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IN THE UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA – OAKLAND DIVISION

GREGORY K. TUCKER and REBECCA TUCKER,

Plaintiffs,

vs.

WRIGHT MEDICAL TECHNOLOGY, INC., WRIGHT MEDICAL GROUP, INC., and DOES 1 through 100, inclusive,

Defendants.

Case No. 4:11-cv-03086 YGR

~~[PROPOSED]~~ ORDER GRANTING IN PART AND DENYING IN PART MOTIONS TO EXCLUDE CERTAIN OPINIONS, TESTIMONY, AND EVIDENCE OF L. HENDRICKSON, M. TRUMAN, K. BOSIC, M.D., AND EVIDENCE PRESENTED IN SUPPORT OF PLAINTIFFS' OPPOSITION TO MOTION FOR SUMMARY JUDGMENT

Date: January 15, 2013
Time: 2:00 p.m.
Action Filed: May 6, 2011

Defendant Wright Medical Technology submitted its Motions to Exclude Testimony of Lester Hendrickson, Motion to Exclude Certain Testimony of Mari Truman, P.E., Motion to Exclude Testimony of Kevin Bosic, M.D., and Evidentiary Objections contained in its Reply to Motion for Summary Judgment. Having considered Defendant Wright Medical Technology, Inc.'s Motions, which came before the Court on January 15, 2013, the papers filed in support thereof, the papers filed in response thereto, and all other arguments presented, and GOOD CAUSE SHOWING THEREFORE, IT IS HEREBY ORDERED that the following evidence, opinions, and testimony are excluded:

	Bozic's Opinions in Report and Rebuttal	**Evidentiary Objection(s)**	**Ruling on the Objection:**
	Exclude all of Dr. Bozic's Opinions regarding **complications** experienced by patients with total hip replacements resulting from their abuse of alcohol. Bozic Rebuttal, p. 1, ¶¶ 2, 3, 4	• FRE 702(c) - Not the product of reliable principles and methods • FRE 702(d) – Unreliable • FRCP 26(a)(2) – facts and data needed to support expert opinion must be disclosed	Sustained: _____ Overruled: XX
	Exclude all of Dr. Bozic's Opinions regarding the impact of plaintiff Gregory Tucker's alcohol abuse on the **failure** of his hip prosthesis. Bozic Rebuttal, p. 1, ¶¶ 2, 3, 4	• FRE 702(a) - Expert not qualified • FRE 702(c) - Not the product of reliable principles and methods • FRE 702(d) – Unreliable	Sustained: _____ Overruled: XX
	Exclude all **case reports** and all of Bozic's Opinions based on those reports. Bozic Report, p. 1 ¶ 3, p. 2 ¶ 1	• FRE 702(c) - Not the product of reliable principles and methods • FRE 702(d) – Unreliable	Sustained: _____ Overruled: XX

	Declaration of Kevin Bozic	**Evidentiary Objections**	**Ruling on the Objection:**
2	As treating physician for the plaintiff, I have formed opinions regarding the fracture of the hip implant at issue in this matter. My report letter dated September 6, 2012, and my rebuttal report letter dated September 24, 2012 are incorporated by reference and attached hereto as Exhibit "B." This declaration will expand on and explain my	• FRE 403 (re-presentation of cumulative evidence, waste of time) • FRE 403 (prejudicial); *Laser Design, Intern. LLC v. BJ Crystan, Inc.*, Case Nos. C 03-1179 JSW, C 03-3905 JSW, 2007 WL	Sustained: _____ Overruled: XX

	Declaration of Kevin Bozic	Evidentiary Objections	Ruling on the Objection:
	opinions as an expert witness and treating physician.	735763 at *4 (N.D. Cal. Mar. 7, 2007) (expert testimony offered after close of expert discovery, in opposition to motion for summary judgment, excluded as prejudicial).	
4	It is within the expertise of an orthopaedic surgeon to diagnose the basic fact of failure of an orthopaedic implant, and the probable cause of that failure based upon patient history, and knowledge and experience in the field of orthopaedic surgery in general and specifically hip replacement surgery, In this case, as treating physician I have firsthand knowledge regarding Mr. Tucker's hip replacement at issue.	• FRE 403 (prejudicial); *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX
5	In 2006, Mr. Tucker was 42 years old with a history of alcohol-induced osteonecrosis involving both hips. He had previously underwent a hemi-resurfacing arthroplasty on the left hip in November 2003 with an excellent result.	• FRE 403 (re-presentation of cumulative evidence, waste of time)	Sustained: _____ Overruled: XX
6	The Profemur modular hip system was selected to allow use of a hard-on-hard (ceramic-ceramic) bearing, which was felt to be beneficial in a young, active patient who is at risk for wear and osteolysis with a metal-on-polyethylene bearing.	• FRE 403 (prejudicial); *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX
7	The risks and benefits of the hard-on-hard bearing, specifically the ceramic-ceramic characteristic was discussed with Mr. Tucker. As part of this discussion and as noted in my operation report dated March 30, 2006, we also discussed the potential risk of "fracture", This discussion of fracture related to the ceramic-ceramic component of the hip implant. This discussion of fracture did not relate to the long neck of the modular hip system.	• FRE 403 (re-presentation of cumulative evidence, waste of time) • FRE 403 (prejudicial); *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX
8	After the completion of Mr. Tucker's right hip total hip replacement surgery in 2006, I observed excellent results in Mr. Tucker's right hip. There	• FRE 403 (re-presentation of cumulative evidence, waste of time)	Sustained: _____

	Declaration of Kevin Bozic	Evidentiary Objections	Ruling on the Objection:
	were no issues noted regarding his right hip biomechanics being compromised or having an alternation in his gait. The results for the right hip were excellent, until May 7, 2010, when the hip implant fractured.		Overruled: XX
9	As an orthopedic surgeon and Mr. Tucker's treating physician, I reasonably expected the hip implant in Mr. Tucker to be designed in such a way and to such specifications that the modular neck would not fracture during Mr. Tucker's routine activities.	• FRE 403 (prejudicial); *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX
10	In my treatment of Mr. Tucker, none of the activities or personal history of Mr. Tucker, who worked as a professional engineer, operated a ranch on his property, and engaged in the use of alcohol, would have lead me to believe the modular neck would fracture.	• FRE 403 (prejudicial); *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX
11	In my treatment of Mr. Tucker and through my years of experience as an orthopaedic surgeon, I reasonably expected the hip system and neck to be able to withstand the same forces in use as are encountered in the activities of daily living. An artificial hip system that is not able to withstand this level of activity is unreasonably dangerous to the patient, and needlessly places the patient's health and safety at risk.	• FRE 403 (prejudicial); *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX
12	As an experienced well qualified orthopaedic surgeon, I am aware of the medical literature regarding modularity of total hip replacements systems and the effect of patient weight and obesity on hip implants, and I reasonably expect designers and manufacturers, such as Wright Medical, to be aware of the same available medical literature and to account for such in the design and manufacturing of their hip replacement products.	• FRE 403 (prejudicial); *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX
13	In selecting Wright Medical's product, Wright and its agents never disclosed that it had encountered fractures of the modular neck prior	• FRE 403 (prejudicial); *Laser Design*, 2007 WL 735763 at *4	Sustained: _____

	Declaration of Kevin Bozic	Evidentiary Objections	Ruling on the Objection:
	to Mr. Tucker's 2006 surgery and never informed me that obesity was a significant concern regarding fractures of the Profemur long neck.		Overruled: XX
14	In the article "Corrosion-Induced Fracture of a Double-Modular Hip Prosthesis, published by my research group, we discuss the risks and benefits of Wright Medical's modular Profemur product. While it is recognized that modularity allows the surgeon to more closely restore patient anatomy, such as limb length, lateral offset, and femoral anteversion, and to better balance the soft tissue to achieve optimal biomechanics, it must also be weighed against the increases in the number of mechanical junctions, which introduce potential failures through fretting (micromotion), corrosion, and ultimately fracture. The articles discusses that the long neck is 25% longer than the standard neck, which produces roughly 25% higher bending stresses, The long neck may contribute to a greater risk of fracture, Ultimately the article concludes, that there is a risk of implant fracture at the stem-neck junction when a long neck is implanted in heavy patients.	• FRE 403 (prejudicial); *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX
15	As treating physician for Mr. Tucker had Wright Medical or its agents informed me of the previous fractures or the increased fracture risk associated with the Profemur long neck in heavier patients, I would have selected a different hip system for Mr. Tucker.	• FRE *403* (prejudicial); *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX
16	Additionally, as a treating physician, I have stopped using the Profemur Modular Hip System in its entirety. I stopped after the second fracture of a Profemur long neck in my patients, which was Mr. Tucker in 2010.	• FRE 403 (prejudicial); *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX

	Hendrickson's Opinions in Report and Rebuttal	Evidentiary Objection(s)	Ruling on the Objection:
	Opinion That "Failure" After Four Years is Evidence That the Implant was Defective and Unreasonably Dangerous at the Time of Implantation.	• FRE 702(b) - Not based on sufficient facts or data (*ipse dixit*) • FRE 702(c) - Not the	Sustained: _____

	Hendrickson's Opinions in Report and Rebuttal	Evidentiary Objection(s)	Ruling on the Objection:
	Report, at p. 7 ¶ 8.	product of reliable principles and methods • FRE 702(d) - Does not apply the principles and methods to the facts of the case	Overruled: XX
	Opinions Related to The Manufacture of the Implant. Report, at p. 5, p. 7 ¶¶ 7, 9; Rebuttal, at pp. 1-2.	• FRE 702(b) - Not based on sufficient facts or data (*ipse dixit*) • FRE 702(c) - Not the product of reliable principles and methods • FRE 702(d) - Does not apply the principles and methods to the facts of the case	Sustained: XX Overruled: _____
	Opinions Relating to Implantation As Evidence of Intended Use. Rebuttal at p. 4.	• FRE 702(b) - Not based on sufficient facts or data (*ipse dixit*) • FRE 702(c) - Not the product of reliable principles and methods • FRE 702(d) - Does not apply the principles and methods to the facts of the case	Sustained: _____ Overruled: XX
	Opinions Relating to Modular Design As The Cause Of The Implant "Failure" Rebuttal, at pp. 2, 4, 7.	• FRE 702(b) - Not based on sufficient facts or data (*ipse dixit*) • FRE 702(c) - Not the product of reliable principles and methods • FRE 702(d) - Does not apply the principles and methods to the facts of the case	Sustained: _____ Overruled: XX
	Opinions Regarding Abuse Or Misuse Of Implant After Implantation And Mr. Tucker's Contribution To "Failure" Report, at p. 7 ¶¶12-13; Rebuttal, at p. 4.	• FRE 702(b) - Not based on sufficient facts or data (*ipse dixit*) • FRE 702(c) - Not the product of reliable principles and methods	Sustained: _____ Overruled: XX

