IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF GEORGIA ATLANTA DIVISION

IN RE: WRIGHT MEDICAL TECHNOLOGY INC., CONSERVE HIP IMPLANT PRODUCTS LIABILITY LITIGATION MDL DOCKET NO. 2329

This Document Relates to: ROBYN CHRISTIANSEN 1:13-cv-297-WSD

ROBYN CHRISTIANSEN,

Plaintiff,

1:13-cv-297-WSD

 \mathbf{v}_{ullet}

WRIGHT MEDICAL TECHNOLOGY INCORPORATED and WRIGHT MEDICAL GROUP, INC.,

Defendants.

OPINION AND ORDER

This matter is before the Court on Defendants Wright Medical Technology, Inc.'s ("Wright Medical") and Wright Medical Group, Inc.'s ("WMG") (together, "Defendants") Motion in Limine [171] ("Defendants' Motion") and Plaintiff

Robyn Christiansen's ("Plaintiff") (together with Defendants, the "Parties")

Motion in Limine [172] ("Plaintiff's Motion").

I. BACKGROUND²

On January 29, 2013, Plaintiff filed her Complaint [1]³ and initiated this action against Defendants. On October 6, 2014, Plaintiff filed her First Amended Complaint [10] and, on October 10, 2014, she filed a Second Amended Complaint [11] ("Second Amended Complaint").

Plaintiff alleges that, on April 24, 2006, Dr. Lynn G. Rasmussen replaced Plaintiff's right hip by implanting the Wright Conserve Hip Implant System (the "Conserve Hip Implant System"). (Second Am. Compl. ¶ 13). Plaintiff claims that, on or about October 24, 2012, she experienced severe pain in her right hip and

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Late on Thursday, October 29, 2015, the Parties sent the Court their "Position Statements Regarding Witness/Evidentiary Issues." This "position statement," which the Court construes as a motion in limine submitted after the deadline to do so expired, raises three evidentiary issues that the Parties did not address in the pending Motions in Limine. The Court will consider these three new issues in a separate Order that will be entered promptly.

In the "Introduction" and "Background" sections of its August 31, 2015, Order, [167] the Court set forth the factual and procedural background for this case. (August 31, 2015, Order, at 1-9). These sections are incorporated by reference. The Court here discusses only the background relevant to the pending motions.

Unless otherwise identified as docketed in <u>In re: Wright Medical</u>
<u>Technology, Inc., Conserve Hip Implant Products Liability Litigation,</u>
1:12-md-2329, the Court will cite to documents in <u>Christiansen v. Wright Medical</u>
Technology Inc., 1:13-cv-297 (N.D. Ga. 2013).

groin during exercise. (Id. ¶ 27). Plaintiff scheduled an appointment with Dr. Rasmussen to address the occurrence. (Id.). Dr. Rasmussen diagnosed Plaintiff as having a loose and displaced acetabular cup in her right hip replacement. (Id. ¶ 28). Surgery to revise Plaintiff's April 2006 implant⁴ was performed on October 29, 2012. Plaintiff filed this action based on the failure of the Conserve Hip Implant System that was surgically implanted on April 24, 2006, to replace her right hip. This case is set for trial on November 9, 2015. The claims to be tried are: (1) Strict Product Liability (Design Defect) (Count I); (2) Negligence (Design Default) (Count III); (3) Fraudulent Misrepresentation (Count V); (4) Fraudulent Concealment (Count VI); and (5) Negligent Misrepresentation (Count VII). (Second Am. Compl. ¶¶ 32-109; August 31, 2015, Order, [167] at 122). Plaintiff seeks compensatory damages and punitive damages. (Second Am. Compl. at 42; August 31, 2015, Order, at 122).

The Parties filed Motions in Limine to address various evidentiary issues.⁵
The Court now considers these motions.

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⁴ Revision surgery generally involves the replacement of the implanted hip device with a new implant.

The Parties also filed their Joint Stipulation of Agreed To In Limine Topics [173] (the "Stipulation"), which lists thirty-six (36) categories of evidence the Parties agree that neither side will seek to admit or refer to at trial.

II. DISCUSSION

A. <u>Plaintiff's Motion in Limine</u>

Plaintiff seeks to exclude: (1) references to certain potential effects, including on Defendants, of an award of damages against Defendants; (2) attempts to bolster the purportedly "good corporate character" of Wright Medical; (3) attempts to bolster the unchallenged character of any witness or Wright Medical employee, agent, distributor, or manager; and (4) Plaintiff's legal claims in prior, unrelated, litigation. (Pl.'s Mot. at 2).

1. Potential Extrinsic Effects of an Award of Damages

Plaintiff seeks to exclude any evidence, argument, inference or testimony about the effects, including on Defendants, of an award of damages against Defendants. The effects sought to be excluded regard (1) the availability of implant devices or the cost of such devices, and (2) the economic impact on Defendants or their ability to compete in the marketplace, the negative economic impact on the economy, or layoffs at Defendants' companies that might result. (Pl.'s Mot. at 4). Defendants argue this evidence is directly related to Plaintiff's claim for punitive damages because a punitive damages award could have a chilling effect on the development of new joint replacement devices and treatments

and, if the award is excessive, could affect Defendants' ability to compete in the marketplace. (Defs.' Resp. [177] at 3-5).

a) Availability and Costs of New Joint Replacement Devices

Defendants' relevance argument is similar to the one advanced in their summary judgment motion in which they sought dismissal of Plaintiff's punitive damages claim. In their summary judgment motion, Defendants argued that an award of punitive damage would be against Utah public policy because punitive damages would have a chilling effect on the development of new medical devices. This argument was rejected by the Court. (August 31, 2015, Order, at 119-120).

Under Utah law, punitive damages are allowed only if

compensatory or general damages are awarded and it is established by clear and convincing evidence that the acts or omissions of the tortfeasor are the result of willful and malicious or intentionally fraudulent conduct, or conduct that manifests a knowing and reckless indifference toward, and a disregard of, the rights of others.

Utah Code Ann. § 78B-8-201. The Utah legislature exempted manufacturers of drugs that received Food and Drug Administration ("FDA") premarket approval from punitive damage awards. Utah Code Ann. § 78B-8-203(1). The FDA's pre-approval of certain drugs extended an imprimatur of safety for such medications and to allow them to be subject to punitive damage awards, the legislature reasoned, could suppress drug and medication innovation. The question

here is whether the drug exception to punitive damages in Section 78B-8-203(1) which seeks to avoid chilling of drug innovations is, in this medical device case, relevant to the issue of punitive damages under Rule 401 of the Federal Rules of Evidence.

The Court previously determined that medical devices do not fall within the § 78B-8-203(1) drug exception for punitive damages awards. That is, the Court found that punitive damages are an allowable element of damages in this action if Plaintiff can meet the requirements of Section 78B-8-201 of the Utah Code. Section 78B-8-201 generally requires a plaintiff to show by "clear and convincing evidence" that the defendant's acts or omissions, (i) resulted from willful and malicious, or intentionally fraudulent, conduct, or (ii) conduct that manifests a knowing and reckless indifference toward, and a disregard for, the rights of others. See Utah Code Ann. § 78B-8-201. Defendants seek to present evidence of, and argument about, the impact of punitive damages on device innovations and on Defendants' business for the jury's consideration of a punitive damages award. Rule 401 provides the test for evidence relevancy:

Evidence is relevant if: (a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action

Fed. R. Evid. 401. Only relevant evidence is admissible at trial. Fed. R. Evid. 402.

