UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

GREGORY K. TUCKER and REBECCA TUCKER,

Plaintiffs,

vs.

WRIGHT MEDICAL TECHNOLOGY, INC., et al.,

Defendants.

Case No.: 11-cv-03086-YGR

ORDER GRANTING IN PART AND DENYING IN PART DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

Pending before the Court is Defendant Wright Medical Technology, Inc.'s Motion for Summary Judgment on All Causes of Action. Plaintiffs Gregory Tucker and Rebecca Tucker filed this products liability action against Defendants Wright Medical Technology, Inc., Wright Medical Group, Inc., and Does 1–100 in state court on May 6, 2011. Arising from an alleged failure of a Profemur hip implant manufactured by Defendant, Plaintiffs allege claims for: (1) strict liability based on theories of design defect, manufacturing defect, and failure to warn; (2) negligence based on design defect; (3) negligence based on failure to warn; and (4) loss of consortium by Rebecca Tucker. (*See* Dkt. No. 1.)

Defendant Wright Medical Technology filed a Motion for Summary Judgment on All Causes of Action on December 5, 2012. ("Motion" or "Mot." [Dkt. No. 76].) Plaintiffs filed their Opposition to Defendant's Motion for Summary Judgment on All Causes of Action on December 18, 2012. ("Opposition" or "Opp." [Dkt. No. 86].) Defendant filed its reply and objections to evidence on January 3, 2013. ("Reply" [Dkt. No. 98].) On January 15, 2013, the Court held oral argument on the Motion. (Dkt. No. 108.)

Having carefully considered the papers submitted and the pleadings in this action, the arguments of counsel, and for the reasons set forth below, the Court hereby:

- **DISMISSES WITH PREJUDICE** Defendants Wright Medical Group, Inc. and Does 1–100;
- **GRANTS** Defendant's Motion for Summary Judgment as to the claim for strict liability based on design defect;
- **DENIES** Defendant's Motion for Summary Judgment as to the claim for negligence based on design defect;
- **GRANTS** Defendant's Motion for Summary Judgment as to the claim for strict liability based on manufacturing defect;
- **GRANTS** Defendant's Motion for Summary Judgment as to strict liability based on failure to warn;
- **GRANTS** Defendant's Motion for Summary Judgment as to the claim for negligence based on failure to warn; and
- **DENIES** Defendant's Motion for Summary Judgment as to Mrs. Tucker's claim for loss of consortium.

I. FACTUAL AND PROCEDURAL BACKGROUND

Plaintiff Gregory Tucker was diagnosed with osteonecrosis in both hips in 2003. (RSS No. 3.)[1] Mr. Tucker's medical history includes obesity, alcohol abuse, degenerative disc disease, right knee meniscus tear, falls, and alcohol-induced osteonecrosis. (RSS No. 18.)

On March 20, 2006, Mr. Tucker underwent a right hip replacement surgery performed by a treating physician, Dr. Kevin Bozic. (RSS No. 54.) Dr. Bozic prescribed the Profemur® hip system and implanted it in Mr. Tucker. (RSS No. 6.) Among other reasons, Dr. Bozic chose this prosthesis "to allow use of a hard-on-hard (ceramic-ceramic) bearing." (*Id.*) The implant consisted of a cup, a head, a neck and a stem (PHA0-1224 long neck combined with a Plasma Z-Stem). (RSS No. 54.) At

[1] "RSS" refers to Plaintiffs' Response and Supporting Separate Statement of Undisputed Material Facts and Supporting Evidence in Support of Its Opposition to Defendant's Motion for Summary Judgment of All Counts. (Dkt. No. 89.) Unless otherwise noted, the references to the material fact numbers include the evidence supporting the same.

the time of this surgery, Mr. Tucker was 6'3" tall and weighed 257 pounds. (RSS Nos. 50 & 54.)[2]

On May 7, 2010, Mr. Tucker's right hip implant fractured. (RSS No. 1.) Metal fatigue is a well-known phenomenon and modular orthopedic implants are known to be susceptible to fretting and fretting-induced fatigue. (RSS No. 8.)[3] Although the parties seem to disagree on what initiated the failure of the implant, the parties agree that fretting, corrosion, and metal fatigue each played a role in the fracture of the neck of the implant. (RSS No. 60.) Prior to the implant breakage on May 7, 2010, Dr. Bozic observed positive results with Mr. Tucker's right hip and no complications. (Declaration of Kevin Bozic, M.D. in Support of Plaintiffs' Opposition to Defendant's Motion for Summary Judgment ("Bozic Decl." [Dkt. No. 90]) ¶ 8.)

Plaintiffs initiated this action in state court on May 6, 2011, alleging claims for strict liability based on theories of design defect, manufacturing defect, and failure to warn; negligence based on design defect; negligence based on failure to warn; and loss of consortium by Mrs. Tucker. Defendant filed three motions to exclude opinion testimony of Plaintiffs' experts in conjunction with the summary judgment motion and at trial. (Dkt. Nos. 62, 63 & 67.) Specifically, Defendant sought to exclude: (1) the expert opinion of Dr. Lester Hendrickson in its entirety, or in the alternative, certain opinions of Dr. Hendrickson (Dkt. No. 63); (2) certain opinion testimony of Dr. Bozic (Dkt. No. 62); and (3) certain opinion testimony of Mari Truman, P.E. (Dkt. No. 67). Plaintiffs opposed each of the motions to exclude (Dkt. Nos. 77, 80 & 83) and Defendant, in turn, filed replies and evidentiary objections. (Dkt. Nos. 95, 96 & 97.) The Court issued its rulings on the motions to exclude and expert-related evidentiary issues on February 27, 2013. (Dkt. No. 115.)

[2] Mr. Tucker also had procedures performed on his left hip. Mr. Tucker underwent a left hip hemiresurfacing on November 24, 2003 and a total left hip replacement surgery on April 26, 2007. (RSS No. 4.)

[3] Fretting is a process that results from very slight oscillatory motion between surfaces pressed together in physical contact. (Declaration of Lester Hendrickson, PhD, in Support of Plaintiffs' Opposition to Defendant's Motion for Summary Judgment on All Causes of Action (Dkt. No. 88 ["Hendrickson Decl."]) ¶¶ 8–9; *see also* Expert Report of Brad James, Ph.D., P.E., FASM [Dkt. No. 73-4] at 5 ("Fretting occurs at the contact area between two metal surfaces that are under load and subject to cyclic relative micro-motion. The contact force and relative motion causes adhesion between the mating surfaces. Adhered particles are removed from the surfaces, resulting in metal loss and the presence of potentially abrasive material between the surfaces.") (footnote omitted), attached as Ex. D to Declaration of Michael O. Fawaz in Support of Defendant Wright Medical Technology, Inc.'s Motion for Summary Judgment on All Causes of Action [Dkt. No. 73].)

II. LEGAL STANDARD

Summary judgment is appropriate when no genuine dispute as to any material fact exists and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). A party seeking summary judgment bears the initial burden of informing the court of the basis for its motion, and of identifying those portions of the pleadings, depositions, discovery responses, and affidavits that demonstrate the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Material facts are those that might affect the outcome of the case. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The "mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact." *Id.* at 247–48 (dispute as to a material fact is "genuine" if there is sufficient evidence for a reasonable jury to return a verdict for the non-moving party).

