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,** **v.** **WRIGHT MEDICAL TECHNOLOGY INCORPORATED and WRIGHT MEDICAL GROUP, INC.,** **Defendants.**	**1:13-cv-297-WSD**

OPINION AND ORDER

I. INTRODUCTION

On February 27, 2012, the United States Judicial Panel on Multidistrict Litigation (the "Panel") ordered the centralization of five actions pending in five districts, involving alleged defects in Wright Medical Technology Inc.'s Conserve line of hip implant products. (In re: Wright Medical Technology, Inc., Conserve Hip Implant Products Liability Litigation, 1:12-md-2329 ("MDL"), [1] (the

"February 27, 2012, MDL Order")). Most of the plaintiffs' claims focus on the alleged propensity of the metal-on-metal design of the Conserve products "to generate high levels of metal debris, causing metallosis in the surrounding tissue [and to] fail early (including loosening of the acetabular cup)." (Id. at 1).

On May 23, 2013, the Court ordered that any plaintiff whose case is subject to transfer to the MDL was allowed to file their claims directly in the MDL. (MDL [86]). The Court approved an Abbreviated Short Form Claim ("Short Form Complaint") to facilitate the filing of cases.[1] On January 30, 2013, Plaintiff Robyn Christiansen ("Plaintiff")[2] filed her Short Form Complaint in the MDL. (MDL [404]).

The parties identified ten (10) cases they proposed to submit to the Bellwether trial process (the "Bellwether Nominees."). (MDL [1037] at 1). Plaintiff's case was selected as the first Bellwether case to be tried.

[1] There are approximately 440 pending cases that were transferred to, or filed in, this MDL.

[2] Mr. Gene Christiansen, Plaintiff's husband, was also a named plaintiff in this action. Mr. Christiansen has since dismissed his claim for loss of consortium.

II. BACKGROUND OF PLAINTIFF'S CASE

A. Plaintiff's Allegations

Plaintiff's Short Form Complaint [1][3] names Defendants Wright Medical Technology, Inc. ("Wright Medical") and Wright Medical Group, Inc. ("WMG") (together, "Defendants") as defendants in this action. 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, she was implanted with the Wright Conserve Hip Implant System (the "Conserve Hip Implant System" is sometimes referred to as the "Conserve implant"). (Second Am. Compl. ¶ 13).[4] A hip joint can be replaced by an artificial replacement system implanted to replace the body's natural joint. The typical replacement joint

> consists of four separate components: (1) a femoral stem, (2) a femoral head, (3) an acetabular shell, and (4) a liner. To replace a patient's hip joint, a surgeon hollows out a patient's femur bone and implants a femoral stem. Then a metal ball is fixed on top of the femoral stem to become the new femoral head. The surgeon also reams out the acetabulum and fits an artificial acetabular shell into the

[3] Unless otherwise identified as docketed in the MDL Case, the Court will cite to documents in Christiansen v. Wright Medical Technology Inc., 1:13-cv-297 (N.D. Ga. 2013).

[4] The hip joint is the connection of the femur to the pelvis, and is made up of a femoral head ("a ball-like structure at the top of the femur") rotating within the acetabulum ("a cup-like structure at the bottom of the pelvis") that is protected and lubricated by cartilage and other body fluids. (Second Am. Compl. ¶ 14).

> bone. Then . . . a liner made of polyethylene would be inserted into a titanium acetabular shell, and the new femoral head (made of metal or ceramic) would rotate inside the shell, creating a metal-on-polyethylene or ceramic-on-polyethylene articulation.

(Id. ¶ 15).

Plaintiff asserts that the Conserve Hip Implant System "omits the polyethylene liner and instead puts the Cobalt-Chromium metal Conserve femoral ball directly in contact with a Cobalt-Chromium metal Conserve acetabular cup." (Id. ¶ 16). The "movement of this artificial joint [Plaintiff claims] produces metal-on-metal wear debris, and the amount of toxic metal debris produced increases as a patient's activity increases." (Id.).

Dr. Lynn G. Rasmussen ("Rasmussen") has provided Plaintiff with orthopedic medical treatment since 1995. (Id. ¶¶ 20-21). In 1995, Rasmussen completed a total hip revision surgery on Plaintiff's left hip, utilizing a ceramic femoral ball and a polyethylene liner in a metal acetabular shell. (Id. ¶ 21).

Rasmussen later told Plaintiff she met the criteria for a total hip replacement of her right hip, and recommended replacement with the Conserve Hip Implant System. (Id. ¶¶ 22-23). Plaintiff alleges that Rasmussen made this recommendation based on information he received from Defendants, specifically: (1) that the Conserve implant was a good option for active patients, such as Plaintiff; (2) that the Conserve implant "should [last] longer than a hip replacement

utilizing a polyethylene liner because the cobalt-chromium cup was touted to last longer than a polyethylene liner;" and (3) "that there were no known issues with Cobalt and Chromium ions." (Id. ¶ 23).

Based on Rasmussen's recommendation and the information provided by Defendants, Plaintiff elected a total hip replacement of her right hip using the Conserve Hip Implant System. (Id. ¶ 24). On April 24, 2006, "Dr. Rasmussen implanted the following Conserve [implant] components: a Wright Conserve Plus Cup, a Wright ProFemur RAZ Stem, a Wright ProFemur Neck, and a Conserve Total A-Class head, into [Plaintiff's] right hip . . . ." (Id. ¶ 25).

Plaintiff claims that, on or about October 24, 2012, she was doing yoga "when she felt and heard a crunching sound and then felt immediate, severe pain in her right hip and groin." (Id. ¶ 27). Plaintiff alleges the pain prohibited her from ambulating without assistance, and she called Dr. Rasmussen's office. (Id.). Rasmussen saw Plaintiff on October 25, 2012. (Id. ¶ 28).

Rasmussen diagnosed Plaintiff as having a loose and displaced acetabular cup in her right hip replacement, which required revision surgery.[5] (Id.). The surgery was performed on October 29, 2012. (Id. ¶ 29). During the surgery, Rasmussen noted signs of a "metalosis [sic] reaction of her hip, with an

[5] Revision surgery generally involves the replacement of the implanted hip device with a new implant.

inflammatory synovium" and he "removed the displaced acetabular component [and] soft tissue that had been damaged by the metal debris." (Id.).

Plaintiff "endured a painful recovery from her right [hip] revision surgery and continues to suffer from injuries of a permanent and lasting nature and discomfort as a result of the failed Conserve Hip Implant System[,] takes ibuprofen on a daily basis, [and although] she has been able to return to many of her activities, she can no longer run." (Id. ¶ 30). Plaintiff alleges that she "requires continuous medical monitoring and treatment as a direct and proximate cause of her failed Conserve Hip Implant System." (Id. ¶ 31).

Plaintiff asserts that the design of the Conserve Hip Implant System was defective and dangerous because it omits a liner separating the cobalt/chromium acetabular cup from the cobalt/chromium femoral head, resulting in the creation of metal-on-metal wear debris. (Id. ¶ 16). She claims that the "Conserve Thin Shell, marketed as the Conserve Plus Cup," which was used in her 2006 implant, "was not cleared for marketing until 2012." (Id. ¶ 17). Prior to 2012, Plaintiff claims this component was sold to the public pursuant to an "internal Wright letter to file" that Defendants "knew was inappropriate and in violation of FDA requirements." (Id.).

Plaintiff asserts claims for: (1) Strict Product Liability (Design Defect) (Count I); (2) Strict Product Liability (Failure to Warn) (Count II); (3) Negligence (Design Default and Failure to Warn)(Count III); (4) Fraudulent Misrepresentation (Count V); (5) Fraudulent Concealment (Count VI); and (6) Negligent Misrepresentation (Count VII). (Id. ¶¶ 32-109).[6] Plaintiff seeks compensatory damages, punitive damages, and prejudgment interest. (Id. at 42).

B. Pending Motions[7]

1. Daubert Motions

On January 15, 2015, Defendants filed their: (1) Motion to Exclude the Expert Testimony of Lance A. Waller, Ph.D. [49] ("Waller Motion"); (2) Motion to Exclude the Expert Testimony of Jay M. Vincelli, MSc, and John D. Jarrell, Ph.D., PE [50] ("Vincelli Motion"); (3) Motion to Exclude the Expert Testimony of Reed Ayers, Ph.D. [51] ("Ayers Motion"); and (4) Motion To Exclude

[6] By an agreement between Plaintiff and Defendants (the "Parties"), Plaintiff voluntarily dismissed her claims for (1) Breach of Implied Warranties (Count IV) and (2) Violation of the Utah Consumer Sales Practices Act (Count VIII), and Gene Christiansen abandoned his claim for Loss of Consortium (Count IX). The caption of the case was amended to reflect that Mr. Christiansen does not assert claims in this action.

[7] The Parties filed motions for leave to file their submissions under seal. [18, 19, 54, 56, 91, 93, 99, 120, 124, 131, 141, 142, 160, 161] (the "Motions to Seal")). The Motions to Seal are granted to allow redaction of specific confidential or proprietary information from the pleadings filed.

Testimony Relating to Metallosis [52] ("Metallosis Motion")[8] (together, the "Daubert Motions").[9]

2. Motions for Summary Judgment

On January 9, 2015, Plaintiff filed her Motion for Partial Summary Judgment [20] ("Plaintiff's MSJ"). Plaintiff argues that Defendants are, as a matter of law, foreclosed from arguing that the Medical Device Amendment of 1976 preempts Plaintiff's design defect claims. Plaintiff also argues that Defendants provided false and misleading information to Rasmussen and, for that reason, the learned intermediary defense does not apply. Also on January 9, 2015, Defendants filed their Motion for Summary Judgment [24].

On March 31, 2015, the Court held a teleconference to discuss the pending motions. The Court noted that Plaintiff's MSJ generally raised and advanced arguments in anticipation of claims and arguments Plaintiff expected would be raised in Defendants' summary judgment motion. To facilitate the efficient consideration of the motions, particularly the preemption and learned intermediary

[8] Defendants filed 23 exhibits in support of their Metallosis Motion. [53].

[9] On February 3, 2015, Plaintiff filed her Responses in Opposition to Defendants' Waller Motion [94] ("Waller Response"), Vincelli Motion [95] ("Vincelli Response"), Ayers Motion [96] ("Ayers Response"), and Metallosis Motion [97] ("Metallosis Response"). On February 10, 2014, Defendants filed their Replies in Support of Defendants Waller Motion [115], Vincelli Motion [113], Ayers Motion [112], and Metallosis Motion [114] ("Metallosis Reply").

defenses, the Parties and the Court agreed that the Parties would submit substitute summary judgment briefs in which Plaintiff would raise her preemption and learned intermediary arguments in her response to Defendants' summary judgment motion.

On April 7, 2015, Defendants refiled their Motion for Summary Judgment [140] ("Defendants' MSJ"), and, on April 23, 2015, Plaintiff filed her Response in Opposition to Defendants' MSJ [143].[10] The filing of Defendants' motion for summary judgment and Plaintiff's response addressing all of the arguments raised by Defendants in their summary judgment motion succinctly presented the Parties' arguments and helped the Court to evaluate each party's position.

On January 9, 2015, Defendant WMG filed its separate Motion for Summary Judgment [38] ("WMG's MSJ") on grounds applicable only to WMG.[11]

The Court first considers the Daubert Motions.

III. DAUBERT MOTIONS

A. Legal Standard

The admissibility of expert opinions is governed by Rules 702 and 703 of

[10] On April 23, 2015, Plaintiff also filed her "Combined Statements of Additional Material Facts Submitted in Opposition to Defendants' Motion for Summary Judgment and Undisputed Material Facts in Support of Her Cross-Motion For Partial Summary Judgment" [144] ("Plaintiff's CAF").

[11] On February 17, 2015, Plaintiff filed her Motion to Strike the Declaration of Deborah Daurer Submitted in Support of WMG's MSJ [121] ("Motion to Strike").

the Federal Rules of Evidence.

1. Rule 702

Rule 702 of the Federal Rules of Evidence addresses the sufficiency and reliability of an expert's opinion. Rule 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. The proponent of expert testimony must establish by a preponderance of the evidence that the Rule 702 requirements have been satisfied. United States v. Frazier, 387 F.3d 1244, 1260 (11th Cir. 2004).

The criteria for evaluating the admissibility of expert opinion evidence under Rule 702 are stated by the Supreme Court in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), and have been summarized as follows:

> Expert testimony may be admitted into evidence if: (1) the expert is qualified to testify competently regarding the matters he intends to address; (2) the methodology by which the expert reaches his conclusions is sufficiently reliable as determined by the sort of inquiry mandated in Daubert; and (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue.

City of Tuscaloosa v. Harcros Chems., Inc., 158 F.3d 548, 562–63 (11th Cir. 1998)

(footnote omitted) (citing Fed. R. Evid. 702; Daubert, 509 U.S. at 589). Daubert sets several factors for use in assessing whether expert testimony is admissible. They include (1) whether a theory or technique applied by the expert can be or has been tested, (2) whether the theory has been subjected to peer review and publication, (3) in the case of a particular scientific technique, the Court should consider the known or potential rate of error, (4) and whether the theory or technique has gained general acceptance in the relevant community. Daubert, 509 U.S. at 593-94. The Rule 702 inquiry is ultimately a flexible one. Id. at 594.

Daubert focused on the admissibility of scientific testimony. Six years later, in Kumho Tire Co. v. Carmichael, 526 U.S. 137 (1999), the Supreme Court extended Daubert's methodology to experts in other fields. The Supreme Court held that the specific factors mentioned in Daubert may be used to assess non-scientific expert testimony, and a trial court retains discretion to decide if non-scientific expert testimony is sufficiently reliable and relevant to be admissible. Kumho Tire, 526 U.S. at 141. To determine admissibility, the trial court must

> make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field . . . . [T]he trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable. That is to

> say, a trial court should consider the specific factors identified in Daubert where they are reasonable measures of the reliability of expert testimony.

Id. at 152.

The Court's gatekeeping role under Rule 702 "is not intended to supplant the adversary system or the role of the jury: 'vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.'" United States v. Alabama Power Co., 730 F.3d 1278, 1282 (11th Cir. 2013) (quoting Allison v. McGhan Med. Corp., 184 F.3d 1300, 1311-12 (11th Cir. 1999)). But the Court must first decide if an expert's opinion is admissible.

2. Rule 703

The basis for an expert's opinion--that is, the type of facts or data an expert may rely upon in reaching their opinion--is evaluated under Rule 703 of the Federal Rules of Evidence. Rule 703 provides:

> An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed. If experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject, they need not be admissible for the opinion to be admitted. But if the facts or data would otherwise be inadmissible, the proponent of the opinion may disclose them to the jury only if their probative value in helping the jury evaluate the opinion substantially outweighs their prejudicial effect.

Fed. R. Evid. 703. Experts, thus, are entitled to rely on facts or data in the case that they (1) personally have observed, or (2) of which they have been made aware. See id.

"When an expert relies on inadmissible information, Rule 703 requires the trial court to determine whether that information is of a type reasonably relied on by other experts in the field. If so, the expert can rely, under Rule 703, on the information in reaching an opinion." Fed. R. Evid. 702, Advisory Committee's Notes (2000 Amendments); see also Broussard v. Maples, 535 F. App'x 825, 828 (11th Cir. 2013) (Rule 703 of the Federal Rules of Evidence "allows an expert to base his opinion on facts or data that would otherwise be inadmissible, such as hearsay, if other 'experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion.'") (quoting Fed. R. Evid. 703); Greenwood Utilities Comm'n v. Mississippi Power Co., 751 F.2d 1484, 1495 (5th Cir. 1985) ("[W]hen an expert's opinion is based on facts not admissible in evidence the court should make a threshold factual inquiry to determine whether the data providing the basis for the opinion is of a type reasonably relied on by experts in that field to form such opinions.").

The "case law under F.R.E. 703 is not particularly enlightening on the subject of standards to be employed in assessing an expert's reliance [on

inadmissible evidence]." Zenith Radio Corp. v. Matsushita Elec. Indus. Co., 505 F. Supp. 1313, 1326 (E.D. Pa. 1980). The Third Circuit, setting the bottom line for considering whether reliance on inadmissible evidence is reasonable under Rule 703, opined that if "the data underlying the expert's opinion are so unreliable that no reasonable expert could base an opinion on them, the opinion resting on that data must be excluded." In re TMI Litig., 193 F.3d 613, 697 (3d Cir. 1999), amended, 199 F.3d 158 (3d Cir. 2000). One district court has stated, "[t]o serve as the basis of the expert's opinion, evidence need not meet any specific standard of reliability--or even be admissible on its own--so long as 'experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject . . . .'" Burton v. Riverboat Inn Corp., No. 4:12-CV-40-WGH-RLY, 2013 WL 6153231, at *8 (S.D. Ind. Nov. 20, 2013) (quoting Fed. R. Evid. 703).

The facts and data upon which an expert may rely in reaching an expert opinion includes the opinions and findings of other experts, if experts in their respective field would reasonably rely on other expert's opinions and findings. See United States v. Winston, 372 F. App'x 17, 20 (11th Cir. 2010) (allowing an expert witness's testimony that was based in part on an opinion of a non-testifying expert, noting that "an expert witness may base his testimony on inadmissible information so long as such information is 'regularly relied upon by experts in his field.'")

(quoting United States v. Steed, 548 F.3d 961, 975 (11th Cir. 2008)); see also Tamraz v. Lincoln Elec. Co., 620 F.3d 665, 675 (6th Cir. 2010); United States v. Day, 524 F.3d 1361, 1371 (D.C. Cir. 2008); Eberli v. Cirrus Design Corp., 615 F. Supp. 2d 1357, 1364 (S.D. Fla. 2009) ("an expert's testimony may be formulated by the use of the facts, data and conclusions of other experts") (quoting Ohio Environmental Development Ltd. Partnership v. Envirotest Systems Corp., 478 F. Supp. 2d 963, 976 (N.D. Ohio 2007)); Malletier v. Dooney & Bourke, Inc., 525 F. Supp. 2d 558, 664 (S.D.N.Y. 2007).

The Court applies these admissibility standards under Rules 702 and 703 to address the Daubert Motions filed in this action.

B. Motion To Exclude Testimony Relating to Metallosis

1. Metallosis Motion

Metallosis involves a build-up of metal debris in the soft tissues of the body. Plaintiff contends she suffered from metallosis as a result of the abrasion of components of the Conserve Hip Implant System which were implanted to replace her right hip. (See Second Am. Compl. ¶¶ 1, 16, 30).

Defendants move the Court to exclude all expert testimony that "argues, contends, or concludes that metallosis was present in Plaintiff . . . and that such metallosis caused the failure of her Wright hip implant . . . ." (Metallosis Motion

at 1). Defendants move specifically to exclude the testimony, opinions, and expert reports of Plaintiff's experts Dr. Elizabeth Laposata, Dr. Brent Morgan, Dr. John Jarrell, Dr. John Waldrop, Dr. Suzanne Parisian, Dr. Joel Bach, and Dr. Reed Ayers. (Id.). Defendants argue:

> In very basic terms, the theory of Plaintiff['s] experts is that metal particles and ions caused a reaction in the tissues and bone surrounding Plaintiff's acetabular cup, which resulted in bone fixation of the cup essentially dissolving ("resorption" or "osteolysis"), which in turn caused the cup to loosen and the device construct to fail. The problem is there is no sufficient observable evidence to support this theory.

