seeks to exclude the testimony of Plaintiff's expert, Dr. Reed Ayers Ph.D., taking issue with seven conclusions in his report.[6] Dr. Ayers is a multi-discipline engineer specializing in the synthesis and design of orthopedic materials as well as their failure in clinical application.[7] (Ayers Report at 1). As a preliminary matter, because Plaintiff is no longer pursing claims of manufacturing and metal-on-metal defects of the device, Dr. Ayers's opinions pertaining to those claims in Conclusions 1, 2, 3, and 5 are excluded by agreement of the parties. Additionally, Defendant stated at the hearing that its own expert agrees with Dr. Ayers as to the mode of failure stated in Conclusion 7. Therefore, the only contested opinion testimony of Dr. Ayers is in Conclusions 4 and 6. Because the challenged opinion testimony of Dr. Ayers is relevant and based upon reliable principles and methods, it is admissible at trial.

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[6] Dr. Ayers's Conclusions 1 through 6 are listed on page four of his report. Defendant also refers to "Conclusion 7," which appears on page two of the report under the heading "Opinion 1." For the sake of consistency with Defendant's motion, I will refer to "Opinion 1" as "Conclusion 7" in this Order.

[7] Defendant does not challenge Dr. Ayers's qualifications.

Conclusions 4 and 6 address Plaintiff's claim of a design defect and state that: (1) fretting induced corrosion is common in modular implants and should have been considered during the design of the implant, and (2) "[g]iven the susceptibility of Ti6Al4V to fretting corrosion, fatigue corrosion, and stress crack corrosion, it is a poor candidate for the chosen design of the modular neck of the Profemur[®] hip system." (Id. at 3–4). Defendant argues that these conclusions lack foundation and are devoid of analytical support. Defendant also argues that Dr. Ayers failed to consider the scientific literature and state of the art that existed at the time the device was manufactured and instead retrospectively applied current scientific knowledge to a device manufactured in 2004.[8]

Dr. Ayers's challenged conclusions have sufficient foundation. Dr. Ayers bases his conclusions, in part, on studies dating from the 1970s and 1980s that provide direct support that titanium alloy has long been investigated for its propensity to fret in corrosive environments. (Id. at 3–5). Additionally, relying on several pre-2004 studies, Dr. Ayers explains that the fretting propensity of titanium in biological environments can lead to corrosion, eventual stress cracking, and catastrophic failure.[9] (Id. at 3). That Dr. Ayers

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[8] Defendant also argues that Dr. Ayers impermissibly fails to identify a safer alternative design that was available in 2004. However, during the hearing, Defendant conceded that the availability of an alternative design is not a reason to exclude testimony under Daubert. Florida does not require a plaintiff to prove the availability of an alternative design in design defect cases. Aubin v. Union Carbide Corp., 177 So. 3d 489, 510 (Fla. 2015) ("[I]n approaching design defect claims, we adhere to the consumer expectations test, as set forth in the Second Restatement, and reject the categorical adoption of the Third Restatement and its reasonable alternative design requirement.").

[9] See Ayers Report at 6–7 (citing a study by Waterhouse and Dutta discussing "[t]he fretting fatigue of titanium and some titanium alloys in a corrosive environment"); id. (citing a study by Parkins and Greenwell discussing "[t]he interface between corrosion fatigue and stress-corrosion cracking"); id. (citing a study by Jones discussing "[a] unified mechanism of stress corrosion and corrosion fatigue cracking"); id. (citing a study by Morita et al. discussing "[t]he corrosion fatigue properties of surgical implants in a living body").

cited some studies from after 2004 does not render his opinion inadmissible; rather, Defendant may challenge Dr. Ayers's reliance on those studies on cross-examination. Primrose Operating Co. v. Nat'l Am. Ins. Co., 382 F.3d 546, 562 (5th Cir. 2004) ("[A]s a general rule, questions relating to the bases and sources of an expert's opinion affect the *weight* to be assigned that opinion rather than its *admissibility* and should be left for the jury's consideration.") (emphasis in original) (internal quotations and citations omitted). Based upon Dr. Ayers's significant experience in the field of metallurgy, I find that he is qualified to draw upon the cited literature and make conclusions as to whether the use of titanium alloy was the scientific state of the art in 2004 and whether fretting induced corrosion was a design issue in modular implants that should have been considered by Defendant. (Ayers Report at 2; Addendum to Ayers Report, Doc. 70-2, at 33). Because I find Dr. Ayers's opinions relevant and reliable, his testimony is admissible as to Conclusions 4, 6, and 7.