Where the moving party will have the burden of proof at trial, it must affirmatively demonstrate that no reasonable trier of fact could find other than for the moving party. *Soremekun v. Thrifty Payless, Inc.*, 509 F.3d 978, 984 (9th Cir. 2007). On an issue where the non-moving party will bear the burden of proof at trial, the moving party can prevail merely by pointing out to the district court that the non-moving party lacks evidence to support its case. *Id.* If the moving party meets its initial burden, the opposing party must then set out "specific facts" showing a genuine issue for trial in order to defeat the motion. *Id.* (quoting *Anderson*, 477 U.S. at 250). The opposing party's evidence must be more than "merely colorable" but must be "significantly probative." *Id.* at 249–50. Further, that party may not rest upon mere allegations or denials of the adverse party's evidence, but instead must produce admissible evidence that shows a genuine issue of material fact exists for trial. *Nissan Fire & Marine Ins. Co. v. Fritz Cos., Inc.*, 210 F.3d 1099, 1102–03 (9th Cir. 2000); *Nelson v. Pima Cmty. College Dist.*, 83 F.3d 1075, 1081–1082 (9th Cir. 1996) ("mere allegation and speculation do not create a factual dispute"); *Arpin v. Santa Clara Valley Transp. Agency*, 261 F.3d 912, 922 (9th Cir. 2001) ("conclusory allegations unsupported by factual data are insufficient to defeat [defendants'] summary judgment motion").

When deciding a summary judgment motion, a court must view the evidence in the light most favorable to the non-moving party and draw all justifiable inferences in its favor. *Anderson*, 477 U.S. at 255; *Hunt v. City of Los Angeles*, 638 F.3d 703, 709 (9th Cir. 2011). However, in determining whether to grant or deny summary judgment, it is not a court's task "to scour the record in search of a genuine issue of triable fact." *Keenan v. Allan*, 91 F.3d 1275, 1279 (9th Cir. 1996) (internal quotations omitted). Rather, a court is entitled to "rely on the nonmoving party to identify with reasonable particularity the evidence that precludes summary judgment." *See id.*; *Carmen v. San Francisco Unified Sch. Dist.*, 237 F.3d 1026, 1031 (9th Cir. 2001) ("The district court need not examine the entire file for evidence establishing a genuine issue of fact, where the evidence is not set forth in the opposing papers with adequate references so that it could conveniently be found.")

III. DISCUSSION

A. Dismissal of Defendant Wright Medical Group and Does 1–100

Moving party Wright Medical Technology, Inc. seeks dismissal of Wright Medical Group, Inc. and Does 1–100 with prejudice, arguing that Wright Medical Group has not been served and Plaintiffs have offered no explanation why they have not named any Doe defendants. Plaintiffs stated at oral argument that they have no objection to dismissing these defendants. Accordingly, the Court hereby **DISMISSES WITH PREJUDICE** Wright Medical Group, Inc. and Does 1–100.

B. Motions to Exclude Expert Testimony and Objections to Evidence

As discussed above, Defendant filed three motions to exclude opinion testimony of three of Plaintiffs' experts concurrently with its summary judgment motion. (*See* Dkt. Nos. 62, 63 & 67.) The Court has issued its order granting in part and denying in part Defendant's motions to exclude (Dkt. No. 115), including rulings on evidentiary objections to expert declarations submitted with Plaintiffs' Opposition to Defendant's Motion (*see* Dkt. Nos. 87, 88 & 90; Reply at 1–4).[4] Additional evidentiary issues with respect to the Motion for Summary Judgment are addressed below.

[4] The proposed form of order regarding Defendant's motions to exclude and evidentiary objections to expert declarations was provided to the Court by Defendant. (*See* Dkt. Nos. 105 & 107.) To the extent that Defendant failed to include any objection to a particular expert opinion or declaration statement in its proposed order, those objections are deemed waived.

1. Declaration of Debby Daurer

Plaintiffs object to the Declaration of Debby Daurer in Support of Defendant's Motion ("Daurer Decl."). (*See* Dkt. No. 72.) They argue that Defendant failed to identify Ms. Daurer both in its initial disclosures and in response to a deposition notice of the person most knowledgeable about modular necks. Having not identified her, Plaintiffs contend that "Wright is now attempting to use Ms. Daurer to provide testimony regarding the history of the Profemur system, including the FDA clearance, changes to the devices design [*sic*], the total amount of systems sold, the fracture rate of the necks, availability of the hip system, the CAPA testing, and Safety Alert letters that went out." (Opp. at 5.)

Defendant responds that the Daurer Declaration should not be excluded because she has long been known to Plaintiffs, and her declaration only identifies background information, information disclosed through other sources, or authenticates facts already in the record that Plaintiffs are not otherwise disputing. (Reply at 5.) Specifically, Mr. Tucker testified in his deposition regarding communications with Ms. Daurer, she was identified by Defendant's 30(b)(6) witness at deposition, and Plaintiffs cite to an email by Ms. Daurer in support of their Opposition. (*Id.*) In addition, Defendant asserts Ms. Daurer authenticates information that is uncontested, known through other sources, and/or has otherwise been produced during discovery. Plaintiffs do not object to the authenticity of any documents she attaches. (*Id.* at 6.)

The Court agrees with Defendant. Plaintiffs do not object to the substance of the Daurer Declaration or the exhibits attached thereto. Her identity comes as no surprise to Plaintiffs, and Plaintiffs could have elected—but chose not—to depose Mr. Daurer. Moreover, Plaintiffs do not claim that the 30(b)(6) witness whose deposition was taken was inadequate or unprepared. For these reasons, the Court **DENIES** Plaintiffs' request to exclude the Daurer Declaration.

2. Declaration of Thomas M. Gray in Support of Plaintiffs' Opposition

Defendant objects to portions of the Declaration of Thomas M. Gray in Support of Plaintiffs' Opposition ("Gray Decl." [Dkt. No. 91]) as new and cumulative, prejudicial, and/or a waste of time. (*See* Reply at 4–5; Gray Decl. ¶¶ 2–24, 25–29 & 31.) Defendant fails to make even a colorable effort at explaining the basis for *any* of its objections, particularly the nature of the alleged

prejudicial effect or how the evidence "waste[s]" this Court's time. Defendant's objections are **OVERRULED**.

Defendant previously objected to Ex. S attached to the Gray Declaration. (Reply at 5.) Defendant has now withdrawn this evidentiary objection. (Dkt. No. 112 at 4.) Accordingly, the Court need not rule on this objection.

C. Design Defect

Plaintiffs allege claims for strict liability and negligence based on design defect. The Court will address each claim of design defect in turn.

1. Design Defect: Strict Liability

a. Summary of California Law Regarding Strict Liability for Medical Implants

"A manufacturer is strictly liable for injuries caused by a product that is (1) defectively manufactured, (2) defectively designed, or (3) distributed without adequate instructions or warnings of its potential for harm." *Hufft v. Horowitz*, 4 Cal. App. 4th 8, 13 (Cal. Ct. App. 1992) (citing *Barker v. Lull Eng'g Co.*, 20 Cal. 3d 413, 428 (1978)). Generally, design defects exist where a product is built in accordance with its intended specifications, but the design itself is inherently defective. *Barker*, 20 Cal. 3d at 429. "[A] product is defective in design either (1) if the product has failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner, or (2) if, in light of [] relevant factors . . . , the benefits of the challenged design do not outweigh the risk of danger inherent in such design." *Barker*, 20 Cal. 3d at 418.