(Id.). Defendants note:

> No tissue or bone samples were taken at the time of Plaintiff's revision surgery, no microscopic evaluation of tissue cells was undertaken, and no pathology tests, histology slides, photographs, blood ion concentration levels, or other observable data exist. There is no evidence of necrosis, bony resorption or dark, stained tissue. There is no evidence of pseduotumors or lesions. All that Plaintiff['s] experts have to rely upon for their opinions is the operative report of Dr. Lynn Rasmussen, in which he states, in conclusory terms, that he observed "signs" of a "metalosis [sic] reaction." Due to a dearth of objective data, Plaintiff's experts are forced to speculate on what Dr. Rasmussen's comments meant, and make improper assumptions about the facts (such as the presence and levels of metallosis). The experts' opinions and conclusions based on such speculation [are] unreliable and should be excluded.

(Id. at 2). Defendants argue that, in relying on Rasmussen's clinical observations, Plaintiff's experts failed to apply the rigorous methodology required under Daubert in reaching their conclusions. (Id.). They claim that the experts' opinions "focus

on a purported causal link between metallosis and Plaintiff's implant failure, but fail to identify or account for facts that contradict their opinion, as well as possible alternate causes and explanations of the injury." (Id.). Plaintiff's arguments and contentions regarding metallosis, Defendants assert, are based almost entirely on speculation that metallosis was present and are not based on objective supporting evidence, and thus the opinions should be excluded. (Id. at 2-3).

Defendants do not challenge the qualifications of Plaintiff's metallosis experts and they do not contend that the expert testimony will not assist the trier of fact. Defendants also do not challenge Rasmussen's credibility, and they do not suggest that "Dr. Rasmussen did not truly observe 'signs' of a metallosis 'reaction,' inflammation, or cloudy synovial fluid." (Metallosis Reply at 6). Defendants contend that even if "Dr. Rasmussen's observations are true, they do not provide sufficient foundation for Plaintiff's [other] experts to form a reliable opinion" regarding the presence of metallosis in Plaintiff and its causal relationship to the failure of her hip implant. (Id.).

The question central to the motion to exclude the testimony of Dr. Elizabeth Laposata, Dr. Brent Morgan, Dr. John Jarrell, Dr. Reed Ayers, Dr. Joel Bach, Dr. Suzanne Parisian, and Dr. John Waldrop is whether they may rely on the clinical observations and opinions of Rasmussen that there were "signs of a metalosis [sic]

reaction of her hip with an inflammatory synovium" and that the acetabulum was exposed and that it was "cleaned of the soft tissue debris from the metalosis [sic] reaction." (Operative Report at 1-2). Defendants argue that the metallosis experts' opinions all rely on Rasmussen's observations of metallosis and, based upon it, assume that metallosis was present in stating their various opinions to support or extrapolate on Rasmussen's metallosis findings and the relationship of metallosis to the failure of the Conserve implant. The Court first addresses whether the metallosis experts may rely, under Rule 703 of the Federal Rules of Evidence, on Rasmussen's opinion, even in part, in offering their further opinions.

2. Rasmussen

In 1995, Rasmussen completed total hip replacement surgery on Plaintiff's left hip, utilizing a ceramic femoral ball and a polyethylene liner in a metal acetabular shell. (Second Am. Compl. ¶ 21). Sometime prior to April 24, 2006, Rasmussen told Plaintiff that she met the criteria for a total hip replacement of her right hip, and recommended replacement with the Conserve Hip Implant System. (Id. ¶¶ 22-23). On April 24, 2006, "Dr. Rasmussen implanted the following Conserve Hip Implant System components: a Wright Conserve Plus Cup, a Wright ProFemur RAZ Stem, a Wright ProFemur Neck, and a Conserve Total A-Class head, into [Plaintiff's] right hip . . . ." (Id. ¶ 25).

On or about October 24, 2012, Plaintiff claims she was doing yoga "when she felt and heard a crunching sound and then felt immediate, severe pain in her right hip and groin." (Id. ¶ 27). The pain she experienced from the event prohibited her from "ambulating without assistance." (Id.). Rasmussen saw Plaintiff on October 25, 2012, and diagnosed her as having a loose and displaced acetabular cup in her right hip replacement, requiring revision surgery, which Rasmussen performed on October 29, 2012. (Id. ¶¶ 28-29).

Rasmussen, in his operative notes from the October 29, 2012, revision operation [53.4] ("Operative Report"), stated that Plaintiff "had signs of a metalosis [sic] reaction of her hip with an inflammatory synovium . . . ." (Operative Report at 1-2). Rasmussen noted that the acetabulum was exposed, and that it was "cleaned of the soft tissue debris from the metalosis [sic] reaction." (Id. at 2).

At his February 26, 2014, deposition, Rasmussen testified that the "acetabular component was completely loose, displaced; that there was a significant inflammatory reaction in the joint and fluid that was cloudy and inflammatory fluid. It was a -- you know, the inside of the hip was very consistent with what I'd seen with revisions of failed metallosis hips." (Tr. of Feb. 26, 2014,

Rasmussen Dep. [53.5] ("Rasmussen First Dep.") at 41:14-20). When asked what "metalosis [sic] reaction" meant, Rasmussen stated:

> Well, what we've seen with prior revisions which -- and this was very similar to what we've seen with hips that have failed as a result of metallosis -- is an inflammatory reaction of the soft tissue, granulomatous change where you have hypertrophy, built up soft tissue within the joint, oftentimes pigment stained. The fluid very cloudy. Normal fluid in a well-functioning hip replacement is just a clear yellow. This is a very cloudy fluid. And also some cystic changes within the soft tissues.

(Id. at 42:14-24). Referring to the sentence in the Operative Report about cleaning the soft tissue debris, Rasmussen explained "that there was a soft tissue reaction that appeared to be consistent with other metallosis reactions we'd seen, a buildup of inflammatory soft tissue, that we cleaned out the acetabulum, removed that tissue so that we could repair for the reaming for the new acetabular component." (Id. at 43:10-16)

At his further deposition on December 15, 2014, Rasmussen noted that he did not preserve tissue samples or send tissue samples to pathology for histological examination. (Tr. of Dec. 15, 2014, Rasmussen Dep. [53.6] ("Rasmussen Second Dep.") at 60:7-23).[12] When asked whether a histological or microscopic

[12] Rasmussen was deposed on February 26, 2014, and on December 15, 2014. The portions of the December 15, 2014, deposition filed by Plaintiff and Defendants do not contain all of the same pages, and, when they include the same portions, the page and line numbers are not necessarily the same. (Compare [53.6]

examination would have provided important information regarding Plaintiff, Rasmussen stated that he had seen this situation numerous times before and knew the problem and the necessary treatment, and that, even without sending tissue samples for analysis, knew what Plaintiff's "problem was based upon seeing this time and time again." (Id. at 56:7-21). Rasmussen testified that Plaintiff's tissue "look[ed] exactly like the tissue that I've seen before then it's, in my mind, pretty certain, you know, what would have been found" if a pathological examination had been performed. (Id. at 56:22-57:4). Because he has seen metallosis reactions many times before in his patients, Rasmussen no longer provides a more extensive description in his operative notes and will instead only use the term "metalosis [sic]" which, in his view, refers to those more extensive descriptions he has in the past authored in cases involving metallosis. (Id. at 58:22-59:8).

Defendants claim the opinions of Plaintiff's metallosis experts, because they rely, even if only in part, on the observations and opinions of Rasmussen, render their respective expert opinions unreliable because they are founded on insufficient metallosis evidence, and are thus inadmissible. The Court disagrees.

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with [97.2]. The transcripts appear to have been prepared by different companies. Unless otherwise stated, the Court will cite to [53.6], Defendants' version of the December 15, 2014, deposition transcript

Under Rule 703 of the Federal Rules of Evidence, Plaintiff's metallosis experts may rely on facts or data of which they have been made aware--here Rasmussen's observation of metallosis in Plaintiff's right hip. See Fed. R. Evid. 703. This is true even if Rasmussen's observations are inadmissible, so long as experts in the respective field "would reasonably rely on those kinds of facts or data in forming an opinion on the subject . . . ." See id.

In view of Rasmussen's considerable background and experience in hip replacement and revision surgeries, the number of instances where he has performed revision surgeries in which metallosis was present, his experience in recognizing and diagnosing it, and his credentials and qualifications as an expert in original and revision hip replacement surgeries, the Courts find Rasmussen's observations and opinions reliable. Those of Plaintiff's metallosis experts who rely on Rasmussen's observations, conclusions, and opinions, are entitled to do so. Rasmussen's observations, conclusions, and opinions are the kind of medically reliable evidence that medical experts would consider in reaching a conclusion about medical conditions or complications. That is, medical professionals and researchers often rely on the observations of treating physicians to reach diagnostic conclusions, decide on courses of treatment and opine on the commonality of disease and injury among patients to determine if there is a common course of

disease or injury. The observations of an experienced treating physician are especially reliable because they serve to record a patient's medical history and often form the basis for a person's treatment and health issues throughout the person's life. In short, it is reasonable for an expert to rely on a treating physician's observations, comparisons, conclusions, and opinions in seeking to reach a conclusion on the course of a disease, injury, health complication or, in this case, the cause of an undisputed hip replacement device failure. The certainty and sufficiency of the treating physician's observations and conclusions, of course, may very well impact the persuasiveness of the opinions reached by the expert relying on them.

Defendants here do not challenge Rasmussen's credibility, or suggest that "Dr. Rasmussen did not truly observe 'signs' of a metallosis 'reaction,' inflammation, or cloudy synovial fluid." (Metallosis Reply at 6). Defendants contend only that even if "Dr. Rasmussen's observations are true, they do not provide sufficient foundation for Plaintiff's experts to form a reliable opinion" regarding the presence of metallosis and its connection to the failure of her Conserve implant. (Id.). The crux of Defendants' argument is, instead, that Plaintiff's experts' reliance on *only* Rasmussen's opinion is insufficient and thus

cannot be reasonably relied upon by Plaintiff's metallosis experts because it does not provide a sufficient factual basis.[13] The Court disagrees.

Rasmussen has been Plaintiff's orthopedic surgeon since before 1995, and, in the course of his practice, has performed multiple metal-on-metal hip device revisions, and has seen metallosis in many of these patients. ([97.2] at 52:6-53:5). Rasmussen was engaged by Wright Medical as a consultant and device designer in 2006, and in the October 1, 2006, consulting agreement by which Rasmussen was retained, Wright Medical noted that Rasmussen is "an orthopaedic surgeon and inventor with extensive knowledge and expertise in the field of knee and hip arthroplasty and orthopaedic surgery . . . ." ([97.1] at 1). There is little doubt that Rasmussen, based on his extensive experience, as acknowledged by Wright Medical, and who had an interest in the design of medical devices, including for Wright Medical, would accurately and objectively record his observations and conclusions in the record of patients on whom he performed device replacement

[13] Certain of Plaintiff's experts rely on Rasmussen's observations, conclusions, and opinions, generally as expressed in the Operative Report, to establish that metallosis was present in Plaintiff. Several of these experts, in reviewing the Operative Report and other materials, as explained below, reach conclusions regarding the cause of the failure of Plaintiff's hip implant, tying this conclusion to the presence of metallosis. For example, Dr. Joel Bach concluded that a metallosis reaction caused the failure of Plaintiff's hip implant, relying on Rasmussen's observations during the revision surgery. (See, e.g., Tr. of Jan. 7,2015, Bach Dep. [53.17] at 100:8-11).

and revision surgeries. It is not disputed that he was qualified to observe signs of metallosis in Plaintiff when he performed her revision surgery. It is also undisputed that Rasmussen observed metallosis when he performed revision surgery on Plaintiff on October 29, 2012. Against this qualifications and credibility backdrop it is reasonable, if not necessary, for a qualified expert who seeks to determine the cause of Plaintiff's Conserve implant failure, to consider and rely on this particular treating surgeon's observations, conclusions and opinion reached as a result of Plaintiff's revision surgery.

That there may have been corroborating information that Rasmussen could have sought does not impact the reliability of his observations, including where, as here, Rasmussen testified that he was familiar with, and experienced in, failure of this kind of metal-on-metal device and the revision surgery this type of failure required. (Rasmussen Second Deposition Transcript at 56:7-21). He was familiar with metallosis, having seen it numerous times when revising a metal-on-metal implant. (Id.). He was sufficiently practiced in this kind of surgery and the common characteristics of this kind of implant failure that ultimately he needed only to state basic observations in his case notes to record his observations, conclusions and opinions regarding the presence of metallosis rather than the more extended record entries he made in earlier surgeries. (Id.). Rasmussen had

encountered metallosis many times before Plaintiff's revision procedure, and he knew when the revision surgery was performed what the problem was and the necessary treatment. (Id.). He did not need to send tissue samples for analysis. (Id.). Rasmussen stated Plaintiff's tissue looked "exactly like the tissue that I've seen before then it's, in my mind, pretty certain, you know, what would have been found" if a pathological examination had been performed. (Id. at 56:22-57:4).

Defendants may, of course, at trial challenge the observations, conclusion and opinions expressed by Rasmussen and the opinions offered by other experts who rely upon them. Viterbo v. Dow Chem. Co., 826 F.2d 420, 422 (5th Cir. 1987) ("[A]s a general rule, questions relating to the bases and sources of an expert's opinion affect the weight to be assigned that opinion rather than its admissibility and should be left for the jury's consideration."); see also Duling v. Domino's Pizza, LLC, No. 1:13-CV-01570-LMM, 2015 WL 3407602, at *13 (N.D. Ga. Jan. 14, 2015) (citing Viterbo). That a defendant may challenge the usefulness and persuasiveness of an expert's opinion is different from the obligation of the Court to evaluate whether the opinion and the bases for it requires that it be precluded from being presented to the jury at all. It is commonly accepted that medical records and statements by a patient's treating physician are materials upon which testifying medical experts may reasonably rely. See Paine ex

rel. Eilman v. Johnson, No. 06 C 3173, 2010 WL 749854, at *2 (N.D. Ill. Feb. 25, 2010); see also Henderson v. Goodyear Dunlop Tires N. Am., Ltd., No. 3:11-CV-295-WKW, 2013 WL 5729377, at *5 (M.D. Ala. Oct. 22, 2013) (concluding that a physician's reliance on other doctors' medical records are the types of evidence contemplated under Rule 703 because they are the type of evidence that medical doctors reasonably rely upon). There is no authority to support Defendants' contention that Rasmussen's observation, conclusions, and opinions regarding metallosis cannot be reasonably relied upon by Plaintiff's experts.

The observations, conclusions, and opinions reached by Rasmussen are sufficient to be relied on by other experts in reaching opinions in this case to establish the cause of Plaintiff's Conserve implant failure. The Court specifically determines that Rasmussen's observations, conclusions, and opinions were not required to be corroborated by laboratory or other corroborating testing before other experts could reasonably rely upon them.

Having found that Rasmussen's observations, conclusions, and opinions may be relied on by other experts under Rule 703 of the Federal Rules of Evidence, the Court next addresses whether the opinions reached by the experts Plaintiff seeks to present at trial are based on sufficient facts and are sufficiently

reliable to satisfy the standards set forth in Daubert and Rule 702 of the Federal Rules of Evidence.[14]

[14] Defendants do not move to exclude Rasmussen's testimony that he observed metallosis, the impact of metallosis on the environment of the hip including the surrounding tissue and that the presence of metallosis was consistent with other surgeries he performed to revise hip implant devices. Rasmussen, as explained *supra*, has considerable background and experience in hip replacement and revision surgeries in which metallosis was present, has substantial experience in diagnosing metallosis, and personally performed Plaintiff's revision surgery and recorded his observations of metallosis directly. Rasmussen was also a consultant and device designer for Wright Medical, granting him particular insight into Wright Medical's devices. Rasmussen's operative notes and testimony are based on sufficient facts and data and is the product of reliable principles and methodology applied by Rasmussen. Rasmussen's testimony, if offered by Plaintiff, is thus admissible. See Fed. R. Evid. 702. Because Rasmussen's testimony and operative notes are admissible, other experts may rely upon his observations, conclusions, and opinions in reaching their own expert opinions. Even if Rasmussen's observations, conclusions, and opinions were not admissible--although the Court finds they are--they could be relied upon by other experts under Rule 703. See Fed. R. Evid. 702, Advisory Committee's Notes (2000 Amendments); see also Broussard , 535 F. App'x at 828 (Rule 703 of the Federal Rules of Evidence "allows an expert to base his opinion on facts or data that would otherwise be inadmissible, such as hearsay, if other 'experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion.'") (quoting Fed. R. Evid. 703); Greenwood Utilities, 751 F.2d at 1495 ("[W]hen an expert's opinion is based on facts not admissible in evidence the court should make a threshold factual inquiry to determine whether the data providing the basis for the opinion is of a type reasonably relied on by experts in that field to form such opinions.").

3. Dr. Elizabeth A. Laposata, MD, FCAP, FASCP

a) Expert Opinion

Dr. Elizabeth A. Laposata ("Laposata") is a forensic pathologist. She was retained by Plaintiff to analyze patient records and pathology specimens to assess adverse local tissue pathology and systemic reactions to Wright Medical Conserve hip orthopedic devices removed during revision surgeries. She prepared an expert report dated July 17, 2013 [53.8] ("Laposata Report"),[15] and a supplemental expert report dated November 21, 2014 [53.7] ("Laposata Supplemental Report").

Laposata concluded that the "Conserve metal-on-metal hip orthopedic implant generates nanoparticles of cobalt/chromium and chromium phosphate aggregates." (Laposata Report at 4). This metal debris, Laposata opines, can cause "adverse tissue reactions," including: "necrosis (death) of local tissues," "cyst formation," "metallosis (presence of metal wear debris)," "effusions (fluid build-up)," "chronic inflammation," and "other adverse reactions to metal debris--namely, pseudotumors, periprothetic soft tissue masses, aseptic lymphocytic vasculitis associated lesions." (Id.). According to Laposata, these "adverse tissue reactions may cause clinical failure of the implant. Data from joint

[15] The page numbering of the Laposata Report is confusing. Each section and appendix are numbered separately, starting with page one. The Court, accordingly, cites to the CM/ECF page numbers for Docket No. 53.8.

registries show that metal-on-metal hip orthopedic implants have a higher failure rate than metal-on-polyethylene devices." (Id.).

Laposata explains how the body integrates a hip implant, primarily as a result of "bone repair and remodeling during the healing process called osseointegration" and notes that if osseointegration does not occur, the prosthesis will become loose. If implant integration is impacted by the osteolysis, causing bone dissolution or destruction, "the prosthesis also will loosen. A loose hip implant can lead to clinical implant failure and may require removal (explantation) and revision." (Id. at 5). Laposata opines that bodily movement causes wear on hip implants that produce debris:

> Metal-on-metal hip implants generate wear debris that is unique in terms of size, composition and number. All of these properties cause pathophysiologic responses in the body that are unique to metal-on-metal implants. These pathophysiologic responses by the body then cause changes in cells and tissues surrounding the implant, generally known as adverse reaction to metal debris (ARMD), which is diagnosed by examining the explanted tissues with the naked eye (i.e., gross pathologic examination) and under the microscope (i.e., histologic examination). These adverse cell and tissue reactions can cause implant loosening and clinical failure of the implant.