C. Mari Truman

Defendant also seeks to exclude the opinion testimony of Mari Truman, objecting to six categories of opinions provided in her report. Ms. Truman is a professional engineer with significant experience in orthopedic medical device design, manufacturing, testing, and warnings. Because I find Ms. Truman's opinions relevant and her methods reliable, her opinion testimony is admissible.

1. Opinions regarding ASTM testing

Defendant argues that Ms. Truman's opinion regarding its testing of the devices is contradicted by her testimony in another case and therefore inadmissible. In a previous deposition in another case, Ms. Truman answered affirmatively when she was asked whether the device complied with ASTM and ISO tests required by the FDA, (Ex. B to Mot.

Exclude Truman, Doc. 60-3), but in her instant report she states that "[t]he ASTM and ISO endurance tests . . . applied by [Defendant] during the development of the Profemur system are inadequate for active and heavier patients." (Truman Report, Doc. 60-1, at 36). These statements are not contradictory, as the latter focuses on the adequacy of the testing in active and heavy patients. Moreover, Ms. Truman states that "[Defendant] was not compliant with the *spirit* of ISO [testing] . . . as evidenced by the deficiencies in risk assessment and performance testing." (Id. at 98 (emphasis added)). This statement is also not contradictory—Ms. Truman is qualified to opine as to whether the device complied with the goals of ISO testing. Ms. Truman may testify as to these opinions.

2. ***Opinions regarding effects of metal-on-metal articulation on corrosion, fretting, and fatigue of modular implants***

Defendant next argues that Ms. Truman relies on unsupportive literature in formulating two of her opinions. The first opinion is that some combinations of metal-on-metal articulations and cobalt-chromium stem designs have exhibited unusual corrosion and that the modular neck combination with the Plasma Z Stem is unreasonably dangerous. Defendant specifically takes issue with the Donell et al. paper cited by Ms. Truman because the "failures" she cites in that paper include "patient pain, bone fractures, and dislocation" but that paper does not discuss actual implant failure. That Ms. Truman's cited literature does not specifically mention implant failure does not make her opinion inadmissible. Given Ms. Truman's qualifications in this area, she may make reasonable extrapolations from her cited literature. Her testimony will not be excluded on this ground.

Defendant next objects to Plaintiff's opinion that combining a titanium stem and a cobalt-chromium alloy bearing has been shown to lead to corrosion and has led to implant fracture. Defendant states that only one journal article cited by Ms. Truman observed

increased corrosion at dissimilar metal couples and that the same article concluded that dissimilar alloy couples should not be avoided. Because there is some support in the literature for Ms. Truman's opinion, her testimony will not be excluded on this ground.

3. *Opinions regarding ability of surface treatments to prevent premature failure of implant*

Defendant argues that Ms. Truman's opinion with regard to surface treatments is unreliable because she cites reported device failures without knowing whether those devices had surface treatments and because she has not done her own testing. In formulating her opinion, Ms. Truman relied on other manufacturers who utilized surface treatments and showed that such treatments provided significant increases in overall strength of their devices.[10] (Id. at 61–66). Defendant does not dispute the potential for surface treatments to strengthen prosthetic implants. Indeed, it acknowledges that "[o]bviously, corrosion resistance is a critical factor in implant performance and is likely affected by surface processing." (Mot. Exclude Truman, Doc. 60, at 12). Because Ms. Truman is highly qualified in the field of biomechanics and orthopedics, I find that she may opine as to the benefits of surface treatments by pointing to the effects of surface treatments in similar devices. Additionally, given Ms. Truman's familiarly with the process, I disagree that Ms. Truman must have conducted her own testing in order to opine on the strength properties of surface treatments. Thus, her opinion as to surface treatments is sufficiently reliable.

[10] I reject Defendant's argument that Ms. Truman cannot rely on outcomes from other manufacturers who applied surface treatments to their various devices. Defendant may cross-examine Ms. Truman on the particular manufactures upon which she relies.