California courts have found an "exception" to the above general rule of strict liability when it comes to prescription drugs. *Artiglio v. Superior Court*, 22 Cal. App. 4th 1388, 1392 (Cal. Ct. App. 1994). In *Brown v. Superior Court*, the California Supreme Court concluded that "a drug manufacturer's liability for a defectively designed drug should not be measured by the standards of strict liability" but, rather, the "appropriate test for determining responsibility is the test stated in comment k [to section 402A of the Restatement Second of Torts ("Comment k")]."[5] 44 Cal. 3d 1049,

[5] Comment k provides: "*Unavoidably unsafe products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. . . . Such a product, properly prepared, and accompanied by proper

1061 (1988) (basing its conclusion, in part, on "the public interest in the development, availability, and reasonable price of drugs"). *Brown* established that "a manufacturer is not strictly liable for injuries caused by a prescription drug so long as the drug was properly prepared and accompanied by warnings of its dangerous propensities that were either known or reasonably scientifically knowable at the time of distribution." 44 Cal. 3d at 1069.[6] Despite the exception for prescription drugs set forth in *Brown*, drug manufacturers remain subject to liability for manufacturing defects, negligence, and for failure to warn of known or reasonably knowable side effects. *Id.* at 1069 n.12.

While the holding in *Brown* was limited to prescription drugs, the Court of Appeal in *Hufft v. Horowitz* "follow[ed] *Brown*'s lead [to] hold that a manufacturer is not strictly liable for injuries caused by an *implanted prescription medical product* which has been (1) properly made and (2) distributed with information regarding risks and dangers of which the manufacturer knew or should have known at the time." 4 Cal. App. 4th at 11 (emphasis supplied). The extension to medical implants was further addressed by the Court of Appeal in *Artiglio v. Superior Court*:

> We therefore follow the lead of the *Hufft* and *Plenger* courts, and conclude that the *entire category of medical implants available only by resort to the services of a physician are immune from design defect strict liability*. There is no contention anywhere in the record of these coordinated cases that any of the breast implants, the subject of the various claims, were obtained other than by the services of a physician. Therefore, the determination that strict liability based on design defect is unavailable for all such claims is one to be made as a matter of law, and without the benefit of any factfinding, except for the sole factual determination, made without dispute in these cases, that the breast implants are all physician-directed and physician-applied. Summary adjudication was therefore appropriate.

22 Cal. App. 4th at 1397 (emphasis supplied).

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directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. . . . The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk."

[6] *Brown* explicitly disapproved of prior precedent that held Comment k should not be applied to a drug unless the trial court first determined that the drug was "unavoidably dangerous." 44 Cal.3d at 1068–69. The court held that Comment k "was intended to and should apply to all prescription drugs." *Id.* at 1069 n.11 ("[T]he benefit of the negligence standard stated in the comment would be greatly diminished if all drugs were required to run the gauntlet of a risk[-]benefit analysis in order to qualify for application of the standard.").

b. Summary of Argument and Analysis

Defendant argues that *Brown*, *Hufft*, and the unavoidably unsafe defense set forth in Comment k act as a complete bar to Plaintiffs' strict liability design defect claim. (Mot. at 8–9.) Defendant notes that numerous district courts in California have prohibited such strict liability claims. *See, e.g.*, *Rhynes v. Stryker Corp.*, No. 10-5619 SC, 2011 WL 2149095 (N.D. Cal. May 31, 2011); *Currier v. Stryker Corp.*, No. 2:11-cv-1203 JAM-EFB, 2011 WL 4898501 (E.D. Cal. Oct. 13, 2011). Here, the parties agree that the device at issue was available only through a prescribing physician, and that Mr. Tucker's physician, Dr. Bozic, prescribed and installed the device. (RSS Nos. 5–6.) As such, Defendant contends the claim cannot withstand summary judgment.

While recognizing that *Hufft* extended the holding in *Brown* to implanted prescription medical devices, Plaintiffs principally respond that in order to be exempt from strict liability, Defendant must still show that the device was properly made and distributed with information regarding known risks and dangers. (Opp. at 15.) They argue the evidence shows that the product's design outweighed the benefits, that safer alternatives existed, that known neck breakages prior to 2006 were not disclosed in warnings, and that a manufacturing defect could "[]not be ruled out." (*Id.*) Plaintiffs fail to address Defendant's cited authority directly. In doing so, Plaintiffs assert the Motion must be denied.

Plaintiffs' failure to address Defendant's authority is telling.[7] In *Rhynes* and *Currier*, two district courts granted motions to strike plaintiffs' strict liability design defect claims because "controlling California law unequivocally prohibits strict liability claims for design defect against manufacturers of prescription implantable medical devices." *Rhynes*, 2011 WL 2149095, at *6 (citing *Brown*, *Hufft*, and *Artiglio*); *Currier*, 2011 WL 4898501, at *2 (stating the same). While these were not summary judgment motions, it was undisputed in *Rhynes* (as here) that "Rhyne's hip implant prosthesis was obtained through a physician and qualifies as a prescribed device." 2011 WL

[7] Plaintiffs cite to *Rosburg v. Minnesota Mining & Mfg. Co.*, 181 Cal. App. 3d 726 (Cal. Ct. App. 1986) for the proposition that "[a] design defect in strict liability still requires the benefits of the challenged design to outweigh the risk of danger inherent in the design." (Opp. at 14.) *Rosburg*, however, preceded *Brown*, *Hufft*, and *Artiglio* and the district court cases referenced herein. Moreover, *Rosburg* did not mandate that a risk-benefit analysis be undertaken in a strict liability case. Rather, the Court of Appeal inquired into whether there was substantial evidence to support the trial court's decision that benefits of the product outweighed the risk of injury. *Rosburg*, 181 Cal. App. 3d at 734. There, the court held that there was substantial evidence to support the trial court's finding regarding the risk-benefit analysis. *Id.*

2149095, at *6. Moreover, the *Rhynes* court confronted the precise argument Plaintiffs make here—namely, that *Hufft* limited liability to cases where the product has been properly made and distributed with adequate warnings and defendant Stryker was not immune from strict liability since the complaint contained allegations of manufacturing defect and improper warnings. *Id.* at *7. Importantly, the district court held:

> Plaintiffs misconstrue the quoted language from *Hufft* to suggest that a manufacturer is only immune from strict liability for defective design if there are no allegations of manufacturing defects or inadequate warning labels. Properly read, and as the rest of *Hufft* makes clear, this statement means that a manufacturer of prescription medical devices can be held strictly liable only for manufacturing defects or inadequate warnings-it may not be held strictly liable for design defects. . . . California law categorically protects manufacturers of prescription medical devices from strict liability for design defects.

Rhynes, 2011 WL 2149095, at *7 (striking strict liability design defect allegations without leave to amend); *Currier*, 2011 WL 4898501, at *3 (dismissing with prejudice plaintiff's claim based "on the design defect theory [because] such a claim is prohibited under California law").