(Id.). Laposata explains the unique reactions that occur in the body when nanoparticles of cobalt-chromium are shed from metal-on-metal hip replacements. (Id. at 6-9).

In the Laposata Supplemental Report, Laposata discusses Plaintiff's Conserve implant. She states that she reviewed Plaintiff's medical records and a transcript of Plaintiff's February 27, 2014, deposition, viewed photographs of the explanted head and cup, and examined the explant itself. (Laposata Supplemental Report at 2). Based on her analysis of this information and the explanted device, Laposata opines that Plaintiff's "sudden displacement of the acetabular cup indicates that any osseointegration initially present had been destroyed."[16] (Id. at 3). Laposata states that her "[v]isual examination of the acetabular side of the cup showed only a few minuscule islands of bone scattered between the beaded elements of the cobalt-chromium surface," and that Plaintiff's acetabular cup was not substantially attached to the pelvic bone. (Id.). Laposata opines that this "caused loosening and failure of the implant. The cause of the lack of any initial osseointegration, as well as osteolysis[17] of any existing direct bone-to-component attachments, is the inflammatory response to the cobalt-chromium metallic wear debris and corrosion products from her hip implant components." (Id.). After reviewing and analyzing Plaintiff's medical records, a transcript of Plaintiff's February 27, 2014, deposition, photographs of the explanted head and cup, and the

16 Osseointegration is the "development of direct bone-to-implant contact." (Laposata Supplemental Report at 3).

17 "Destruction of the bone-to-implant contact is known as osteolysis." (Laposata Supplemental Report at 3).

explant itself, Laposata concludes that metallosis caused by the deposit of cobalt-chromium debris from the hip implant, inhibited the grown of bone into the implant and destroyed the bone already in place, resulting in the failure of the implant. (Id.).

b) Analysis

Defendants argue that Laposata's conclusion that metallosis caused the failure of Plaintiff's implant is based solely on Rasmussen's observation of "metalosis [sic]." (Metallosis Motion at 6). Defendants claim this reliance is a "sharp departure from the methodology she recommends in [the Laposata Report]," which Defendants contend requires not only gross visual observation but also microscopic examination. (Id. at 6-7). Defendants claim further that Laposata did not conduct any pathology analysis of the tissue, because it was unavailable, and thus relied on Rasmussen's observation of metallosis. (Id. at 7-8).

Defendants misconstrue Laposata's statements about methodology and the evidence she relied upon in reaching her conclusion that metallosis was present in Plaintiff. Laposata states that she "relied on the eyes of the experienced surgeon in the description of the appearance of the tissues at surgery and then I relied on my examination of the explant." (Tr. of Dec. 29, 2014, Laposata Dep. [53.23] ("Laposata Dep.") at 57:3-6). Laposata states that she reviewed Plaintiff's medical

records and a transcript of Plaintiff's February 27, 2014, deposition, viewed photographs of the explanted head and cup, and examined the explant components. (Laposata Supplemental Report at 2). Laposata, thus, relied on more than just Rasmussen's observations in reaching her conclusions. Laposata testified that, while you can rely on visual examination of tissues by a pathologist and the microscopic examination of the slides created from those tissues, you can also rely on medical records and testimony. (Laposata Dep. at 54:10-18).

> Under Daubert, the Court must admit expert testimony if:
>
> (1) the expert is qualified to testify competently regarding the matters he intends to address; (2) the methodology by which the expert reaches his conclusions is sufficiently reliable as determined by the sort of inquiry mandated in Daubert; and (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue.

City of Tuscaloosa, 158 F.3d at 562-63 (11th Cir. 1998) (footnote omitted) (citing Fed. R. Evid. 702; Daubert, 509 U.S. at 589). The Court finds that Laposata's reliance on the observations, conclusions, and opinions Rasmussen made and reached during Plaintiff's revision surgery, Plaintiff's medical records, Plaintiff's February 27, 2014, deposition, and her personal examination of photographs of the explanted head and cup, and the explant itself, are sufficient under Daubert and Rule 702 of the Federal Rules of Evidence for her opinions to be admitted. See id.

Defendants do not contend that Laposata is unqualified to testify competently in the field of forensic pathology, or that her testimony will not assist the trier of fact. The Court concludes that Laposata is qualified in the discipline of forensic pathology, applies theories accepted in the field of forensic pathology, and that her testimony will assist the trier of fact in this case to understand the evidence and determine the issue of causation in this case. Laposata's opinions are not required to be excluded under Daubert. See id.[18]

4. Dr. Brent W. Morgan

a) Expert Opinion

Dr. Brent W. Morgan ("Morgan"), a medical doctor Board certified in medical toxicology, was retained by Plaintiff and prepared an expert report [53.9] ("Morgan Report"). Morgan states that he is "experienced as an investigator of toxic metals such as lead and other metals on the human body" and has "evaluated several patients with metal on metal (MoM) hip implants and [has] observed the surgical removal of a Wright Medical Conserve MoM hip." (Morgan Report at 1). Morgan reviewed Plaintiff's medical records and states that her "operation

[18] Defendants assert that Laposata's findings are not supported by objective evidence, citing Dr. Patricia Campbell, Ph.D's report [53.11]. Dr. Campbell was engaged by Defendants as an expert witness. Daubert, however, does not permit the Court to "evaluate the credibility of opposing experts and the persuasiveness of competing scientific studies." Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd., 326 F.3d 1333, 1341 (11th Cir. 2003). That can be done at trial.

revealed the presence of metallosis reaction, an inflamed joint synovium and the accumulation of soft tissue debris from the metallosis. The acetabular component of her hip had failed, loosened and rotated." (Id.). Morgan opines that Plaintiff's hip implant "had broken down and produced enough metal debris that the tissue in her body had been visibly altered." (Id.). Morgan states:

> Visual inspection of Mrs. Christiansen's failed hip prosthesis reveals poor osteo-integration of the cup while microscopy revealed the presence of significant wear and tear that produced the metal debris in her hip joint. Metal debris released from the Wright Medical metal on metal hip prosthesis caused corrosive and direct toxic effects in the tissue surrounding Mrs. Christiansen's hip prosthesis.

(Id.). Morgan opines that Plaintiff's Conserve implant "was continuously releasing metal debris, the immune system response produced the chronic inflammatory condition that developed in Mrs. Christiansen," and the "chronic inflammation surrounding her bone plus the direct toxic effects of the metal debris produced bone resorption that caused degradation of Mrs. Christiansen's hip to the point that the prosthesis loosened and failed." (Id. at 2).

b) Analysis

Defendants assert that Morgan's conclusion that metallosis was present is based on Rasmussen's references to "signs of metalosis [sic]" and "metalosis [sic] reaction." (Metallosis Motion at 8) (citing Tr. of Jan. 14, 2015 Morgan Dep. [53.10] ("Morgan Dep.") at 73:1-17, 78:11-13). Defendants note that Morgan

states that metallosis produces "tissue that has been altered in appearance because it contains such a large amount of metal debris," and opines that Plaintiff's hip implant "had broken down and produced enough metal debris that the tissue in her body had been visibly altered." (Id.) (citing Morgan Report at 1). Defendants assert that Morgan assumes that the metallosis was widespread and that there was metal debris throughout the hip joint, despite that neither the Operative Report nor Rasmussen's deposition testimony specifies the extent to which metallosis affected Plaintiff's soft tissue. (Id. at 10). Defendants assert also that Morgan assumes that metallosis existed, despite neither the Operative Report or Rasmussen's testimony mentioning tissue color or bone resorption. (Id.).

Defendants also argue that Morgan did not "apply any discernable [] methodology to arrive at his opinion that metallosis caused Mrs. Christiansen's hip to fail. Moreover, Dr. Morgan's opinion is unique in that Dr. Morgan lacks the expertise in medical device failure to provide a meaningful opinion in this case." (Id. at 9).

Morgan testified at his deposition:

> Q. Okay. But you're not in a position--you don't have the background and experience to say what caused this hip to fail; right?
>
> [Morgan]. To what exactly--I think I have the experience to talk about the toxicological issues and how, you know, chromium and

cobalt that get released into a hip can cause a weakening of a joint and causing it to fail.

Q. You can say that, but you can [sic] say in Ms. Christiansen's case what caused it to fail; right?

[Morgan]. I think with the metallosis that's here and the soft tissue debris, I think I can say more likely than not that it was, you know, the -- the nano particles of this that contributed, you know, to this failure of the hip.

Q. Without knowing anything about the extent of the metallosis?

[Morgan]. Yes.

Q. Without knowing anything about that, you can say that -- that metal debris caused this woman's hip failure?

[Morgan]. I think more likely than not, yes.

Q. Without seeing any pathology material?

[Morgan]. Yes.

Q. Without seeing any X-rays?

[Morgan]. Yes.

Q. And even though you've said that you're not really qualified to say what causes a hip to fail, you would need to have the surgeon's input?

[Morgan]. I would need to have the surgeon's input, yes.

Q. Okay. All you can say is that Ms. Christiansen appeared to have some -- some amount of metallosis and that could have possibly caused her hip to fail; right?

[Morgan]. I think it--yes, I think that it--I can say that, yes.

> . . .
> Q. Yeah. You're not in a position to distinguish the cause of what caused her hip to fail, whether it was the metallosis versus a traumatic event?
>
> [Morgan]. I think I would want to get input from the orthopedic surgeon on that.

(Morgan Dep. at 87:6-89:7).

A fair reading of Morgan's deposition testimony establishes that Morgan's opinion that Plaintiff's specific hip implant failed due to metallosis is not sufficiently reliable to present to the jury. Morgan states that it was "more likely than not" that the metallosis "contributed . . . to the failure of the hip." (Id. at 87:16-20). Morgan does not provide any specific support for this opinion, other than Rasmussen's opinion that there was metallosis in Plaintiff's hip.

Morgan did not examine any x-rays of the dislocated implant, and he is not sure of the extent of the metallosis and what, if any, inflammation it caused in Plaintiff's soft tissues. Morgan defers to the operating surgeon for a conclusion on what caused the failure. He does not have an independent opinion, only a highly qualified view of what may here have caused the failure. Morgan's conclusion, thus, appears to be mere *ipse dixit*. See Guinn v. AstraZeneca Pharm. LP, 602 F.3d 1245, 1255-56 (11th Cir. 2010) ("[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected

to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.") (citing Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997)). The analytical gap between the "data" upon which Morgan relies and the "opinion" he offers simply is too wide to allow the opinion to be admitted.

Considering that Morgan relies almost exclusively on Rasmussen's clinical observations and opinions, Morgan's expert opinions in this case, besides being unreliable, are also cumulative of Rasmussen's opinion, and other admissible expert opinions, including those of Laposata, Jarrell, and Waldrop, regarding the presence of metallosis and its impact, if any, on Plaintiff's implant failure. Morgan's conclusion that the failure of Plaintiff's hip implant was caused by metallosis is not based on sufficient facts and data, is not "sufficiently reliable" and would not be helpful to the jury. It is, therefore, excluded. See City of Tuscaloosa, 158 F.3d at 562-63.

5. Dr. John D. Jarrell, Ph.D., PE[19]

a) Expert Opinion

Dr. John D. Jarrell ("Jarrell"), a biomedical engineer employed by Materials Science Associations, LLC ("MSA"), was retained by Plaintiff and prepared an expert report, dated November 21, 2014 [53.19] ("Jarrell Report"). Jarrell states he is an "experienced multi-discipline engineer specializing in the analysis of complex designs and failures involving materials, mechanical and biological systems." (Jarrell Report at 1).

Jarrell reviewed Plaintiff's medical records, including the Operative Report, and, on December 11, 2012 and November 19, 2014, he examined Plaintiff's explanted Conserve implant. (Id. at 5-6). The initial examination included "visual inspection, photodocumentation, [and] microscopy wear measurements using a sensitive coordinate measuring machine (CMM)." (Id.). It was evident from Jarrell's "inspection that metal ions and particles were released from wear and corrosion of the articular surfaces of Ms. Christiansen's WMT Conserve® hip implant. It was also evident from her medical records that she experienced metallosis to the tissues surrounding [her] cup implant." (Id. at 7).

[19] Defendants, in their Vincelli Motion, seek to exclude Jarrell's expert opinion to the extent that it relies on Dr. Jay M. Vincelli's calculations of the wear rate for the Conserve hip implant system. The Court addresses this argument *infra* in Section III(C) and footnote 34.

Jarrell opines "there was little evidence of bony ingrowth remaining in the porous back of Ms. Christiansen's implant after removal. There were some areas with white bone ingrowth and also areas where remaining bone was discolored." (Id.). Jarrell noted that "the titanium alloy stem was still fixed well to the bone with good signs of integration and no sign of loosening. Titanium and titanium alloys are recognized for superior osseointegration and bony ingrowth." (Id.). Jarrell further observed

> localized corrosion, carbide pull out and scratching characteristic of third-body wear and abrasive wear, during my inspection of Ms. Christiansen's explanted WMT Conserve® metal on metal head and cup. Corrosion was also evident in the general discoloration of the explant when compared to an unused implant (exemplar).

(Id.). Jarrell states,

> It is evident from my inspection of Ms. Christiansen's WMT implants, the results of the gross wear using CMM and her medical records indicating metallosis, that she was exposed to cobalt and chromium metal wear debris, metal ions and corrosion products. It is also evident that this exposure had a negative impact on the tissues surrounding her WMT CoCr acetabular cup.

(Id. at 16-17).[20]

[20] Jarrell, in his report, also opines more generally on the alleged design defect present in Defendants' metal-on-metal hip implant.

b) Analysis

Defendants argue that Jarrell relied solely on the Operative Report to conclude that Plaintiff experienced metallosis in the tissues surrounding her implant. (Metallosis Motion at 15). This argument is unfounded. In addition to reviewing the Operative Report, Jarrell twice examined Plaintiff's hip implant. (Jarrell Report at 1). When asked what evidence existed that Plaintiff had either cobalt or chromium metal ions in her system, Jarrell states:

> The evidence that we have is the medical records with the observations of metallosis twice and also the loss of metal, at least the visual appearance of scratching on the inside of the cup and the ball and also the corrosion inside of the taper joint. So we see evidence that metal ions and particles and wear debris was released. Conservation of matter, if the metal ions and debris are missing from the cup and ball, they went into the adjacent areas.

(Tr. of Dec. 30, 2014 Jarrell Dep. [97.8] ("Jarrell Dep.") at 123:10-19). Jarrell's inspections show that "metal ions and particles were released from wear and corrosion of the articular surfaces of Ms. Christiansen's WMT Conserve® hip implant," and Plaintiff's medical records supported that "she experienced metallosis to the tissues surrounding her cup implant." (Jarrell Report at 7). Jarrell states: "there was little evidence of bony ingrowth remaining in the porous back of Ms. Christiansen's implant after removal. There were some areas with white bone ingrowth and also areas where remaining bone was discolored." (Id.).

Jarrell reached his opinions based on articulated evidence that supported Rasmussen's conclusion that Plaintiff experienced metallosis in the tissue surrounding her hip implant. Jarrell's expert testimony is "sufficiently reliable" and would be helpful to the jury to understand the evidence and determine the issue of causation. The opinion is not required to be excluded under Daubert. See City of Tuscaloosa, 158 F.3d at 562-63.[21]

6. Dr. Reed Ayers, Ph.D.[22]

a) Expert Opinion

Dr. Reed Ayers ("Ayers"), a metallurgist employed by Verkko Biomedical, also was retained by Plaintiff. Ayers prepared an expert report dated November 21, 2014 [53.14] ("Ayers Report").[23] Ayers states he is "an experienced multi-discipline engineer specializing in the synthesis and design of orthopedic materials as well as their failure in a clinical application . . . ." (Ayers Report at 2) (internal citations omitted). His "experience includes work on the

[21] Defendants do not appear to contest that Jarrell is qualified as a biomedical engineer, and that his testimony will assist the trier of fact.

[22] Defendants, in their Ayers Motion, seek to exclude Ayer's expert opinion regarding the suitability of the materials selected to manufacture the Conserve hip implant system. The Court addresses this argument *infra*.

[23] Defendants docketed another copy of the report, without Ayers' curriculum vitae, as Docket No. 51.3. The Ayers Report does not contain internal page numbers. The Court, accordingly, will cite to the CM/ECF page numbers of Docket No. 53.14

synthesis/manufacture of CoCrMoC[24] alloys bone ingrowth to porous materials the corrosion of biomedical alloys and how the corrosion products of these alloys affect bone and other tissues." (Id.) (internal citations omitted).

Ayers reviewed images of Plaintiff's explanted Conserve cup and ball, Plaintiff's medical records, the Jarrell Report, and the Laposata Report in forming his opinion. (Id.). Ayers does not discuss Plaintiff's hip implant specifically, but discusses general issues with Wright Medical's Conserve cup, opining that Wright Medical's implant could produce "localized discoloration" evidencing metallosis that could lead to the failure of the implant. (Id. at 5).

b) Analysis

Defendants argue that Ayers' opinion is based solely on the Operative Report, and that Ayers' opinion is that the Operative Report's indication of "staining" in Plaintiff's tissue resulted from metallosis. (Metallosis Motion at 12). Defendants argue that Ayers testified that he focused on surgical observations in the Operative Report that the "tissue itself [was] discolored." (Tr, of Jan. 8, 2015, Ayers Dep. [53.15] ("Ayers Dep.") at 57:20). Ayers explained that tissue discoloration indicates the presence of metallosis. (Id. at 58:2-13). Defendants appear to argue that because the Operative Report did not state that Plaintiff's

[24] CoCrMoc is shorthand for cobalt, chromium, and molybdenum. (See Ayers Report at 4).

tissue was stained, but discolored, Ayers use of "staining" in his report renders his opinion unreliable.

While Rasmussen did not use the word "staining" in his Operative Report, metallosis involves the release of metals into the body, often signified by tissue staining and discoloration. (See, e.g., Laposata Supplemental Report at 2 ("Metallosis is a grey/black tissue discoloration due to the build-up of metal debris and corrosion products in the tissues of the body"); Dr. Edward F. DiCarlo's expert report, dated December 22, 2014, [53.12] at 3 (in "some cases, it is possible to see a large amount of metal in the tissue with the naked eye. In this case, the tissue has a gray or black appearance depending on the amount of metallic debris in the tissue. Such a finding is often referred to as 'metallosis.'")). Ayers makes the same point, noting that he interpreted the Operative Report's reference to metallosis as staining. (Ayers Dep. at 91:15-92:9).[25]

Defendants' sole objection to the admissibility of Ayers' expert opinion, that he characterized the tissue discoloration as "staining"--a term not used in the Operative Report--is unpersuasive. This alone is not a credible reason to exclude

[25] Ayers' explanation that tissue discoloration is the result of the presence of ions within the cells, while cumulative of other expert testimony in this case, appears to be relied upon to show that Rasmussen's notes concerning signs of metallosis indicate that Rasmussen saw signs of discoloration or staining of Plaintiff's soft tissues.