Applying this test, the Court determines that the evidence Defendants seek to introduce regarding the impact of punitive damages on device innovation does not make any fact regarding whether punitive damages may be awarded more or less probable, nor is it factual information of consequence in deciding the action. See Fed. R. Evid. 401. To allow evidence that an award of punitive damages might stifle or chill innovation in the development of medical devices generally, and hip implant devices specifically, would require a distracting departure in the trial of the core issues in this case to litigate the nebulous issue of whether an award of punitive damages would actually chill innovation and, even if it did, to what extent would innovation be stifled. This would delay the trial of this case and likely waste considerable time. For these reasons this impact evidence, even if marginally relevant, is required to be excluded. See Fed. R. Evid. 403. Evidence and argument regarding the residual impact of an award of punitive damages on device innovation is excluded.

b) Net Worth Evidence

Evidence of Defendants' net wealth is relevant to the jury's consideration of an award of punitive damages. The "purpose of punitive damages is to deter further wrongdoing." E.g., Lawrence v. Intermountain, Inc., 243 P.3d 508, 517 (Utah. Ct. App. 2010). The Utah Supreme Court has noted that "a defendant's

wealth can be either an aggravating or a mitigating factor in determining the size of a punitive damage award, since punitive damages should be tailored to what is necessary to deter the particular defendant, as well as others similarly situated, from repeating the prohibited conduct." Diversified Holdings, L.C. v. Turner, 63 P.3d 686, 694-95 (Utah 2002); see also Wachocki v. Luna, 330 P.3d 717, 724. (Utah Ct. App. 2014) ("court has an obligation to assess the relative wealth of each defendant individually, as the award needed to deter one defendant from future misconduct may differ from that needed to deter another."); Nelson v. Jacobsen, 669 P.2d 1207, 1219 (Utah 1983) ("defendant's net worth and income are always relevant in determining the amount of punitive damages that would be appropriate for punishment."). In short, the impact of an award of punitive damages on Defendants is relevant in determining a punitive damages award and its deterrent effect on Defendants. See Perrin v. Anderson, 784 F.2d 1040, 1048 (10th Cir. 1986) ("The jury must know the impact an award will have on the defendant to properly assess punitive damages."); see also Atencio v. City of Albuquerque, 911 F. Supp. 1433, 1446 (D.N.M. 1995) ("A close look at the deterrent and retributive purposes of punitive damages indicates that one crucial factor that a jury should consider in determining an appropriate amount of punitive damages is the defendant's financial capacity."); Wynn Oil Co. v. Purolator Chemical Corp.,

403 F. Supp. 226 (M.D. Fla. 1974) (the award of punitive damages should only hurt, not bankrupt, a defendant; the amount awarded should substantially punish the defendant but not place it beyond a reasonable potential financial capacity to pay the award).

Defendants are entitled to present evidence of their net wealth and the financial impact a punitive damages award would have on Defendants' business.^{6, 7}

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The Court also concludes that evidence of punitive damages awarded by other juries against other companies does not meet the Rule 401 test for relevance. A defendant's net worth is relevant in considering the punitive damages sought against that particular defendant. The award's purpose is to deter the defendant. The net worth of the defendant on trial is what is relevant to the punitive damages sought. Evidence of the net worth and punitive damage awards against other companies, even if they are manufacturers of hip implant devices, is not relevant to the punitive damages issue in this case and to admit it risks confusion of the jury and a substantial likelihood of prejudice to Defendants. See Fed. R. Evid. 401, 402, 403.

Plaintiff asserts that if Defendants are allowed to present evidence of their net worth and financial circumstances, evidence of Defendants' insurance coverage could become relevant. (Pl.'s Mot. at 5). There is authority to support the contention that insurance coverage for punitive damage awards is relevant and admissible evidence to rebut a defendant's assertion that a punitive damages award would impact its finances. See, e.g., Humana Health Ins. Co. of Florida, Inc. v. Chipps, 802 So.2d 492, 497-98 (Fla. Ct. App. 2001) (holding that trial court correctly admitted evidence of indemnity agreement to rebut defendant's assertions that a large punitive damages award would force the company into financial straits); Wheeler v. Murphy, 452 S.E.2d 416, 424 (W. Va. 1994) ("A defendant's net worth is relevant to the issue of punitive damages, and in this case, where defense counsel offered evidence of Mr. Murphy's meager finances, the plaintiff's rebuttal evidence disclosing the existence and policy limits of Mr. Murphy's liability insurance is not barred by either [West Virginia Rules of Evidence] 401-03 or Rule 411."); see also Wallace v. Poulos, 861 F. Supp. 2d 587, 602

(D. Md. 2012) ("informing the jury of the indemnification agreement makes jurors aware that Defendants' ability to pay is essentially a moot point [and] ensures that jurors have an accurate understanding of the likely deterrence effect of their judgment.").

Plaintiff has not presented any evidence that any policy of insurance under which Defendants are insured covers punitive damages and, even if they did, it is uncertain whether punitive damages, if awarded in this case, would be covered under any particular policy provision. Certain states have forbidden insurers from insuring against punitive damage awards. E.g., Utah Code Ann. § 31A-20-101(4) ("No insurer may insure or attempt to insure against . . . punitive damages."); U.S. Concrete Pipe Co. v. Bould, 437 So.2d 1061, 1064 (Fla. 1983) ("Florida public policy prohibits liability insurance coverage for punitive damages assessed against a person because of his own wrongful conduct. The Florida policy of allowing punitive damages to punish and deter those guilty of aggravated misconduct would be frustrated if such damages were covered by liability insurance."); In re September 11th Litigation, 494 F. Supp. 2d 232 (S.D.N.Y. 2007) (under New York law, insurer cannot be compelled to indemnify an insured for punitive damages under any circumstances). Certain other states, including Delaware, where Defendants are incorporated, do not prohibit insurers from insuring against punitive damage awards. E.g., Whalen v. On-Deck, Inc., 514 A.2d 1072 (Del. 1986) (Delaware public policy does not prohibit issuance of insurance contract covering punitive damages); Federal Ins. Co. v. Nat'l Distributing Co., Inc., 417 S.E.2d 671 (Ga. Ct. App. 1992) (insurance coverage for punitive damages does not violate Georgia public policy) (citing Greenwood Cemetery v. Travelers Indem. Co., 232 S.E.2d 910 (Ga. 1977)); Lazenby v. Universal Underwriters Ins. Co., 383 S.W.2d 1 (Tenn. 1964) (insured who had an accident while driving intoxicated was protected by liability policy against claims for compensatory and punitive damages; coverage for punitive damages was not against Tennessee public policy); Virginia Code § 38.2-227 ("It is not against the public policy of the Commonwealth for any person to purchase insurance providing coverage for punitive damages arising out of the death or injury of an person as the result of negligence, including willful and wanton negligence, but excluding intentional acts.").

The Court is advised there is a considerable dispute and litigation over the extent of Defendants' insurance coverage of the issues presented in all of the MDL cases. For this further reason, evidence and litigation of insurance coverage issues

2. Defendants' Good Corporate Character

Plaintiff moves to exclude any evidence, argument, inference or testimony that Defendants are "good corporate citizens." (Pl.'s Mot. at 4-10). Defendants argue that evidence of Defendants' good deeds and character is relevant to rebut Plaintiff's punitive damage claim. (Defs.' Resp. at 5-11).

"Evidence of a person's character or character trait [generally] is not admissible to prove that on a particular occasion the person acted in accordance with the character or trait." Fed. R. Evid. 404(a). Defendants seek to admit evidence of their "actions, achievements and distinctions in commercial and community-based settings" and their "corporate mission statement and how [they] uphold[] that mission statement in designing and manufacturing medical devices that improve the quality of people's lives " (Defs.' Resp. at 6-8). The evidence, Defendants claims, is offered "to refute allegations of willful, malicious, or reckless conduct." Id. Although good works, charity, community involvement, and other good deed evidence is not evidence that is generally admissible at trial, (see Fed. R. Evid., 404(a), 401, 402), it is conceivable, if not likely, that Defendants' mission statement and the manner in which it guided them in the manufacture of hip implant devices is probative of Defendants' intent for the

in this case would prolong the trial and confuse the jury and thus insurance coverage evidence is precluded. <u>See</u> Fed. R. Evid. 403.

purpose of the jury's consideration of a punitive damages award. The Court reserves for trial its ruling on the admissibility of this genre of Defendants' corporate character evidence.