Plaintiffs' attempt to salvage the strict liability claim by bootstrapping it to their negligent design claim—*i.e.*, the risk-benefits analysis—is unavailing. (*See* Opp. at 14.) Plaintiffs ignore that the California Supreme Court has rejected conditioning strict liability on a risk-benefit analysis. *Brown*, 44 Cal. 3d at 1069 n.11 ("[T]he benefit of the negligence standard stated in [Comment k] would be greatly diminished if all drugs were required to run the gauntlet of a risk[-]benefit analysis in order to qualify for application of the standard."). In addition, the district court in *Adams v. I-Flow Corp.* stated that under *Brown*, "the California Supreme Court held that both of the tests for establishing design defect in California-i.e., the consumer expectations test and the risk-benefit test-are *inappropriate* in the context of prescription pharmaceutical products." No. CV09-09550 R(SSx), 2010 WL 1339948, at *6 (C.D. Cal. Mar. 30, 2010) (emphasis supplied). There, the court held that the design defect claim based on strict liability was "unequivocally barred by California law" and thus "stricken without leave to amend." *Id.*

"[T]he determination that strict liability based on design defect is unavailable for all such claims is one to be made as a matter of law, and without the benefit of any factfinding, *except* for the sole factual determination, made without dispute in these cases, that the . . . implants are all physician-

directed and physician-applied." *Artiglio*, 22 Cal. App. 4th at 1397 (emphasis supplied; affirming summary adjudication). Accordingly, because the implant at issue was prescribed and installed by Dr. Bozic, the Court finds that Plaintiffs' strict liability claim based on design defect is precluded as a matter of California law. Defendant's Motion for Summary Judgment on this claim is **GRANTED**.

2. Design Defect: Negligence

a. Summary of Law

A plaintiff alleging a design defect claim under a negligence theory must prove "that the defect in the product was due to negligence of the defendant." *Chavez v. Glock, Inc.*, 207 Cal. App. 4th 1283, 1305 (Cal. Ct. App. 2012) (quoting *Merrill v. Navegar, Inc.*, 26 Cal. 4th 465, 479 (2001)). As with a general negligence claim, the plaintiff must show breach of duty, causation, and damages. *Howard v. Omni Hotels Mgmt. Corp.*, 203 Cal. App. 4th 403, 428 (Cal. Ct. App. 2012); *see also* Jud. Council of Cal. Civ. Jury Instructions ("CACI") No. 1220 (entitled "Negligence—Essential Factual Elements"). As to the standard of care for negligence, a "[designer/manufacturer/etc.] is negligent if [it] fails to use the amount of care in [designing/manufacturing/etc.] the product that a reasonably careful [designer/manufacturer/etc.] would use in similar circumstances to avoid exposing others to a foreseeable risk of harm. [¶] In determining whether [defendant] used reasonable care, [the jury] should balance what [defendant] knew or should have known about the likelihood and severity of potential harm from the product against the burden of taking safety measures to reduce or avoid the harm." *Howard*, 203 Cal. App. 4th at 428 (seventh alteration supplied; all other alterations in original) (quoting CACI 1221 [entitled "Negligence—Basic Standard of Care"]).

Generally, "the test of negligent design involves a balancing of the likelihood of harm to be expected from a [product] with a given design and the gravity of harm if it happens against the burden of the precaution which would be effective to avoid the harm." *Merrill*, 26 Cal. 4th at 479 (internal citations and quotations omitted); *Chavez*, 207 Cal. App. 4th at 1305 (quoting *Merrill*). Even if a manufacturer has done all it reasonably could have done to warn about a risk or hazard related to a product's design, a reasonable person could conclude that the magnitude of the reasonably foreseeable harm as designed outweighed the utility of the product as designed. *Chavez*, 207 Cal. App. 4th at 1305. "Thus, 'most of the evidentiary matters' relevant to applying the risk[-]benefit test in strict

liability cases 'are similar to the issues typically presented in a negligent design case.'" *Id.* (quoting *Merrill*, 26 Cal. 4th at 479–80). Here, both parties have addressed Plaintiffs' negligent design claim under the framework of a risk-benefit analysis. (Mot. at 9; Opp. at 6.)

"In evaluating the adequacy of a product's design under the risk-benefit test, 'a jury may consider, among other relevant factors, the gravity of the danger posed by the challenged design, the likelihood that such danger would occur, the mechanical feasibility of a safer alternative design, the financial cost of an improved design, and the adverse consequences to the product and to the consumer that would result from an alternative design.'" *Chavez*, 207 Cal. App. 4th at 1308–09 (quoting *Barker*, 20 Cal. 3d at 431–32); *see also* CACI 1204 (entitled "Strict Liability—Design Defect—Risk-Benefit Test—Essential Factual Elements—Shifting Burden of Proof").

b. Summary of Argument

Defendant submits that Plaintiffs cannot make a prima facie showing of causation because their experts have not and cannot prove that the Profemur® design was inherently defective. (Mot. at 10.) Relying exclusively on another case against Wright entities in the Central District of Illinois, Defendant argues that summary judgment is appropriate when a plaintiff "does not submit evidence necessary to undergo the risk-benefit analysis." (*Id.* (citing *Cappellano v. Wright Medical Group, Inc.*, 838 F. Supp. 2d 816 (C.D. Ill. 2012).)

In that case, determined under Illinois law, the district court found that plaintiff provided sufficient evidence that an alternate (monolithic) design was available at the time the Profemur® prosthesis was manufactured, and that there were advantages to a modular design over the monolithic. *Id.* at 829. However, plaintiff's evidence failed to provide "information from which th[e] court could compare the risks of the modular design of the Profemur® prosthesis with the risks of the proposed alternate monolithic design." *Id.*; *see id.* at 832 (granting summary judgment because plaintiff failed to offer evidence from which the court could conduct a "threshold risk-utility analysis"). Specifically, the court held that "[b]ased on *Jablonski* [*v. Ford Motor Co.*, 353 Ill. Dec. 327, 955 N.E.2d 1138, 1158 (2011)], Defendants [were] correct that Plaintiff [was] required to show that the monolithic design did not have dangers of equal or greater magnitude." *Id.* at 829. The *Cappellano* court also held that even though plaintiff produced evidence that chromium cobalt may be stronger, he failed to

provide a basis for whether the risks of a titanium alloy neck outweighed the benefits, and he failed to provide a cost comparison between the two alternate designs. *Id.* at 829–30.

Defendant next contends that any showing Plaintiffs have made regarding defect is "inconsequential" because Defendant has met its burden showing that "on balance, the benefits of the [chosen] Profemur® design outweigh[ed] its risks and that the Profemur® met the state of the art standard at the time of its design." (Mot. at 10.) Specifically, Defendant argues that its experts opine that modular systems, such as the Profemur, have distinct advantages in fitting patient anatomy that better enable surgeons to optimize a patient's biomechanics. (*Id.* at 11 (citing RSS Nos. 9, 10 & 17).) The medical community "generally believes" these benefits outweigh disadvantages because modular hip prostheses continue to be extensively used. (Mot. at 11 (citing RSS Nos. 11 & 12).) As to material selection, Defendant argues that titanium alloy has "superior biocompatibility and superior corrosion resistance" compared to cobalt chromium alloys, which is the primary alternative material suggested by Plaintiffs. (Mot. at 11 (citing RSS No. 13).) Recognizing that cobalt chromium generally has superior wear resistance and fatigue strength than titanium, Defendant argues that such implants may be too stiff and may result in stress shielding of nearby bone, bone resorption, and possible implant loosening. (Mot. at 11 (citing RSS No. 13).) In sum, Defendant argues that Plaintiffs only identify "potential risks with different design elements, such as the material selection and modular form" but ignore the benefits of the Profemur design. (Mot. at 13.)[8]