Ayers' opinion and in the absence of a reasoned basis to exclude Ayers' opinion testimony, the Court concludes that Plaintiff satisfies the requirements of Daubert and his opinion is not required to be excluded on the basis of his characterization of the discoloring as staining.[26] See City of Tuscaloosa, 158 F.3d at 562-63.

7. Dr. Joel Bach, Ph.D.

a) Expert Opinion

Dr. Joel M. Bach ("Bach"), a mechanical engineer employed by Thin Air Engineering, LLC, was retained by Plaintiff, and prepared an expert report dated November 21, 2014 [53.16] ("Bach Report"). In reaching the opinion he offers in this case, Bach's review included Plaintiff's medical records, Plaintiff's February 27, 2014, deposition transcript, photographs of Plaintiff's explanted components, the Jarrell Report, and Dr. Jay M. Vincelli's ("Vincelli") July 16, 2014, and November 20, 2014, reports. (Bach Report at 1-2). Bach is expected to testify regarding hip biomechanics, the history of hip replacement components, the biomechanics of total hip replacement, and the biomechanics of metal-on-metal total hip replacement. Bach opines that Plaintiff's Conserve implant "led to corrosion, wear, and ion release, which in turn led to loss of

[26] Ayers' opinion appears to be specifically limited and less comprehensive than other experts who may testify in this case. The Court does not take a position at this point whether his testimony is cumulative of testimony that may be offered by other experts at trial.

osseointegration of the cup [of Plaintiff's hip implant device]. This directly affected the stability of the cup, which caused the cup to loosen, and ultimately fail in Mrs. Christiansen, resulting in the need for the 2012 revision." (Id. at 8). In reaching this opinion, Bach relies on Vincelli's examination of Plaintiff's explanted components and Vincelli's finding of "'deep and shallow scratches, gouges, and pitting' on both the femoral head and acetabular cup." (Id. at 7). Bach further notes that Vincelli found "this heavy surface damage is consistent with a lower gross-wearing articulating couple," and the "acetabular shell exhibited minimal bony ingrowth, which is indicative of poor osseointegration." (Id.). Bach notes that Rasmussen observed metallosis during Plaintiff's revision surgery. (Id. at 8).

b) Analysis

Defendants assert that Bach "based his opinions that metallosis caused Plaintiff's cup component to fail solely upon his review of Dr. Rasmussen's operative report." (Metallosis Motion at 14). Defendants note that Bach testified he relied on "[t]he evidence of the tissue reaction that Dr. Rasmussen saw at the revision surgery [as] evidence of metallosis. That's pretty much it." (Tr. of Jan 7, 2015, Bach Dep. [53.17] ("Bach Dep.") at 100:8-11). When asked if he relied on anything else, Bach stated "No. Pretty much that's what I saw." (Id. at

100:18). Bach noted that Rasmussen's finding of metallosis was the strongest evidence. (Id. at 101:1). Rasmussen had to remove some of the tissue affected by metallosis, and, when combined "with the evidence or the lack of evidence of bony fixation in the implant in the retrieval photos and the mechanism of failure, I think that all goes together and supports [my conclusion]." (Id. at 101:10-16). Bach opined that, because Plaintiff's non-metal-on-metal hip and knee implants have not failed or showed evidence of bone resorption, there is no "systemic explanation for lack of fixation" on Plaintiff's metal-on-metal hip implant. (Id. at 101:22-102:6).

Defendants claim that Bach relied solely on the Operative Report in reaching the opinion Bach offers is not accurate. Bach reviewed, in addition to the Operative Report, Plaintiff's medical records, photographs of Plaintiff's explanted components, Plaintiff's February 27, 2014, deposition transcript, and the Jarrell Report and Vincelli's July 16, 2014, and November 20, 2014, reports. (Bach Report at 1-2).[27] Bach's experience as a mechanical engineer, coupled with the

[27] Defendants do not assert, and the Court has found no reason to believe, that Bach was not entitled to rely on these other experts' reports. Cf. Winston, 372 F. App'x at 20 (allowing an expert witness's testimony that was based in part on an opinion of a non-testifying expert, noting that "an expert witness may base his testimony on inadmissible information so long as such information is 'regularly relied upon by experts in his field.'"); see also Tamraz, 620 F.3d at 675; Day, 524 F.3d at 1371; Eberli, 615 F. Supp. 2d at 1364 ("an expert's testimony may be formulated by the use of the facts, data and conclusions of other experts")

information he reviewed before offering the opinion, sufficiently support that the expert testimony he offers is "sufficiently reliable" and not required to be excluded under Daubert.[28] See City of Tuscaloosa, 158 F.3d at 562-63.

8. Dr. Suzanne Parisian, M.D.

a) Expert Opinion

Dr. Susanne Parisian ("Parisian"), a medical doctor and Plaintiff's Food and Drug Administration ("FDA") regulatory expert, was retained by Plaintiff and prepared her expert report dated November 21, 2014 [53.18] ("Parisian Report"). Parisian offers an opinion regarding Defendants' compliance with FDA regulatory requirements. (Parisian Report at 7).

Parisian references metallosis in her report only twice, and only to refer to Rasmussen's note in the Operative Report that Plaintiff "required revision and additional loss of bone in [Plaintiff] in 2012 as a result of acute pain, device failure with dislocation and tissue metallosis," and that "[a]t

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(quoting Ohio Environmental Development Ltd. Partnership v. Envirotest Systems Corp., 478 F. Supp. 2d 963, 976 (N.D. Ohio 2007).

[28] Bach's expert testimony also may be determined to be cumulative. The Court can consider at trial whether Bach's testimony is admissible.

time of her revision surgery, [Plaintiff's] right hip tissue had findings of metallosis with an inflammatory response in her synovia." (Id. at 86-87).[29]

b) Analysis

Defendants assert that Parisian's statement that Plaintiff "required revision and additional loss of bone in [Plaintiff] in 2012 as a result of acute pain, device failure with dislocation and tissue metallosis," and that "[a]t time of her revision surgery, [Plaintiff's] right hip tissue had findings of metallosis with an inflammatory response in her synovia" is based solely Rasmussen's Operative Report. (Metallosis Motion at 14) (citing Parisian Report at 86-87). Defendants assert that Parisian's statement concerning metallosis should be excluded. (Id.). Plaintiff asserts that Parisian, a physician, is entitled to base her opinion on facts or data that other experts in her field would rely upon, such as Rasmussen's surgical notes. (Metallosis Response at 13-14).

Parisian was retained by Plaintiff to offer an opinion regarding Defendants' compliance with regulatory requirements. (Parisian Report at 7). Parisian was not retained by Plaintiff to provide an opinion regarding causation and she has not provided a sufficient credible basis to do so. Plaintiff also has not provided sufficient support to establish by a preponderance of the evidence that Parisian's

[29] These references occur in Appendix C of the Parisian Report, which contains a timeline of "key events."

references to Rasmussen's observations, in her capacity as a regulatory expert, will assist the trier of fact in understanding the regulatory matters at issue in this case. See City of Tuscaloosa, 158 F.3d at 562-63; see also Frazier, 387 F.3d at 1260 (The proponent of expert testimony must establish the Rule 702 factors by a preponderance of the evidence.). The Court concludes that Parisian's testimony regarding Plaintiff's metallosis and its relationship to Plaintiff's implant failure is required to be excluded.[30]

9. Dr. John I. Waldrop, M.D.

a) Expert Opinion

Dr. John I. Waldrop ("Waldrop"), an orthopedic surgeon practicing at Hughston Clinic in Columbus, Georgia, was retained by Plaintiff. He prepared an expert report dated July 17, 2013 [53.22] ("Waldrop Report"), and a supplemental expert report dated November 21, 2014 [53.21] ("Waldrop Supplemental Report").

Waldrop's initial report generally discusses medical issues Waldrop has encountered with regard to metal-on-metal hip implants, including occurrences of metallosis. Waldrop states that he "examined the medical records of [Plaintiff], the digital x-rays of her original right hip replacement with the Wright Medical Conserve Total Hip, and photographs of the explant." (Waldrop Supplemental

[30] The Court notes that Defendants did not move to exclude any of Parisian's other expert testimony regarding FDA regulations.

Report at 1). Based on his examination of these materials, Waldrop concludes that the: (i) "failure of her hip implant was due to the lack of osteo-integration at the time of her dislocation and revision, as indicated in the medical records and by photographs of the back of the thin cup;" (ii) "Xrays [sic] in 2011 and 2012 prior to the revision, show evidence of bone resorption on the back of the acetabular cup;" and (iii) "findings by Dr. Rasmussen at revision surgery of evidence of metallosis is consistent with my own findings on revision of Metal-on-Metal hips as more fully shown in my earlier report." (Id.)

b) Analysis

Defendants assert that Waldrop, in his initial report,

> reveals different evidentiary requirements for a determination of metallosis which are not present here. Most significantly, Dr. Waldrop's general report concludes "Across the board, all of the M-O-M hips I have revised have elevated Cobalt and Chromium blood ions in excess of 10 parts per billion." See Ex. S, Waldrop Report, at 20. Dr. Waldrop's general report also notes findings of pseudotumors, tissue necrosis, discoloration, tissue staining, and unexplained lesions, none of which were observed in Dr. Rasmussen's operative report.

(Metallosis Motion at 16) (citing Waldrop Report at 6-20).

The Court has reviewed the Waldrop Report. The report does not, as Defendants suggest, state that "pseudotumors, tissue necrosis, discoloration, tissue staining, and unexplained lesions" are all present when metallosis exists. Although "elevated Cobalt and Chromium blood ions in excess of 10 parts per billion," were

present in the metal-on-metal hip replacements Waldrop has revised, he did not state that a cobalt and chromium blood ion test showing an excess of 10 parts per billion is required to conclude that metallosis exists. Waldrop did not "reveal[] . . . evidentiary requirements for a determination of metallosis which are not present here," although the process he uses to evaluate patients he treats and the occurrences requiring revisions may well impact the credibility of the opinion he seeks to offer in this case.

Waldrop is an experienced orthopedic surgeon who reviewed Plaintiff's medical records, digital x-rays of her original right hip replacement with the Wright Medical Conserve Total Hip, and photographs of the explant in reaching his opinion that Plaintiff's hip implant failed because of the consequences of metallosis. Waldrop's expert testimony is sufficiently reliable, and will assist the trier of fact in understanding the evidence in this case and to determine the issue of causation. See City of Tuscaloosa, 158 F.3d at 562-63. Waldrop's opinions are not required to be excluded under Daubert. See id.

The Court having determined that Drs. Laposata, Morgan, Jarrell, Ayers, Bach, Parisian, and Waldrop may rely on the observations, conclusions, and opinions offered by Rasmussen, and having evaluated the underlying sufficiency of the expert opinions they seek to offer, now turns to Defendants' three remaining

Daubert motions and whether the expert opinions of Drs. Vincelli, Ayers, and Waller are sufficiently reliable under Daubert.

C. Jay M. Vincelli, MSc

Vincelli is a materials science and biomedical engineer retained by Plaintiff to provide "opinions regarding wear analysis of retrieved Wright Conserve metal-on-metal hip components and WMT's simulator testing." (Vincelli Report at 1). He prepared an expert report dated July 16, 2013 [50.4] ("Vincelli Report"), and a supplemental expert report dated November 20, 2014 [50.3] ("Vincelli Supplemental Report").

Vincelli analyzed wear measurements of thirty-three (33) "bearing couples from retrievals involved in this MDL" using a coordinate measurement machine ("CMM") and through microscopic and visual analysis of the wear patterns. (Id. at 1-2). Vincelli's initial report addresses Wright Medical's metal-on-metal hip implant generally as it relates to wear volume, wear rate, and location of wear. Vincelli's supplemental report addresses Plaintiff's hip implant specifically. (Vincelli Supplemental Report at 1). Vincelli performed photographic, microscopic, and visual analyses of the hip implant, and measured the gross wear on the implant using a CMM. (Id. at 5-6)

Vincelli concludes that: (i) wear volumes were observed in excess of Wright Medical's simulator results and published literature; (ii) the location of wear on Wright Medical's simulator samples was not similar to the components removed from patients; (iii) Wright Medical's simulator tests were not performed according to available standards; (iv) Wright Medical's simulator testing was performed according to an improper loading profile; (v) Wright Medical's simulator testing was not performed according to the scientific method; and (vi) Wright Medical's simulator testing represented motions not typical of *in vivo* motions. (Vincelli Report at 2-8).

Vincelli measured the gross wear volume of the femoral head and acetabular cup articular surfaces in Plaintiff's hip implant to be 1.6mm^3. (Vincelli Supplemental Report at 5). Vincelli notes that the CMM analysis "cannot quantify wear caused by debris, such as scratches and gouges, or material loss due to corrosion. As such, the wear volumes and rates [he measured] represent only a portion of the metal liberated from the metallic surfaces and can be considered a minimum value for the overall metal volume released into the body." (Id. at 3; Vincelli Report at 2).

To calculate the additional wear that the CMM cannot measure, Vincelli employs a methodology he developed as part of his Master's thesis at Dartmouth

College against data from Wright Medical's simulated wear testing, and concludes that a "simulated wear volume of approximately 2.1mm^3 . . . after 78.2 months"[31] existed. (Vincelli Supplemental Report at 6). In other words, while the CMM measured a gross wear volume of 1.6mm^3, Vincelli opines that the actual gross wear rate is approximately 2.1mm^3. The difference between these two measurements is the wear that the CMM cannot measure, but which Vincelli opines his methodology can calculate.

Defendants request that the Court exclude Vincelli's opinions and testimony regarding the "the wear rates from the bearing surface of the CONSERVE® hip implant components received by [Plaintiff] beyond actual gross wear measurements . . . because any such opinions are not based upon a reliable and scientifically valid methodology." (Vincelli Motion at 1).

Defendants do not object to Vincelli testifying that he measured Plaintiff's explanted femoral head and acetabular cup articular surfaces and found the gross wear volume to be 1.6mm^3. (Id.). Defendants object to Vincelli's use of a methodology he developed for his Master's thesis to calculate a simulated wear volume of 2.1mm^3. (Id. at 2). They argue that Vincelli's simulated wear rate methodology "has never been tested or vetted by anyone else in this scientific

[31] 78.2 months is the approximate length of time the Conserve implant was implanted in Plaintiff when the revision surgery occurred.

field, and at best is only supported by Mr. Vincelli's thesis written while obtaining his Master's Degree . . . ." (Id. at 11).

Defendants contend also that Vincelli's methodology is not reliable because it inappropriately assumes a certain number of cycles (or steps), assumes other variables of the simulated wear test, and then arrives as a calculated wear volume as if the implant was run through a simulator. (Id. at 2, 12). Defendants object to Vincelli assuming that two microns of additional, but immeasurable, wear were lost, because such wear is not supported by any other expert in the field and cannot be tested. (Id. at 2). Defendants object to Vincelli's opinion regarding this immeasurable wear, and to Jarrell's opinion to the extent he also relies on it. (Id. at 2, 14-15).

Defendants' objection to Vincelli's method of calculating the "immeasurable" wear of Plaintiff's hip implant is based on: (1) the methodology never having been tested or vetted; (2) the methodology not having been peer reviewed; and (3) Vincelli's factual assumptions in reaching his conclusions. "In ascertaining the reliability of a particular scientific expert opinion, [a court considers], to the extent possible: (1) whether the expert's theory can be and has been tested; (2) whether the theory has been subjected to peer review and publication; (3) the known or potential rate of error of the particular scientific

technique; and (4) whether the technique is generally accepted in the scientific community." Quiet Tech., 326 F.3d at 1341. These factors, however, "do not exhaust the universe of considerations that may bear on the reliability of a given expert opinion, and a federal court should consider any additional factors that may advance its Rule 702 analysis." Id. "[I]t is not the role of the district court to make ultimate conclusions as to the persuasiveness of the proffered evidence." Id.

Vincelli notes that the analysis he performed on the CMM data "was developed as part of [his] Master's thesis at Dartmouth College, which was subjected to, and passed, a public defense including committee members who are experts in the fields of tribology, orthopedic surgery, biomaterials, and hip and knee implants. The written thesis was also peer reviewed and accepted by the same committee." (Vincelli Report at 2). Vincelli notes also that this thesis paper, titled "Numerical Methods for Quantifying Wear in Metal-on-Metal Hip Retrievals," was published by Dartmouth College, and while the thesis has not been critically reviewed by experts in the field, aside from the professionals on the committee, written abstracts have been submitted to conferences by biomedical engineering journals that were peer-reviewed and accepted. (Tr. of Dec. 29, 2014 Vincelli Dep. [95-2] ("Vincelli Dep.") at 21:1-22:16).

Plaintiff asserts that general acceptance is a factor to consider, but is not dispositive, and the amount or extent of peer review Vincelli's methodology has received does not render his methodology flawed. (Vincelli Response at 11). Plaintiff asserts that the level or extent of peer review is a matter of weight for the jury to decide. (Id.). Daubert, however, establishes that acceptance in the scientific community and whether and to what extent a theory has been peer reviewed are factors to consider in ensuring that "any and all scientific testimony or evidence admitted is not only relevant, but reliable." Daubert, 509 U.S. at 589. The Court, thus, must consider the factors in Daubert to determine if Vincelli's calculation of immeasurable wear has been shown to be sufficiently reliable to allow it to be presented to the jury.

Assuming, *arguendo*, that the public defense of his thesis in front of the committee and the inclusion of abstracts submitted to peer review journals is sufficient to satisfy Rule 703 and Daubert, the Court notes that Vincelli's theory has not and apparently cannot be tested in such a way that would show that the actual "immeasurable" wear on an explanted device matched the mathematical calculations he utilized in this case.[32] The Court notes further that, as a result of

[32] The Court is unaware of any authority in case or in the scientific community that defense of a master's thesis before an academic panel at the institution where a student is enrolled in a master's program constitutes peer review for purposes of

the wear being "immeasurable" and Vincelli's methodology not being tested, it cannot ascertain the potential rate of error of his technique. That is, Vincelli's specific methodology in calculating "immeasurable" wear does not appear to have been generally accepted in the scientific community.[33]

It appears undisputed that a CMM is incapable of measuring all wear and, therefore, it may be likely that wear volumes on an explanted device may be higher than the wear volume identified by a CMM. The Court only notes that Vincelli's calculation of a wear volume of 2.1mm^3 is not based on a methodology that can be tested or which has been widely accepted by the scientific community. The Court concludes that Vincelli's expert testimony regarding his calculation of the immeasurable wear on Plaintiff's hip implant is not established as sufficiently reliable, would not be useful to the jury in understanding evidence or on issues to

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acceptance of a theory, process, study, or research. Such an academic panel is not engaged in the kind of peer review envisioned under Daubert, including because the purpose of it is directed at qualification for meeting requirements and expectations of a degree program within an academic institution.