3. <u>Character of Defendants' Witnesses or Employees</u>

Plaintiff seeks to exclude any evidence, comments, or inferences designed to bolster the unchallenged character or traits of Defendants' witnesses, employees or agents. (Pl.'s Mot. at 11-13). Plaintiff did not discuss the evidence Plaintiff seeks to exclude, and in the absence of a description, the Court denies Plaintiff's Motion to exclude this ambiguous evidence.

4. <u>Plaintiff's Prior Legal Claims</u>

Plaintiff seeks to exclude any evidence or references to her prior legal claims, asserting that such evidence is irrelevant and prejudicial. (Pl.'s Mot. at 13-18). Plaintiff filed two workers' compensation claims for compensation for injuries she sustained to her knee while working as a ski instructor.⁸ (Pl.'s Reply [180] at 11). Plaintiff seeks only to exclude evidence of, or references to, the fact that her knee injuries resulted in two workers' compensation claims. (<u>Id.</u>). She

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Plaintiff also filed a claim against Merck arising from a reaction she had to a vaccine. (Pl.'s Mot. at 13). Defendants do not intend to offer evidence of Plaintiff's vaccination claim at trial for any purpose. (Defs.' Resp. at 11 n.3). The Court grants Plaintiff's Motion to exclude any evidence of, or reference to, Plaintiff's prior legal claim against Merck.

does agree the underlying medical evidence is admissible. (<u>Id.</u>). Defendants claim that Plaintiff, in filing a workers' compensation claim for a prior knee injury, misrepresented that the injury was suffered at the ski resort where she worked, entitling her to worker's compensation coverage. (Defs.' Resp. at 13-15).

The Parties agree that evidence of Plaintiff's medical history is relevant, including the knee injuries she allegedly suffered. These injuries are relevant to the pain she alleged she was, and is, experiencing as a result of the hip implant that is at issue in this case. That Plaintiff's medical history records contain references to the fact she sought compensation through a workers' compensation claims process is not a sufficient basis to exclude relevant evidence on damages.⁹

Defendants next argue that Plaintiff's 2011 workers' compensation claim is relevant to her credibility. Defendants claim that, in 2011, Plaintiff was employed

That Plaintiff filed claims for workers' compensation coverage for injuries she alleged she suffered does not have the "tendency to make [Plaintiff's claims] more or less probable than [they] would be without the evidence." See
Fed. R. Evid. 401(a); see also, e.g., Batiste-Davis v. Lincare, Inc., 526 F.3d 377, 380 (8th Cir. 2008). The disclosure that these injury claims were processed as workers' compensation claims also does not appear to be consequential in this litigation. To address that the filing of the workers' compensation claims is not relevant to the jury's consideration of damages, the Court will give the following limiting instruction to address any claimed prejudice, including that the jury may consider Plaintiff to be litigious, by the appearance of workers' compensation claim references in medical records or during testimony: "Reference has been made that Plaintiff filed workers' compensation claims for injuries she sustained. The references to a workers' compensation claim should not be considered by you in evaluating the existence or scope of Plaintiff's claimed injuries."

by the Alta Ski Area. (Defs.' Resp. at 14). The 2011 knee injury she suffered and for which she filed a workers' compensation claim were, she told her doctor, sustained at the Snowbird Ski Area. (Id.). Plaintiff was not employed at Snowbird. (Id.). That Plaintiff misstated where she suffered this injury, Defendants contend, is evidence relevant to Plaintiff's credibility, and is admissible under Rule 608 of the Federal Rules of Evidence. (Id. at 14-15).

Plaintiff contends the reference to Snowbird Ski Area as the place of injury is an obvious error in the physician's record. (Pl.'s Reply at 12). Dr. Charles L. Beck, Jr. saw Plaintiff on April 12, 2012. The notes of this visit, which were dictated to Dr. Beck's assistant, Robert Townsley, stated that Plaintiff had fallen "at Snowbird." (Id. at Ex. 2 [180.2]). The report notes later that Plaintiff's injury was a workers' compensation injury. (Id.). Dr. Beck prepared a "Physician's Initial Report of Work Injury" that states Plaintiff's employer was "Alta Ski School" and that the injury occurred after Plaintiff lost her balance while working. (Id. at Ex. 3 [180.3]). Dr. Beck, on May 5, 2012, sent the Worker's Compensation Fund of Utah a letter in which he stated that Plaintiff's knee injury occurred "while working as a ski instructor at Snowbird Ski Resort." (Id. at Ex. 5 [180.5]).

There are two references in which Dr. Beck recorded Plaintiff's injury as having been sustained at a location other than the ski area where she worked. The

Court concludes the jury is the proper body to decide the extent to which, if any, this evidence supports that Plaintiff misrepresented the place of her injury to obtain the benefits of workers' compensation coverage. Reference to these records may be used to cross-examine witnesses. If Defendants seek to admit into evidence one or more of the records, the Court will consider their admissibility when offered at trial.

B. Defendants' Motion in Limine

Defendants, in their Motion, seek to exclude: (1) evidence of other lawsuits, claims, product failures, or product complaints involving Wright Medical; (2) evidence of Defendants' conduct or knowledge that post-dates Plaintiff's implantation surgery; (3) evidence concerning a department of justice subpoena and a deferred prosecution agreement involving Wright Medical; (4) evidence concerning other manufacturers' hip products and product decisions; (5) evidence of marketing materials not actually reviewed by Dr. Rasmussen or Plaintiff; (6) evidence of a civil lawsuit filed by Ms. Irina Timmerman against Wright Medical; (7) evidence of "Pull Through Dollars" resulting from revision surgeries or the business implications of revision surgeries; (8) evidence of personnel decisions or employee turnover; and (9) any argument or testimony that Defendants had a duty to make their products safe and effective.

1. <u>Evidence of Other Lawsuits, Claims, Product Failures, or</u> Product Complaints¹⁰ Involving Wright Medical

Defendants seek to exclude testimony concerning other complaints or claims involving Conserve products, including evidence of "(a) other litigation (such as matters pending in MDL 2329) involving CONSERVE® devices, (b) registry data, (c) revision or failure rates, (d) complaints or criticism from other surgeon users, and (e) reports of revision surgeries other than the Plaintiff's revision in this case." (Defs.' Mot. at 3). Defendants argue this evidence is unreliable and irrelevant, would lead to mini-trials to determine whether each complaint or data point is relevant, is unduly prejudicial and confusing, and constitutes inadmissible hearsay. (Id.). Plaintiff agrees that the above categories of evidence that post-date Plaintiff's April 24, 2006, implantation surgery, should be excluded, but contends that evidence of complaints, litigation, and failures before Plaintiff's implantation surgery is admissible. (Id. at 3, n.2; Pl.'s Resp. at 4). Plaintiff agrees that registry data and revision and failure rates should be excluded. (Pl.'s Resp. at 4 n.2).¹¹

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The term "complaints" is defined in the Parties' Stipulation to mean complaints from surgeons to or about Wright Medical and its products, the complaint process at Wright Medical, failure rates and registry data. (Stipulation ¶ 26).

In light of Plaintiff's agreement that "registry data and revision and failure rates should be excluded" Defendants' Motion to exclude registry data and revision and failure rates is granted.

a) <u>Evidence of Product Complaints Involving Wright</u> Medical

Plaintiff states she may introduce evidence that, prior to Plaintiff's April 24, 2006, implantation surgery, surgeons expressed concerns regarding metal ions or complained about the presence of metallosis as a result of surgical implantations of the Conserve Hip Implant System. (Pl.'s Resp. at 7). Plaintiff argues this evidence is relevant to whether Defendants were on notice that, before the device used in Plaintiff's 2006 surgery was sold, the Conserve Hip Implant System caused metallosis and whether representations to Dr. Rasmussen about the Conserve Hip Implant System were made fraudulently, recklessly, grossly negligently, or negligently. (Id.).

Plaintiff's fraudulent misrepresentation claim requires Plaintiff to prove:

(1) a representation; (2) concerning a presently existing material fact;

(3) which was false; (4) which the representor either (a) knew to be false, or (b) made recklessly, knowing that he had insufficient knowledge upon which to base such representation; (5) for the purpose of inducing the other party to act upon it; (6) that the other party, acting reasonably and in ignorance of its falsity; (7) did in fact rely upon it; (8) and was thereby induced to act; (9) to his injury and damage.