4. *Opinions regarding acceptable rates of failure*

Defendant argues that Ms. Truman's testimony as to what is an "acceptable" failure rate in the industry is "based on nothing but [her] own assertions" and notes that the medical device industry does not, itself, set a threshold for what is an "acceptable" rate of failure. (Id. at 13). I find that Ms. Truman's opinions as to the rates of failure are reliable. That the device industry does not set its own acceptable rates of failure has no effect on whether Ms. Truman may draw upon her undisputed experience in designing and developing joint implants and analyzing performance characteristics of implants to make her own opinion as to whether Defendant's rate of failure is acceptable. I find that Ms. Truman's methodology, including comparing the rate of failure in similar prosthetic devices, is reliable.

5. *Opinions regarding sufficiency of warnings*

While Defendant does not challenge Ms. Truman's qualifications as an expert in biomechanical engineering and orthopedics, it does challenge her qualifications to opine on the adequacy of a warning to a physician. Florida follows the learned intermediary doctrine in products liability cases involving medical devices, Beale v. Biomet, Inc., 492 F. Supp. 2d 1360, 1368 (S.D. Fla. 2007), which requires Plaintiff to establish that Defendant's warning to his implanting physician was inadequate and did not sufficiently inform him about the risks involved in the device. See Ocasio v. C.R. Bard, Inc., No. 8:13-cv-1962-T-36AEP, 2015 WL 3496062, at *4 (M.D. Fla., June 3, 2015). Defendant argues that only a physician can opine as to whether the warning was adequate and that because Ms. Truman is not a physician, she is unqualified.

Ms. Truman is qualified to opine on the adequacy of Defendant's warning because she has thirty-five years of experience in biomechanics and orthopedics, which includes experience serving on design and development teams creating and reviewing warnings

accompanying several orthopedic medical devices.[11] (Truman Report at 2–3). Moreover, the design and development teams on which Ms. Truman served included orthopedic surgeons and other experts. (Id.). Unlike the primary case on which Defendant relies, Gebhardt v. Mentor Corp., 191 F.R.D. 180 (D. Ariz. 1999), Ms. Truman will not be opining on the behavior of surgeons—that is, whether Plaintiff's implanting surgeon would have acted differently had the warning been better, or whether an adequately warned surgeon would have implanted the device. Rather, Ms. Truman opines on the quality of the Instructions for Use provided by Defendant to Plaintiff's physician. Because Ms. Truman is highly qualified with regard to drafting and reviewing warnings for orthopedic devices, her testimony will not be excluded on this ground.[12]

*6. **Opinions as legal conclusions***

Defendant argues that Ms. Truman impermissibly offers legal conclusions that simply tell the jury what result to reach. Federal Rule of Evidence 704 provides in relevant part that testimony in the form of "[a]n opinion is not objectionable just because it embraces an ultimate issue." Fed. R. Evid. 704(a); see also United States v. Milton, 555 F.2d 1198, 1203 (5th Cir.1977) ("Rule 704 abolishes the per se rule against testimony regarding ultimate issues of fact. By the same token, however, courts must remain vigilant against

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[11] Defendant does not dispute Ms. Truman's qualifications as stated in her report.

[12] I further disagree with Defendant's argument that Ms. Truman's opinion as to the warning's adequacy is unreliable. Defendant cites a case from the District of Massachusetts for the proposition that Ms. Truman cannot rely solely on her experience and that an expert must take steps to determine if the label was actually misleading or incomplete. (Mot. Exclude Truman at 17 (citing Calisi v. Abbott Labs., No. CIV.A. 11-10671-DJC, 2013 WL 5441355, at *3 (D. Mass. Sept. 27, 2013))). Whether or not the Calisi standard applies here, it is clear from Ms. Truman's report that in formulating her opinion she relied on several sources other than her own experience: the testimony of a doctor, the warnings of another manufacturer, evidence of changes in patient demographics, and evidence of device failures. (Truman Report at 80–96).

the admission of legal conclusions, and an expert witness may not substitute for the court in charging the jury regarding the applicable law."). Because Ms. Truman's testimony in this case inherently touches on the ultimate issues that must be reached by the jury, and because each of her opinions is based upon reliable methodology and vast experience, her testimony will not be excluded.