[33] Plaintiff asserts, in a footnote, that Vincelli's "work was in accordance with widely accepted and recognized standards." (Vincelli Response at 11, n.3). The Court, in reviewing the Vincelli Response and supporting documents, did not locate any scientific literature that supported the claim that Vincelli's specific methodology in ascertaining "immeasurable" wear was in accordance with widely accepted and recognized standards.

be determined, and his opinion on immeasurable wear is excluded under Daubert. See, e.g., Quiet Tech., 326 F.3d at 1341.[34]

D. Reed Ayers, Ph.D.

Ayers, a metallurgist employed by Verkko Biomedical, is "an experienced multi-discipline engineer specializing in the synthesis and design of orthopedic materials as well as their failure in a clinical application," whose "experience includes work on the synthesis/manufacture of CoCrMoC alloys bone ingrowth to porous materials the corrosion of biomedical alloys and how the corrosion products of these alloys affect bone and other tissues." (Ayers Report at 2) (internal citations omitted).

Ayers offers a general opinion on the materials used in manufacturing Wright Medical's Conserve cup. He opines that the materials selection for the Wright Medical Conserve cup was faulty because:

> CoCrMoC, while wear resistant in a typical engineering application, is an inappropriate material for use as a bearing surface and a porous scaffold in-vivo due to the wear products from scratching and ions released from intergranular corrosion are toxic to the surrounding tissue and should not have been considered in the WMT Conserve® cup.

[34] Defendants note that Vincelli's wear rates were relied upon by Jarrell in reaching his expert opinions. (Vincelli Motion at 1). To the extent Jarrell relies on Vincelli's simulated wear volume calculation methodology in rendering his expert opinions, those opinions are determined, under Daubert, to be not sufficiently reliable, and they are excluded.

(Id. at 3). Ayers, in reaching this opinion, relies on the Laposata and Jarrell Reports which identify how cobalt, chromium, and molybdenum ions and intact CoCrMoc particles were produced from the functions of the implant and caused its resultant failure. (Id. at 4). Ayers opines that the "ions released into the surrounding tissue come from both the corrosion of the wear particles, as the result of biodegradation and directly from leaching of Cr, Co and Mo ions from the exposed substrate material on the cup surface." (Id. at 5) (internal citations omitted). Ayers' examination of microscopic images taken of the explanted device showed scratches and wear debris on the surfaces of the cup and ball. (Id.). Ayers opines:

> CoCrMoC is not an effective material to engender osseointegration due to the forms of oxides and the corrosion products, e.g. toxic ions, released into the tissue.

(Id.).

> Ayers' previous scientific work established that:
>
> CoCr based alloy had less than 1/2 the amount of boney ingrowth as Ti6AI4V[35] with an equivalent porosity. When considering the previously described passivation and ion release issues, the cause of reduced [] bone ingrowth is evident. Both titanium alloys and calcium phosphate based ceramics have a much greater potential for bone ingrowth and subsequent implant stabilization than CoCr alloy and

35 Ti6AI4V is a type of titanium alloy.

> both can be applied to a CoCrMoC bearing surface as a porous coating, e.g. diffusion bonding or plasma spray . . . .

(Id. at 6).

Ayers concludes that the

> CoCrMoC alloy fails to sufficiently osseointegrate into the surrounding bone due to the release of ion[s] during corrosion of both wear particles and the wear surfaces of the implant. The selection of CoCrMoC as a bearing surface is faulty due to the instability of the passivation layer as the result of lack of lubrication and continuous abrasive attack, releasing metal ions and wear particles into the surrounding tissues.

(Id.).

Defendants contend that Ayers' opinion concerning the suitability of the materials selected to manufacture the Conserve implant "should be excluded because there is no scientific connection between Dr. Ayers' opinions and the specific facts of this case." (Ayers Motion at 1). Defendants claim that Ayers failed to examine Plaintiff's explanted device, failed to perform any tests on the device, and failed to apply his material suitability opinions to this case. (Id. at 2). Defendants claim specifically that Ayers failed to: (i) measure the degree of metal particles released by Plaintiff's device or the amount of wear on the device; (ii) measure the levels at which exposure to chromium becomes toxic; (iii) perform any studies concerning fluid film lubrication layers in hip devices; (iv) measure the timing or duration of ion production from cobalt-chrome wear particles;

(v) measure the sizes of cobalt-chrome wear particles; and (vi) measure free ion concentrations from cobalt-chrome wear particles. (Id.).

Defendants argue that Rule 702 requires an expert's testimony to "fit" a case, meaning that it will assist the trier of fact to determine disputed factual issues. Defendants claim that Ayers "expressed a theory of general scientific properties of cobalt and chromium in an unspecific manner and without any valid scientific application to the specific facts of this case." (Id. at 9). Defendants rely on Hoffman v. Ford Motor Co., 493 F. App'x 962 (10th Cir. 2012), to argue that Ayers' opinions do not "fit" the facts of this case.

In Hoffman, the plaintiff was severely injured in the rollover of a 1999 Ford Mercury Cougar Coupe in which she was a passenger. Hoffman v. Ford Motor Co., 493 F. App'x 962, 963 (10th Cir. 2012). The plaintiff sued Ford, claiming she was wearing a seatbelt during the accident but that a defect in the buckle caused it to release during the accident resulting in her ejection from the car. Id. The plaintiff retained a mechanical engineer, who opined that the "seatbelt buckle 'most probably' inertially unlatched during the accident due to a defect in its design." Id. at 963-64. To reach this conclusion, the expert

> ran a series of component tests on buckles similar in design to [the plaintiff's] (but not her buckle) to determine their lowest inertial unlatch threshold, i.e., the lowest level of acceleration needed to unlatch the buckle. After obtaining his results he was required (as he

> acknowledged) "to make a comparison with data from rollover crash tests to determine if the scenarios measured in the laboratory could occur in the real world." However, citing a lack of rollover crash test data, he compared his results to data from planar crash tests—ones conducted on only the horizontal plane (as opposed to the considerably more dynamic and elusive forces present in a rollover)—and determined his results could occur in the real world.

Id. at 964. The defendant moved to exclude the expert's testimony, arguing that the testimony was, under Daubert, unreliable and irrelevant because the expert "failed to demonstrate that the levels of acceleration he found necessary to cause inertial unlatch in the laboratory occurred or could have occurred on [the plaintiff's] buckle in this accident." Id.

The Hoffman court concluded that the expert "failed to present a scientific connection between the accelerations he found necessary to inertially unlatch buckles tested in the laboratory and accelerations that occurred or could have occurred on [the plaintiff's] buckle during the rollover." Id.

Defendants claim that Ayers also failed to present a scientific connection between his materials opinion and the device implanted to replace Plaintiff's hip. Defendants argue that Ayers opines, in only a general sense, that the "properties of cobalt and chromium . . . render it an inappropriate material for use as a bearing surface in metal alloy form." (Ayers Motion at 9-10). Defendants assert further that Ayers' conclusion is based entirely on his reading of materials data sheets for

the powder form of cobalt and chromium, and fails to "consider and connect how the handling precautions stated on materials safety data sheets for pure form powder elements equates to its safety and functioning in metal alloy form in a medical device." (Id.). Like the expert in Hoffman, Defendants claim, Ayers makes an "unsupported scientific leap" by contending that because "cobalt and chromium in their raw powder form require special handling, they must also be dangerous when used in metal alloy form in a medical device." (Id. at 10).

Finally, Defendants assert that Ayers failed to examine Plaintiff's hip implant or otherwise measure, test, or inspect the device, and thus failed to provide any foundation and fit of his opinions to Plaintiff's hip implant. (Id.). Without these tests and measurements, Defendants claim that Ayers "makes the unsupported scientific leap to the opinion that toxicity of the elemental materials cobalt and chromium caused the devices at issue to fail." (Id. at 11).

"Under *Daubert*, scientific testimony does not assist the trier of fact unless the testimony has a justified scientific relationship to the pertinent facts." McDowell v. Brown, 392 F.3d 1283, 1299 (11th Cir. 2004) (citing Daubert, 509 U.S. at 591). The "relationship must be an appropriate 'fit' with respect to the offered opinion and the facts of the case." Id.

In this case, Ayers linked his findings to the specific design of Plaintiff's metal-on-metal Conserve hip implant. In addition to examining Plaintiff's medical records and the Laposata Report and Jarrell Report, Ayers examined microscopic images of Plaintiff's Wright Medical Conserve cup and ball, and found scratches and wear debris on the surfaces of both components. (Ayers Report at 2, 5). Ayers thus relied on more than just the "materials safety data sheets for pure form powder elements" to form his opinion that Wright Medical's use of CoCrMoc was a design defect that caused harmful metal ions to be released into Plaintiff's body. The materials data sheets were one source Ayers considered, but he states his opinions also were based on orthopedic research he has conducted, work he has performed, and his knowledge of the synthesis and manufacture of CoCrMoC alloys, bone ingrowth to porous materials, the corrosion of biomedical alloys and how the corrosion products of these alloys affect bone and other tissues. (Id. at 2) (internal citations omitted).

Based on this professional background, Ayers testified that chromium, if it becomes mobile "will move outside of the device and leach out. The only way chromium would be safe is if it was bound metallically within the alloy itself."

(Plaintiff's Tr. of Jan. 8, 2015 Ayers Dep. [96-2] at 61:11-21).[36] Ayers stated that in the case of a CoCrMoc alloy, it is not safely bound. (Id. at 61:23-62:4). Ayers' opinions applied to "any cobalt-chromium product" and "any cobalt medical device." (Id. at 62:5-10).

A close examination of Ayers' qualifications, research, experience, and the basis for his opinions that the chromium contained in a CoCrMoc alloy, such as that used in the Conserve implant, is mobile and will leach out of the device, causing harm to the person with the implant, establishes that his expert testimony "fits" the facts of this case and is not an "unsupported scientific leap." Ayers connects his opinions regarding CoCrMoc alloys to the specific facts in this case by opining that the Conserve hip system is defective because it uses CoCrMoc that releases metal ions and wear particles into the surrounding tissue and fails to sufficiently osseointergrate into the surrounding bone due to this release. (Ayers Report at 6).[37] The Court concludes that Ayers' expert opinion is sufficiently

[36] Plaintiff, in opposition to Defendants' Ayers Motion, filed this version of Ayers' January 8, 2015, deposition transcript, which contains additional pages not included in the Ayers Deposition filed by Defendants.

[37] Defendants' argument that Ayers failed to examine the explanted device (despite having viewed microscopic photographs of the cup and ball to confirm that there was wear on these components), and that he failed to perform other tests that Defendants deem necessary, are ultimately legitimate subjects to explore and may impact the credibility of Ayers' testimony. Credibility, of course, is an issue

reliable, would be useful to the jury to understand the evidence and to determine issues in this case and is not required to be excluded under Daubert. See City of Tuscaloosa, 158 F.3d at 562-63.

E. Lance A. Waller, Ph.D.

Lance A. Waller, Ph.D. ("Waller") is a biostatician and professor of Biostatistics and Bioinformatics at the Rollins School of Public Health at Emory University.[38] Plaintiff seeks to offer Waller's opinion on:

> (1) the reported conduct of clinical studies relating to the CONSERVE Plus Total Resurfacing Hip System and subsequent impacts on data quality, study design, and study implementation; and (2) an assessment of the statistical analysis results reported by Wright Medical Technologies with particular attention on the reported revision and/or failure rates.

(Waller Report at 1).

Waller evaluated Wright Medical's clinical studies and documentation regarding the Conserve Plus Total Resurfacing Hip System[39] and compared them

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for the jury to decide after "[v]igorous cross-examination [and the] presentation of contrary evidence . . . ." See Quiet Tech., 326 F.3d at 1341.

[38] Plaintiff submitted Waller's expert report dated July 15, 2013, [49-3] ("Waller Report"). Waller's background and experience is not a basis for Defendants' Daubert motion.

[39] 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,

and their results to a series of "Good Clinical Practice" statements published by the FDA. (Id. at 1-2). Waller calls the guidelines "the gold standard for clinical studies," acknowledging the statements are guidelines, and not regulations. (Id. at 1-2). Based on this review, Waller opines on alleged deficiencies in Wright Medical's listing of adverse events and its data verification procedures, Wright Medical's failure to follow FDA guidance on data security, and deviations from protocols. (Id. at 2).

Waller then offered his opinion on revision and failure rates reported by Wright Medical by comparing these revision rates to those reported in two other reports. (Id. at 2-4) The first was a 1994 Consensus Statement of the National Institute of Health ("NIH") regarding total hip replacements which showed revision rates for cemented components "to be less than 5 percent at 10-year follow-up," and to be "approximately 2 percent" for uncemented components "at 5-year follow-up." (Id. at 2). The second was a National Institute of Health Care Excellence report published in the United Kingdom which recommended "a 10% cumulative 10-year revision rate as a 'benchmark' for acceptable performance." (Id. at 3). Waller compared these two reports' observations and conclusions with revision rates found in Wright Medical's April 15, 2010, Conserve Plus Total Hip

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by contrast, is used for total hip arthroplasty, the surgical replacement of the hip joint with an artificial prosthesis.

Resurfacing Statistical Analysis Report (the "2010 Report"). (Id. at 3-4). The reported revision rates, according to Waller, are "15 out of 278 procedures (5.4%) in the CONSERVE® Plus Total Resurfacing Hip System All Enrolled Audited cohort (which includes both unilateral and bilateral patients)" and "38 out of 612 procedures (6.2%) in the All Enrolled Unilateral (original Shell) cohort." (Id.). Waller acknowledges the 2010 Report revision rates were based generally on two years or more of post-implantation follow-up, making it difficult to compare to the NIH numbers. (Id.). Because the NIH numbers are based on 5-year and 10-year periods of follow-up, he "reasonably expect[s] these rates to increase as follow-up time increases." (Id.). Waller, based on his comparison, opines that because the reported rates for two years or more of follow-up already exceed the NIH values, the 2010 Report "does not provide convincing evidence that the CONSERVE Plus System provides better performance than the consensus standard given in the NIH Consensus statement." (Id.). Waller also opines on several deficiencies in the 2010 Report's methodology, namely that the sample size was too small, the possibility that a proportion of the revisions and implants are "lost to follow up," and the findings are potentially biased for a lack of a "survival analysis" for the data findings. (Id. at 3-4).

In light of these supposed deficiencies in the 2010 Report's methodology, Waller claims the "the most precise estimates of total hip replacement revision rates are provided by the population-based registries from the Australian Orthopaedic Association's National Joint Replacement Registry (NJRR) and the National Joint Registry (NJR) of England, Wales, and Northern Ireland." (Id. at 4). The "NJRR 2007 Annual Report provides a 5-year cumulative revision rate for the CONSERVE Plus hip replacement of 16.4%," and the 2008 NJRR Annual Report estimates a revision rate of 10.1%, the 2009 NJRR Annual Report estimates a revision rate of 9.7%, and the 2012 NJR Annual Report (in the United Kingdom) estimates a 5-year cumulative revision rate of 8.52%. (Id.). Relying on these studies, Waller concludes that the Conserve Plus system has a significantly higher revision rate than the standards in the NIH Consensus Statement and the National Institute of Health Care Excellence report.

Defendants move to exclude Waller's opinions and testimony "because they are not based upon a scientifically valid or reliable methodology." (Waller Motion at 1). Defendants argue that Waller's conclusions are not based on reliable methodology because Waller selectively chose studies and medical literature favoring his views on Wright Medical's revision rates, excluding others that did not agree with his conclusion. (Id.). Defendants also assert that Waller did not

have experience in designing or analyzing clinical studies, and the opinions he offered are outside his area of expertise. (Id.).

The Court begins with Defendants' claim that Waller's opinion that Wright Medical deviated from acceptable clinical practices in its submissions to the FDA should be excluded as outside his expertise because Waller does not have experience in designing or analyzing studies of medical devices or hip implants for safety or efficacy. (Id. at 13). Defendants assert that Waller "does not have any experience in clinical studies for medical devices or FDA standards for clinical studies before it during the approval process. He is a biostatistician only, with experience in data collection, review, modeling and analysis." (Id.).

Waller has over twenty-three (23) years of experience in developing and applying statistical methods in biomedical research and his work typically requires him to work with data collected in other people's studies. (Waller Report at 1). Waller noted that he works with people who work on clinical trial design and analysis and has had many discussions with them regarding data quality and guidelines for compliance with FDA regulation, and that, as part of his work, he applies the FDA Good Clinical Practice standards to studies that go out of his department, and to studies under design. (Tr. of Jan. 13, 2015, Waller Dep. ("Waller Dep.") [94.2] at 52:4-15, 106:12-16). Waller claims that he applies the

FDA Good Clinical Practice standards to all the studies that go out of his department, including a tuberculosis study that was being designed at that time. (Id. at 52:4-10).[40] Waller's opinion regarding Wright Medical's studies are based, in part, on two letters--dated January 29, 2004 and May 27, 2008--from the FDA to Wright Medical detailing deviations from the FDA's guidelines, with which Waller is familiar based on his twenty-three years of experience.

Waller relies heavily on the 2010 Report to support his opinion regarding the revision rate for Wright Medical's metal-on-metal hip implant system. This report is for revision rates for Wright Medical's resurfacing system, not Wright Medical's total hip arthroplasty. These are two different procedures and resurfacing is not at issue here. (Waller Motion at 22-23). Waller has not shown that total hip replacement and resurfacing procedures produce the same revision rates or that revision is required for the same or similar reasons.[41] In seeking to admit expert testimony, it is the proponent's burden to show the reliability of the opinion

[40] The Court notes that Waller has not designed or otherwise been involved in studies regarding metal-on-metal implants. Defendants, however, have not identified how the FDA Good Clinical Practice standards, or Waller's other opinions regarding the efficacy of Defendants' studies, require the specificity that Defendants seem to demand.

[41] Plaintiff argues that the "thin cup" in Wright Medical's Conserve Plus Total Resurfacing System analyzed in the 2010 Report is the same "thin cup" used in Wright Medical's Conserve implant. (Waller Response at 13-14). Plaintiff fails, however, to show that the implantation of the cup in a total resurfacing procedure can or does produce the same conditions requiring revision.

offered. Frazier, 387 F.3d at 1260. Plaintiff fails to show the reasons for revision in the data used here.

Here, it appears Waller is qualified generally to offer expert opinions based on bio-statistical evaluation. The question in this case is whether the opinion he seeks to offer, based on his comparison of studies and standards, is reliable. The Court determines it is not, including because the studies and standards against which the 2010 Report's revision rates are based are not shown to be generally accepted within the scientific community as acceptable for revision rate comparison and standardization. The follow-up periods are not consistent with the follow-up data from the 2010 Report, Waller admits that his extrapolation of rates in the studies used to compare to the 2010 Report are not certain, and the 10-year follow-up rates are unknown. More fundamentally, the revision rate comparison that Waller seeks to offer is not sufficiently connected to the alleged failure in this case to be reliable. Waller seeks to compare similar implant products but he does not provide information to show that the revisions accounted for were caused by the alleged metallosis-based failure at issue in this case. He does not offer any data on the cause of the revisions included in the rates calculated. He simply looks at revisions as a whole without providing any basis for reasonably reliable conclusions that the revisions were required, in whole or in part, because of the

failure cause and manner alleged in this case. The record compels the conclusion that his opinion is not sufficiently reliable to be allowed at trial.