Giusti v. Sterling Wentworth Corp., 201 P.3d 966, 977 n.38 (Utah 2009) (citing Dugan v. Jones, 615 P.2d 1239, 1246 (Utah 1980)) (emphasis omitted). Plaintiff's negligent misrepresentation claim has elements which "are similar to those of fraud

except that negligent misrepresentation 'does not require the intentional mental state necessary to establish fraud." See Shah v. Intermountain Healthcare, Inc., 314 P.3d 1079, 1085 (Utah Ct. App. 2013) (quoting Price—Orem Inv.

Co. v. Rollins, Brown & Gunnell, Inc., 713 P.2d 55, 59 n.2 (Utah 1986)). Plaintiff also asserts a claim for fraudulent concealment. This claim requires a plaintiff to prove that (1) the defendant had a legal duty to communicate information, (2) the defendant knew of the information he failed to disclose, and (3) the nondisclosed information was material. Anderson v. Kriser, 266 P.3d 819, 823 (Utah 2011).

Plaintiff here claims that Defendants knew that the Conserve Hip Implant
System presented a risk of metallosis and thus had an attendant risk of implant
device failure because Defendants knew that metallosis was reported in cases
involving the Conserve Hip Implant System before Plaintiff's surgery in 2006.
What Defendants knew about the occurrences or evidence of metallosis before the
sale of Plaintiff's implant device is relevant to a fact of consequence in Plaintiff's
state common-law claims in this action. That is, if Defendants knew about
surgeons' metallosis observations regarding the Conserve Hip Implant System,
including from Defendants' own consulting surgeons, this knowledge is relevant to
whether Defendants had notice of an alleged risk inherent in the Conserve Hip
Implant System. See Fed. R. Evid. 401, 402.

Federal courts "routinely permit introduction of substantially similar acts or occurrences in product liability actions to demonstrate the existence of a defect, to prove notice, or to refute testimony given by defense witnesses." C.A. Associates v. Dow Chem. Co., 918 F.2d 1485, 1489 (10th Cir. 1990). "In a product liability action, the occurrence of similar accidents or failures involving the same product holds great relevance, since evidence of such failures tends to make the existence of a defect more probable than it would be without the evidence." Id.; see also Weeks v. Remington Arms Co., 733 F.2d 1485, 1491 (11th Cir. 1984) ("Evidence of similar accidents might be relevant to the defendant's notice, magnitude of the danger involved, the defendant's ability to correct a known defect, the lack of safety for intended uses, strength of a product, the standard of care, and causation.") (quoting Ramos v. Liberty Mut. Ins. Co., 615 F.2d 334, 338-39 (5th Cir. 1980)). "Because of the potential impact that evidence of similar accidents can have on juries, [the Eleventh Circuit] has placed two additional limitations on the use of such evidence: (1) the prior failure(s) must have occurred under conditions substantially similar to those existing during the failure in question, and (2) the prior failure(s) must have occurred at a time that is not too remote from the time of the failure in question." Weeks, 733 F.2d at 1491. "Substantially similar" conditions do not need to be identical. Wheeler v. John

<u>Deere Co.</u>, 862 F.2d 1404, 1408 (10th Cir. 1988). The similarity requirement appears to be less restrictive when the similar failures are submitted to prove the existence of notice. <u>See Worsham v. A.H. Robins Co.</u>, 734 F.2d 676, 689 (11th Cir. 1984).

Plaintiff represents that her other evidence will focus on "metal ions and metallosis-related failures and what Wright Medical knew or had notice of from such complaints." (Pl.'s Resp. at 9). Plaintiff acknowledges that the scope of this "substantially similar occurrence" evidence as it relates to the issue of notice is limited. The Court also agrees that evidence of metal ions and metallosis and its use by the jury is limited. The substantially similar occurrence evidence that is admissible must meet the following criteria: (1) it must be evidence of metallosis that was observed or verified through some scientifically accepted testing procedure before Plaintiff's 2006 implant surgery; (2) the evidence or test must be shown to have been reported to Defendants; and (3) the observed or verified metallosis must have resulted from the implant of a Conserve Implant Hip System, the same device which was implanted in Plaintiff in 2006. Because this evidence is admitted for a limited purpose, and to address any unfair prejudice or confusion that might accompany its introduction, the Court will give the following limiting instruction: "Evidence has been admitted regarding metal ions and metallosis that

may have been present in patients who had the implant of a Conserve Hip Replacement System prior to April 24, 2006. This evidence is offered for a limited purpose. Specifically, it may be considered to evaluate whether Defendants knew of reports of metal ions and metallosis before Defendants marketed and sold the Conserve Hip Implant System that was implanted in Plaintiff on April 24, 2006. This evidence may not be considered by you in considering whether metal ions or metallosis was present in Plaintiff as a result of Plaintiff's implant."¹²

Defendants also contend that complaints of metal ions and metallosis in other implants are inadmissible hearsay. To the extent that such evidence is offered to prove notice, and is not offered for the truth of the matter asserted in the complaint, it is not hearsay. <u>See</u> Fed. R. Evid. 801(c)(2) ("Hearsay' means a

Defendants contend also admitting metal ions and metallosis-related failure complaints would be unduly prejudicial because it would suggest that there are problems with the Conserve Hip Implant Device based solely on the existence of the complaints. (Defs.' Mot. at 9-10). A court may exclude relevant evidence only if its probative value is substantially outweighed by a danger of unfair prejudice. Fed. R. Evid. 403. The probative value of the complaint evidence as it relates to notice is significant, and the Court cannot conclude that Defendants are unfairly prejudiced by allowing the jury to know that Defendants had received complaints from surgeons regarding metal ions and metallosis issues with the Conserve Hip Implant Device before Plaintiff's April 24, 2006, implantation surgery. To the extent that Defendants contend that the admission of complaint evidence would require a "mini-trial" on each complaint, the Court requires that the evidence must meet the requirements set out in page 20 of this Order, including that the complaints relate only to the Conserve Hip Implant System, and not a different metal-on-metal device.

statement that: (1) the declarant does not make while testifying at the current trial or hearing; and (2) a party offers in evidence to prove the truth of the matter asserted in the statement."). Statements from Defendants' employees or agents, including their consulting surgeons, "on a matter within the scope of that relationship and while it existed" are also not hearsay. See Fed. R. Evid. 801(d)(2)(D). Evidence of surgeon reports of metal ions or metallosis in other implants of the same device as the one implanted in Plaintiff that were discovered in Defendants' records are, if certain conditions are met, not excludable hearsay. Fed. R. Evid. 803(6).

b) Evidence of Product Failures

Plaintiff seeks to introduce evidence from Dr. Rasmussen¹³ of other "Conserve Device metallosis failures and revision surgeries" he observed or performed (i) to prove the Conserve Hip Implant System was defective, and (ii) to prove the claimed product defect in the Conserve Hip Implant System resulted in the failure of Plaintiff's device resulting in the revision surgery he performed on Plaintiff in 2012. (Pl.'s Resp. at 10). Plaintiff seeks to elicit testimony from Dr. Rasmussen that he has "revised 43 of 328 patients that he implanted with

It is unclear if Plaintiff seeks to offer this testimony through other witnesses or by other means. If so, the analysis here applies equally to other evidence sources, subject to the application of Rule 403 of the Federal Rules of Evidence.

Conserve Hip Devices . . . due to metallosis issues and cup loosening, and that he is monitoring another 41 patients for metallosis due to their reported pain symptoms." (Id. at 10-11). Dr. Rasmussen also will testify that his observations during Plaintiff's revision surgery were consistent with his observations from prior "revisions of failed metallosis hips." (Id. at 11). Dr. Rasmussen will opine that Plaintiff's need for revision surgery was a result of the Conserve Hip Implant System, based on his experience revision other patience with metallosis issues from that device. (Id.).