	Hendrickson's Opinions in Report and Rebuttal	Evidentiary Objection(s)	Ruling on the Objection:
		• FRE 702(d) - Does not apply the principles and methods to the facts of the case. • FRE 702(a) - not qualified to provide opinions on this issue.	
	Opinions Regarding Stresses and Mr. Tucker's Fall. Report, p. 6.	• FRE 702(b) - Not based on sufficient facts or data (*ipse dixit*) • FRE 702(c) - Not the product of reliable principles and methods • FRE 702(d) - Does not apply the principles and methods to the facts of the case	Sustained: _____ Overruled: XX
	Opinions Regarding Permanency and Life Expectancy of Implants. Report, at p. 7 ¶¶ 1-2; Rebuttal, at p.8.	• FRE 702(b) - Not based on sufficient facts or data (*ipse dixit*) • FRE 702(c) - Not the product of reliable principles and methods • FRE 702(d) - Does not apply the principles and methods to the facts of the case	Sustained: _____ Overruled: XX
	Opinions Regarding Knowledge of Wright Medical and Designers/Manufacturers. Report, at p. 7 ¶10.	• FRE 702(b) - Not based on sufficient facts or data (*ipse dixit*) • FRE 702(c) - Not the product of reliable principles and methods • FRE 702(d) - Does not apply the principles and methods to the facts of the case	Sustained: _____ Overruled: XX
	Opinions Related to Comparisons to Non-Medical Device Consumer Products. Rebuttal, at p.3.	• FRE 702(b) - Not based on sufficient facts or data (*ipse dixit*) • FRE 702(c) - Not the product of reliable	Sustained: XX Overruled: _____

	Hendrickson's Opinions in Report and Rebuttal	Evidentiary Objection(s)	Ruling on the Objection:
		principles and methods • FRE 702(d) - Does not apply the principles and methods to the facts of the case	
	Opinions related to warnings to Mr. Tucker. Rebuttal, at p. 8.	• FRE 702(a) - Not helpful to trier of fact - Legal Conclusion. • FRE 702(a) - not qualified to provide opinions on this issue.	Sustained: XX (sustained to extent that opinion references direct warnings to Mr. Tucker, rather than warnings to doctor Overruled: _____
	Opinions Alleging That Wright Medical Introduced Into The Stream of Commerce a Device That Was Defective and Unreasonably Dangerous. Report, at p. 7 ¶ 11.	• FRE 702(a) - Not helpful to trier of fact - Legal Conclusion.	Sustained: XX Overruled: _____
	Opinions Regarding Exhibit E and Exhibit E (schematic). Report, Exhibit E.	• FRE 702(a) - Not helpful to trier of fact, may confuse trier of fact	Sustained: _____ Overruled: XX
	Opinions Related to Ethical Obligations of Designers/Manufacturers. Rebuttal, at p. 3.	• FRE 702(a) - not qualified to provide opinions on this issue.	Sustained: XX Overruled: _____

	Hendrickson Declaration	Evidentiary Objection(s)	Ruling on the Objection:
2	My Report dated September 17, 2012 ("Report") is attached hereto as Exhibit "B." My Rebuttal Report dated October 2, 2012 ("Rebuttal Report")	• FRE 403 (*presentation* of cumulative evidence, waste of time)	Sustained: _____

	Hendrickson Declaration	Evidentiary Objection(s)	Ruling on the Objection:
	is attached hereto as Exhibit "C."		Overruled: XX
5	My examination in this case consisted of the review of relevant documents, peer reviewed technical literature, and a physical examination of the failed hip implant.	• FRE 403 (re-presentation of cumulative evidence, waste of time)	Sustained: _____ Overruled: XX
6	My physical examination of the hip implant included a visual inspection, physical measurements, stereo optical microscopy, x-ray radiography, and energy dispersive x-ray spectroscopy. This was a nondestructive approach that is standard for the industry and is substantially similar to the methods used by defendant's expert Dr. James.	• FRE 403 (re-presentation of cumulative evidence, waste of time)	Sustained: _____ Overruled: XX
7	My Report dated September 17, 2012 ("report") is attached hereto as Exhibit "B," clearly states that my conclusions are based on the non-destructive examination and analysis of components, the information contained within the documents reviewed, my educational background, and my experience of more than forty years analyzing failed consumer products, including artificial hips and other prosthetic implants. Many, if not all of my conclusions and opinions are supported by the peer reviewed literature "ASM Handbook, Volume 11, Failure Analysis and Prevention," referenced in my report, and "Engineering Design, A Materials and Processing Approach," referenced in my rebuttal report.	• FRE 403 (re-presentation of cumulative evidence, waste of time)	Sustained: _____ Overruled: XX
8	Based on my education and my experience of 40 years as a University Professor responsible for developing and teaching numerous times, a graduate level course on the subject Failure Analysis and Prevention, and based on my physical examination of the failed hip implant, as well as my experience in examining numerous other failed prosthetic implants, I was able to determine that the subject implant fractured due to metal fatigue initiated by a process known technically as fretting.	• FRE 403 (re-presentation of cumulative evidence, waste of time)	Sustained: _____ Overruled: XX
9	Fretting results from very slight oscillatory motion between two surfaces pressed together in physical contact. My examination of the design of the modular neck and stem of the subject Wright Profemur prosthetic hip confirmed that inherent in	• FRE 403 (re-presentation of cumulative evidence, waste of time)	Sustained: _____ Overruled: XX

	Hendrickson Declaration	Evidentiary Objection(s)	Ruling on the Objection:
	its design, it contains two surfaces pressed together in physical contact, a condition necessary for the initiation of fretting. In other words, fretting is not possible, nor is the subsequent fatigue fracture of the subject prosthetic hip, without the modular nature of the device.		
10	Based on the physical evidence available from my analysis, the fatigue fracture was initiated by fretting, which was a direct result of the design of the device, with errors in manufacturing most likely contributing factors.	• FRE 403 (re-presentation of cumulative evidence, waste of time)	Sustained: _____ Overruled: XX
11	Manufacturing defects cannot be ruled out merely by relying on device history records as a manufacturing defect is device specific and requires examination of the specific device at issue. While defense expert Dr. James claims in his rebuttal report that "the necks that fractured in Mr. Tucker's implant passed all dimensional and surface inspection," he offers no evidence that the stem in which the neck is pressed was inspected in a similar manner, or that the stem dimensions were compatible with the neck.	• FRE 403 (prejudicial); *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX
12	In this case, as discussed in my rebuttal report, both Dr. James and Dr. Ochoa admit in their reports that given the damage suffered to the device because of the fracture and extraction of the device during the revision surgery the presence or absence of any surface of dimensional defect cannot be made. This means that a manufacturing defect cannot be ruled out. Furthermore, Dr. James did not perform the type of tests necessary to determine whether or not a manufacturing defect of a metallurgical nature existed, therefore he has no basis for excluding that type of manufacturing defect as a contributing factor to fracture of the subject hip prosthesis.	• FRE 403 (re-presentation of cumulative evidence, waste of time)	Sustained: _____ Overruled: XX
13	Wright knew or should have known of the propensity for failure of the device due to fretting wear and metal fatigue and should have designed the device to resist this failure phenomenon. As explained in the report, this conclusion is drawn from my over 40 years of experience. This was later admitted by defendant's expert Brad James in his deposition. (James Dep. 23:10-24-2.)	• FRE 403 (re-presentation of cumulative evidence, waste of time)	Sustained: _____ Overruled: XX

	Hendrickson Declaration	Evidentiary Objection(s)	Ruling on the Objection:
14	Additionally, all modular hip implants contain one feature that non-modular implants do not, and that is a tapered, press-fit connection between the neck and stem. It is precisely this feature in the design that introduces the risk of failure by the mechanism of fretting, corrosion, and fatigue.	• FRE 403 (re-presentation of cumulative evidence, waste of time)	Sustained: _____ Overruled: XX
15	My conclusion that there is no evidence the subject total hip replacement device was abused or misused after implantation is right hip of Mr. Tucker is based on the review of the medical records and other discovery materials.	• FRE 403 (re-presentation of cumulative evidence, waste of time)	Sustained: _____ Overruled: XX
16	In my report and rebuttal report I refer to the hip implant that fractured in Mr. Tucker as a permanent implant. The reason I use the term "permanent" is that the device is intended to be a long term solution for the problem the device is correcting as opposed to temporary, which would imply that it was a short term solution. Also permanent refers to the fact that the medical device is surgically inserted and will not be removed or revised until it is medically necessary. There is no option for the patient to elect to remove the medical device themselves. This definition is in contrast to other temporary fixation prosthetic devices such as bone plates, which must retain their structural integrity only long enough to permit complete healing of the fractured bone, and then may be electively removed with no adverse effects to the patient.	• FRE 403 (prejudicial); *Laser* Design, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX
17	Exhibit E to my report is a schematic illustrating the relative positions of the component parts of the hip replacement. While the exhibit is not the implant that failed in this matter, it is substantially similar and is useful in showing how the various parts of the hip implant relate to each other and provides visual context to the discussion of the different parts of the implant.	• FRE 403 (prejudicial); *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX
18	My report goes into great detail describing how generally accepted testing procedures (the same ones used by defense expert Dr. James) were used to determine, using the scientific method, that the mechanism of fracture was metal fatigue. This is the same conclusion reached by Dr. James. Fatigue is considered as a "Failure Mechanism" universally in the scientific community. This is common knowledge. The technical definition of "Failure" as it applies to the field of metallurgy is well known to	• FRE 403 (presentation of cumulative evidence, waste of time) • FRE 403 (prejudicial); *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX

	Hendrickson Declaration	Evidentiary Objection(s)	Ruling on the Objection:
	every competent metallurgist, and can be found in any number of peer reviewed publications, including the Metals Handbook, Volume 11, referenced in my report on page 5. That definition is: *"Failure." "A general term used to imply that a part in service (1) has become completely inoperable, (2) is still operable but is incapable of performing its intended function, or(3) has deteriorated seriously, to the point that it has become unreliable or unsafe for continued use."* This definition is an integral part of the knowledge gained from my education and training as a metallurgist, and when applied to the subject Wright Medical prosthetic hip, shows conclusively that the hip has "Failed", i.e. it has become completely inoperable.		
19	From an engineering design perspective, as discussed in the reference "Engineering *Design, A Materials and Processing Approach"* listed on page 3 of my rebuttal report, those factors that promote fatigue failure are, or should be, well understood by the designers of products such as prosthetic hips that are known by virtue of their very function to be subject to repeated or cyclic loads. There are engineering design philosophies familiar to those educated in the field of metallurgy that serve to provide ways of eliminating, or greatly reducing the probability of fracture by fatigue, and for predicting with reasonable accuracy the fatigue life of products that have a propensity to fracture by fatigue. My knowledge of these design philosophies, and my understanding of the mechanisms that are involved in the time dependent aspect of the fatigue fracture process, indicate that any product that fails by fatigue in four years when there is a reasonable expectation that the product will survive and function as intended for much longer times, has failed to perform as a reasonable consumer would anticipate, and consequently is defective. The consequences of failure are considerable discomfort and anguish, and financial hardship to the patient and therefore the defective product is unreasonably dangerous.	• FRE 403 (prejudicial); *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX
20	The fact that medical industry anticipates that prosthetic hips should survive and function safely for a period of time much longer than four years is reflected in the failure statistics quoted by Dr. James in his rebuttal report in section 3.1, in which he states "That large studies have shown that just	• FRE 403 (prejudicial); *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX

	Hendrickson Declaration	Evidentiary Objection(s)	Ruling on the Objection:
	over one-percent of all hip implant revisions are necessary because of implant fracture." This means that 99% of those that require revision surgery do not fail by fracture. In his original report, on page 12 Dr. James includes a table of data on hip prosthesis fracture rates reported in the literature. In his deposition he removed the DePuy S-Rom implants from the list, but the others listed show that the failure rates are in the range of 0.27% to 11.0% , which means that most hip implants do not fail by fracture. It implies that those that do fail by fracture are different in some aspect which caused failure. They did not perform as expected, based on survival statistics, consequently they are defective.		
21	My report goes into much more detail in describing the observed "parallel groves" than is cited in Defendant's motion. For example, the grooves were not readily visible to the unaided eye; these grooves were located on the neck at and adjacent to the location of the fatigue fracture origin; there is a line of demarcation on the groove pattern between where the surface has worn, from an area where there is no apparent wear. All of these observations, when combined with the knowledge obtained from my educational training and experience explain how and why the fatigue fracture supports my conclusion. It is common knowledge within the metallurgy profession that any series of uniformly spaced, parallel lines on the free surface of any product subjected to dimensional control are generated by a cutting or grinding tool. The machine controlled mechanical finishing processes used in manufacturing produce periodic movements, thus the symmetry of the surface features. The location of the "parallel grooves" which is on the neck extending to the location of the fracture origin (a location which is not disputed by defendant's expert Dr. James) and the surface wear, which is a clearly visible feature which, as a metallurgist I was trained to interpret, invokes the mechanism of fretting, which was clearly defined in my report (page 5), and discussed in detail. The bases for my opinion to which the defendant objects, and the how and why it was reached, are included in my fundamental knowledge of the field of metallurgy, and are clearly spelled out in my report.	• FRE 403 (presentation of cumulative evidence, waste of time) • FRE 403 (prejudicial); *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX

	Hendrickson Declaration	Evidentiary Objection(s)	Ruling on the Objection:
22	My stated opinion that "[t]he fact that it was implanted in Mr. Tucker, who weighed in the range of 257 to 265 pounds, is in itself evidence that it was being used as intended," is taken out of context by the defendant. It fails to include the fact that my report includes several bases that support this opinion, and when considered collectively clearly support the opinion expressed. It fails to include the statement that if Mr. Tucker's weight was excessive (by Wright Medical standards) for this particular modular hip implant, it should not have been implanted in Mr. Tucker. It was not Mr. Tucker's decision to use this particular implant. Documents reviewed show no evidence that Wright Medical provided any information to the physician, and certainly not to Mr. Tucker, that this specific implant was improper for Mr. Tucker. Furthermore, the defendant fails to recognize that I reviewed documents describing Mr. Tucker's activity subsequent to the date of implant, and found no evidence that these were excessively vigorous. Collectively, these observations form the basis for the opinion that the subject implant was being used as intended and this is contained in my report.	• FRE 403 (prejudicial); *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX
23	The defendant claims that the underlying theme of the opinions in my report and rebuttal report is that "the failure of the hip implant occurred because, and only because of the modular design of the implant." The Defendant claims that I did not perform an analysis of the Profemur design or explain how I reached this conclusion. This is a complete mischaracterization of the contents of my original report and of my rebuttal report.	• FRE 403 (re-presentation of cumulative evidence, waste of time, evidence mischaracterized) • FRE 403 (not helpful to trier of fact) • 702(a) (qualification to provide opinion testimony)	Sustained: _____ Overruled: XX
24	The statement is based first on the facts resulting from a scientific examination of the physical evidence, which is described in detail in my original report, and which reached the same conclusions as those reported by Dr. Brad James, defendant's expert metallurgist. The conclusions were, to quote Dr. James' original report "The subject device fractured by a combination of corrosion, fretting and fatigue." The only difference between Dr. James' conclusions and my conclusions is that Dr. James concluded that there was no evidence of a manufacturing defect. My conclusion was that errors in manufacturing were contributing factors. Dr. James admits nevertheless, (page 5 of his report) that given the "substantial	• FRE 403 (prejudicial); *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX

	Hendrickson Declaration	Evidentiary Objection(s)	Ruling on the Objection:
	fretting of the neck and stern modular taper surfaces, no determination of the presence of absence of any surface or dimensional defect could be made." Therefore he cannot rule out any contribution of a surface or dimensional defect to the cause of fracture. Most importantly, however, is the common conclusion that there was "substantial fretting of the neck and stern modular taper surfaces". Once this fact is established, *i.e*. fretting has occurred on the surface where the fatigue crack originated (both Dr. James and I agree as to the location of the fatigue crack origin) as pointed out several times in my report, it follows that there was microscopic movement between the neck and stern. This is the only possible way that fretting can occur. As pointed out numerous times in my report, the only possible reason that any movement occurred is because the subject hip was of modular design, *i.e*. the neck and stein were two different pieces of metal. Absent this fact, fretting is impossible. It follows that if fretting is impossible, and if the fatigue fracture initiated because of fretting damage, then absent the fretting damage a fatigue crack would not have initiated, and absent the initiation of a fatigue crack, there would have been no fatigue fracture. The chain of events that caused fracture of the specific prosthetic hip that was implanted in Mr. Tucker, and which failed by fatigue fracture, started because of the modular design of the hip implant. My report clearly describes this process and the basis for the opinion to which the defendant objects.		
25	Defendant objects to my stated opinions that: (1) There is no evidence the subject total hip replacement device was abused or misused after implantation in the right hip of Mr. Tucker, (2) There is no evidence that Mr. Tucker's actions during the time period he depended on the performance of the subject total hip replacement device to allow him to function normally did anything contribute to the ultimate failure of the device, (3) There is no evidence that Mr. Tucker's activity after the device was implanted was excessively vigorous. The reasons for reaching these opinions are spelled out in detail in both my original report and my rebuttal report. They are based on the results of the examination of the physical evidence which identified the cause of fracture, which both Dr. James and I agree was fretting corrosion and fatigue, and on information	• FRE 403 (re-presentation of cumulative evidence, waste of time) • FRE 403 (prejudicial); *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX

	Hendrickson Declaration	Evidentiary Objection(s)	Ruling on the Objection:
	gleaned from my review of the documents listed in my original report. These documents indicate that there is no evidence that Mr. Tucker's activity subsequent to implantation of the subject prosthetic hip was in violation of any admonitions he received from either his physician or Wright Medical. There is no evidence that Mr. Tucker received any notice in the form of pain or discomfort when performing his activities that he was acting inappropriately for an individual with a prosthetic hip. Absent any of these indicators of misuse, it follows logically that there is no evidence of misuse. After the subject device failed, and the failure mechanism was established, there is no feasible way of load testing the device to obtain any scientific data relating to possible misuse. The bases for the opinions are that misuse implies a violation of some written or verbal detailed instruction or prohibition, or the participation in an activity that is anticipated to produce some physical sensation of pain. Absent either of these events, there is no evidence of abuse or misuse. These bases are clearly represented in my reports.		
26	The defendant does not object to my conclusion, that the remaining 5% fractured instantaneously when a force acted that produced a local stress in excess of the strength of the alloy used to manufacture the neck. Even though there is no objection to this part of the conclusion, it is important to note that the basis for this opinion is the fact that a scientific examination of the failed prosthetic hip produced the results that the fracture mechanism was metal fatigue. The final fracture by an overstress mechanism is a characteristic of metal fatigue, and is unique to that mechanism.	• FRE 403 (prejudicial); *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX
27	The defendant appears to object to my opinion as to when or how this actually occurred, My statement was based on the University of San Francisco Medical Center Discharge Summary for patient Gregory Tucker, admitted on 05/17/10 and discharged on 05/20/10, which lists Dr. Telmer J. Guillaume as the provider, and is dated 05/24/10, contains the following statement in part: "*He underwent a right ceramic on ceramic total hip replacement with a modular femoral stem in March 2006. He did well until Friday, May 7, 2010, when he suffered a fall and was seen in the local emergency department. X-rays showed a broken femoral stem at the modular neck.*" Regardless of	• FRE 403 (prejudicial); *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX

	Hendrickson Declaration	Evidentiary Objection(s)	Ruling on the Objection:
	when or how it occurred, this has no bearing on other opinions presented in either my original report or my rebuttal report.		
29	My experience in analyzing failed prosthetic devices in the past has resulted in understanding that the industry classifies implants into two broad categories. One category is "permanent" implants, and the second is "temporary" fixation devices. Permanent implants are devices that are intended to be permanent, with no intended date of removal absent a failure to perform the intended function. A "temporary" fixation device is one that is implanted for the purpose of assisting the body in a healing process, with the option of removing the implant after its intended function has been performed. My opinions are based on this knowledge and experience.	• FRE 403 (prejudicial); *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX
30	There are numerous technical publications that support my contention that prosthetic hips are intended to be permanent devices, however I saw no need to provide documentation of what is considered to be an accepted distinction. For example, an article located on the website, www.fda.gov/MedicalDevices/..../Implants and Prosthetics/default.htm, states the following: "Implants can be placed permanently or they can be removed once they are no longer needed. For example, stents or hip implants are intended to be permanent. But chemotherapy ports or screws to repair broken bones can be removed when they are no longer needed." The same article lists examples of questions a patient should ask a doctor before agreeing to an implant procedure. One such question is "Will my implant be permanent or removable? If the device is permanent, find out how long it should last."	• FRE 403 (prejudicial); *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX
31	Defendant contends that my assertion that a consumer has the right to expect the device to perform for more than four years fails to take into account any bio-mechanical, physiological, behavioral, surgical, or environmental factors that are known to affect the performance of total hip replacements. However, Wright Medical, as the designer and manufacturer of the hip implant is the party responsible for considering and accounting for the bio-mechanical, physiological, behavioral, surgical and environmental factors of their target market when designing prosthetic hips, and has the	• FRE 403 (prejudicial); *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX

	Hendrickson Declaration	Evidentiary Objection(s)	Ruling on the Objection:
	ethical responsibility to minimize the effects of these factors on the durability of the device, rather than simply tell the consumer that we don't know how long this device will last and someday at some unspecified time, you may need revision surgery. A consumer has the right to know, and the manufacturer has the obligation to provide accurate information, concerning the anticipated lifetime of a product that, in the event of failure, can cause harm to the consumer.		
33	As a result of my university education and training, which began in the year 1959, and as a result of my experience in analyzing numerous other prosthetic implants including prosthetic hips, I have acquired knowledge concerning fretting, corrosion and fatigue that are contained within scientific publications. These same publications are part of the general scientific literature and were, or should have been available to the design engineers employed by Wright Medical at the time the modular Profemur prosthetic hip was designed.	• FRE 403 (prejudicial); *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX
34	The initiating cause of the failure of the subject Wright Medical prosthetic hip was a phenomenon called "fretting." The physical evidence that this phenomenon in fact occurred is in the form of damage unique to fretting discovered during examination of the subject failed prosthesis. Dr. Brad James (Opinion 1, page ii of his report) agrees that fretting and the associated phenomena of corrosion and fatigue caused fracture of the subject implant. Through my education and experience, I am aware that this failure phenomenon has been known to the scientific community for decades. The *Metals Handbook,* Published by the American Society for Metals in 1948, on page 6, defines fretting corrosion. Another peer reviewed text book titled Mechanical Metallurgy, authored by George Dieter, and published by McGraw Hill in 1961, on page 322, contains a section on "Fretting", and states *"Fretting is the surface damage which results when two surface in contact experience slight periodic relative motion"*. It also states *"Fatigue cracks often start in the damaged areas"*. There are numerous other peer reviewed technical publications describing the detrimental effects of fretting and the associated corrosion and fatigue phenomenon in the scientific literature in the time period prior to the time in 2001 or 2002 when the Wright Medical modular Profemur prosthetic hip	• FRE 403 (re-presentation of cumulative evidence, waste of time) • FRE 403 (prejudicial); *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX

	Hendrickson Declaration	Evidentiary Objection(s)	Ruling on the Objection:
	was designed.		
35	The detrimental aspects of "fretting" described in the scientific literature was, or should have been known to Wright Medical engineers and designers when they designed the modular Profemur prosthetic hip, and elected to incorporate into the design, two metal surfaces pressed into contact, the exact condition that must exist in order for the fretting phenomenon to even be a potential cause of failure. By electing to design a modular neck and stein combination into the prosthetic hip, Wright Medical introduced into the device, a well known and publicized mechanism of failure that would not exist absent the modular design. This very mechanism of failure caused fracture of the neck of the subject prosthetic hip that failed when implanted in Mr. Tucker.	• FRE 403 (prejudicial); *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX
36	There is considerable evidence that Wright Medical was aware of the potential for failure by fretting prior to the design and manufacture of the modular profemur prosthetic hip. Wright's expert, Dr. Brad James, in his report on page 5, includes a section titled "Fretting-induced fatigue is a relatively common issue in modular hip implants." In the second paragraph of that section, he states "Fretting, corrosion and fatigue are well-known issues (emphasis added) in modular implants, such as the subject device." He then references eight scientific publications, with publication dates of 1994, 2007, 1999,1993, 1996, 1997, 2008, and 1997. Six of the eight were published before Wright Medical placed the modular Profemur prosthetic hip into the stream of commerce. All of these deal directly with fretting damage in modular prosthetic hips, rather than fretting in general, and should have been known to Wright Medical engineers and designers prior to designing the modular Profemur hip.	• FRE 403 (prejudicial); *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX
37	Wright Medical's expert, Dr. James admits that "modular orthopedic implants are well known to be susceptible to fretting and fretting-induced fatigue, modular systems allow distinct advantages in terms of fitting patient anatomy." This statement does not identify the specific advantages of fitting patient anatomy, or why these advantages outweigh the disadvantages of pain and suffering to the patient resulting from failure of the device by the well known mechanism of fretting and fretting induced	• FRE 403 (prejudicial); *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX

	Hendrickson Declaration	Evidentiary Objection(s)	Ruling on the Objection:
	fatigue.		
40	One of the textbooks used in my course on Engineering Design at Arizona State University is referenced in my rebuttal report. The title of that book is *"Engineering Design, A Materials and Processing Approach."* That textbook, contains an entire section on "Ethics in Engineering." The ethical responsibility of a design engineer requires that the product designed be analyzed for potential hazards. This same textbook includes an entire chapter on Risk and Reliability which includes a section on Hazard Analysis. With respect to the potential hazard of sudden and unanticipated failure by fatigue, this textbook describes three commonly accepted approaches to product design. One approach is termed Infinite-Life Design; the second is Safe-Life Design; and the third is Damage-Tolerant Design. These approaches allow a designer to understand those factors that influence the fatigue life of any product, and when properly applied through analysis and testing, enable the designer to predict with a reasonable degree of accuracy the anticipated lifetime of the product. This is all related to the ethical responsibility of the design engineer, to produce products that are free of hazards and safe for use by consumers, regardless of their intended use of the product. Training in engineering ethics was part of my educational curriculum, and part of my responsibilities as a university professor during my 40 years of teaching engineering course at Arizona State University.	• FRE 403 (prejudicial); *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX
41	As part of the requirements for my design course, I used other authoritative peer reviewed reference publications such as the *Standard Handbook of Machine Design, Second Edition.* This reference contains a chapter titled *"Safety."* That chapter ends with the following summary: *"The designer or manufacturer of a product has a moral, ethical and legal obligation to provide safe products. If that is not enough motivation, there is a matter of enlightened self-interest. There are three aspects to this obligation: (1) The product must be made safe. (2) If it is not possible to design out all hazards, guarding must be provided. (3) If complete and proper guarding cannot be provided, appropriate directions and warnings must be provided. It is absolutely unacceptable to use a warning in a situation where safe design or proper guarding is*	• FRE 403 (prejudicial); *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX

	Hendrickson Declaration	Evidentiary Objection(s)	Ruling on the Objection:
	possible". I have had knowledge of these ethical responsibilities of design engineer since my years as student many years ago.		

	Truman's Opinions in Report and Rebuttal	Evidentiary Objection(s)	Ruling on the Objection:
	Truman's Opinion That Wright Medical's Testing Was Inadequate Truman Report: Finding Nos. 5, 6, 14, 15 (pp. 47-48); pp. 12-16, 19, 25-30; 31, 46-47	• FRE 402 (irrelevant) • FRE 403 (more prejudicial than probative) • FRE 702(a) (not helpful to trier of fact) • FRE 702(d); Unreliable: Contradicted By Witnesses Own Report and Sworn Testimony	Sustained: ——— Overruled: XX
	Truman's Opinions Regarding Cobalt Chromium Truman Report: Finding Nos. 8, 11, 14, 15 (p. 48); pp. 21, 31-32, 35, 46	• FRE 402 (irrelevant) • FRE 403 (more prejudicial than probative) • FRE 702(a) (not helpful to the trier of fact) • FRE 702(c) (not the product of reliable principles and methods) • FRE 702(d) (does not apply principles and methods to the facts of the case; Contradicted By Witnesses Own Report and Sworn Testimony)	Sustained: ——— Overruled: XX
	Truman's Opinion that Various Surface Treatments Could Have Avoided Injury Truman Report: Finding Nos. 9, 11, 14, 15 (p. 48); pp. 31-33	• FRE 403 (more prejudicial than probative) • FRE 702(a) (not helpful to the trier of fact) • FRE 702(c) (not the product of reliable principles and methods)	Sustained: ——— Overruled: XX
	Truman's Opinions Regarding Acceptable Rates of Failure Truman Report: Finding Nos. 3, 15 (pp. 47-48); pp. 36-42	• FRE 402 (irrelevant) • FRE 403 (more prejudicial than probative) • FRE 702(a) (not helpful to the trier of fact) • FRE 702(c) (not the	Sustained: ——— Overruled: XX (but sustained as to the ultimate