Waller's expert opinion regarding alleged inaccuracies in the 2010 Report also is not sufficiently reliable, including because the data and conclusions in the report discredit Waller's opinions. Waller agrees with the 2010 Report's conclusions regarding the number of revisions it found over the twenty-four-month follow-up period. Waller also acknowledges that, because the 2010 Report was based on only two years of follow-up, it was insufficient to determine what the revision rates would be at ten-year follow-ups. (Waller Report at 3-4). Yet, it is a 10-year rate in other reports he viewed for his biostatistical comparisons. He seeks to overcome this apples-to-oranges comparison by making a conclusory finding that the rates of revision identified in the 2010 Report for a two-year follow-up period would "likely increase" when extended to a ten-year follow-up period. (Id. at 3-4). This is not reliably supported by evidence or data.

In short, Waller does not provide any factual support for his contention that the revision rates found in the 2010 Report will increase over time. While it may be logical to assume that revision rates will increase, as opposed to remaining unchanged, over an additional eight years, Waller does not provide any specific support for this opinion, the rate he believes applies, or the reasons for the later

year revisions. And, as previously stated, there is no underlying support to connect general revision rates with revisions required for the defect alleged in this case. Experts are generally entitled to "extrapolate from existing data," Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997), but they cannot provide opinions on matters that are not sufficiently or reliably connected to existing data. Guinn v. AstraZeneca Pharm. LP, 602 F.3d 1245, 1255-56 (11th Cir. 2010).

Waller's revision rate opinion for total hip arthroplasty also is unreliable because he selectively relied only on data and findings that support his views without a reasonable basis, accepted within the scientific community, to do so. Waller bases his conclusions regarding Wright Medical's revision rates on two FDA letters from 2004 and 2008 and data from registries published in Australia and the United Kingdom. These registries make up only a small fraction of the available and relevant scientific literature, and are not specific to total hip arthroplasty procedures. The registries also do not control the revision rates based on the cause of the failure of the implant sufficient to show the revision rates identified in the registries are germane to the reasons in this case.[42] Waller fails to cite results from randomized controlled trials, which are more reliable.

[42] Waller did consider randomized clinical trials, concluding that no well-designed randomized clinical trials exist for revision rate. (Waller Aff. [94.1] at 7). Waller notes that one issue is that many of the trials only have duration of

Plaintiff admits there is no registry in the United States that tracks revisions, but argues the American Academy of Orthopaedic Surgeons has found the Australian Orthopaedic Association's National Joint Replacement Registry and the National Joint Registry of England, Wales, and Northern Ireland to be "two high quality joint registries." (Waller Response at 11) (citing Am. Acad. of Orthopaedic Surgeons, Modern Metal-on-Metal Hip Implants: A Tech. Overview 4, 49 (Dec. 2, 2011) [49.7]). This may be so, if the issue was revision rates irrespective of the reasons for revision. Here, revision rates are meaningful only if caused by, or connected to, the defect alleged by Plaintiff.

The Court finds fundamental shortcomings in Waller's comparison analysis that discredits the reliability of the opinion, and to admit it would risk confusing, and likely misleading, the jury. Applying the analysis required by Daubert, the Court concludes these opinions are unreliable and they are excluded. See City of Tuscaloosa, 158 F.3d at 562-63.

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one to three years, making calculation and estimation of a 5 or 10-year revision rate challenging. (Id. at 4) (citing C.A. Engh, et al., Metal Ion Levels After Metal-on-Metal Total Hip Arthroplasty: A Five-Year Prospective Randomized Trial, 96A Journal of Bone & Joint Surgery, 448-49 (Mar. 19, 2014)).

IV. MOTIONS FOR SUMMARY JUDGMENT

A. Legal Standard

A court "shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Parties "asserting that a fact cannot be or is genuinely disputed must support that assertion by . . . citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials." Fed. R. Civ. P. 56(c)(1).

The party seeking summary judgment bears the burden of demonstrating the absence of a genuine dispute as to any material fact. Herzog v. Castle Rock Entm't, 193 F.3d 1241, 1246 (11th Cir. 1999). Once the moving party has met this burden, the non-movant must demonstrate that summary judgment is inappropriate by designating specific facts showing a genuine issue for trial. Graham v. State Farm Mut. Ins. Co., 193 F.3d 1274, 1282 (11th Cir. 1999). Non-moving parties "need not present evidence in a form necessary for admission at trial; however, [they] may not merely rest on [their] pleadings." Id.

The Court must view all evidence in the light most favorable to the party opposing the motion and must draw all inferences in favor of the non-movant, but only "to the extent supportable by the record." Garczynski v. Bradshaw, 573 F.3d 1158, 1165 (11th Cir. 2009) (quoting Scott v. Harris, 550 U.S. 372, 381 n.8 (2007)). "[C]redibility determinations, the weighing of evidence, and the drawing of inferences from the facts are the function of the jury . . . ." Graham, 193 F.3d at 1282. "If the record presents factual issues, the court must not decide them; it must deny the motion and proceed to trial." Herzog, 193 F.3d at 1246. But, "[w]here the record taken as a whole could not lead a rational trier of fact to find for the non-moving party," summary judgment for the moving party is proper. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986).

B. WMG's Motion for Summary Judgment

WMG moves the Court for summary judgment on the grounds that the Court lacks personal jurisdiction over it and because Plaintiff has failed to present any evidence of wrongful conduct by WMG. (WMG's MSJ at 4-14).

1. Personal Jurisdiction Defense

Rule 12 provides that a party "may assert [certain] defenses by motion" including the defense of "lack of personal jurisdiction." Fed. R. Civ. P. 12(b)(2). The rule states further that a "motion asserting any of these defenses must be made

before pleading if a responsive pleading is allowed." Fed. R. Civ. P. 12(b). Rule 12(h) provides that a "party waives any defense listed in Rule 12(b)(2)-(5)," including the defense of lack of personal jurisdiction, by "failing to either: (i) make it by motion under this rule; or (ii) include it in a responsive pleading . . . ."[43] Fed. R. Civ. P. 12(h). A defense is not "waived by joining it with one or more other defenses or objections in a responsive pleading . . . ." Fed. R. Civ. P. 12(b).

Plaintiff argues that WMG waived its right to assert lack of personal jurisdiction as a defense by failing to raise it in a motion to dismiss or a responsive pleading. WMG asserts that Case Management Order No. 1 ("Order No. 1") prohibited Defendants from filing motions to dismiss that were not dispositive of all of Plaintiff's claims. (See Case Management Order No. 1 (MDL [86]) at ¶ 2) ("Defendants only may file a motion to dismiss in response to a Short-Form Complaint if it would be dispositive of all of Plaintiff's claims"). WMG contends that this provision of Order No. 1 excused WMG's failure to assert a lack of personal jurisdiction defense and allows the defense to be asserted in its summary judgment motion. (WMG's Reply [108] at 8-9). The Court disagrees.

[43] Rule 12(h) also allows a party to avoid waiver of a defense if the defense is asserted in an "amendment allowed by Rule 15(a)(1) as a matter of course." Fed. R. Civ. P. 12(h)(1)(B)(ii). This exception does not apply here.

On February 22, 2013, Defendants filed their Short Form Answer [7] to Plaintiff's Short Form Complaint. The Short Form Answer contained thirty (30) affirmative defenses, including the defense for failure to "state a claim upon which relief may be granted," one of the defenses listed under Rule 12(b). (Short Form Answer at 4). The Short Form Answer did not assert a Rule 12(b)(2) defense based on lack of personal jurisdiction but did contain a reservation of rights to assert further affirmative defenses after a more fully developed complaint was filed. (Id.).

On October 10, 2014, Plaintiff filed her Second Amended Complaint. On October 24, 2014, WMG filed its Answer [12] to the Second Amended Complaint ("WMG Answer"). The WMG Answer again contained thirty (30) affirmative defenses, but again did not assert a Rule 12(b)(2) lack of personal jurisdiction defense. (WMG Answer at 20-26). In its WMG Answer, WMG this time did not reserve the right later to assert additional affirmative defenses, including based on lack of personal jurisdiction. (See id.).

WMG argues that Order No. 1 prohibited WMG from filing a motion to dismiss if it did not dispose of all of Plaintiff's claims and, thus, the order preserved WMG's ability to assert now its defense based on lack of personal jurisdiction. In short, WMG argues that because it was prohibited from asserting a

lack of personal jurisdiction defense in a motion to dismiss, it is entitled to raise it now in its motion for summary judgment, despite not having asserted it as an affirmative defense in its WMG Answer. The plain language of Rule 12(b) and (h) and the interdependence of these two subsections discredits WMG's argument. The "implicit reservation of right to assert a defense" argument advanced by WMG is inconsistent with the express language of Rule 12(h).

Rule 12(h) unequivocally provides for a waiver of the defenses set out in Rule 12(b)(2)-(5), including one based on lack of personal jurisdiction, if a defendant fails to raise a Rule 12(b)(2)-(5) affirmative defense either in a (i) motion to dismiss under Rule 12(b), or (ii) in a defendant's answer. Here, Defendant failed to assert a Rule 12(b)(2) lack of personal jurisdiction defense in either of the answers it filed in this action. Importantly, WMG did not take any action to preserve the right to file a motion based on lack of personal jurisdiction after its answers were filed. In fact, in its WMG Answer, WMG did not include a reservation of defenses as it did when it filed its answer to the Short Form Complaint

These failures to assert the defense when required results in waiver of the defense. See Fed. R. Civ. P. 12(h). WMG claims that In re Cathode Ray Tube (CRT) Antitrust Litig., 27 F. Supp. 3d 1002 (N.D. Cal. 2014), a multidistrict

litigation case from California, supports that WMG may, in this multidistrict litigation, raise a lack of personal jurisdiction defense other than in a motion to dismiss or an answer. WMG's reliance on Cathode Ray Tube is misplaced. The Cathode Ray Tube court considered whether a defendant in a multidistrict litigation case waived its right to assert lack of personal jurisdiction in one case because, in earlier responses to other plaintiffs' complaints, it failed to raise the affirmative defense. The Cathode Ray Tube court found that the defendant did not waive the right to assert lack of personal jurisdiction as an affirmative defense, even though it failed to assert it in responsive pleadings to other complaints, because the defendant expressly reserved its right to raise a personal jurisdiction defense later. Cathode Ray Tube, 27 F. Supp. 3d at 1009. There is no such reservation in this action and Cathode Ray Tube simply does not apply.

Here, in its WMG Answer to Plaintiff's Second Amended Complaint, WMG failed to raise its lack of personal jurisdiction defense, as required by Rule 12. It also failed to reserve its right to assert a lack of personal jurisdiction or other defenses at a later time. As a result, WMG waived its right to assert a lack of personal jurisdiction defense because WMG failed to assert it in a responsive pleading and failed to reserve the right to do so later. See Fed. R. Civ. P.

12(h)(B)(ii). WMG's motion for summary judgment on the ground of lack of personal jurisdiction is denied.

2. Absence of Wrongful Conduct

WMG next argues that it is entitled to summary judgment because there is not any evidence that WMG committed the wrongful conduct that Plaintiff alleges caused her injury. WMG contends that it is merely a holding company, and that it held Wright Medical's stock in its holding company capacity. (WMG's MSJ at 4). WMG claims that it was not involved in the design, manufacture, sale, or marketing of the Conserve hip implant components and that no reasonable juror could find it liable for the claimed defect, failure to warn, or other liability-creating conduct Plaintiff alleges in this case. (Id. at 2).

WMG offers the sworn declaration of Ms. Deborah Daurer ("Daurer"), a senior manager at Wright Medical--not employed by WMG--to support that WMG was not involved in the design, manufacture, sale, or marketing of the Conserve hip implant components. (Daurer Decl. [38.4] ¶¶ 2, 8). In her declaration, Daurer swore she had personal knowledge of the facts stated in it. (Id. ¶ 1). Daurer, however, admitted during her deposition that she did not have personal knowledge whether WMG was involved in the design, manufacture, sale, or marketing of the Conserve hip implant components, and admitted the statements in her declaration

were based on what she was told by outside counsel and Wright Medical's tax director. (Tr. of Feb. 6, 2014, Daurer Dep. [121.2] at 153:12-154:11). Daurer testified that she is not aware whether WMG paid for, managed, approved, or made decisions regarding the design, specifications, testing, or development of the Conserve devices. (Id. at 69:16-22). WMG did not provide sworn declarations from any individual, other than Daurer, to support that WMG is merely a holding company that was not involved in the design, manufacture, sale, or marketing of the Conserve hip implant components.

The Court first considers whether Daurer's declaration is competent and may be used by the Court to consider WMG's claim it did not engage in actionable conduct. Under Rule 56(c), the Court can evaluate a variety of evidence to determine if a fact or facts are generally disputed. Besides relying on evidence in the record, Rule 56(c)(4) allows a party to support a summary judgment motion with affidavits or declarations. Subsection (c)(4) provides, however, that an "affidavit or declaration used to support or oppose a motion must be made on personal knowledge, set out facts that would be admissible in evidence, and show that the affiant or declarant is competent to testify on the matters stated." Fed. R. Civ. P. 56(c)(4). Daurer's declaration fails to meet these fundamental requirements for the Court to consider it in support of WMG's summary judgment

motion. The declaration is not made based on her personal knowledge. To the contrary, she apparently does not have much, if any, personal knowledge of the "facts" and conclusions stated in her declaration. Rather, the declaration is founded on hearsay which is not admissible, thus failing another requirement of Subsection (c)(4). Because WMG's summary judgment motion essentially relies only on the Daurer Declaration, and the declaration fails to meet the basis requirements of Rule 56(c)(4), summary judgment cannot be granted.[44]

Even if the Daurer Declaration met the Rule 56 requirements, summary judgment is not appropriate here considering there are record facts that dispute those set out in the Daurer Declaration. WMG routinely filed annual and quarterly reports with the Securities and Exchange Commission ("SEC"). In its 2002 10-K [61.1] ("2002 10-K"), WMG defines itself as the "Company" and states that, through Wright Medical, WMG "is a global orthopaedic device company specializing in the design, manufacture and marketing of reconstructive joint devices . . . ." (2002 10-K at 2). WMG notes that (i) the "Company specializes in reconstructive joint devices," (ii) the Company's products and research and development activities are strictly regulated, and (iii) "before the Company can market a new medical device, marketing clearance must be obtained through a

[44] The submission of this under-oath declaration is troubling.

510(k) premarket notification . . . ." (Id. at 3-4). WMG states also that (i) it "offers a comprehensive line of products for hip joint reconstruction," (ii) its research and development staff are focused on developing new products in the knee, hip, extremity, reconstruction, and bio- orthopaedic material markets; and (iii) its sales and marketing staff targets orthopaedic surgeons. (Id. at 8, 11-12). WMG states further that it "employed *directly* and through [its] subsidiaries 797 people in the following areas: 359 in manufacturing, 224 in sales and marketing, 143 in administration and 71 in research and development." (Id. at 15) (emphasis added). WMG's 2003, 2004, 2005, and 2006 10-Ks provide similar descriptions of WMG's involvement in the research, development, production, marketing, and sale of its orthopaedic products. (See [61.3], [61.4]).[45] There is no evidence that has been presented to the Court to show any description of the operations and responsibilities of WMG and Wright Medical upon which the Court can now conclude that WMG was not involved in the manufacture, marketing or sale of the Conserve hip replacement device or its component parts.

[45] The Court is entitled to take judicial notice of WMG's SEC filings. See, e.g., Fed. R. Evid. 201(b), (c). Judicial notice of these filings does not constitute a determination that WMG's statements in its filings are true, or are assertions or admissions of WMG's involvement in the manufacture and sale of Conserve products.

Some documents that Defendants produced during discovery, including bills of material, also support that WMG was more involved in the manufacture and sale of orthopaedic products, including the Conserve implant components, than one ordinarily might expect of a holding company. (See [62.11]). For example, documents entitled WMG's "Bill of Print Material," for the Profemur Neck 8DGA/R, Conserve Total A-Class Head, Profemur Plasma Z Stem, and Conserve Plus Cup, WMG's inventory by branch and location, and WMG's item listing by customer program, all facially support that WMG may have been involved in the manufacture, sale, or marketing of the Conserve hip replacement components. (Id. at 5, 9-11, 14, 15-30, 35).

The SEC filings and documents produced in discovery create a genuine issue of material fact over WMG's involvement in the production and marketing of the Conserve implant components, including those implanted in Plaintiff. In light of these documents, and in light of WMG's failure to provide admissible evidence to support that WMG was not involved in the design, manufacture, sale, or marketing of the Conserve hip implant components, the Court determines that WMG is not entitled to summary judgment.[46]

[46] Plaintiff filed a Motion to Strike the Declaration of Deborah Daurer [121] ("Motion to Strike"). Having concluded that WMG is not entitled to summary judgment, Plaintiff's Motion to Strike is denied as moot.

C. Defendants' Motion for Summary Judgment

Plaintiff asserts claims for: (1) Strict Product Liability (Design Defect) (Count I); (2) Strict Product Liability (Failure to Warn) (Count II); (3) Negligence (Design Defect and Failure to Warn) (Count III); (4) Fraudulent Misrepresentation (Count V); (5) Fraudulent Concealment/Non-Disclosure (Count VI); and (6) Negligent Misrepresentation (Count VII). (Second Am. Compl. ¶¶ 32-109). Plaintiff seeks compensatory damages, punitive damages, and prejudgment interest.

Defendants assert five grounds to support their summary judgment motion: (1) Plaintiff's claims for strict liability design defect and negligent design defect (Counts I and III) are preempted by the Medical Device Amendment of 1976; (2) Comment K of Section 402A of the Restatement (Second) of Torts bars Plaintiff's strict liability claim for design defect (Count I); (3) Plaintiff failed to present evidence to support her claims for strict liability failure to warn and negligent failure to warn (Counts II and III); (4) Plaintiff cannot establish prima facie claims for fraudulent misrepresentation, fraudulent concealment, and negligent misrepresentation (Counts V, VI, and VII); and (5) punitive damages and

prejudgment interest are not recoverable in this action. These grounds are discussed separately below.[47]

1. Design Defect Claims (Counts I and III)

Plaintiff asserts claims for design defect based on strict liability (Count I) and negligence (Count III). Defendants argue that Plaintiff's claims for design defect are expressly preempted by the Medical Device Amendment of 1976, and that Plaintiff's strict liability claim also is barred by Comment K to Section 402A of the Restatement (Second) of Torts.

a) Express Preemption by the Medical Device Amendment of 1976

Defendants argue that Plaintiff's claims for strict product liability and negligence (Counts I and III) based on design defect are "expressly preempted by the Medical Device Amendment of 1976 ('MDA') . . . because the FDA has granted [premarket approval] ("PMA") clearance on three occasions, including for the CONSERVE® Resurfacing Device, which contains the same [metal-on-metal] bearing surfaces as the products at issue here." (Def. MSJ at 19-20).