In its August 31, 2015, Order on the summary judgment motions, the Court determined that Dr. Rasmussen's testimony about his observations of metallosis during Plaintiff's revision surgery is relevant and reliable. It may be offered at trial. The question here is to what extent he may testify about other surgeries and his observations about them. Dr. Rasmussen's testimony about his experience with metallosis and revision surgeries necessarily must be substantially related to the facts of this case. Any testimony regarding prior revision surgeries and signs of metallosis thus must involve the Conserve Hip Implant System, and not a different metal-on-metal device, and it must involve patients who required revision surgery due to metallosis. These criteria must be met for the testimony to be offered.

Testimony about cases he is "monitoring" are not relevant to the metallosis and

metal ion issues in this case because it is unknown whether any design defect is present in this monitored devices and it is unknown whether the devices will require revision as a result of metallosis. For these reasons, testimony about monitoring of cases may not be admitted.

c) Evidence of Other Lawsuits

Defendants seek to exclude evidence of other lawsuits on the grounds that evidence of other litigation is not relevant and would be unduly prejudicial. Plaintiff argues that evidence of other lawsuits is relevant to explore the bias of expert witnesses, and to punitive damages. (Id. at 13-16).¹⁴ Plaintiff asserts that she seeks to cross-examine Defendants' witnesses on the compensation they have been paid by Defendants or their counsel for work they performed in connection with the MDL.¹⁵

Plaintiff is entitled to cross-examine Defendants' expert witnesses concerning fees earned in this and other cases, to the extent the examination is limited to testimony regarding fees paid for expert work relating to the Conserve Hip Implant System. See Collins v. Wayne Corp., 621 F.2d 777, 783 (5th Cir.

Plaintiff does not appear to argue that evidence of other lawsuits should be admitted to establish notice.

Plaintiff appears to argue that this fee information is admissible under Rule 403 of the Federal Rules of Evidence because a presentation of just the dollar amounts without explaining the volume of cases handled by testifying experts would be confusing and misleading to the jury.

1980) ("A showing of a pattern of compensation in past cases raises an inference of the possibility that the witness has slanted his testimony in those cases so he would be hired to testify in future cases."). The fact of the MDL and the number of other cases related to the Conserve Hip Implant System is not, in and of itself, relevant to the bias of Defendants' witnesses. What is relevant is that Defendants' witnesses received significant compensation, over time, for their expert work regarding the Conserve Hip Implant System. See United States v. Dean, 221 F. App'x 849, 852 (11th Cir. 2007) ("The major function' of Rule 403 is limited to excluding matter of scant or cumulative probative force, dragged in by the heels for the sake of its prejudicial effect.") (internal quotations omitted). ¹⁶

Plaintiff contends that evidence of the other lawsuits against Defendants relating to the Conserve Hip Implant System generally is admissible on the issue of punitive damages. Plaintiff argues these other lawsuits show Defendants imposed

Plaintiff seeks to cross-examine Dr. Harlan Amstutz, an expert listed as a witness by Defendants. Plaintiff proffers that Dr. Amstutz will opine that Dr. Rasmussen's surgical technique was the cause of the failure of Plaintiff's Conserve Hip Implant System. Plaintiff asserts numerous and varied alleged facts that would tend to show that Dr. Amstutz is biased, including that Dr. Amstutz is a named defendant in almost 700 cases filed in California relating to Conserve devises. (Pl.'s Resp. at 14-15). Plaintiff is entitled to cross-examine Dr. Amstutz on proper matters to show potential bias. That he is named as a defendant in other cases on which liability has not been established is not relevant to his credibility and would mislead and confuse the jury, and would waste time. See Fed. R. Evid. 403. The Court will rule at trial on any questions to which Defendants object during the cross-examination.

repeated adverse health impacts on others and that their conduct was reprehensible. (Pl.'s Resp. at 16).

"[A] plaintiff may show harm to others in order to demonstrate reprehensibility [but] a jury may not . . . use a punitive damages verdict to punish a defendant directly on account of harms it is alleged to have visited on nonparties." Westgate Resorts, Ltd. v. Consumer Prot. Grp., LLC, 285 P.3d 1219, 1222 (Utah 2012). This "harm to others" evidence may be relevant to a punitive damages determination because evidence of "actual harm to nonparties can help to show that the conduct that harmed the plaintiff also posed a substantial risk of harm to the general public, and so was particularly reprehensible." Id. at 1222.

Plaintiff has not presented the Court with any evidence of "actual harm to nonparties." The mere filing of other lawsuits does not demonstrate that Defendants actually harmed other people, or otherwise demonstrate Defendants' reprehensibility. It is now uncertain whether Defendants are liable at all, and, thus, uncertain whether they harmed any nonparties.¹⁷ The Court rejects Plaintiff's

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The Court agrees that to establish any particular lawsuit as relevant in this case to show harm to a nonparty, would require a mini-trial on each of the underlying claims in each of these other lawsuits to determine if they were similar to the claims in this case and whether the other claimant was harmed by Defendants' conduct. Even if the evidence was relevant, it would result in confusion of the issues, mislead the jury, and cause undue delay. For these reasons it is excluded under Federal Rule of Evidence 403. See Fed. R. Evid. 403.

theory of admissibility of other litigation on the issue of punitive damages.

Evidence of other lawsuits filed against Defendants related to the Conserve Hip

Implant System is not admissible and Defendants' Motion to exclude this evidence is granted.

2. Evidence of Defendants' Conduct or Knowledge that Post-Dates Plaintiff's Implantation Surgery

Defendants seek to exclude evidence of studies, testing, or research

Defendants conducted after Plaintiff's April 24, 2006, surgery in which the

Conserve Hip Implant System was implanted in Plaintiff. Defendants contend that
this evidence should be excluded because: (1) it is not relevant to Plaintiff's

claims; (2) it is an inadmissible subsequent remedial measure; and (3) the danger
of prejudice and jury confusion outweighs any probative value of such evidence.

(Defs.' Mot. at 12-16).

Utah law provides that, in

any action for damages for personal injury, death, or property damage allegedly caused by a defect in a product, a product may not be considered to have a defect or to be in a defective condition, unless at the time the product was sold by the manufacturer or other initial seller, there was a defect or defective condition in the product which made the product unreasonably dangerous to the user or consumer.

Utah Code Ann. § 78B-6-703(1) (emphasis added); see also Gudmundson v. Del Ozone, 232 P.3d 1059, 1071 (Utah 2010) ("a product is defective if it is

'unreasonably dangerous' at the time of sale by the manufacturer.").

Plaintiff, to establish her claim for design defect, must have admitted, evidence that there was a defect in the Conserve Hip Implant System that was present at the time it was sold by Defendants that made the product unreasonably dangerous. See id. Product defect is generally discovered only after it is sold and causes injury. The existence of a defect, however, is measured against the standard and state-of-the-art that existed at the time the product was manufactured and sold. See Sexton By & Through Sexton v. Bell Helmets, Inc., 926 F.2d 331, 337 (4th Cir. 1991) ("product can only be defective if it is imperfect when measured against a standard existing at the time of sale or against reasonable consumer expectations held at the time of sale."). Evidence of Defendants' knowledge acquired after Plaintiff's April 24, 2006, implantation surgery is not relevant to the issue of whether the Conserve Hip Implant System was defective or unreasonably dangerous at the time it was sold by Defendants. See Fed. R. Evid. 401(a); Gudmundson, 232 P.3d at 1071.¹⁸ Similarly, Defendants' post-April 24, 2006,

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An example of the evidence Plaintiff seeks to present is the "A-Class metal ion study" conducted by Defendants after the implantation surgery. Plaintiff argues this study "confirmed Wright Medical's prior understanding that a reduction in metal wear does not produce a correlating reduction in metal-ion levels." (Pl.'s Resp. at 17). Plaintiff contends the study confirmed that Defendants' representation to Dr. Rasmussen that the Conserve Hip Implant System's "A-Class metal acted more like a ceramic and that it resulted in a lower

conduct is not relevant to whether the Conserve Hip Implant System was defective or unreasonably dangerous at the time it was sold by Defendants.¹⁹

Plaintiff next argues that Defendants' withholding of the results of its studies from publication is relevant to Plaintiff's punitive damages claim because it shows Defendants' "degree of reprehensibility." (Pl.'s Resp. at 19).