D. Conclusion

Dr. Ayers and Ms. Truman are sufficiently qualified and apply reliable methodology to form opinions that will assist the jury; thus, their testimony is admissible.

III. Motion for Summary Judgment

After stipulation of the parties, the remaining claims on which Defendant is seeking summary judgment are strict products liability for defective design (Count I), strict products liability for failure to warn (Count II), and negligence (Count III). Defendant bases its motion (Doc. 61) on Plaintiff's alleged lack of mandatory expert testimony and insufficient evidence. As to Count I, Defendant's motion must be denied because it was made contingent upon the exclusion of Dr. Ayers's and Ms. Truman's expert testimony. Now that Plaintiff's experts are allowed to testify, Plaintiff may proceed on Count I. Regarding Count II, I find that the motion is due to be denied because there are genuine issues of material fact as to whether Defendant failed to adequately warn of the dangers involved in the device. Likewise, to the extent the motion seeks summary judgment on Count III, it must be denied.

A. Standard

Summary judgment shall be granted "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). The moving party bears the burden of demonstrating that no genuine

issues of material fact remain. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). That burden "may be discharged by 'showing'—that is, pointing out to the district court—that there is an absence of evidence to support the nonmoving party's case." Id. at 325.

In ruling on a motion for summary judgment, a court construes the facts and all reasonable inferences therefrom in the light most favorable to the nonmoving party, and it may not weigh evidence or determine credibility. Reeves v. Sanderson Plumbing Prods., Inc., 530 U.S. 133, 150 (2000). However, summary judgment should be granted "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." Celotex, 477 U.S. at 322.

B. Analysis

Plaintiff bases his failure to warn claim on the allegedly inadequate Instructions for Use ("IFU") that were included as a package insert with Defendant's device. Plaintiff alleges that the IFU failed to adequately inform Dr. Markovich of the risks associated with overweight and highly active patients and further that it did not communicate that its Profemur® modular necks were fracturing and that the risk of fracture was significant.

To succeed on a claim of strict products liability for failure to warn, "a plaintiff must prove that the defendant is a manufacturer or distributor of the product at issue and that the defendant did not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution." Marzullo v. Crosman Corp., 289 F. Supp. 2d 1337, 1347 (M.D. Fla. 2003). Additionally, Florida requires manufacturers to continue to adequately warn of risks that are learned even after the product is sold. High v. Westinghouse Elec. Corp., 610 So. 2d 1259, 1263 (Fla. 1992) (finding that a

manufacturer "had a duty to timely notify the entity to whom it sold the electrical transformers . . . once it was advised of [a] contamination").[13]

The learned intermediary doctrine applies with regard to medical devices and requires the manufacturer to provide adequate warnings to the patient's physician rather than to the patient directly. Ocasio, 2015 WL 3496062, at *4. Dr. Markovich, as the prescribing physician, served as the learned intermediary between Defendant and Plaintiff. See Guarino v. Wyeth, LLC, 719 F.3d 1245, 1250 (11th Cir. 2013). Thus, the issue before the Court is whether Dr. Markovich was aware of the risk of the device's alleged premature failure and whether he would have prescribed the device if the warning had been different. See Small v. Amgen, Inc., No. 2:12-CV-476-FTM-29, 2015 WL 5687668, at *8 (M.D. Fla. Sept. 25, 2015).

Defendant argues that under the learned intermediary doctrine, the undisputed evidence demonstrates that the IFU warnings are adequate as a matter of law—specifically, that the IFU warned of the precise failure that occurred here. Defendant points to the IFU's warnings that "overweight or obese patient[s] can produce high loads on the prosthesis, which can lead to failure of the prosthesis"; that "patient[s] . . . involved in an occupation or activity, which includes substantial walking, running, lifting, or muscle strain . . . can cause failure of the . . . device"; 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"; and that "[w]hile rare, fatigue fracture of the

[13] Defendant argues that "[i]t does not appear that Florida law requires a post-sale duty to warn as it relates to an implantable medical device," (Def.'s Reply, Doc. 72, at 2 n.1), but provides no authority to support its position. In light of Westinghouse, and without any Florida case law to the contrary, a post-sale duty to warn applies in this case.

prosthetic component can occur as a result of trauma, strenuous activity, improper alignment, or duration of service." (IFU, Doc. 101-1, at 1–2, 7–8).