Plaintiffs respond that Defendant itself glosses over the risks of its chosen design and that the risks outweighed the benefits here based on increased risks in higher demand patients, Defendant's knowledge, and the availability of safer alternatives. (Opp. at 6.) More specifically, Plaintiffs argue that they have provided expert opinion showing: (i) Defendant's knowledge of the susceptibility of

[8] Defendant also makes a number of arguments regarding the reasonableness of its conduct and causation. First, at the time of the implant, Defendant contends that it knew of only two failures out of more than 58,000 installations. (Mot. at 12 (citing RSS No. 35).) Second, the Profemur had been fully tested to industry standards and met FDA requirements, which Plaintiffs' expert Truman admitted in another Profemur litigation. (Mot. at 13 (citing RSS Nos. 24–26, 28–29 & 61–62).) Defendant argues that because the design was "consistent with the then-state-of-the-art, . . . [it has] a defense that can defeat [the] negligent design claim[] under California law." (Mot. at 13 (citing *Rosburg*, 181 Cal. App. 3d at 735).) Finally, Defendant argues that factors or conditions in Mr. Tucker's medical history, including his obesity, alcohol abuse, and alcohol-induced osteonecrosis, served as contraindications and risk factors, which ultimately "affect[ed] his biomechanics by acutely and chronically overloading his right hip joint." (Mot. at 11–12 (citing RSS Nos. 18–20 & 27).)

the modular design to fretting and fracture because titanium alloy was not strong enough to withstand foreseeable forces on the device for heavier patients; (ii) Defendant's awareness from testing that the device could not sustain forces of those in higher weight groups, who were the target group of users; (iii) Defendant failed to consider safer alternatives of either switching to a stronger material (cobalt chromium) or using surface treatments; and (iv) potential costs of these alternatives. (Opp. at 6–7; *see id.* at 14 ("the risks in using the titanium alloy for long necks outweighed the benefits touted by Wright, especially in light of the viable safer alternatives that were not cost prohibitive").)

c. Analysis

The Court first notes that the *Cappellano* decision is not persuasive authority as Plaintiffs' negligent design defect claim is based on California law.[9] To grant summary judgment to Defendant, this Court would have to find that a juror could not reasonably find that the risks of the Profemur outweighed its benefits. Similarly, the Court would have to hold that no juror could find that Defendant failed to use the amount of care in designing the product that a reasonable designer would have used in similar circumstances to avoid exposing others to a foreseeable risk of harm. *See Howard*, 203 Cal. App. 4th at 428; CACI 1221.

Plaintiffs have presented sufficient evidence from which a jury could balance what defendant "knew or should have known about the likelihood and severity of potential harm . . . against the burden of taking safety measures to reduce or avoid the harm" (*Howard*, 203 Cal. App. 4th at 428; CACI 1221), such that it could find that Defendant's conduct fell below the standard of reasonable care. In analyzing the risks and benefits, a jury may consider, *among other relevant factors*, the gravity of the danger posed by the challenged design, the likelihood that such danger would occur, the mechanical feasibility of a safer alternative design, the financial cost of an improved design, and the adverse consequences to the product and to the consumer that would result from an alternative design. *Chavez*, 207 Cal. App. 4th at 1308–09 (quoting *Barker*, 20 Cal. 3d at 431–32); *see also* CACI 1204.[10]

[9] Neither *Jablonski* nor *Cappellano* has been adopted by a state or district court outside of Illinois or the Seventh Circuit.

[10] The parties agree that implant design is a balancing act that takes into consideration many factors. (RSS No. 12.)

Plaintiffs' evidence relates to various factors that, when taken in the light most favorable to Plaintiffs, directly implicate the balancing that must be done to determine the reasonableness of Defendant's conduct. For example, Plaintiffs' expert Dr. Lester Hendrickson concludes that the Profemur's modular design introduced a risk of failure to the device by fretting, corrosion, and fatigue. (Hendrickson Decl. ¶ 14; *id.* ¶ 10 (fatigue, fracture, and fretting were direct result of design).) According to Dr. Hendrickson, fretting is well-known in the industry. (*Id.* ¶ 34.) Plaintiffs' expert Mari Truman states that the Profemur and its long neck were defectively designed, in part, because Defendant failed to use cobalt chromium, which was a stronger material and a reasonable, available alternative that could have been used at a minimal cost. (Declaration of Mari Truman, P.E. in Support of Plaintiffs' Opposition to Defendant's Motion for Summary Judgment ("Truman Decl." [Dkt. No. 87]) ¶¶ 62–65 & 70–71.) Truman also states that surface treatments (such as "shock peening, roller burnishing, and surface hardening/coatings") could have been utilized by Defendant to enhance the fatigue strength of the Profemur. (*Id.* ¶ 61.) These treatments were common, available, and not cost prohibitive had Defendant chosen to use them. (*Id.* ¶¶ 61 & 69–70.) Truman further states that in light of Defendant's marketing of the product to heavier and/or more active individuals (such as Mr. Tucker), its testing—while perhaps meeting industry standards[11]—was insufficient in light of the implants' foreseeable use. (*Id.* ¶¶ 56, 68–69.)

Plaintiffs also argue that Defendant knew of twelve neck breakages prior to the time of Mr. Tucker's implant surgery. (RSS No. 53.) To summarize Truman's conclusions: "[h]ad Wright used [cobalt chromium] in the long neck from the beginning, applied available surface treatments to the titanium neck, properly tested the implant for heavier-active individuals in the U.S., or provided adequate warnings and contraindications[,] the fracture rate of the Profemur Long Necks would have been much lower. . . . [I]t is [her] opinion that the risks of Wright Medical's titanium alloy long neck

[11] "Deviation from an industry norm is not necessarily the test for a defective product." *Howard*, 203 Cal. App. 4th at 426. "[E]xpert evidence about compliance with industry standards can be considered on the issue of defective design, in light of all other relevant circumstances, even if such compliance is not a complete defense. An action on a design defect theory can be prosecuted and defended through expert testimony that is addressed to the elements of such a claim, including risk-benefit considerations." *Id.* Expert evidence regarding a manufacturer's compliance with regulations and trade custom are evidence for a jury to consider with other facts and circumstances. *Id.* at 421 (noting that where a manufacturer has reason to know of greater dangers despite its compliance with regulations, that manufacturer may not be insulated from negligence liability).

outweigh[ed] the general benefits described by Wright's experts in active-heavy individuals, such as Mr. Tucker." (*Id.* ¶¶ 70–71.)

Defendant's response to Plaintiffs' evidence and experts is largely to explain why the evidence does not show that the risks were so great as to outweigh the benefits, how its conduct was reasonable in light of what it knew, and/or to argue that Plaintiffs' evidence is incorrect or misleading. (*See* Reply at 8–12.)[12] This all goes to weight of the evidence that must be considered in a balancing of factors. Taking the evidence in the light most favorable to Plaintiffs, there are triable issues of fact as to relevant factors, including but not limited to, the risks and benefits of the Profemur, Defendant's knowledge of the risks, the likelihood and foreseeability of harm, the magnitude of foreseeable harms, available safety measures, and—as with any negligence claim—whether Defendant's conduct was reasonable. California law requires such balancing to be done by the jury, not the Court.

For these reasons, Defendant's Motion for Summary Judgment on the negligent design claim is **DENIED**.