	Truman's Opinions in Report and Rebuttal	Evidentiary Objection(s)	Ruling on the Objection:
		product of reliable principles and methods) • FRE 702(d) (does not apply the principles and methods to the facts of the case)	issue of what is acceptable)
	Truman's Conclusion that Warnings Were Inadequate Truman Report: Finding Nos. 12, 13, 14, 15 (p. 48); pp. 16, 19, 20, 42-47 Truman Rebuttal Report: p. 3	• FRE 403 (more prejudicial than probative) • FRE 702(a) (not helpful to the trier of fact) • FRE 702(c) (not the product of reliable principles and methods) • FRE 702(a) - not qualified to offer opinion as to warnings because witness is an engineer, not a medical doctor, surgeon, or other individual who treats patients. Gebhardt v. Mentor Corp., 15 F. App'x 540, 541-42 (9th Cir. 2001); Squires v. Goodwin, 829 F.Supp.2d 1041, (D. Colo. 2011) (finding proposed expert had no experience designing product warning labels); Magoffe v. JLG Indus. Inc., 2008 WL 2967653 (D. N.M. 2008) (engineer not qualified to offer opinions as to warnings); Bourelle v. Crown Equipment Corporation, 220 F.3d 532, 538 (7th Cir. 2000) (holding "Only a physician or someone with specialized knowledge would be	~~Sustained:~~ _____ ~~Overruled:~~ _____ RESERVED[1]

[1] As used herein, "RESERVED" indicates that the Court will make a determination at trial if the expert has sufficient foundation to offer the opinion.

	Truman's Opinions in Report and Rebuttal	Evidentiary Objection(s)	Ruling on the Objection:
		qualified to determine whether the warning was **inadequat**e").	
	Truman's Conclusion that the Profemur® was Unreasonably Dangerous Truman Report: Finding Nos. 1, 2 (p. 47); pp. 28, 30, 47	• FRE 402 (irrelevant) • FRE 403 (more prejudicial than probative) • FRE 702(a) (not helpful)	Sustained: ——— Overruled: XX
	Truman Opinion that Alcohol and Alcohol Abuse Played No Role in Failure Truman Report: Finding No. 4 (p. 47) Truman Rebuttal Report: Findings (p.4); pp. 3-4	• FRE 403 (more prejudicial than probative) • FRE 702(a) (not helpful to the trier of fact) • FRE 702(c) (not the product of reliable principles and methods)	Sustained: ——— Overruled: XX

	Truman Declaration	Evidentiary Objections	Ruling on the Objection:
2.	My Engineer's Report dated September 19, 2012, ("Truman Report") and my rebuttal report dated September 23, 2012, ("Truman Rebuttal") are incorporated herein by reference and are attached hereto as Exhibit "B."	• FRE 403 (re-presentation of cumulative evidence, waste of time)	Sustained: ——— Overruled: XX
5.	My methodologies for coming to the conclusions contained in my Report and Rebuttal Report are sound and well supported by peer-reviewed published scientific and medical literature and textbooks that I cite in my reports and discuss further in this declaration.	• FRE 403 (not helpful to trier of fact) • FRE 702(a) (qualification to provide opinion testimony)	Sustained: ——— Overruled: XX
6	My curriculum vita lists my work experience, but does not specifically list all of the areas that I have experience in within that work experience. A person knowledgeable of the biomechancial engineering field, who reviewed my education and work experience, would reasonably assume that I have significant experience with the issue of labeling.	• FRE 403 (prejudicial); *Laser Design*, 2007 WL 735763 at *4	Sustained: ——— Overruled: XX
7.	I have been an engineer in the orthopaedic industry for over 32 years.	• FRE 403 (re-presentation of cumulative evidence, waste of time)	Sustained: ———

	Truman Declaration	Evidentiary Objections	Ruling on the Objection:
			Overruled: XX
8.	In those years I have been a designer, development team member, and more recently a consultant to the industry. As part of my responsibilities I have been involved in both the creation and review of warnings and precautions provided in package inserts and surgical techniques for well over a dozen orthopaedic product lines for at least 12 different orthopaedic companies.	• FRE 403 (prejudicial); *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX
9.	As part of the development teams, I routinely complete failure modes and effects analyses, risk estimates and identify and apply methods to reduce risk of hazards and harm. This work is complete with the development team, which includes engineers, marketing personnel, surgeons, and medical reviewers.	• FRE 403 (prejudicial); *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX
10.	The warnings provided in package inserts for new products are reviewed by the design teams. In my career I have been a member of many such teams.	• FRE 403 (prejudicial); *Laser* Design, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX
11.	Through my experience and training in reviewing, writing, and discussing warnings with team members and with orthopaedic surgeons I am qualified to comment on the adequacy of the information contained in Wright Medical's IFUs and promotional materials. I am qualified to write and interpret the warnings as an industry expert, and have done so in the past.	• FRE 403 (prejudicial); *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX
12.	In my report, I provided a reasonable alternative warning that is used by Exactech. Additionally, Wright Medical's 230 pound weight restriction for its current, more durable, Profemur Modular Neck is a more reasonable alternative to the non-definitive warnings initially provided with the titanium Profemur Modular necks.	• FRE 403 (re-presentation of cumulative evidence, waste of time) • FRE 403 (prejudicial); *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX
13.	Exactech's Accumatch M modular femoral stem, a titanium alloy product whose design is stronger than the Wright ProFemur, contraindicates the Accumatch M femoral	• FRE 403 (prejudicial); Laser *Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX

	Truman Declaration	Evidentiary Objections	Ruling on the Objection:
	stems for moderately active to vigorously active patients weight greater than 250 lb. (Source: Exactech's Accumatch M brochure, ©2006 #711-06-30, Rev C 0506).		
14.	The warning pages supplied by Wright for this device were insufficient concerning weight and/or activity restrictions to prevent implant overload, failure, and patient injury.	• FRE 403 (re-presentation of cumulative evidence, waste of time)	~~Sustained:~~ _____ ~~Overruled:~~ _____ RESERVED
15a	Stating that obesity or high activity levels can lead to implant fracture in an Instructions for Use (IFU) documents is an insufficient warning for the following reasons: (a) This statement provides no definitive guideline to the physician as to how much weight or how much activity this product can withstand. There were no specific weight or activity restrictions in Wright's IFUs for the ProFemur neck implants prior to 2010. Given that there are several peer reviewed articles supporting the effectiveness of total hip implants in heavier or obese individuals, despite an increase in complications, more information concerning the relative endurance limit or specific implants is needed for the surgeon to make an informed choice of appropriate implants for use in heavier or high-demand, high-activity patients. In addition, Wright did not contraindicate the use of this product in high demand patients (heavy patients, active patients). In fact, Wright clearly marketed their hip products for use in high demand patients and their brochures appeared to show comparatively greater strength to selected (weaker) devices. [Wright advertisements/patient testimonials]. Wright's technical brochures and testimonials imply to consumers (surgeons and their patients) that this product had been designed and tested for high demand situations.	• FRE 403 (re-presentation of cumulative evidence; waste of time)	~~Sustained:~~ _____ ~~Overruled:~~ _____ RESERVED

	Truman Declaration	Evidentiary Objections	Ruling on the Objection:
15b	(b) It is well known that surgeons do not routinely read the IFU documents provided with the implants in the packaging. Simply placing an ambiguous warning on a document that is not routinely read is an insufficient method to assure patient safety. Among other things, surgeon-to-surgeon training, and salesman-to-surgeon training tips, promotions/educational brochures, physician letters, and literature or literature reviews (when available) are more effective in communicating and clarifying such critical issues to surgeons.	• FRE 403 (re-presentation of cumulative evidence; waste of time)	~~Sustained:~~ _____ ~~Overruled:~~ _____ RESERVED
15c	(c) The warnings provided at the time that Tucker's procedure was completed simply did not provide sufficient information concerning the capability of this implant or the risk of fracture of this device in high demand patients. Specific weight and activity level limitations, as per Exactech's guidance, and/or comparative strength or endurance data with a clinical relevance discussions should have been provided by Wright.	• FRE 403 (re-presentation of cumulative evidence; waste of time)	~~Sustained:~~ _____ ~~Overruled:~~ _____ RESERVED
16	In MH179-703, Rev.0904, Wright Medical advertised that in 19 years of clinical use there were no fractures in the implanted Profemur Necks, and they boasted that over 50,000 had been implanted. However, the Wright Medical design control and regulatory documentation documents that several ProFemur necks had fractured in 1985-2004 time frame. This mis-information implies to the surgeon that there is no risk of fracture of the ProFemur modular neck. A true and correct copy of MH179-703 is attached hereto as Exhibit "C."	• FRE 402 (irrelevant, not relevant time period) • FRE 403 (prejudicial); *Laser Design*, 2007 WL 735763 at *4 • FRE 702(a) (lack of qualification, no foundation)	Sustained: XX Overruled: _____
17	In my experience working with surgeons, if surgeons are specifically informed that a product does not have sufficient strength for a specific weight or for patients performing a specific set of higher demand actives; they will generally seek out a product that does have sufficient strength for patients with those requirements. If surgeons are not informed of strength limitations of a device in specific terms, they have no reason to select an alternative, especially when the new device is claimed to be the same as a device with 19+ years free of fractures in clinical use, as this product was	• FRE 702(a) (lack of qualification, no foundation) • FRE 403 (prejudicial); *Laser Design*, 2007 WL 735763 at *4	~~Sustained:~~ _____ ~~Overruled:~~ _____ RESERVED