Under Utah law, punitive damages are allowed only if

compensatory or general damages are awarded and it is established by clear and convincing evidence that the acts or omissions of the tortfeasor are the result of willful and malicious or intentionally fraudulent conduct, or conduct that manifests a knowing and reckless indifference toward, and a disregard of, the rights of others.

Utah Code Ann. § 78B-8-201. "To prove that a tortfeasor's actions were knowing and reckless, a party must prove that the tortfeasor knew of a substantial risk and proceeded to act or failed to act while consciously ignoring that risk."

volume of metal debris and fewer metal ions" was wrong. (<u>Id.</u>). Even if the study shows what Plaintiff contends, it does not establish that, on or before Plaintiff's April 24, 2006, implantation surgery, the Conserve Hip Implant System was defective or unreasonably dangerous. Plaintiff is entitled to present evidence of "Wright Medical's prior understanding that a reduction in metal wear does not produce a correlating reduction in metal-ion levels" only if this knowledge was

Rule 407 of the Federal Rules of Evidence provides: "[w]hen measures are taken that would have made an earlier injury or harm less likely to occur, evidence of the subsequent measures is not admissible to prove . . . negligence [or] a defect in a product or its design" Fed. R. Evid. 407. Some or all of the conduct Plaintiff seeks to admit, even if relevant to Plaintiff's design defect claim, may be required to be excluded by Rule 407.

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known by Defendants on or before April 24, 2006.

-V Daniels v. Gamma W. Brachytherapy, LLC, 221 P.3d 256, 269 (Utah 2009). To prove that Defendants' acts or omissions in designing the Conserve Hip Implant System were "the result of willful and malicious or intentionally fraudulent conduct" or that Defendants' conduct manifested "a knowing and reckless indifference toward, and a disregard of, the rights of others," Plaintiff must prove Defendants' conduct and knowledge at the time the Conserve Hip Implant System was marketed, sold to, and implanted in Plaintiff.²⁰ Defendants' alleged refusal to publish studies and research that post-date Plaintiff's implantation surgery does not have a tendency to make it more or less probable that the Conserve Hip Implant System was defective at the time it was marketed, sold, and implanted in Plaintiff, or that Defendants fraudulently or negligently misrepresented, or fraudulently concealed, information they had at the time they marketed and sold the Conserve Hip Implant System that was implanted in Plaintiff in April 2006. See Fed. R. Evid. 401(a); Utah Code Ann. § 78B-6-703(1); Giusti, 201 P.3d at 977 n. 38; Shah, 314 P.3d at 1085; Anderson, 266 P.3d at 823. Defendants' refusal to publish their

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To the extent that Defendants subsequently learned more information about the alleged risk of metallosis from the Conserve Hip Implant System, and continued to sell it, another plaintiff that purchased and was implanted by the Conserve Hip Implant System after this knowledge was acquired may be entitled to present this evidence to a jury. Plaintiff here must establish her design defect claim and right to punitive damages based on Defendants' knowledge and conduct on or before her April 24, 2006, implantation surgery.

studies and research that post-date Plaintiff's implantation surgery also does not have a tendency to make it more or less probable that Defendants' actions in manufacturing, marketing, and selling the Conserve Hip Implant System that was implanted in Plaintiff in April 2006 were "willful and malicious" or "knowing and reckless" to support a punitive damages award. See Fed. R. Evid. 401(a); Utah Code Ann. § 78B-8-201; Daniels, 221 P.3d at 269.

Evidence of studies, testing, or research Defendants conducted after Plaintiff's April 24, 2006, surgery is not admissible and Defendants' Motion to exclude this evidence is granted.

3. Evidence Concerning a Department of Justice Subpoena and a Deferred Prosecution Agreement

Defendants next seek to exclude evidence concerning a Department of

Justice subpoena and a deferred prosecution agreement ("DPA") involving Wright

Medical and its product offerings. (Defs.' Mot. at 17-20). The subpoena was

issued in 2012, and it requested documents related to Wright Medical's Profemur

modular neck product line. (Id. at 18). The DPA was entered into with the U.S.

Attorney's Office for the District of New Jersey, and concerned issues regarding

compensation Wright Medical paid to surgeons. (Id.). Defendants argue the

subpoena and the DPA are not relevant to the issues in this case including because

they do not relate to the Conserve Hip Implant System, and because evidence of the subpoena and DPA would be unduly prejudicial to Defendants.

Plaintiff agrees that evidence of the subpoena and the DPA are "highly prejudicial." (Pl.'s Resp. at 32). Plaintiff does not intend to offer the subpoena or DPA in her case-in-chief, but might offer the evidence if Defendants have admitted evidence of Defendants' "good corporate character." (Id.). If Plaintiff contends Defendants have introduced evidence of their good corporate character, and this causes Plaintiff to seek to introduce evidence of the subpoena and the DPA, Plaintiff should make this request outside the presence of the jury.

4. Evidence Concerning Other Manufacturers' Hip Products and Product Decisions

Defendants seek to exclude any evidence of "complaints, lawsuits, failure data, or recalls relating to products sold by other manufacturers of metal-on-metal hip implants" to prove that Defendants' Conserve Hip Implant System was defective. (Defs.' Mot. at 20-22). Defendants argue that evidence of other manufacturers' revision rates or failure reports are not relevant and the introduction of this evidence in this case would be highly prejudicial, and require Defendants to defend the performance and marketing decisions of other manufacturers and their devices. (Id. at 20-21). Evidence of other metal-on-metal product recalls would, Defendants submit, improperly suggest that the jury infer that the Conserve Hip

Implant System is defective because other manufacturers have recalled metal-on-metal products they designed, manufactured and sold. (<u>Id.</u> at 21-22).

Plaintiff argues that, because Defendants have asserted a state-of-the-art defense, state-of-the-art evidence is admissible. (Pl.'s Resp. at 21-22). Plaintiff also contends that she is entitled to present evidence of reasonable alternative designs to the Conserve Hip Replacement System to support her design defect claim. (Id. at 22). Finally, Plaintiff argues that Defendants' continued marketing of the Defendants' Conserve Hip Implant System, when other manufacturers' metal-on-metal products were recalled, is probative of Defendants' "reprehensibility," supporting Plaintiff's punitive damages claim. (Id.).

In product liability actions, "the plaintiff must show that the product was dangerous beyond the expectation of the ordinary customer. State-of-the-art evidence helps to determine the expectation of the ordinary consumer."

Robinson v. Audi Nsu Auto Union Aktiengesellschaft, 739 F.2d 1481, 1486

(10th Cir. 1984). "[A]Ithough compliance with the custom or practice of an industry is not an absolute defense to a strict liability action, the state-of-the-art employed by the industry is relevant in determining the feasibility of other alternatives." Id. By its nature, a state-of-the-art defense is based on the state of the art that existed at the time the product was manufactured. E.g., Rexrode v. Am.

Laundry Press Co., 674 F.2d 826, 832 (10th Cir. 1982) ("Manufacturers are not to be held strictly liable for failure to design safety features, if the technology to do so is unavailable at the time the product is made."). Defendants assert that Plaintiff seeks to introduce evidence of other manufacturers' product failures or recalls, all of which occurred after the Conserve Hip Implant System at issue was manufactured. (Defs.' Reply at 9).

Evidence of the state-of-the-art of hip implants as it existed after the Conserve Hip Implant System in this case was designed, marketed, manufactured and sold, is not relevant to Plaintiff's claims or Defendants' state-of-the-art defense. Indeed, Plaintiff does not, in her response to Defendants' Motion, identify the competitors, product lines, recalls, or failures about which she seeks to introduce evidence. To the extent Plaintiff seeks to introduce evidence she shall, out of the presence of the jury, specifically state the evidence she seeks to introduce and offer the specific legal basis, including supporting authority, she contends supports the admission of this other product recall evidence.