D. Manufacturing Defect: Strict Liability

To establish a claim for manufacturing defect under a strict liability theory, a plaintiff has the burden of establishing that: (1) he has been injured by the product; (2) the injury occurred because the product was defective; and (3) the defect existed when the product left the hands of the defendant. *Fender v. Medtronic, Inc.*, 887 F. Supp. 1326, 1333 (E.D. Cal. 1995); *see* CACI 1201 (entitled "Strict Liability—Manufacturing Defect—Essential Factual Elements"). A manufacturing defect exists if the product "differs from the manufacturer's intended result or from other ostensibly identical units of the same product line." *Barker*, 20 Cal. 3d at 429. In other words, such a claim posits "that a suitable design is in place, but that the manufacturing process has in some way deviated from that design." *In re Coordinated Latex Glove Litig.*, 99 Cal. App. 4th 594, 613 (Cal. Ct. App. 2002); *Gonzalez v. Autoliv ASP, Inc.*, 154 Cal. App. 4th 780, 792 (Cal. Ct. App. 2007) ("A manufacturing defect occurs when an item is manufactured in a substandard condition.").

[12] Defendant disputes that it had notice of twelve neck breakages prior to 2006, but admits that as of the date of Mr. Tucker's implant surgery, it was aware of two fractures of a Profemur product, which were both in Europe. (RSS Nos. 7 & 53.)

Defendant argues that summary judgment must be granted on the manufacturing defect claim because the sole expert opining on the existence of a manufacturing defect (Dr. Hendrickson) simply states that "[b]ased on the physical evidence available from [his] analysis, the fatigue fracture was initiated by fretting, which was a direct result of the design of the device, with errors in manufacturing most likely contributing factors." (Hendrickson Decl. ¶ 10; RSS No. 31.) Defendant argues that Dr. Hendrickson has failed to elaborate or even specify what the manufacturing error was that contributed to the device's failure. (Mot. at 14.) At the same time, he contradicts his other statements that "the subject hip device failed because, and only because, it is modular in design." (RSS No. 32.) Absent Dr. Hendrickson's conclusion, Defendant contends there is no evidence in the record supporting a manufacturing defect claim.

Plaintiffs respond that this claim presents a "classic" dispute of material fact because the parties' experts (both metallurgists) disagree on the existence of a manufacturing defect. (Opp. at 15–15.) Plaintiffs argue that Dr. Hendrickson's opinion regarding the manufacturing defect is based on his "thorough examination" of the device. (Opp. at 16.) Dr. Hendrickson also states that a "[m]anufacturing defect[] cannot be ruled out merely by relying on device history records as a manufacturing defect is device specific and requires examination of the specific device at issue." (Hendrickson Decl. ¶ 11; *see* RSS Nos. 29 & 33.) In addition, he concludes that "a manufacturing defect cannot be ruled out" because Defendant's experts "admit" that the damage caused during the device's extraction makes it impossible to determine the "presence or absence of any surface of dimensional defect." (Hendrickson Decl. ¶ 12.) Finally, Dr. Hendrickson notes that Defendant's expert Dr. James "did not perform the type of tests necessary to determine whether or not a manufacturing defect of a metallurgical nature existed, therefore he has no basis for excluding that type of manufacturing defect as a contributing factor." (*Id.*)

The Court finds that Plaintiffs fail to meet their burden of identifying "specific facts" showing a genuine issue for trial to defeat Defendant's Motion on this claim. *Soremekun*, 509 F.3d at 984 (quoting *Anderson*, 477 U.S. at 250); *Arpin*, 261 F.3d at 922 ("conclusory allegations unsupported by factual data are insufficient to defeat [defendants'] summary judgment motion"). The Court has sustained Defendant's objections to Dr. Hendrickson's opinions related to the manufacture of the

implant. Such opinions have not been supported with any facts showing the existence of such defect. Even considering statements the statements in the Hendrickson Declaration at paragraphs 10–12 in the light most favorable to Plaintiffs, they still have provided *no facts* showing that the defect existed when the product left the hands of Defendant. To state here that a manufacturing defect "cannot be ruled out" is simply speculation based on an absence of facts. The same is true of the argument that a manufacturing defect "most likely contribut[ed]" to a design defect. Notably, no evidence in the record, other than Dr. Hendrickson's own statements, has been identified in Plaintiffs' responsive separate statement. Moreover, to the extent that Dr. Hendrickson asserts that *Defendant's* experts have not conducted sufficient testing to rule *out* a manufacturing defect, he misunderstands the burden on this Motion.

Having failed to identify (or even explain) *how* the device at issue deviated from Defendant's intended design or from other implants of the same product line, Plaintiffs have failed to raise a triable issue of fact on their manufacturing defect claim. For these reasons, Defendant's Motion for Summary Judgment on the strict liability manufacturing defect claim is **GRANTED**.

E. Failure to Warn

Plaintiffs assert two claims for failure to warn: one under a strict liability theory and the second under a negligence theory. Defendants seek summary judgment on both claims.

The California Supreme Court has provided the following explanation of the differences between a strict liability and negligent failure to warn claim:

> [F]ailure to warn in strict liability differs markedly from failure to warn in the negligence context. Negligence law in a failure-to-warn case requires a plaintiff to prove that a manufacturer or distributor did not warn of a particular risk for reasons which fell below the acceptable standard of care, i.e., what a reasonably prudent manufacturer would have known and warned about. Strict liability is not concerned with the standard of due care or the reasonableness of a manufacturer's conduct. . . . [I]n strict liability, as opposed to negligence, the reasonableness of the defendant's failure to warn is immaterial.

Anderson v. Owens-Corning Fiberglas Corp., 53 Cal. 3d 987, 1002–03 (1991) (footnote omitted).

A manufacturer of a prescription drug is obligated warn physicians, not patients, of potential side effects associated with its pharmaceutical products. *Motus v. Pfizer Inc.*, 358 F.3d 659, 661 (9th Cir. 2004) ("*Motus II*"). Known as the "learned intermediary" doctrine, the duty to warn the

physician—rather than the patient—also applies to prescription implants. *Valentine v. Baxter Healthcare Corp.*, 68 Cal. App. 4th 1467, 1483 (Cal. Ct. App. 1999) ("In the case of prescription drugs and implants, the physician stands in the shoes of the 'ordinary user' because it is through the physician that a patient learns of the properties and proper use of the drug or implant.") A manufacturer discharges its duty to warn if it provides an adequate warning to the physician, regardless of whether the warning reaches the patient. *Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984, 991 (C.D. Cal. 2001) ("*Motus I*"), *aff'd*, 358 F.3d 659 (9th Cir. 2004). A plaintiff must prove that "no warning was provided or that the warning was inadequate" and "also that the inadequacy or absence of a warning caused the plaintiff's injury." *Id.* "[A] product defect claim based on insufficient warnings cannot survive summary judgment if stronger warnings would not have altered the conduct of the prescribing physician." *Motus II*, 358 F.3d at 661.