	Truman Declaration	Evidentiary Objections	Ruling on the Objection:
	described by Wright Medical.		
18	As discussed in my Report and obtained from Wright Medical's own website, there are at least three Wright Medical brochures that imply superior strength of the ProFemur hip when compared to other hips.	• FRE 403 (re-presentation of cumulative evidence; waste of time, irrelevant)	Sustained: _____ Overruled: XX
19	Wright marketed their Metal-on-Metal ("MoM") products for use in active individuals. Refer to: CONSERVE Total Hip System with BFHTM Technology Big Femoral Heads iBFHTM) Restore an Active Lifestyle. Case Study, Harold S. Boyd, M.D. and Younger age patient testimonials, Wright website (e.g., Jimmy Connors, Evelyn, Gary, Jon, Kevin, Larry, Mark, Rick).	• FRE 402 (irrelevant) • FRE 403 (re-presentation of cumulative evidence; waste of time, irrelevant, prejudicial does not relate to Profemur® product or specific failure at issue)	Sustained: _____ Overruled: XX
20	Gregory Tucker was a moderately-active/active 46-year-old when his hip implant failed. His weight was within the normal distribution of today's U.S. population, which was one of Wright's target markets for this product. Tucker was not unforeseeably heavy for a total hip implant patient. Tucker did not act or react improperly in a manner that caused his injury.	• FRE 403 (re-presentation of cumulative evidence; waste of time, irrelevant)	Sustained: _____ Overruled: XX
22	A failure rate of either 0.30% or 0.47%, as claimed by Wright, is not an acceptable failure rate in the industry for the fracture of the modular neck component of an artificial hip.	• FRE 402 (irrelevant) • FRE 403 (re-presentation of cumulative evidence; waste of time, prejudicial, irrelevant not related to relevant time frame)	Sustained: XX (as to the conclusion, but not as to the rate) Overruled: _____
23	The North American long neck fracture rate was calculated by Wright to be 0.546% (55 out of every 10,000) when 146 fractures had occurred as of November 18, 2010, this computes to 1 in 183 long necks fracturing.	• FRE 402 (irrelevant) • FRE 403 (re-presentation of cumulative evidence; waste of time, prejudicial, irrelevant not related to relevant time frame)	Sustained: _____ Overruled: XX
24	Wright has stopped distributing titanium Profemur modular necks in North America, and has replaced them with cobalt chrome necks.	• FRE 402 (irrelevant) • FRE 403 (re-presentation of cumulative evidence; waste of time, prejudicial, irrelevant not related to	Sustained: _____ Overruled: XX

	Truman Declaration	Evidentiary Objections	Ruling on the Objection:
		relevant time frame)	
25	In its December 3, 2010 Modular Neck update, Wright Predicted that neck fractures would continue at the rate of 6.5 per month.	• FRE 402 (irrelevant) • FRE 403 (re-presentation of cumulative evidence; waste of time, prejudicial, irrelevant not related to relevant time frame)	Sustained: _____ Overruled: XX
26	As of December 1, 2011, the long neck fracture rate is 0.88%.	• FRE 402 (irrelevant) • FRE 403 (re-presentation of cumulative evidence; waste of time, prejudicial, irrelevant not related to relevant time frame)	Sustained: _____ Overruled: XX
27	Based upon review of FDA MAUDE reports for fractured components between December 2011 and October 2012, the monthly fracture rate is greater than what Wright predicted in 2010, averaging about 8.7 per month.	• FRE 402 (irrelevant) • FRE 403 (re-presentation of cumulative evidence; waste of time, prejudicial, irrelevant not related to relevant time frame)	Sustained: _____ Overruled: XX
28	Assuming, as Wright predicted, that modular neck fractures continued in 2012 at the rate of 6.5 a month, 78 additional fractures will have occurred in 2012.	• FRE 402 (irrelevant) • FRE 403 (re-presentation of cumulative evidence; waste of time, prejudicial, irrelevant not related to relevant time frame)	Sustained: _____ Overruled: XX
29	With 58% of the fractures occurring in the U.S., and 89% of the fractures being long necks, there will be approximately 40 additional long neck fractures reported in the U.S. in 2012, for a total of 173 U.S. long neck fractures. This is a U.S. long neck fracture rate of approximately 1.15% (173 U.S. long neck fractures; 15,060 U.S. long neck sales), or a fracture rate of 1 out of every 81 long necks implanted in the U.S.	• FRE 402 (irrelevant) • FRE 403 (re-presentation of cumulative evidence; waste of time, prejudicial, irrelevant not related to relevant time frame)	Sustained: _____ Overruled: XX
30	The total number of fractured ProFemur necks is nearly 346 in mid-2012, and a rate of 8.7 fractures per month indicates a total of 372 fractures by year end, and about 192 U.S. long neck fractures for a U.S. long neck fracture rate of 1.27% by year end.	• FRE 402 (irrelevant) • FRE 403 (cumulative evidence; waste of time, irrelevant - not related to relevant time frame; misquotes own report which claims 8.5 per	Sustained: _____ Overruled: XX

	Truman Declaration	Evidentiary Objections	Ruling on the Objection:
		month) • FRE 403 (prejudicial), *Laser Design*, 2007 WL 735763 at *4	
31	To a device manufacturer, the failure rate that has evolved, and is projected for the life of the product is what is material.	• FRE 402 (irrelevant) • FRE 403 (prejudicial); *Laser Design*, 2007 WL 735763 at *4	Sustained: XX Overruled: _____
32	The present and projected fracture rates of the Wright Medical Titanium long modular neck exceed what is an acceptable rate of fracture in the industry for an artificial femoral neck or an artificial femoral stem, and is an unacceptable failure rate.	• FRE 402 (irrelevant) • FRE 403 (cumulative evidence; waste of time, prejudicial, irrelevant not related to relevant time frame)	Sustained: XX Overruled: _____
33	While the precise combination of stem model and neck model should not be particularly relevant to the industry in calculating and evaluating the significance of failure rate of these modular neck devices, it does appear from the data cited by Wright's experts that the use of a modular neck with the Profemur stem results in failure rates more than 50% higher than the fracture rates of modular necks across all stems.	• FRE 402 (irrelevant - not related to relevant time frame;) • FRE 403 (prejudicial*), Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX
34	The failure rates relied on by Wright Medical and their experts Dr. James and Dr. Ochoa contain several rates that are not similar and are not comparable to the fracture rate of Wright Medical's long necks.	• FRE 403 (prejudicial) *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX
37	In Wright's original 510(k) application for clearance to market these devices Wright represents that the Profemur hip system is substantially similar to five other hip systems, the Wright Infinity, Portland Orthopedic Margron, Zimmer ZMR hip system, OTI Omega II, and Link-Link MP. [Exhibit 14 to Wright's 510(k) application. WMT 849-852.] The neck fracture rates of those systems which Wright represents to be "substantially similar" are not offered by Dr. James.	• FRE 403 (irrelevant, prejudicial) *Laser Design, Intern.* 2007 WL 735763 at *4	Sustained: _____ Overruled: XX
38	Of the articles cited by Dr. James and Dr. Ochoa,	• FRE 402 (irrelevant)	Sustained: _____

	Truman Declaration	Evidentiary Objections	Ruling on the Objection:
	only the Grupp article analyses a hip system with a modular neck, the Metha Short Hip System Prostheses, made in Germany and never authorized for distribution in the United States by the FDA. That system initially had a titanium (Ti6A14V) neck and stem, the same as the Wright Profemur modular implants in issue here, and appears to have a modular junction in the stem similar to that of the Profemur. A true and correct copy of the article is attached hereto as Exhibit "F."	• FRE 403 (re-presentation of cumulative evidence; waste of time, prejudicial)	Overruled: XX
39	The Metha modular neck failure rate is supportive of that design being defective, and how a reasonable manufacturer should have responded to notice of such a defect.	• FRE 402 (irrelevant) • FRE 403 (re-presentation of cumulative evidence; waste of time, irrelevant, prejudicial)	Sustained: _____ Overruled: XX
40	The Grupp article shows that the Metha Short Hip had a failure rate of 1.4%. The article shows that the Metha titanium modular necks implanted from August 2004 to November 2006 fractured on average at 24 months (0.7 - 4.0 years) after implantation. After the third fracture Aesculap AG, the manufacturer of Metha, replaced its titanium necks with cobalt chrome necks in November of 2006. Aesculap removed the product from the market when there was a failure rate of only 0.06% (3 fractures out of 5,000 implants.) The manufacturer also published the results of their failure analyses at least three tunes in peer reviewed literature to benefit the general orthopaedic community.	• FRE 402 (irrelevant) • FRE 403 (re-presentation of cumulative evidence; waste of time, irrelevant, prejudicial, involves irrelevant time period)	Sustained: _____ Overruled: XX
41	Wright Medical documents [WMT_TUC 00874-885, 00939-950] disclose that Wright Medical Europe marketed over 50,000 modular necks over the period of 1986-2002. Product complaints were recorded over the period of January 1997 - October 2006. It received notice of seven neck breakages (fracture) of its titanium modular necks in that time. The causes of the failures included micro movements, fretting, and metal fatigue	• FRE 402 (irrelevant) • FRE 403 (re-presentation of cumulative evidence; waste of time, irrelevant, prejudicial, involves irrelevant time period) • FRE 702 (Not helpful to trier of fact)	Sustained: _____ Overruled: XX