5. Evidence of Marketing Materials Not Actually Reviewed by Dr. Rasmussen or Plaintiff

Defendants seek to exclude evidence of marketing materials not actually reviewed by Dr. Rasmussen or Plaintiff on the ground that this evidence is not relevant. (Defs.' Mot. at 23-25). Defendants argue that unread marketing

materials did not impact Dr. Rasmussen's or Plaintiff's decision to select the Conserve Hip Implant System for Plaintiff's implant surgery in April 2006. (<u>Id.</u> at 23). Defendants do not seek to exclude marketing materials or representations that were allegedly made to, or read by, Dr. Rasmussen, or on which he relied, in recommending the Conserve Hip Implant System to Plaintiff. (Defs.' Reply at 10).

The Court, in its August 31, 2015, Order, noted that Defendants' representatives told Dr. Rasmussen that the Conserve Hip Implant System was ideal for active patients, and that a "cobalt chromium cup should last longer than a traditional Metal/Poly liner, and that there were no known issues associated with cobalt and chromium ions," and that the use of A-Class metal would result in "less metal wear, fewer cobalt and chromium ions, and thus a lower risk of any metallosis problems." (August 31, 2015, Order, at 113-114). Defendants do not contend that these marketing representations, or any others that Dr. Rasmussen was told or read, are not admissible. ²¹ (See Defs.' Reply at 10).

Plaintiff argues that marketing materials not read by Dr. Rasmussen are admissible to demonstrate Defendants' consistent marketing message that the Conserve Hip Implant System was ideal for active patients, was biocompatible,

Plaintiff conceded that she did not read or rely on any marketing materials, and instead relied on what Dr. Rasmussen told her about the Conserve Hip Implant System. (Pl.'s Resp. at 26 n.21).

and resulted in low levels of metal ions. (Pl.'s Resp. at 26-28).²² Marketing materials, however, not actually reviewed by Dr. Rasmussen or Plaintiff cannot be used to establish reliance by Dr. Rasmussen or Plaintiff. See, e.g., Okuda v. Pfizer Inc., No. 1:04-CV-00080, 2012 WL 2685053, at *1 (D. Utah July 6, 2012) (granting summary judgment on fraud claim because there was no evidence that the plaintiff's prescribing physician read or relied on any statements from the defendant); Okuda v. Wyeth, No. 1:04-CV-80 DN, 2012 WL 12337860, at *1 (D. Utah July 24, 2012) (granting motion in limine to exclude marketing evidence on which neither plaintiff or her physicians relied). Plaintiff is not entitled to present evidence or testimony concerning marketing materials that were not reviewed or relied upon by Dr. Rasmussen. If Plaintiff contends at trial that the evidence presented by Defendants provides a basis to admit marketing material upon which Dr. Rasmussen and Plaintiff did not rely, Plaintiff may, out of the presence of the jury, state the basis for seeking the admission of unrelied-upon marketing materials.²³

Plaintiff does not argue that the marketing materials are admissible for any other purpose, including for the jury's consideration of a punitive damages award.

For example, if the evidence develops that Defendants knew before Plaintiff's April 24, 2006, surgery of the risk of metallosis in its Conserve Hip Implant System, then marketing materials regarding the product's use for patients with an active lifestyle may be relevant to the issue of punitive damages.

6. Evidence of a Civil Lawsuit Filed by Irina Timmerman Against Wright Medical

Ms. Irina Timmerman, Wright Medical's Senior Director of Clinical Affairs and Post-Market Surveillance, filed a lawsuit against Wright Medical in 2005, concerning allegations of workplace harassment. Defendants seek to exclude evidence of this lawsuit on the ground that it is irrelevant. Plaintiff seeks to admit the existence of this prior lawsuit to impeach Ms. Timmerman's credibility, contending that Ms. Timmerman lied about the existence of this lawsuit under oath during her deposition. (Pl.'s Resp. at 28-30).

During her November 19, 2012, deposition, Ms. Timmerman had the following exchange with Plaintiff's counsel:

Q. Do you recall whether or not you have sat for more than one deposition involving the Profemur –

A. I don't recall.

Q. -- line of product?

A. I'm sorry. I don't recall that.

Q. Do you recall whether you've ever sat for a deposition that did not involve the Profemur line of products?

A. I have. Yes.

Q. And what did that involve?

A. Prior depositions had to do with the intellectual property.

Q. And did that involve your lawsuit against Wright Medical with regards to intellectual property?

MR. KRAMER: Objection to the form.

A. I don't quite understand.

BY MR. POPE:

Q. Have you ever been involved in a lawsuit as a party?

A. Myself, personally?

O. Yes.

A. No.

Q. With regards to the lawsuit that you remember involving intellectual property, do you remember who the parties were to that lawsuit?

A. I believe it was Stryker.

(WHEREUPON, EXHIBIT NO. 2 WAS MARKED . . .)

BY MR. POPE:

Q. Let me show you what I have marked as Exhibit Number 2 to your deposition.

(BRIEF PAUSE)

BY MR. POPE:

Q. And Ms. Timmerman, in 2005, do you remember filing a lawsuit against Wright Medical Technology, Incorporated?

A. Yes, I have.

Q. And what did that lawsuit entail?

MR. KRAMER: Objection to the form.

BY MR. POPE:

Q. What were your claims?

A. My claim was that I was harassed by my then supervisor.

Q. Has that been resolved?

A. Yes.

(Defs.' Reply, Ex. A [182.1], Tr. of Nov. 19, 2012, Dep. of I. Timmerman ("Timmerman Deposition") at 26:15-28:11).

Plaintiff contends that Ms. Timmerman's initial answer of "no" to Plaintiff's counsel's question about whether she had ever been in a lawsuit as a party shows that she "previously lied under oath." (Pl.'s Resp. at 29). The Court disagrees. In the deposition, Plaintiff's counsel asked Ms. Timmerman about prior lawsuits against Wright Medical that concerned intellectual property, and depositions she gave in relation to intellectual property cases. (Timmerman Dep. at 26:15-27:2).

Plaintiff's counsel then asked if these prior depositions "involve[d] your lawsuit against Wright Medical with regards to intellectual property." (Id. at 27:3-5). It is undisputed that Ms. Timmerman's lawsuit against Wright Medical concerned workplace harassment, not intellectual property. Ms. Timmerman stated that she did not understand, and Plaintiff's counsel appears to have changed the topic to ask if she had ever personally been in a lawsuit as a party, to which Ms. Timmerman responded that she had not. (Id. at 27:7-13). Plaintiff's counsel then asked about the lawsuit involving intellectual property, before going back to refresh Ms. Timmerman's recollection regarding the 2005 lawsuit she filed against Wright Medical, which she testified she did file. (Id. at 27:14-28:3).

A review of the Timmerman Deposition transcript supports that

Ms. Timmerman was confused about the question, since it immediately followed questions about a separate lawsuit against Wright Medical. Characterizing this testimony as a lie when Plaintiff's counsel switched topics, and when

Ms. Timmerman confirmed that she had been a party to a lawsuit against Wright Medical once the nature of the question was made clear, is questionable at best. A plaintiff may be entitled to impeach a witness by "catching the witness in a lie."

<u>United States v. Cerno</u>, 529 F.3d 926, 944 (10th Cir. 2008). To be admissible impeachment evidence, however, the evidence must be "probative of truthfulness"

or untruthfulness." <u>Id.</u>; <u>see also</u> Fed. R. Evid. 608(b). Ms. Timmerman's testimony does not support that she testified falsely, and the subject of her employment lawsuit is not even reasonably related to Ms. Timmerman's credibility or any other issue in this case.²⁴ Defendants' Motion to exclude this testimony evidence of the harassment lawsuit is granted.