1. Summary of Law

a. Failure to Warn: Strict Liability

In California, a defendant manufacturer can be held strictly liable for failure to warn if the plaintiff proves the following: "(1) the defendant manufactured, distributed, or sold the product; (2) the product had potential risks that were known or knowable at the time of manufacture or distribution, or sale; (3) that the potential risks presented a substantial danger to users of the product; (4) that ordinary consumers would not have recognized the potential risks; (5) that the defendant failed to adequately warn of the potential risks; (6) that the plaintiff was harmed while using the product in a reasonably foreseeable way; (7) and that the lack of sufficient warnings was a substantial factor in causing the plaintiff's harm." *Rosa v. City of Seaside*, 675 F. Supp. 2d 1006, 1011 (N.D. Cal. 2009), *aff'd sub nom., Rosa v. Taser Int'l, Inc.*, 684 F.3d 941 (9th Cir. 2012), (citing CACI 1205 [entitled "Strict Liability—Failure to Warn—Essential Factual Elements"]). With respect to a known or knowable risk, the plaintiff must prove 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." *Rosa*, 675 F. Supp. 2d at 1012 (citing *Anderson*, 53 Cal. 3d at 1002).[13]

Generally, the purpose of requiring adequate warnings is to inform consumers about a product's hazards of which they are unaware, so that they may either refrain from using the product altogether or avoid the danger by careful use. *Taylor v. Elliott Turbomachinery Co., Inc.*, 171 Cal. App. 4th 564, 577 (Cal. Ct. App. 2009); *Anderson*, 53 Cal. 3d at 1003. The duty to warn continues for as long as the manufacturer is manufacturing and distributing the product. *Valentine*, 68 Cal. App. 4th at 1482. On the other hand, "[t]here is no duty to warn of known risks or obvious dangers." *Chavez*, 207 Cal. App. 4th at 1304; *Carlin v. Superior Court*, 13 Cal. 4th 1104, 1116 (1996) ("a pharmaceutical manufacturer may not be required to provide warning of a risk known to the medical community"). "In most cases, . . . the adequacy of a warning is a question of fact for the jury." *Jackson v. Deft, Inc.*, 223 Cal. App. 3d 1305, 1320 (Cal. Ct. App. 1990).

b. Failure to Warn: Negligence

To prevail on a claim for negligent failure to warn, a plaintiff must prove that: "(1) the defendant manufactured, distributed, or sold the product; (2) the defendant knew or reasonably should have known that the product was dangerous or was likely to be dangerous when used in a reasonably foreseeable manner; (3) the defendant knew or reasonably should have known that users would not realize the danger; (4) the defendant failed to adequately warn of the danger or instruct on the safe use of the product; (5) a reasonable manufacturer, distributor, or seller under the same or similar circumstances would have warned of the danger or instructed on the safe use of the product; (6) the plaintiff was harmed; and (7) the defendant's failure to warn or instruct was a substantial factor in causing the plaintiff's harm." *Rosa*, 675 F. Supp. 2d at 1011–12 (citing CACI 1222 [entitled "Negligence—Manufacturer or Supplier—Duty to Warn—Essential Factual Elements]).

As discussed above, this claim "requires a plaintiff to prove that a manufacturer or distributor did not warn of a particular risk for reasons which fell below the acceptable standard of care, i.e., what

[13] In a strict liability warning claim, "a defendant . . . may present evidence of the state of the art, i.e., evidence that the particular risk was neither known nor knowable by the application of scientific knowledge available at the time of manufacture and/or distribution." *Anderson*, 53 Cal. 3d at 1004.

a reasonably prudent manufacturer would have known and warned about." *Anderson*, 53 Cal. 3d at 1002; *Chavez*, 207 Cal. App. 4th at 1305. A "reasonable manufacturer would not be charged with knowing more than what would come to light from the prevailing scientific and medical knowledge." *Valentine*, 68 Cal. App. 4th at 1483–84. It might, for example, prevail against a negligence claim where it decided a risk of harm was not so great as to require a warning based on its own testing that showed a result contrary to that of others in the scientific community. *Anderson*, 53 Cal. 3d at 1003. As with a strict liability warning claim, adequacy of a warning in a negligence claim is usually a question of fact. *Res-Care Inc. v. Roto-Rooter Servcs. Co.*, 753 F. Supp. 2d 970, 991 (N.D. Cal. 2010).

2. Summary of Argument

Defendant argues that both failure to warn claims must be dismissed because Dr. Bozic received adequate warning of the potential risks associated with the Profemur, including warnings relating to an increased likelihood of failure in patients with obesity, those with active lifestyles, or those who cannot follow instructions. (Mot. at 16 (citing RSS Nos. 38–40).) Defendant contends that the warnings repeatedly cautioned the physician of risk factors that could lead to device failure by fracture, that Dr. Bozic—as a skilled orthopedic surgeon—understood these warnings, and that in signing an Authorization for Surgery and Informed Consent, Mr. Tucker acknowledged that he understood that the implant may fail and/or need to be repaired or replaced. (RSS Nos. 36–37 & 40–41.) In addition, Defendant argues that its warnings were reasonable in light of the fractures known to it at the time of Mr. Tucker's implant, and that it promptly issued a Safety Alert to physicians identifying this risk once it become aware of it. (RSS Nos. 46–47 & 53; Mot. at 19.)

Defendant also emphasizes that the record is devoid of any evidence that Dr. Bozic ever read or relied upon Defendant's warnings in deciding to implant the Profemur into Mr. Tucker. (RSS No. 52.) Without this, Defendant contends that Plaintiffs cannot establish the essential element of proximate cause: "[t]here is no evidence that different or additional warnings regarding the potential risks of the Profemur® hip products would have changed Dr. Bozic's decision to use the device." (Mot. at 19; *see* Reply at 14.)

Plaintiffs principally respond that Defendant provided an insufficient warning regarding the risk of fracture of the long neck in heavier demand patients. (Opp. at 17.) Plaintiffs argue that Defendant knew of actual fractures, yet failed to provide specific warnings, and that even as a skilled orthopedic surgeon, Dr. Bozic was not adequately informed of the risk of fractures or the increased likelihood of the same based on weight or activity levels. (*Id.* at 17–21; *see* RSS Nos. 36–42; Bozic Decl. ¶ 13.) To the extent that Dr. Bozic did warn Mr. Tucker of a risk of fracture, he explains that this was limited to the risk of fracture of the ceramic component of the device—not fractures in the long neck. (RSS No. 44.) Plaintiffs also assert that the warnings were "undermined" by Defendant's marketing of the Profemur, and that the Safety Alert sent in 2008 was too little, too late (Opp. at 19; RSS Nos. 46–47.)

Dr. Bozic's declaration in response to the summary judgment motion provides first that "had Wright Medical . . . informed [him] of the previous fractures or the increased fracture risk associated with the Profemur long neck in heavier patients, [he] would have selected a different hip system for Mr. Tucker." (Bozic Decl. ¶ 15.) Second, Dr. Bozic has in fact "stopped using the Profemur Modular Hip System in its entirety . . . after the second fracture of [the] long neck in [his] patients, which was Mr. Tucker in 2010." (*Id.* ¶ 16.) However, Dr. Bozic never states that he read the warning prior to the surgery. (*See* RSS No. 52; Bozic Decl. ¶ 13.)[14]

3. Analysis

The critical issue on Plaintiffs' warning claims is the issue of causation. For both claims, a plaintiff is required to prove that the defendant's failure to warn or instruct was a substantial factor in causing the plaintiff's harm. *Rosa*, 675 F. Supp. 2d at 1011–12; CACI 1205 & 1222. "A plaintiff asserting causes of action based on a failure to warn must prove *not only* that no warning was provided or the warning was inadequate, *but also* that the inadequacy or absence of the warning caused the plaintiff's injury." *Motus I*, 196 F. Supp. 2d at 991 (emphasis supplied).