	Truman Declaration	Evidentiary Objections	Ruling on the Objection:
42	Unlike Metha, who immediately discontinued titanium modular• necks after notice of only 3 failures, Wright continued to manufacture and distribute titanium modular necks, with the predictable result that fractures continued to occur in increasing numbers and rates of fracture.	• FRE 403 (re-presentation of cumulative evidence; waste of time, irrelevant) • FRE 702 (Not helpful to trier of fact)	Sustained: _____ Overruled: XX
43	An article by Kishida is cited by Dr. James and Dr. Ochoa for the claim that the Lubeck total hip has a 2.5% failure rate. A true and correct copy of that article is attached here to as Exhibit "G." This German made hip system was not approved for use in the United States by the FDA, and the device does not have a modular neck. The device had a high failure rate with fractures occurring in the middle third of the stem, not the neck area. The fractures were attributed to the small core diameter of the stem and the lack of proximal stability. These fractures are not the result of micromotion and fretting corrosion, and are unrelated to the failure mechanism at issue.	• FRE 402 (irrelevant) • FRE 403 (re-presentation of cumulative evidence; waste of time, irrelevant)	Sustained: _____ Overruled: XX
44	An article by Gotze is cited by Dr. James to support a claim of a 3.0% failure rate in the Lubeck Total Hip, the same device discussed in the preceding paragraph. The article concluded that the high-fracture rate of the stem is unacceptable. A true and correct copy of the article is attached hereto as Exhibit "H."	• FRE 402 (irrelevant) • FRE 403 (re-presentation of cumulative evidence; waste of time, irrelevant)	Sustained: _____ Overruled: XX
45	An article by Busch is cited by Dr. James and Dr. Ochoa for a claim that DePuy Solution and the Smith & Nephew Echelon Hips had failure rates of 2.3%. This is a misrepresentation of the article and its data. The article identified 5 fractured femoral sterns out of 219 revision surgeries. In other words, there was a fracture rate of 2.3% in the revision surgeries studied. No information was provided regarding the total sales of the hip. Additionally, the hips studied did not have modular necks, and the failures occurred in the body of the stern, not the neck region. A true and correct copy of the article is attached hereto as Exhibit "1."	• FRE 403 (re-presentation of cumulative evidence; waste of time, irrelevant)	Sustained: _____ Overruled: XX
46	To calculate the true fracture rate of the DePuy Solution and the Smith & Nephew Echelon Hips, the total number of hips sold would need to be	• FRE 403 (prejudicial), *Laser Design*, 2007 WL 735763 at *4	Sustained: _____

	Truman Declaration	Evidentiary Objections	Ruling on the Objection:
	known, not just those that are being revised due to a failure. Without this information comparing this "fracture rate" to Wright Medical's fracture rate is disingenuous.		Overruled: XX
47	An article by Goldberg is cited by Dr. James and Dr. Ochoa for the claim that the DePuy S-Rom has a failure rate of 10%. The article is again being misrepresented. The "mechanical" failure rate of the S-Rom cited by Dr. Goldberg references an article by Chandler for that data. A reading of the Chandler article shows that this study was based on a population of 48 patients with 52 total hip revisions among them. "Mechanical loosening" had occurred in 5 hips out of the 52 for a 10% rate. The mechanical loosening was a lack of fixation of the stern. The DePuy S-Rom also does not have a modular neck. A true and correct copy of the article is attached hereto as Exhibit "J."	• FRE 403 (prejudicial), *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX
48	An article by Heck is cited Dr. James and Dr. Ochoa for the claim that the American Association of Hip and Knee Surgeons Survey had determined a failure rate of 0.27%. The article lists 23 device manufacturers by name. The study included 64,483 metallic femoral components. A total of 172 stem fractures were reported, with only three manufacturers and the "unknowns" accounting for more than 91% of the fractures. Sixteen manufactures reported no femoral stern fractures. The article states that the FDA has been concerned with the medical device regulatory process and the lack of sufficient safeguards. A true and correct copy of the article is attached hereto as Exh "K."	• FRE 403 (re-presentation of cumulative evidence; waste of time, irrelevant)	Sustained: _____ Overruled: XX
49	With regards to the fracture rate presented by the Heck article, this rate is half that of the North American experience of Wright's Profemur long neck as of November 18, 2010, and one fourth of the current known fracture rate of Wright's Profemur long neck.	• FRE 403 (prejudicial), *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX
50	An article by Callaghan is cited by Dr. James for the claim that All Mayo Clinic hip replacements had a failure rate of 0.6% and that the Charnley-Mueller hip had a 11% failure rate. The data for the Chamley-Meuller hip was from 1974. Again the	• FRE 403 (prejudicial), *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX

	Truman Declaration	Evidentiary Objections	Ruling on the Objection:
	data is misrepresented by Wright Medical's experts. The 11% failures rate was derived from six fractures of the femoral stem out of 56 replacement arthroplasties. Again this fracture rate is not the fracture rate of implanted hips and does not concern the modular neck. The Mayo experience is based on an article published in 1981. As stated in the article, because of improvements in materials and design, the fracture rate was zero for the improved devices introduced in 1976. A true and correct copy of the article is attached hereto as Exhibit "L."		
51	An article by Carlsson is cited by Dr. James and Dr. Ochoa regarding data from a Swedish hospital in the early 1970s showing a failure rate of 0.67%. The article reports 14 stem fractures of the first generation with a fiat back, which was made of wrought air-melted 316-L stainless steel and all came from the same manufacturer. These hip devices from the 1970s are not substantially similar to the modern artificial hip stem and neck and are not an appropriate comparison. A true and correct copy of the article is attached hereto as Exhibit "M."	• FRE 403 (prejudicial), *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX
52	An article by McNeur is cited by Dr. James and Dr. Ochoa to support a claim that a 1.86% failure rate of a Charnley type is similar to Wright. The article dicusses 1023 hip replacements of the Charnley type from 1968 to 1980. There were 19 reported fractures of the femoral stem for a failure rate of 1.86% (19 fractures out of 1023 hip replacements). This was not a modular device, and the fracture did not occur in the neck region of the device. A true and correct copy of the article is attached hereto as Exhibit "N."	• FRE 403 (prejudicial), *Laser Design*, 2007WL 735763 at *4	Sustained: _____ Overruled: XX
53	To summarize the above discussion of the "comparative" failure rates provided by Dr. James and Dr. Ochoa are not comparable to the fracture rate of Wright's Profemur necks, except for the Metha Short Hip discussed in the Grupp Article. To	• FRE 403 (prejudicial), *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX

	Truman Declaration	Evidentiary Objections	Ruling on the Objection:
	compare, we would need to know the total number of hip devices implanted for each hip device discussed in the above articles.		
54	I will be testifying that Wright employed insufficient testing prior to commercially marketing its titanium ProFemur modular necks in the United states. It was not until Wright received notice of many field failures of its device that they stepped-up the testing to remedy the deficiency in testing. This is supported by the discovery materials, documents relied on by Wright's experts, and additional information that has incrementally become available in this and other Wright Medical modular fracture cases in which I have been retained as a biomechanical engineering expert.	• FRE 402 (irrelevant) • FRE 403 (re-presentation of cumulative evidence; waste of time, irrelevant)	Sustained: _____ Overruled: XX
55	Wright should have known the weight of the patient population and should have tested to assure the product could withstand the loads applied by those patients. Wright failed to do both. There is nothing inconsistent about these facts in my report or in my opinions, in this case or the other Wright fracture cases for which I have been retained as an expert.	• FRE 403 (re-presentation of cumulative evidence; waste of time, irrelevant)	Sustained: _____ Overruled: XX
56	Wright should have known that heavier, more active, high demand patients have an increased risk of fracture due to the increases loads produced. The information was available in the medical literature and should have been accounted for in designing the hip implant.	• FRE 403 (re-presentation of cumulative evidence; waste of time, irrelevant)	Sustained: _____ Overruled: XX
57	My discussion in my report concerning the corrosion issues, metal ions, and taper in taper junctions is gleaned from peer-reviewed literature, and is supported by the literature cited.	• FRE 403 (re-presentation of cumulative evidence; waste of time, irrelevant)	Sustained: _____ Overruled: XX
58	My discussion in my report on the issue of corrosion simply points out yet another deficiency in the Wright testing prior to commercial launch in the U.S. My report itemized more than one design remedy that could have applied together or separately to achieve suitable strength and endurance for use in Wright modular necks.	• FRE 403 (re-presentation of cumulative evidence; waste of time, irrelevant)	Sustained: _____ Overruled: XX

	Truman Declaration	Evidentiary Objections	Ruling on the Objection:
59	The design team has the responsibility to test their products for the ability to withstand the end use environment. Without building the products, processing with the proposed surface finishing treatments on the specific geometries, and without testing them appropriately, the design team cannot predict durability.	• FRE 403 (prejudicial), *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX
60	Surface treatments such as shock peening, roller burnishing, and surface hardening/coatings have long been used to enhance the fatigue life of devices, including orthopaedic implants. Wright's claim in its motion to exclude my testimony that the use of such processes to enhance the fatigue life of an implant is not based on reliable principles is absurd because these treatments are well documented and have long been used to enhance fatigue life. This is a basic of materials science information. Surface treatments (including simple things like smooth finishes) are done all the time and do improve fatigue strength. This demonstrates that whoever is speaking for Wright on this point does not have an understanding of basic biomechanical engineering materials and processes.	• FRE 403 (re-presentation of cumulative evidence; waste of time) • FRE 702(a) (not helpful to the trier of fact) • FRE 702(c) (not the product of reliable principles and methods)	Sustained: _____ Overruled: XX
61	Reduced fretting and increased fatigue life of a CoCr ProFemur neck combined with the ProFemur stems is supported by the discovery documentation produced by Wright in this and other similar cases, by the literature cited (e.g. Grupp et al.) And the discussion of fracture rates in detail in this declaration, by the subsequent testing completed by Wright, and by the fact that Wright no longer sells their Ti alloy ProFemur necks in the U.S. The testing completed by Wright after the products failed should have been done before the implants were launched in the U.S.	• FRE 403 (re-presentation of cumulative evidence; waste of time, irrelevant, prejudicial, involves irrelevant time period)	Sustained: _____ Overruled: XX