[47] Defendants, in a separate section of their summary judgment motion, assert additional grounds to support their argument that they are entitled to summary judgment on Plaintiff's claims for negligent design, negligent failure to warn, and negligent misrepresentation. (Def. MSJ at 45-46). The Court addresses these arguments when addressing each of Plaintiff's claims based on negligence.

The MDA amended the Federal Food, Drug, and Cosmetic Act, and "swept back some state obligations and imposed a regime of detailed federal oversight" over medical devices. Riegel v. Medtronic, Inc., 552 U.S. 312, 316 (2008). The MDA includes an express preemption provision:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement-- (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k. The Supreme Court has held that Section 360k applies where the FDA approves a device pursuant to the PMA process, in part because premarket approval is a "rigorous" process. Riegel, 552 U.S. at 317.[48] The Riegel

[48] To obtain premarket approval, the Riegel court noted that

> a manufacturer must submit what is typically a multivolume application. It includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a "full statement" of the device's "components, ingredients, and properties and of the principle or principles of operation"; "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device"; samples or device components required by the FDA; and a specimen of the proposed labeling. Before deciding whether to approve the application, the agency may refer it to a panel of outside experts . . . and may request additional data from the manufacturer . . . .

court concluded that premarket approval imposed "requirements" under the MDA to trigger Section 360k's preemption. Id. at 322-23. Premarket approval "is specific to individual devices" and is focused on safety. Id. at 323. "[S]tate requirements are pre-empted 'only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device . . . .'" Id. at 322 (quoting 21 C.F.R. § 808.1(d)). The "FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." Id. at 323.

> The FDA spends an average of 1,200 hours reviewing each application . . . and grants premarket approval only if it finds there is a "reasonable assurance" of the device's "safety and effectiveness," [and the FDA] must "weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." § 360c(a)(2)(C). It may thus approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives. It approved, for example, under its Humanitarian Device Exemption procedures, a ventricular assist device for children with failing hearts, even though the survival rate of children using the device was less than 50 percent.
>
> The premarket approval process includes review of the device's proposed labeling. The FDA evaluates safety and effectiveness under the conditions of use set forth on the label . . . and must determine that the proposed labeling is neither false nor misleading . . . .

Riegel, 552 U.S. at 317-18 (citations omitted).

Defendants argue that, because Plaintiff is not simply alleging that the Conserve implant components are defective by design, but rather that all metal-on-metal components are defective by design, Plaintiff's strict liability claims are preempted, because the FDA has granted premarket approval to other metal-on-metal devices, including those designed and sold by other manufacturers. (Def. MSJ at 23-27). Defendants misconstrue Plaintiff's allegations. Plaintiff's Second Amended Complaint specifically alleges that it is the "Conserve Hip Implant System" that is defective,[49] because, among other issues, it has "an inadequate design for the purpose of hip replacement," contains "unreasonably dangerous design defects, including an inherently unstable design which resulted in an unreasonably high probability of early failure," "puts the metal femoral ball directly in contact with the metal acetabular cup which produces metal-on-metal wear debris" and has "a propensity for the acetabular cup to detach, disconnect [or] loosen from the acetabulum, and for some patients to develop adverse reactions to metal debris generated by normal use of the Conserve Hip Implant System . . . ." (Second Am. Compl. ¶ 36). Plaintiff's allegations do not challenge the design

[49] Although certain of Plaintiff's evidence, and particularly her experts' opinions, state or suggest a defect in all metal-on-metal devices, the plain allegations concern only the Conserve Hip Implant System and the alleged defect in its design, component parts, and materials.

efficacy of all of Defendants' metal-on-metal products, or metal-on-metal implants generally.

Defendants do not contend, and it is otherwise undisputed that the Conserve Hip Implant System was not, itself, premarket approved by the FDA. Defendants, however, point to the fact that the FDA granted premarket approval to three (3) metal-on-metal bearing surfaces in devices, including the "Smith & Nephew BHR, the Corin USA Cormet Hip, and the Wright Medical CONSERVE® Plus." (Def. MSJ at 23-24). Defendants argue that these approvals are tantamount to approval of the device implanted to replace Plaintiff's right hip. (Id.). Defendants argue that, because FDA granted premarket approval to the Conserve Plus Total Resurfacing Hip System in 2009, which, Defendants allege, contains metal-on-metal bearing configuration identical to the components at issue in this case, this approval is persuasive evidence that the Conserve Hip Implant System effectively, if not specifically, was approved by the FDA. (Id.).

The Court finds that Plaintiff's allegations are limited to Defendants' Conserve Hip Implant System. She claims this specific system is defective and that the defects caused, among other events, metal-on-metal debris and the failure of the Conserve implant that replaced her right hip. The facts are further that the FDA's premarket approval of other metal-on-metal devices does not support that

the Conserve Hip Implant System was granted premarket approval. See Riegel, 552 U.S. at 323. Premarket approval "is specific to individual devices," and the "FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application . . . ." Id.; see also Wolicki-Gables v. Arrow Int'l, Inc., 634 F.3d 1296, 1301 (11th Cir. 2011) (citing Riegel). That other, similar, metal-on-metal devices may have been preapproved does not establish that the device at issue here in this case was actually preapproved, and this is not sufficient to support Defendants' preemption argument. The premarket approval of the Conserve Plus Total Resurfacing Hip System--a device which, despite its many similar characteristics to the Conserve Hip Replacement System, is a different "specific device"--does not preclude Plaintiff's claim of defect in the specific device at issue in this case.[50]

As Defendants themselves argued in their Daubert motion to exclude Waller's expert opinion, the Conserve Hip Implant System is a device distinct from

[50] One purpose of premarket approval is to afford the FDA the opportunity to review a device and to determine that the device "provides a reasonable assurance of safety and effectiveness." Riegel, 552 U.S. at 323. By not subjecting the Conserve implant to the FDA's premarket approval process, Defendants denied the FDA the opportunity to determine if the Conserve implant provided "a reasonable assurance of safety and effectiveness," and denied the FDA the opportunity to scrutinize and evaluate the device, including by submitting it to review by outside experts, to approve the device and its specific components, and to ensure that the device, as approved be made with almost no deviations from the specifications in the approved application. See id.; see also *supra* n.48.

the Conserve Plus Total Resurfacing Hip System. The Conserve Hip Implant System is manufactured in a way that deviates from the approved specification for the Conserve Plus Total Resurfacing Hip System, including because the Conserve Hip Implant System is used for total hip arthroplasty, and it does not consist of all of the same components as the Conserve Plus Total Resurfacing Hip System. Preemption under Section 360k only applies when the FDA "has established specific counterpart regulations or [if] there are other specific requirements applicable *to a particular device*." Riegel, 552 U.S. at 322 (emphasis added).[51] Defendants are not entitled to summary judgment based on MDA preemption.

b) Comment K to Section 402A of the Restatement (Second) of Torts

Section 402A of the Restatement (Second) of Torts addresses the special liability applicable to sellers of products that cause physical harm to consumers. Section 402A states:

> (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if (a) the seller is engaged in the business of selling such a product, and (b) it is expected to and does reach the user or consumer without substantial change in the condition

[51] Having concluded that Defendants do not have a premarket approval preemption defense, the Court does not decide whether the withdrawal of premarket approval for the Conserve Plus Total Resurfacing Hip System in 2014 has any effect on Section 360k preemption.

> in which it is sold. (2) The rule stated in Subsection (1) applies although (a) the seller has exercised all possible care in the preparation and sale of his product, and (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

Restatement (Second) of Torts § 402A (1965). Comment K to Section 402A of the Restatement (Second) of Torts ("Comment K") provides that manufacturers of certain specific products can only be held strictly liable under certain circumstances. Comment K states:

> 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. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper 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. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. 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.

Restatement (Second) of Torts § 402A, Comment K (1965).

In Grundberg v. Upjohn Co., 813 P.2d 89, 95 (Utah 1991), the Utah Supreme Court[52] applied Comment K to prescription drug cases. Utah courts have not extended Comment K to medical devices. (Def. MSJ at 17). In Creech v. Stryker Corp., No. 2:07CV22 DAK, 2012 WL 33360 (D. Utah Jan. 6, 2012), the United States District Court for the District of Utah discussed Comment K's application to medical devices under Utah law. In Creech, the defendant manufactured a pain pump device to administer prescribed amounts of pain medication directly to a certain area of the body. Creech v. Stryker Corp., No. 2:07CV22 DAK, 2012 WL 33360, at *1 (D. Utah Jan. 6, 2012). The plaintiffs had surgery and were administered an anesthetic solution delivered by the pain pump. Id. The plaintiffs allege the pump caused them injury. Id. The argued that

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[52] It is undisputed that Plaintiff was implanted with the Conserve hip components in Utah. (Second Am. Compl. ¶¶ 24-25). Plaintiff also admits that, but for the MDL, she would have filed her action in the United States District Court for the District of Utah. (Id. ¶ 11). A direct-filed case in an MDL proceeding, such as this one, applies the choice-of-law rules of the state "where the plaintiff purchased and used the prescribed product." See, e.g., In re Watson Fentanyl Patch Prod. Liab. Litig., 977 F. Supp. 2d 885, 888 (N.D. Ill. 2013). It is undisputed that Utah's choice-of-law rules weigh in favor of having Utah's substantive law apply to this case, because the alleged injury and conduct occurred in Utah and the relationship between the Parties is centered in Utah. See, e.g., Waddoups v. Amalgamated Sugar Co., 54 P.3d 1054, 1060 (Utah 2002).

Comment K applied to exclude defendant's device from strict liability under Section 402A. Id. at *5, n. 6. The Creech court disagreed, noting that "Utah law does not preclude strict liability design defect claims against medical product manufacturers." Id.

"Comment k serves as an affirmative defense when the product is incapable of being made safe under present technology, but the social need for the product warrants its production." Tansy v. Dacomed Corp., 890 P.2d 881, 885 (Okla. 1994). Most courts that have considered the question of whether Comment K applies to medical devices have, however, concluded that it does apply, especially for devices that are implanted in the human body. See, e.g., Phelps v. Sherwood Med. Industries, 836 F.2d 296 (7th Cir. 1987) (heart catheter); Brooks v. Medtronic, Inc., 750 F.2d 1227, 1230-31 (4th Cir. 1984) (pacemaker); Breen v. Synthes-Stratec, Inc., 947 A.2d 383, 388 n.5 (Conn. App. Ct. 2008) (collecting cases); Mele v. Howmedica, Inc., 808 N.E.2d 1026, 1030 (Ill. App. Ct. 2004) (artificial hip). The Court concludes, notwithstanding Creech, that Utah state courts would recognize that Comment K's concern about ensuring that the social need for medical products is satisfied and would follow other jurisdictions and apply Comment K to prescribed medical devices that are implanted in the human body.

The record evidence in this case, however, does not allow the Court to conclude that Comment K applies to the Conserve implant. For Comment K to apply, a device design "must be as safe as the best available testing and research permits." Tansy, 890 P.2d at 885. Comment K requires also that the device be "properly prepared and marketed, and [that] proper warning is given . . . ." Restatement (Second) of Torts § 402A, Comment K (1965). The record evidence establishes a genuine issue of material fact regarding whether the Conserve implant was made as safe as it could be made, and whether the product was properly marketed in light of the alleged misrepresentations Defendants' representatives made to Rasmussen while marketing the product for him to prescribe to active patients such as Plaintiff. See *infra* at Section IV(C)(3). Defendants, thus, are not entitled to summary judgment based on Comment K.

2. Failure to Warn Claims (Counts II and III)

Plaintiff asserts failure to warn claims based on strict liability and negligence (Counts II and III).[53] Defendants assert that the learned intermediary doctrine

[53] Defendants incorrectly identify Plaintiff's strict liability failure to warn claim as Count I of the Complaint. Count I contains Plaintiff's strict liability design defect claim. Count II contains Plaintiff's strict liability failure to warn claim. Count III contains Plaintiff's negligent failure to warn and design defect claims.

applies and that, because Rasmussen did not read, and would not have read, any warnings, their inadequacy, if any, is irrelevant. (Def. MSJ at 28-30).[54]

A strict liability defective warning claim, under Utah law, requires proof that: (1) the manufacturer knew or should have known of a risk associated with its products; (2) the risk was not disclosed or was inadequately disclosed; and (3) the failure to give adequate warning caused the injury. Herrod v. Metal Powder Prod., 413 F. App'x 7, 18-19 (10th Cir. 2010) (citing House v. Armour of Am., 929 P.2d 340, 343 (Utah 1996)). To assert a claim for negligent failure to warn, a plaintiff must prove (1) that defendant owed a duty to the plaintiff; (2) that the defendant breached that duty; and (3) the breaching conduct caused the injury. Barson By & Through Barson v. E.R. Squibb & Sons, Inc., 682 P.2d 832, 835 (Utah 1984).

For a warning to be adequate, it must "(1) be designed so it can reasonably be expected to catch the attention of the consumer; (2) be comprehensible and give a fair indication of the specific risks involved with the product; and (3) be of an intensity justified by the magnitude of the risk." House v. Armour of Am., Inc., 886 P.2d 542, 551 (Utah Ct. App. 1994) aff'd, 929 P.2d 340 (Utah 1996).

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[54] Defendants assert also that Plaintiff cannot establish the inadequacy of the warnings absent expert testimony regarding what specific warnings should have been provided, and argue further that the warning included with the Conserve Hip Implant Device were adequate.

Generally, whether "the warning provided by the label was adequate presents a question of fact, to be resolved by the trier of fact." Id.

There are some products manufactured that may be "unavoidably unsafe" but still may be useful and desirable, so long as they are "prepared, distributed, and marketed properly and with appropriate directions and warnings." Schaerrer v. Stewart's Plaza Pharmacy, Inc., 79 P.3d 922, 928 (Utah 2003). The duty under state law is to provide the warning with the product to which the warning applies. Id. It is this failure that gives rise to a duty to warn claim. Id.

A failure to properly warn a product user of a risk that is the proximate cause of an injury to a user, can give rise to a cause of action against the manufacturer. This product user analysis is uniquely altered in cases involving prescription drugs and medical devices. That is because the person who receives a medical device or to whom it is applied, is prescribed the device by a physician. It is thus the physician who is obligated to understand, and thus be warned about, the risks of the drug or device so he may consider them in evaluating whether to prescribe it for a particular patient, and it is the physician upon whom the user, or patient, relies to advise of warnings and risks. It is from this practical reality in the doctor-patient relationship that the learned intermediary doctrine developed.

The doctrine is founded on the principle that "it is the manufacturer's duty to warn the *doctor* of the dangers associated with a dangerous drug, rather than the patient." Tingey v. Radionics, 193 F. App'x 747, 757 n. 4 (10th Cir. 2006) (emphasis added). The reasoning of the rule is practical:

> It is the physician who is best situated to weigh the potential risks associated with a prescription drug against the possible benefits of the drug and the unique needs and susceptibilities of each patient. The physician thus has the ability to combine medical knowledge and training with an individualized understanding of the patient's needs, and is the best conduit for any warnings that are deemed necessary.

Schaerrer, 79 P.3d at 928-29 (internal citations omitted).[55]

It later developed that, where a warning is provided, but a physician does not read it or rely on it, a person cannot assert a failure to warn claim, even if the warning is defective. Emody v. Medtronic, Inc., 238 F. Supp. 2d 1291, 1296 (N.D. Ala. 2003). That is because a "manufacturer cannot be found to have provided inadequate warnings when the physician who used the product failed to read the warnings provided." Allen v. Mentor Corp., No. 3:04CV642 (PCD), 2006 WL 861007, at *5 (D. Conn. Mar. 31, 2006); see also Gebhardt v. Mentor Corp., 15 F. App'x 540, 542 (9th Cir. 2001); In re Trasylol Prod. Liab. Litig-MDL-1928, No. 08-MD-01928, 2011 WL 2117257, at *4 (S.D. Fla. May 23, 2011) ("For

[55] The Tenth Circuit concluded that Utah would apply the learned intermediary doctrine to cases involving allegedly inadequate warnings for medical devices. Tingey, 193 F. App'x at 757 n.4.

failure to warn claims, as here, Plaintiff must produce some evidence that an adequate warning would have been read and heeded, and the injury would have been avoided."); Pinchinat v. Graco Children's Prod., Inc., 390 F. Supp. 2d 1141, 1148 (M.D. Fla. 2005) ("plaintiff's failure to read the warning label extinguishes proximate cause in a failure to warn claim").[56]

Defendants claim that the undisputed facts here do not support a failure to warn claim because Rasmussen did not read any warnings, and his failure to do so forecloses any claim based on adequacy of the warnings. The undisputed facts here are that Rasmussen testified that when he started using Conserve devices, he "educated himself" on the products. ([24.5][57] at 60-61). He reviewed studies on metal-on-metal bearing surfaces, and reviewed what "had gone into" the Wright

[56] No Utah court has directly addressed whether the failure of a learned intermediary to read a warning forecloses a failure to warn claim. The United States District Court for the District of Utah, however, concluded that a prescribing doctor's testimony that he "generally did not read any information received from sales representatives, and that he would not rely upon any such information" precluded a plaintiff's claim for breach of warranty, negligent misrepresentation, and fraud, because the plaintiff could not show any evidence that the plaintiff's prescribing physicians relied on any specific representations made by the defendant. Okuda v. Pfizer Inc., No. 1:04-CV-00080, 2012 WL 2685053, at *1-2 (D. Utah July 6, 2012). The Court concludes that Utah courts would likely follow the reasoning and decisions of many other jurisdictions and find that where a learned intermediary fails to read a warning, a plaintiff is foreclosed from asserting a failure to warn claim.

[57] A transcript of a portion of Rasmussen's December 15, 2014, deposition begins on page 51 of [24.5]. The Court will cite to the CM/ECF page numbers for this document.

Medical design, based on what Wright Medical's representatives reported to him. (Id. at 60-62). Rasmussen was aware the Conserve hip implants came with packaging containing an insert with information about the product. (Id. at 62-63). Rasmussen did not recall reading the insert included in the packaging, stating instead that the information he had about the product came primarily from Wright Medical's representatives. (Id.). When asked if he had ever read a product insert for any hip product he implanted, Rasmussen answered, "[n]ot that I recall." (Id. at 63). Rasmussen stated the insert Defendants provided was in the sterile packaging in which the implant devices were wrapped, suggesting it was impractical to read the insert when the package was opened during the surgical process. (Tr. of Dec. 15, 2014, Rasmussen Dep. [64.3] at 34:17-2). Rasmussen stated, however, that he did have access to the insert. (Id.). There is not any evidence in the record that Rasmussen ever read the Conserve Hip Implant System warning before, or after, the device was implanted in Plaintiff's right hip. The record evidence further is that he cannot recall ever reading the warnings in the product insert for this, or any other, hip implant device.