"[A]lthough the adequacy of warnings concerning [a device] is normally a question of fact, it can 'become a question of law where the warning is accurate, clear and unambiguous.'" Zanzuri v. G.D. Searle & Co., 748 F. Supp. 1511, 1516 (S.D. Fla. 1990) (quoting Felix v. Hoffman-LaRoche, Inc., 540 So. 2d 102, 105 (Fla. 1989)). While the IFU warns of overweight and active patients, and indeed warns that the device may fracture, there is still a genuine issue of material fact as to whether such a warning was adequate. Here, Plaintiff presents expert testimony of Ms. Truman, who is well qualified and unequivocally opines that the IFU warnings were inaccurate and ambiguous. See Ocasio, 2015 WL 3496062, at *5 (finding no issue of material fact precluding summary judgment because the plaintiffs "failed to provide any admissible expert testimony that would establish the inadequacy of the IFU").

The IFU provided by Defendant to Dr. Markovich did not describe the increased risks associated with the modular neck design implanted in Plaintiff as compared to the more common non-modular neck designs. (Truman Report at 32–36). Ms. Truman opines that failures of modular neck hip implants are more common than those of their non-modular counterparts. (Truman Report at 71 (stating that "neck failures are not expected and were not frequently reported until recent hip implant design changes such as . . . neck modularity, as in the Profemur implant" and that "non-modular neck fractures are rare")). This difference in risk is significant because the IFU insert provided with the Plasma Z modular device was the exact same IFU included in all models of Defendant's hip devices, including both modular and non-modular neck designs. (Redden Dep., Doc. 101-2, at 37).

Thus, the IFU's warning that "while rare, fatigue fracture of the prosthetic component can occur as a result of trauma, strenuous activity, improper alignment, or duration of service" does not convey the *increased* risk of fracture in the modular hip design as opposed to the non-modular design.

Because the same IFU was included in both modular and non-modular devices, implanting physicians who were more familiar with the low fracture rate of the non-modular device might prescribe the modular device under the faulty assumption that it posed the same risks as the non-modular device. Indeed, there is a factual question as to whether that happened here. Dr. Markovich stated in his deposition that his understanding was that "nonmodular [sic] necks haven't broken in a long time" and further described fractures in non-modular necks as "extremely uncommon." (Markovich Dep., Doc. 95-1, at 41). Dr. Markovich also stated that he did not tell Plaintiff of the risk that the modular neck could break in half because he was not aware that it was a significant risk. (Id. at 78). Rather, Dr. Markovich discussed the risks of the modular device "in a general form in terms of ['] the prosthesis may fail.[']" (Id. at 78). Dr. Markovich believed in 2004 that modular hip implants had clinical advantages over non-modular necks, but he no longer believes that the advantages outweigh the risks. (Id. at 9–10, 41, 54). Because Dr. Markovich was under the impression that non-modular neck fractures were extremely uncommon and because the IFU did not warn of an increased risk of fracture with the modular neck device, a factual question exists regarding whether Dr. Markovich would have prescribed the device to Plaintiff if he was warned of an increased propensity for modular necks to break.

Ms. Truman also opines that the IFU's generic statements that overweight or obese patients can lead to implant failure are vague. (Truman Report at 83–84). The IFU states

that increased loads on the implant from overweight or obese patients can cause failure, but it does not define what patients would be considered "overweight" and only contraindicates obese patients when they are "three times normal body weight." (IFU at 2). Plaintiff weighed 190 pounds and was 5' 11" tall at the time of the implantation and was not warned that the device could fail under his weight. (Id. at 83–84). Ms. Truman further states that certain fatigue testing was available prior to implantation in Plaintiff that would have "revealed that neck fracture may occur even in average weight North American males like [Plaintiff]" but such testing was not done. (Id. at 25). Thus, risks regarding weight capacity that could have been learned at the time of implantation were not communicated to implanting physicians. A reasonable jury could find that the IFU was incomplete for failing to state that certain testing was not done or that the IFU was unclear for failing to give more particular weight restrictions.