In *Motus I*, the district court considered whether a plaintiff could invoke a rebuttable presumption in California to prove that a failure to warn or inadequate warning was a "substantial

[14] At oral argument, when pointedly asked by the Court whether there was evidence that Dr. Bozic read the warnings, Plaintiffs' counsel stated that he "underst[ood] he read through all the materials," but he did not identify specific evidence in the record supporting this.

factor" in causing harm. 196 F. Supp. 2d at 991. Under such presumption, once plaintiff established that a manufacturer provided inadequate warnings, the burden shifted to defendant to show that an adequate warning would not have affected the doctor's conduct in prescribing the drug. *Id.* The district court concluded that the rebuttable presumption *did not apply*, and thus defendant Pfizer "may prevail in its motion for summary judgment if [plaintiff] has failed to adduce evidence that [the prescribing physician] would have acted differently had Pfizer provided an adequate warning about the risk of suicide associated with the ingestion of [the drug]." *Id.* at 995.

The district court noted that plaintiff may have been able to create a genuine issue of fact if the properly-warned physician could have detected adverse reactions to the drug and reduced the injury, or with evidence that the risk of suicide associated with the drug was so high that it would have affected the physician's (or any reasonable physician's) decision to prescribe the drug to plaintiff. *Id.* at 995. The court also held that:

> Plaintiff has presented *no evidence that Dr. Trostler relied on statements from Pfizer in making his decision to prescribe* Zoloft to Mr. Motus. Dr. Trostler's recollection of how he learned about Zoloft is vague. But he did state unequivocally that in making that decision, he did not rely either on any statements Pfizer representatives made to him nor any written materials they may have provided to him. Indeed, Dr. Trostler stated that he did not read the package insert or PDR entry for Zoloft until after Mr. Motus committed suicide. *It follows that the inclusion of adequate warnings in that information would not have affected his decision*.

Id. at 996 (emphasis supplied).

The Ninth Circuit in *Motus II* affirmed the district court's grant of summary judgment because the prescribing physician testified that "he did not read the warning label that accompanied Zoloft or rely on information provided by Pfizer's detail men [*sic*] before prescribing the drug to Mr. Motus." 358 F.3d at 661. Because he failed to read the published warnings before prescribing the drug, the adequacy of the warnings was *irrelevant to the case's disposition*. *Id.* (claim based on insufficient warnings "cannot survive summary judgment if stronger warnings would not have altered the conduct of the prescribing physician").

As in the *Motus* opinions, despite the fact that it is Plaintiffs' affirmative burden to identify that the inadequate warnings substantially caused the injury, there is no evidence that Dr. Bozic read the warnings provided by Defendant. At best, the Bozic Declaration at paragraph 15 poses a

hypothetical that (i) a stronger warning would have affected his selection of the Profemur and (ii) that he would have necessarily read the stronger warning. But this hypothetical invokes the rebuttable presumption that was rejected in *Motus I*. Even after Defendant's Motion was filed, Plaintiffs fail to sufficiently dispute this issue, nor do they provide any law to support their position. As noted above, inadequacy of the warning and causation are *separate* elements of Plaintiffs' affirmative burden. Where the physician did not read the warnings, adequacy is irrelevant and "it follows that the inclusion of adequate warnings in that information would not have affected his decision." *Motus II*, 358 F.3d at 661; *Motus I*, 196 F. Supp. 2d at 996.

For these reasons, the Court **GRANTS** Defendant's Motion for Summary Judgment on the strict liability and negligent failure to warn claims.

F. Loss of Consortium

On July, 24, 2012, the Court entered an order based on a stipulation that "Mrs. Rebecca Tucker is not making a claim for 'mental pain and suffering' in the above-captioned action and is not pursuing damages for 'mental pain and suffering.'" (Dkt. No. 44.) The parties also stipulated to strike a portion of the complaint, such that paragraph 38 reads as follows: "As a proximate result of said negligent conduct of the defendants, and each of them, plaintiff REBECCA TUCKER has been injured by the loss of her husband's companionship and services, including, the loss of love, companionship, comfort, care, assistance, protection, affection, society, and moral support." (*Id.*)

Defendant contends that Mrs. Tucker's consortium claim fails for three reasons. First, it is derivative of the other claims, and because those claims fail, this one must as well. (Mot. at 20.) Second, Defendant argues that she has no claim because she stipulated that her claim is not based on mental pain and suffering, which is what consortium claims are intended to compensate. (Mot. at 21 (consortium refers to non-economic aspects of marriage relations).) Third, Defendant argues that even if there were no stipulation, she cannot prove her damages without an expert and no retained expert has addressed her damages. (*Id.*) As the record stands, there is no evidence in the record to otherwise calculate the amount of damages. (*Id.*)

Plaintiffs respond that Mrs. Tucker stipulated that she is not seeking "separate damages for mental pain and suffering." (Opp. at 23.) Despite the stipulation, she has suffered damage to her

marital interests with regard to: (i) intimacy and sexual relations; (ii) Mr. Tucker taking out his anger, fear, and/or frustration on her and/or threatening her; and (iii) Mrs. Tucker consequently "feeling bereft of Mr. Tucker's affection and tenderness that she had previously known." (*Id.*) Plaintiffs also assert that no expert is needed to show damages, and that a jury can determine the amount of compensation for her lost marital interests. Plaintiffs do not dispute that Mrs. Tucker's claim is derivative of the products liability claims. (*Id.* at 22.)

The Court agrees with Plaintiffs. In the stipulation, the parties struck a portion of the complaint but left intact Mrs. Tucker's allegations regarding the "loss of her husband's companionship and services, including, the loss of love, companionship, comfort, care, assistance, protection, affection, society, and moral support." (*See* Dkt. No. 44.) The only reasonable conclusion the Court can draw is that these allegations and Mrs. Tucker's claim for damages related thereto remained in the litigation. As such, the Court rejects Defendant's argument that the stipulation itself forecloses this claim.

In addition, Plaintiffs' negligent design claim will proceed to trial. As such, summary judgment on this derivative claim is inappropriate. *Dominguez v. Excel Mfg. Co. Inc.*, C-09-03611 EDL, 2010 WL 4698739, at *16 (N.D. Cal. Nov. 8, 2010) (where negligence claim in products liability case survives summary judgment, so does the loss of consortium claim). The Court further agrees with Plaintiffs that expert testimony is not necessary to determine Mrs. Tucker's damages.

For these reasons, Defendant's Motion for Summary Judgment on Mrs. Tucker's loss of consortium claim is **DENIED**.

IV. CONCLUSION

For the reasons stated above, Defendant's Motion for Summary Judgment is **GRANTED IN PART AND DENIED IN PART**. Specifically, the Court:

- **DISMISSES WITH PREJUDICE** Defendants Wright Medical Group, Inc. and Does 1–100;
- **GRANTS** Defendant's Motion for Summary Judgment as to the first claim for strict liability based on design defect, manufacturing defect, and failure to warn;
- **DENIES** Defendant's Motion for Summary Judgment as to the second claim for

negligence based on a design defect;

- **GRANTS** Defendant's Motion for Summary Judgment as to third claim for negligence based on failure to warn; and
- **DENIES** Defendant's Motion for Summary Judgment as to the fourth claim for loss of consortium.

This Order terminates Dkt. No. 76.

IT IS SO ORDERED.

Dated: March 19, 2013

YVONNE GONZALEZ ROGERS
UNITED STATES DISTRICT COURT JUDGE

United States District Court
Northern District of California