The question here is whether the learned intermediary doctrine precludes Plaintiff's failure to warn claim based on the package insert warning. The Court concludes that it does. Rasmussen was unequivocal in his testimony about how he

determined the risks and benefits of devices he implants. He prefers to "educate himself" on the product, and review the studies and what went into a design. He applied that same approach when evaluating the implanted device at issue in this case. He does not recall reading a product insert, and its warnings, that accompanied any hip replacement device he has implanted. As a result of his personal practices, the undisputed evidence is that Rasmussen did not and would not have read the insert warnings that were provided with the device implanted to replace Plaintiff's right hip.[58] As a result, the evidence here does not support a failure to warn claim based on the warning provided for the implant at issue in this case, even if the warning was defective. See, e.g., Emody, 238 F. Supp. 2d at

[58] Plaintiff asserts that, because Defendants' representatives provided information to Rasmussen that contradicted the warning insert, and because the insert did not provide any information regarding the Thin Shell component of the Conserve Hip Implant System, the fact that Rasmussen did not read the insert is irrelevant. Similarly, Plaintiff asserts that the learned intermediary doctrine does not apply because the warning was inadequate. The Court disagrees. In the absence of evidence that Rasmussen read the insert provided, and in light of the evidence that Rasmussen cannot recall ever reading a product insert for any hip implant device he has implanted in his patients, the alleged inadequacies of Defendants' warning are not relevant. Any allegedly false information provided by Defendants' representatives to Rasmussen is relevant only to Plaintiff's fraudulent and negligent misrepresentation claims, not Plaintiff's failure to warn claim.

1296; Allen, 2006 WL 861007, at *5. Summary judgment is required to be granted on Plaintiff's strict liability and negligence claims based on failure to warn.[59]

3. Fraudulent and Negligent Misrepresentation and Fraudulent Concealment Claims (Counts V, VI, and VII)

Plaintiff asserts common law claims based on alleged misrepresentations or concealment of information about the Conserve implant implanted to replace Plaintiff's right hip. Her theories of common law liability are not entirely clear. Reading her summary judgment submissions as a whole, it appears that Plaintiff asserts two practical results from the misrepresentation and concealment she alleges. First she claims they resulted in Rasmussen not being adequately warned of the metallosis risks associated with implantation of the device. Second, she claims that the representations resulted in Rasmussen electing to implant a device that he believed did not have an associated risk of metallosis. Plaintiff acknowledges the alleged misrepresentations and omissions were not ones which were made, or failed to be made, to her. What she does allege is that she elected to have the device implanted because she was told by Rasmussen that it suited her active lifestyle and because no attendant risk was disclosed, which, Plaintiff alleges, was the result of Defendants' representatives having failed to disclose the

[59] This does not preclude a claim based on representations that were made by Defendants through one or more of its representatives.

metallosis risk to Rasmussen and by representing its safe application, particularly for patients, like Plaintiff, with an active lifestyle.

Defendants move for summary judgment on these claims based on the fact none of the misrepresentations or omissions made were to Plaintiff and thus there was no breach of a duty to her. Defendants also move for summary judgment on the ground that any alleged breach of a disclosure duty to Plaintiff based on a disclosure duty to Rasmussen is not actionable because any inadequate warning Defendants gave with the device was not read, and would not have been read, by Rasmussen.

> A claim for fraudulent misrepresentation requires a 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 (citing Dugan v. Jones, 615 P.2d 1239, 1246 (Utah 1980)) (emphasis omitted). "The elements of negligent misrepresentation are similar to those of fraud except that negligent misrepresentation 'does not require the intentional mental state necessary to establish fraud.'" 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)).

A claim for fraudulent nondisclosure 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's misrepresentation claims are based on representations Defendants allegedly made to Rasmussen which, Plaintiff contends, are deemed misrepresentations made to Plaintiff directly. Plaintiff acknowledges that the alleged misrepresentations made to Rasmussen were not communicated to Plaintiff. Defendants argue that, because Plaintiff cannot show that any misrepresentations were made by Defendants to Plaintiff, she cannot establish a prima facie claim for negligent or fraudulent misrepresentation and thus summary judgment should be granted on both misrepresentation claims.

In Tetuan v. A.H. Robins Co., 738 P.2d 1210 (Kansas 1987), the Supreme Court of Kansas considered a alleged fraudulent misrepresentation claim based on an alleged misrepresentation to a patient regarding the effectiveness of an intrauterine device ("IUD"). The court upheld a jury verdict in the plaintiff's favor, applying the learned intermediary doctrine. The Tetuan court held that it

was irrelevant that the plaintiff was not aware of the specific IUD that had been implanted in her, and the defendant had not made any representations directly to her. Tetuan, 738 P.2d at 1227. The court held that a medical device manufacturer's duty to warn is owed to medical professionals, and the "breach of that duty by the manufacturer will result in the manufacturer being directly liable to the patient." Id. The Tetuan court concluded: "where a patient relies on a physician for treatment or advice as to an ethical[60] or prescription device, justifiable reliance by the physician on misrepresentations or concealment by the manufacturer of that device constitutes justifiable reliance by the patient." Tetuan, 738 P.2d at 1228; see also Allen v. G.D. Searle & Co., 708 F. Supp. 1142, 1161 (D. Or. 1989); Kociemba v. G.D. Searle & Co., 680 F. Supp. 1293, 1303 (D. Minn. 1988).

In Barson, the Utah Supreme Court considered a prescription drug manufacturer's alleged misrepresentation about a medication. The claim was brought by a child's guardians *ad litem* for alleged birth defects the child suffered as a result of prenatal administration of Delalutin, a progestational drug manufactured by the defendant drug manufacturer. Id. at 834. The plaintiffs alleged that the child's mother was told by her doctor that Delalutin was harmless.

60 An ethical device is a device that is available only through licensed medical care providers. Tetuan, 738 P.2d at 1227.

Id. The doctor administered three shots of Delalutin to the mother during her pregnancy. Id. The child was born with multiple birth defects and plaintiffs asserted claims against the Delalutin manufacturer for negligence, breach of warranty, and strict liability. Id.

The Barson court noted that in a "products liability case, the plaintiff must . . . prove that there was a duty owed by the defendant to the plaintiff, that the duty was breached and that the conduct complained of was the cause in fact of the injury." Id. at 835. The court went on to state that the

> manufacturer of ethical drugs has the duty of making timely and adequate warnings to the medical profession of any dangerous side effects produced by its drugs of which it knows or has reason to know. *The manufacturer is directly liable to the patient for the breach of such duty*.

Id. (emphasis added).

The Court concludes that the reasoning in Barson and Tetuan applies here. Patients rely on their treating physicians, who are professionally trained to understand (i) the medical necessity and risks in the treatments they prescribe and (ii) the warnings and information given to them by the manufacturers of medical devices, and to then evaluate this sophisticated information when discussing treatment options with the patient, including the associated risks. As a result, any alleged misrepresentations Defendants' representatives made to Rasmussen, or any

wrongful concealment or nondisclosure of material information, that resulted in Rasmussen prescribing the Conserve Hip Implant System for Plaintiff, supports a claim for liability on the part of Defendants to Plaintiff.

Plaintiff points to evidence in the record of this case that, in 2006, Rasmussen and Plaintiff discussed the relevant factors she should consider to decide which hip implant device to use, in light of "her active lifestyle and the need for a device that would give her the best results for the longest period of time." (Pl. CAF ¶ 198). Based on information Rasmussen was given by Defendants' representatives, he thought Plaintiff was a good candidate for a Conserve implant because she was "an active patient seeking increased range of motion with improved design features to help decrease wear and dislocation." (Id. ¶ 199). Plaintiff was told that patients who received metal-on-metal implants have higher blood chromium levels but that there was no reason to be worried about these chromium ions. (Id. ¶ 201). Plaintiff asserts that she agreed to the implantation of the Conserve implant "based on this low-risk information, the promised greater range of motion, the representations that the device was appropriate for her as an active person, and Dr. Rasmussen's recommendation." (Id. ¶ 202).

Rasmussen's reliance on Defendants' representations, including 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," induced Rasmussen to tell Plaintiff she was a good candidate for the Conserve implant. (Id. ¶¶ 194, 199-200). Rasmussen's reliance on Defendants' representations constitutes reliance by Plaintiff on the same representations. See, e.g., Tetuan, 738 P.2d at 1228.

The record here provides context for the representations Plaintiff claims were wrongful or recklessly made. Plaintiff asserts the record evidence shows that Defendants were aware, since the 1990's, of major risks involved in metal-on-metal hip implants, from "metal toxicity, inflammation, bone loss, allergic reaction, local tumor formation, systemic effects, soft tissue necrosis, osteolysis, and blood-borne metal ions." (Pl. CAF ¶ 26). In 1995, leading surgeons and designers told Defendants about these risks and concluded that CoCr might not be a good alloy to use in implants and that more testing was needed. (Id. ¶¶ 27-28). In 1995, prior to marketing the metal-on-metal devices, Defendants were told by "leading surgeons and designers of a number of major risks that demanded further

testing, such as: metal toxicity, inflammation, bone loss, allergic reaction, local tumor formation, systemic effects, soft tissue necrosis, osteolysis, and blood-borne metal ions." (Id. ¶ 29). Plaintiff asserts that Defendants did not conduct any of these tests. (Id. ¶¶ 48-53). Plaintiff alleges further that Defendants failed to collect, track, or disclose adverse events from the use of Conserve devices. (Id. ¶¶ 108-115).

Defendants' representatives, Plaintiff shows, told Rasmussen that the "Conserve [implant] was ideal for young, very active patients like [Plaintiff] because they can be as active as they want with a greater range of motion without dislocation or wear," and that the "Conserve [implant] was fully biocompatible and had good longevity." (Id. ¶¶ 192-93). Defendants' representatives told Rasmussen that the "Conserve [implant's] use of BFH technology and A-Class metal would increase the range of motion, decrease dislocation issues, result in lower wear, and be biocompatible, all of which were presented as significant benefits for young and active recipients as well as anyone possessing a 'high-demand hip.'" (Id. ¶ 191). Rasmussen was told that the "A-Class metal behaved more like ceramic and that, based upon testing, the A-Class metal . . . would result in less metal wear, fewer cobalt and chromium ions, and thus a lower risk of any metallosis problem." (Id. ¶ 74). Rasmussen was assured, Plaintiff claims, that the "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." (Id. ¶ 194). Plaintiff claims that Defendant should have warned Rasmussen that the Thin Shell (used in the Conserve implant) "was not cleared for marketing by the FDA [and] had been associated with increased risks of loosening, severe complications, premature failure and revision in clinical trials." (Id. ¶ 197)

Rasmussen's reliance on the representations made to him by Defendants' representatives, coupled with Plaintiff's allegations that Defendants knew of the risk of CoCr alloys, metallosis, and Defendants' alleged failure to conduct tests identified by other surgeons and designers and to collect, track, and disclose adverse events, supports that there is a genuine issue of material fact regarding whether these representations were misrepresentations, and whether they were made intentionally, recklessly, or negligently. (See id. ¶¶ 27-29, 48-53, 108-155). These matters must be decided by the jury and summary judgment on Plaintiff's fraudulent and negligent misrepresentation claims is required to be denied. See Garczynski, 573 F.3d at 1165.

For the same reasons, the Court concludes that there are genuine issues of material fact to be decided by the jury on Plaintiff's fraudulent concealment claim. Plaintiff, as noted *infra*, asserts that Defendants knew of the risks associated with

the Conserve Hip Implant System, including the increased risk of elevated metal ion levels and metallosis, adverse tissue reactions, bone resorption, loosening, and premature failure of the device. (See Pl. CAF ¶¶ 25-47, 54-55). Plaintiff asserts that Defendants wrongfully concealed this material, known, information.

Defendants assert that they did not owe a duty to Plaintiff because there was not a direct relationship between Defendants and Plaintiff, and that the learned intermediary doctrine forecloses any claim that Defendants had a duty to disclose any information directly to Plaintiff and, therefore, she fails to establish a claim for fraudulent concealment. (Def. MSJ at 43-45). Defendants, however, are directly liable to Plaintiff for any fraudulent concealment of information from Rasmussen, Plaintiff's learned intermediary. See Tetuan, 738 P.2d at 1228. Whether Defendants fraudulently concealed relevant information from Rasmussen, to Plaintiff's detriment, must be decided by the jury, and summary judgment on Plaintiff's fraudulent concealment claim is required to be denied. See Garczynski, 573 F.3d at 1165.[61]

[61] The Court notes that the alleged misrepresentations and concealment of information from Rasmussen, even if proved at trial, does not impact the Court's decision to grant summary judgment on Plaintiff's failure to warn claims (Counts II and III). Rasmussen's failure to read the Conserve Hip Implant System warning, regardless of any misrepresentations made by Defendants' representatives or their concealment of relevant information, requires dismissal of these claims.

4. Punitive Damages and Prejudgment Interest

It is undisputed that Plaintiff, if she establishes liability at trial, may be entitled to compensatory damages for her alleged injuries. Plaintiff also seeks punitive damages and prejudgment interest.

Defendants assert that Plaintiff is not entitled to an award of punitive damages because the warnings provided with the Conserve implant sufficiently warned of the potential risks, and because punitive damages would be contrary to public policy because they would create a chilling effect on the development of new medical devices. (Def. MSJ at 46-49).

> 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 establish 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." Daniels v. Gamma W. Brachytherapy, LLC, 221 P.3d 256, 269 (Utah 2009).

Plaintiff has presented enough evidence to establish a genuine issue of material fact regarding whether Defendants misrepresented or concealed material

information from Rasmussen, ultimately causing Plaintiff's injuries (See *infra*, Section IV(C)(3)). Defendants' conduct, if proven at trial, could lead a jury to conclude that they had acted willfully or recklessly in misrepresenting or concealing material information regarding the risks of prescribing the Conserve Hip Implant System in patients, such as Plaintiff. Defendants' assertion that the warning it provided with the product was adequate, even if true, does not bar Plaintiff from seeking punitive damages for her misrepresentation or concealment claims. Cf. Wyeth v. Rowatt, 244 P.3d 765, 784 (Nev. 2010) (approving award of punitive damages against drug manufacturer for the misrepresentation and concealment of material information).

An award of punitive damages is not against Utah's public policy. Utah, in enacting its punitive damages statute, created an exception for drug manufacturers where the drug received premarket approval by the FDA and is generally recognized as safe by the FDA. Utah Code Ann. § 78B-8-203(a). Utah did not extend this exception to medical device manufacturers. Utah also enacted an exception to the exception in situations where a drug manufacturer knowingly withheld or misrepresented information--albeit to the FDA and not directly to the consumer or treating physician. Utah Code Ann. § 78B-8-203(b). Defendants do not cite any legal authority to suggest that it would be against Utah public policy to

award punitive damages against a medical device manufacturer and seller where the manufacturer is alleged to have defectively designed the device and misrepresented or concealed the risks involved in using the device. Summary judgment on Plaintiff's punitive damages claim is not supported.

Finally, Defendants contend that, if successful at trial, Plaintiff cannot recover prejudgment interest.[62] "Where damages are incomplete or cannot be calculated with mathematical accuracy, such as in the case of personal injury . . . the amount of the damages must be ascertained and assessed by the trier of the fact at the trial, and in such cases prejudgment interest is not allowed." Cornia v. Wilcox, 898 P.2d 1379, 1387 (Utah 1995). Plaintiff's claim is one for personal injury, where the amount of damages, if any, is uncertain. Plaintiff is not entitled to prejudgment interest.

V. CONCLUSION

For the foregoing reasons,

IT IS HEREBY ORDERED that Defendants Wright Medical Technology, Inc.'s and Wright Medical Group, Inc.'s Motion To Exclude Testimony Relating to Metallosis [52] is **GRANTED IN PART** and **DENIED IN PART**. Dr. Brent W.

[62] Plaintiff did not respond to Defendants' argument that prejudgment interest is not permitted, and, thus, Defendants' motion for summary judgment on this claim is deemed unopposed. See LR 7.1B., NDGa.

Morgan's expert opinion that the failure of Plaintiff's hip implant was caused by metallosis and Dr. Susanne Parisian's expert opinion regarding Plaintiff's metallosis are excluded. The remaining experts identified in Defendants' Motion To Exclude Testimony Relating to Metallosis are entitled to provide their expert opinions related to metallosis.

IT IS FURTHER ORDERED that Defendants Wright Medical Technology, Inc.'s and Wright Medical Group, Inc.'s Motion to Exclude the Expert Testimony of Jay M. Vincelli, MSc, and John D. Jarrell, Ph.D., PE [50] is **GRANTED**. Dr. Jay M. Vincelli's expert testimony regarding his calculation of the immeasurable wear on Plaintiff's hip implant is excluded. To the extent Dr. John D. Jarrell relies on Dr. Vincelli's simulated wear volume calculation methodology in rendering his expert opinion, those opinions are excluded.

IT IS FURTHER ORDERED that Defendants Wright Medical Technology, Inc.'s and Wright Medical Group, Inc.'s Motion to Exclude the Expert Testimony of Reed Ayers, Ph.D. [51] is **DENIED**.

IT IS FURTHER ORDERED that Defendants Wright Medical Technology, Inc.'s and Wright Medical Group, Inc.'s Motion to Exclude the Expert Testimony of Lance A. Waller, Ph.D. [49] is **GRANTED**. Dr. Lance A. Waller's expert opinion regarding the alleged inaccuracies in Defendants' 2010

Report and his comparison of the revision rates in this report to the revision registries he reviewed, is excluded.

IT IS FURTHER ORDERED that Defendant Wright Medical Group, Inc.'s Motion for Summary Judgment [38] is **DENIED**. Plaintiff Robyn Christiansen's Motion to Strike the Declaration of Deborah Daurer [121] is **DENIED AS MOOT**.

IT IS FURTHER ORDERED that Defendants Wright Medical Technology, Inc.'s and Wright Medical Group, Inc.'s Motion for Summary Judgment [140] is **GRANTED IN PART** and **DENIED IN PART**. Defendants' Motion for Summary Judgment is **GRANTED** with respect to Plaintiff's failure to warn claims (Counts II and III)[63] and Plaintiff's claim for prejudgment interest. Defendants' Motion for Summary Judgment is **DENIED** on Plaintiff's remaining claims.

IT IS FURTHER ORDERED that Plaintiff Robyn Christiansen's Motion for Partial Summary Judgment [20] and Defendants Wright Medical Technology, Inc.'s and Wright Medical Group, Inc.'s Motion for Summary Judgment [24], filed on January 9, 2015, are **DENIED AS MOOT**.

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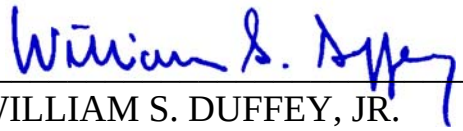
[63] Defendant is not entitled to summary judgment on Plaintiff's negligent design claim in Count III.

IT IS FURTHER ORDERED that the Parties' Motions to Seal [18, 19, 54, 56, 91, 93, 99, 120, 124, 131, 141, 142, 160, 161] are **GRANTED IN PART** and **DENIED IN PART**. The Motions to Seal are **GRANTED** only to the extent that the Parties shall refile the pleadings and supporting documentation originally filed under seal with redactions limited only to the specific confidential or proprietary information the Parties assert must be kept from public view. The Parties must submit redacted versions of the pleadings and supporting documentation on or before October 19, 2015, along with an explanation for why each redaction is necessary to protect confidential or proprietary information.

SO ORDERED this 31st day of August, 2015.



WILLIAM S. DUFFEY, JR.
UNITED STATES DISTRICT JUDGE