7. Evidence of "Pull Through Dollars" Resulting from Revision Surgeries or the Business Implication of Revision Surgeries

Defendants seek to exclude evidence of the business implications for Defendants of revision surgeries involving their hip replacement products and the profit they earn from "pull through dollars." (Defs.' Mot. at 26-27). Defendants contend that the concept of "pull through dollars" is an internal business reference for "capture of all underlying contingencies of an implantation or revision surgery, including the possibility that some devices will be revised and a second surgery may occur." (Id. at 27). Defendants argue that there is no evidence that they sought to improperly profit from revision surgeries, and any argument from Plaintiff in that regard would be speculative, confusing to the jury, and would "entice prejudice and anti-business animus." (Id.).

Plaintiff does not argue that Ms. Timmerman's 2005 lawsuit is relevant to the claims or defenses in this action for any purpose other than impeachment.

Plaintiff contends that Defendants developed a "new business plan case" for their Conserve products, and, in that document, Defendants recognized that "pull through dollars" could be obtained under Defendants' projection that 25% of the devices would need to be revised and that they have a captive audience. (Pl.'s Resp. at 32-33). Plaintiff argues that Defendants' decision to develop the Conserve product lines was made, at least in part, on their ability to profit from revisions and their captive audience, and that this evidence is, thus, relevant. (Id. at 33).

The document in question, under a section entitled "PULL THROUGH DOLLARS," states:

While direct pull through dollars are not available on this device, it is possible to have a captured "audience" when it comes to the revision of the CONSERVE PLUS due to [its] superfinished metal to metal articulation. Based on 500 procedures, it is estimated that 25% will be revised. One of the components will probably still be viable. Experience tells us that the shell will be the viable component. A surgeon's reluctance to revise a well fixed cup will dictate that a Wright Medical Product will need to be used to articulate with the superfinish in the cup. We are estimating that this should bring in approximately 25% of those revisions or 25 procedures.

(Pl.'s Resp. at Ex. 16 [175.16] at 6).

Plaintiff has not presented any evidence, and Defendants' discussion of pull through dollars does not establish, that Defendants designed, or failed to redesign, a product for the purpose of permitting revision surgeries and the sales of further devices or component parts. The Court notes further that the discussion in Exhibit 16 concerns the Conserve Plus Total Resurfacing Hip System product line, which the Court, in its August 31, 2015, Order, found to be a distinct device from the Conserve Hip Implant System. (August 31, 2015, Order at 74, 96). Plaintiff's "pull through dollars" "evidence" is not relevant to facts of consequence to this litigation and thus is not admissible. See Fed. R. Evid. 401. The Court finds further that Plaintiff's "pull through dollars" litigation theory and the evidence on which it is based is at least speculative, but would certainly confuse or mislead the jury and would unduly prejudice Defendants. See Fed. R. Evid. 403. Defendants' Motion to exclude evidence to support Plaintiff's "pull through dollars" claim is granted. See Fed. R. Evid. 401, 403.

8. Evidence of Personnel Decisions or Employee Turnover

Defendants next seek to exclude evidence or references to turnover,
termination, or replacement of management or employees at Wright Medical.

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The Conserve Plus Total Resurfacing Hip System is used for hip resurfacing, which does not involve the removal of the femoral head. Instead, the head is trimmed and capped with a metal covering, while a metal cup, as in total hip arthroplasty, is placed in the acetabulum. The Conserve Hip Implant System, by contrast, is used for total hip arthroplasty, the surgical replacement of the hip joint with an artificial prosthesis.

This evidence would also require additional evidence about the difference between the likely users of the two devices and the marketing strategy for each, and would likely be confusing to the jury. <u>See</u> Fed. R. Evid. 403.

(Defs.' Mot. at 27). Defendants contend that such personnel decisions are internal business decisions that are not relevant to Plaintiff's claims in this case, and that the only reason Plaintiff could offer this evidence is to suggest that the turnover in personnel "was related to misconduct or wrongful actions by those employees or that departures were somehow related to hip system's development or sales." (Id. at 27-28).

Plaintiff does not intend to offer evidence of employee and management turnover in her case-in-chief (Pl.'s Resp. at 32), and Defendants' Motion to exclude this evidence is granted.²⁷

9. <u>Argument or Testimony that Defendants had a Duty to Make</u> Their Product Safe and Effective

Defendants contend that Plaintiff plans to argue at trial that Defendants had a duty to ensure the Conserve Hip Implant System was "safe and effective" and that they should be held liable if they failed to meet the "safe and effective" standard. (Defs.' Mot. at 28). Defendants seek to exclude this argument, asserting

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Plaintiff asserts that in conjunction with the extension of the DPA for a second year, multiple Wright Medical officers were terminated or resigned, resulting in lawsuits by its President and CEO, CTO, General Counsel, Senior Vice President and Vice President of Clinical and Regulatory Affairs, among others. (Pl.'s Resp. at 31). If Plaintiff contends evidence is offered by Defendants that makes this turnover evidence admissible, she may raise this issue with the Court outside of the presence of the jury.

that it is inconsistent with Utah law because there is no duty to ensure a product is safe and effective. (<u>Id.</u>). The Court agrees.

The Court generally is liberal in allowing argument by counsel. The Court, however, observes that argument offered must be fair and consistent with the claims and defenses being tried, and the evidence admitted at trial. The proof requirements in this case are based on Utah law and are straightforward. Plaintiff is required to prove that Defendants' conduct fell below the standard set forth in any claim that is allowed to be decided by the jury. To argue some different standard of conduct would be improper. Defendants' Motion to exclude argument or testimony that Defendants had a duty to make the Conserve Hip Implant System "safe and effective" is granted.

III. CONCLUSION

For the foregoing reasons,

IT IS HEREBY ORDERED that Plaintiff Robyn Christiansen's Motion in Limine [172] is GRANTED IN PART and DENIED IN PART. Plaintiff's Motion is GRANTED, and Defendants are precluded from presenting evidence:

(1) that an award of punitive damages will have a chilling effect on the development of new joint replacement products, and (2) that Plaintiff filed a lawsuit against Merck. Plaintiff's Motion is DENIED regarding evidence of:

(1) Defendants' net wealth and the financial impact a punitive damages award would have on their business; (2) the good character of Defendants' employees and witnesses; and (3) Plaintiff's prior workers' compensation claims.²⁸ The Court **RESERVES** for trial its ruling whether evidence of Defendants' good corporate character is admissible.

IT IS FURTHER ORDERED Wright Medical Technology, Inc.'s and Wright Medical Group, Inc.'s Motion in Limine [171] is **GRANTED IN PART** and **DENIED IN PART**. Defendants' Motion is **GRANTED**, and Plaintiff is precluded from presenting evidence: (1) of registry data and revision and failure rates for the Conserve Hip Implant System; (2) of the patients Dr. Rasmussen is "monitoring" for signs of metallosis; (3) of other lawsuits concerning the Conserve Hip Implant System; (4) of Defendants' conduct or knowledge that post-dates Plaintiff's implantation surgery and studies, testing, and research Defendants conducted after Plaintiff's implantation surgery; (5) concerning other manufacturers' hip implant products and product decisions; (6) concerning marketing materials that were not reviewed or relied upon by Dr. Rasmussen; (7) of Ms. Timmerman's 2005 lawsuit against Wright Medical; (8) of the business implications for Defendants of revision surgeries and the profit it earns from pull

Subject to the limiting instruction described in Section II(A)(4) of this Order.

through dollars; (9) of Defendants' personnel decisions and employee turnover;

and (10) concerning a duty to make a product "safe and effective." Defendants'

Motion is **DENIED** regarding evidence of: (1) complaints regarding metal ions

and metallosis in patients implanted with the Conserve Hip Implant System that

Defendants were aware of before Plaintiff's implantation surgery, ²⁹ and

(2) Dr. Rasmussen's testimony regarding his observations during Plaintiff's

revision surgery and his experience with metallosis and revision surgeries. The

Court **RESERVES** for trial its ruling on whether evidence of the subpoena and the

deferred prosecution agreement is admissible.

SO ORDERED this 30th day of October, 2015.

WILLIAM S. DUFFEY, JR.

UNITED STATES DISTRICT JUDGE

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Subject to the limiting instruction described in Section II(B)(1)(a) of this Order.