Moreover, there is a genuine dispute of material fact as to whether the Profemur® Plasma Z device was cleared by the FDA for sale at the time it was implanted in Plaintiff. Defendant argues that it was permitted to sell the Plasma Z device pursuant to its FDA clearance for a similar device under a prior 510(k) filing in 2000 and a subsequent "Letter-to-File" in 2003. (Mot. Summ. J., Doc. 61, at 3; Def.'s Suppl. Br., Doc. 199, at 12). Plaintiff argues that the "Letter-to-File" procedure was improper to obtain clearance for sale of the Plasma Z device and that therefore Defendant did not have FDA clearance of its device until after the manufacture and sale of the device to Plaintiff. (Pl.'s Resp. in Opp'n, Doc. 71, at 2; Pl.'s Suppl. Br., Doc. 118, at 7–9). On this record, I cannot determine whether Defendant's Plasma Z device was properly cleared for sale. If, however, a jury finds that

the device was not cleared for sale, it could also reasonably find that Defendant should have warned Dr. Markovich of that fact.[14]

Defendant relies on its favorable ruling in Peterson v. Wright Med. Tech., No. 1:11-cv-1330, Dkt. No. 66 (C.D. Ill. Feb. 13, 2014), but that case is distinguishable from the instant case. The Peterson court significantly relied on the fact that prior to Mr. Peterson's implant surgery there were zero known fractures of the device at issue. (Id. at 14). The court further relied on the fact that Illinois does not have a duty to warn post-sale. (Id. at 15). Here, on the other hand, Florida has a duty to warn post-sale, and Plaintiff provides expert testimony that Defendant knew of "up to a dozen clinical failures via breakage of its modular hip-device necks as of September 18, 2003"—before the manufacture and sale of the device in September 2004. (Pl.'s Resp. in Opp'n at 3 n.2 (citing Truman Report at 21)).

Defendant contests the number of pre-implant fractures alleged by Plaintiff, stating that "at the time of [Plaintiff's] implant, the fracture rate . . . was 0.0%." (Mot. Summ. J. at 5). Defendant further argues that, even accepting the number of fractures asserted by Plaintiff, the device's failure rate would amount to 0.03% and that no reasonable juror could conclude that such a risk of failure was "significant." (Def.'s Reply, Doc. 72, at 6–7). However, because the parties do not provide the court with a failure rate of comparable devices over the same period of time, I cannot determine on this record whether a failure rate of 0.03% is statistically significant to discharge Defendant's duty to warn. Moreover, I cannot determine on this record whether Defendant satisfied its post-sale duty to warn when it sent out a Safety Alert in 2008. There are still questions of whether the post-sale

[14] Dr. Markovich stated in his deposition that he was unaware of a design change in the device just prior to 2004 and that he believed that the device implanted in Plaintiff was cleared for sale by the FDA prior to the implantation. (Markovich Dep. at 56).

warning was timely and whether the warnings it provided were adequate—neither of which are satisfactorily addressed by the parties.

Because there are still genuine issues of material fact as to whether the IFU warning was adequate, Defendant's Motion for Summary Judgment is due to be denied with regard to Plaintiff's failure-to-warn claims.

C. Conclusion

As discussed above, Plaintiff's challenged experts pass Daubert scrutiny and there are genuine issues of material fact precluding summary judgment on Counts I, II, and III. Accordingly, it is hereby **ORDERED and ADJUDGED** that:

1. Defendant's Motion to Exclude Opinion Testimony of Reed Ayers, Ph.D. (Doc. 59) is **DENIED**.

2. Defendant's Motion to Exclude Opinion Testimony of Mari Truman (Doc. 60) is **DENIED**.

3. Defendant's Motion for Summary Judgment (Doc. 61) is **GRANTED in part and DENIED in part**. The Motion is **GRANTED** to the extend it seeks dismissal of Maria Diaz-Granados's claim of loss of consortium in Count IV. The Motion is also **GRANTED** insofar as it pertains to assertions of a manufacturing defect; damages from lost wages, income, or capacity to work; and injury based on metal-on-metal design defect. The Motion is **DENIED** to the extent it seeks judgment on Counts I, II, and III.

4. Count IV is **DISMISSED WITH PREJUDICE**.

DONE and **ORDERED** in Orlando, Florida, on March 31st, 2016.

JOHN ANTOON II
United States District Judge

Copies furnished to:
Counsel of Record
Unrepresented Parties