	Truman Declaration	Evidentiary Objections	Ruling on the Objection:
62	After the products failed, testing of both titanium and chrome-cobalt ProFemur modular necks was completed. Comparing the results, the cobalt chrome alloy assemblies demonstrated significantly higher 107 cycle endurance strengths when compared to the titanium neck alloy assemblies. ASTM 2068-01 did not specify an endurance requirement for ISO 7206-6:1992 fatigue tests. ASTM 2068-03 included a new requirement for the fatigue performance of the head and neck region of the stemmed femoral components per ISO 7206-6:1992 of 5340 N (1200 lb). There was no reason that this higher 10' cycle endurance limit of 5340 N (12001b), or greater, could not have been required of this design in the ISO 7206-6:1992 tests prior to Mr. Tucker receiving his implant. Via testing completed as a result of numerous premature product fracture complaints, Wright later realized that the load levels described by the older testing standards, and ISO 7206¬6:1992, and ISO 7206-4:1989 standards were not high enough to simulate the forces imposed on implants by heavy-weight patients engaged in high levels of activity. Consequently, Wright changed the weight guidance on their package inserts to reflect that "higher than normal rates of early failure of the long offset PROFEMUR Titanium Modular necks have been observed for heavyweight (>230 lb) patients ... Alternative devices, such as cobalt chrome modular necks ... may also be considered for these patients." To summarize, before Mr. Tucker was implanted with the ProFemur device, Wright had the knowledge and ability to determine whether the ProFemur device could adequately withstand a higher demand load, but it did not.	• FRE 403 (re-presentation of cumulative evidence; waste of time, irrelevant, prejudicial, involves irrelevant time period)	Sustained: _____ Overruled: XX
63	Wright released their current CoCr modular necks without including a warning concerning an increased risk of acetabular loosening due to the use of CoCR as the neck material, and acknowledged that they have not seen research supporting an increased risk of acetabular cup loosening due to the use of the CoCR neck as opposed to a titanium alloy neck.	• FRE 403 (re-presentation of cumulative evidence; waste of time, irrelevant, prejudicial, involves irrelevant time period, irrelevant product)	Sustained: _____ Overruled: XX

	Truman Declaration	Evidentiary Objections	Ruling on the Objection:
64	The literature does not support an increase incidence of acetabular loosening due to the stiffness of cobalt chromium neck on the femoral stem.	• FRE 403 (prejudicial), *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX
65	Prior to the introduction of neck down-sizing and modularity introduced by Wright and other orthopaedic companies in the late 1990s and early 2000s, implant neck fractures were rare. The McNeur Article States: Over the years there have been improvements in both materials and design, with the result that failure because of fracture is less likely. Improved prostheses of the Charnley type were introduced into this country in 1976, and, since that time, there have been no fractures of the femoral stern in patients fitted with the new type of prostheses. In the absences of severe damage to the implant during installation, the risk of premature fatigue fractures of a prosthesis due to mechanical overload and severe fretting can be virtually eliminated through sound engineering design, manufacturing, and development processes combined with appropriate indications, contraindications and provision of appropriate weight and activity limitations.	• FRE 403 (re-presentation of cumulative evidence; waste of time, irrelevant, no context provided)	Sustained: _____ Overruled: XX
66	Even though current ISO and ASTM test performance standards were initially developed for average size and moderate activity patients, they are insufficient for devices intended to be used in heavier active individuals. In order to help their orthopaedic surgeons understand the capabilities and limitation of the devices, Wright had a responsibility to disclose that the device had not been tested to assure endurance when used in higher demand patients. Furthermore, Wright did not meet the recommended neck strength recommendations of ASTM F 2068-03 as discussed in my report.	• FRE 403 (re-presentation of cumulative evidence; waste of time, irrelevant, prejudicial, involves irrelevant time period)	Sustained: _____ Overruled: XX
67	The current ASTM tests, while simpler and useful for direct comparison to predicate devices, are not sufficient to characterize the performance of a device in high demand patients, especially ones like the ProFemur implant with a high degree of	• FRE 403 (re-presentation of cumulative evidence; waste of time, irrelevant)	Sustained: _____ Overruled: XX

	Truman Declaration	Evidentiary Objections	Ruling on the Objection:
	modularity, used with or without MoM articulations.		
68	Wright could have and should have completed the same analyses completed prior to the release of their CoCr neck prior to launching their Ti alloy necks in 2003. They should have used geometry changes or surface enhancement processes to increase the endurance capabilities of their Ti alloy necks and they should have applied appropriate and definitive weight and activity limitations to the Ti alloy necks prior to marketing them as discussed in my report.	• FRE 403 (re-presentation of cumulative evidence; waste of time, irrelevant, out of context)	Sustained: _____ Overruled: XX
69	To summarize my opinion as discussed and shown in my report, this declaration, and my testimony in other similar Wright Medical fracture cases, for which I have been retained as biomechanical engineering expert, that the Profemur hip system and long neck were defectively designed by not using CoCr for the long neck, not using available surface treatments to increase fatigue strength, not properly testing the implant, and failing to provide adequate warnings. Had Wright used CoCr in the long neck from the beginning, applied available surface treatments to the titanium neck, properly tested the implant for heavier-active individuals in the U.S., or provided adequate warnings and contraindications the fracture rate of the Profemur Long Necks would have been much lower.	• FRE 403 (re-presentation of cumulative evidence; waste of time, irrelevant)	Sustained: _____ Overruled: XX
70	To further summarize, it is my opinion that the risks of Wright Medical's titanium alloy long neck outweigh the general benefits described by Wright's experts in active-heavy individuals, such as Mr. Tucker. As a result, the fracture rate of the titanium long neck continues to rise.	• FRE 403 (prejudicial), *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX
71	In my rebuttal report, I discuss the issue raised by defendant's experts regarding Mr. Tucker's alcohol use.	• FRE 403 (re-presentation of cumulative evidence; waste of time, irrelevant)	Sustained: _____ Overruled: XX

	Truman Declaration	Evidentiary Objections	Ruling on the Objection:
72	As a professional engineer with over 32 years of experience in the field of biomechancial engineering and designing of medical devices I am familiar with the in vivo activities of the end user that may affect the performance of implanted medical devices, including risks associated with alcohol use or misuse. As a designer, development team member, and consultant to the industry, my responsibilities have involved completing failure modes and effects analyses, risk estimates and identifying and applying methods to reduces risk of hazards and harm.	• FRE 403 (prejudicial), *Laser* Design, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX
73	A large part of my engineering practice includes biomechanics analyses. It is well known in the injury biomechanics community that many health conditions, including aging and alcoholism, can directly or indirectly alter tissue injury thresholds. I routinely document and consider the health status of the injured party when opining on whether forces in a particular incident were sufficient to cause a specific injury. I am well qualified to do this. In some soft tissue or bone injury cases it is helpful to have a specialist, such as a toxicologist, an immunologist or a medical doctor address the biochemical mechanisms in a specific disease state, which result in tissue degradation. However, such a specialist is not required in this case because the issue at hand is the fracture of the metallic implant.	• FRE 403 (prejudicial), *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX
74	In Mr. Tucker's case, the neck of his ProFemur implant prematurely fractured. I specifically address the failure of the metallic components, not the failure of human tissues in this case. For example, I am not opining about the force to cause a specific soft tissue or bone injury in Mr. Tucker. No specific bone or soft tissue injuries related to alcohol use caused the metallic neck component to fail. Mr. Tucker's healing potential and health status were altered by his alcohol use, but that is not what caused the metallic component to fracture.	• FRE 403 (prejudicial), *Laser Design*, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX
75	In Mr. Tucker's case, his alcohol misuse played a role in his hip osteonecrosis which lead to his total hip replacement. Had he not had the Wright	• FRE 403 (re-presentation of cumulative evidence; waste of time, irrelevant,	Sustained: _____

	Truman Declaration	Evidentiary Objections	Ruling on the Objection:
	implants installed he would not have been able to load them. However, since he them implanted [sic], they should have been strong enough to support him or the [sic] should have been contraindicated for a person of his size and activity level.	out of context)	Overruled: XX
76	While there is evidence that outcomes may be poorer in persons with alcohol misuse, there is no evidence that the forces applied to his hip were significantly higher or significantly more frequent (higher number of cycles) than should have been expected for any other person, with or without alcohol misuse.	• FRE 403 (prejudicial), *Laser Design*, 2007 WL 735763 at *4 • FRE 702 (Not adequately related to facts at bar, not helpful to trier of fact)	Sustained: _____ Overruled: XX
78	In general alcohol misuse may alter quality of life, healing potential, and general health status. In some instances, the implants may be more likely to be loosened, and the bone may be more likely to be injured. However, Mr. Tucker's medical records do not identify bone injury or loosening as an issue for Mr. Tucker.	• FRE 403 (prejudicial), *Laser* Design, 2007 WL 735763 at *4	Sustained: _____ Overruled: XX
79	Mr. Tucker may have been more prone to stumbling or falling on occasion, but these are expected or foreseeable or normal events of insufficient force to cause an implant to fracture. Generally the implant is overloaded, fractures, and caused the patient to fall due to sudden loss of stability.	• FRE 403 (re-presentation of cumulative evidence; waste of time, irrelevant, out of context) • FRE 702 (Not qualified, not helpful to trier of fact)	Sustained: _____ Overruled: XX
80	The implant in Mr. Tucker cracked due to mechanical overload and fretting, and the crack propagated, over time and with use, until the cross section was too small to withstand normal loading. At that time the remaining section suddenly fractured.	• FRE 403 (re-presentation of cumulative evidence; waste of time, irrelevant, out of context)	Sustained: _____ Overruled: XX
81	To summarize, it is my opinion that the alcohol use by Mr. Tucker played a role in his osteonecrosis that led to the need for a hip implant and that the concerns associated with alcohol use and hip implants are not present in Mr. Tucker's medical records. The alcohol use did not significantly increase the loads on the hip implant and the implant cracked due to mechanical overload and fretting, eventually resulting in fracture of the neck.	• FRE 403 (re-presentation of cumulative evidence; waste of time, irrelevant, out of context)	Sustained: _____ Overruled: XX

	Declaration of Thomas M. Gray	Evidentiary Objection(s)	Ruling on the Objection:
26	Attached hereto as **Exhibit S** is a true and correct copy of an email from Debby D. Daurer of Wright Medical Technology that is available as part of the public record on pacer in Wollant v. WMT, Case No. 1:10-CV-3104-DME-BNB, which was attached as Exhibit 11 to Plaintiff's opposition to Wright Medical Technology's motion to exclude testimony (Doc. No. 186). The Wollain court denied a motion to seal the exhibits. (2012 U.S. Dist. LEXIS 171081 (2012)) The information is still part of this the public records as of the date of the signing of this declaration. The document is incorporated herein by reference as if set forth in full at this point.	• FRE 403 (prejudicial); *Laser Design*, 2007 WL 735763 at *4 • FRE 403 (prejudicial) as to Exhibit – subject to pending motion to seal in that court	~~Sustained:~~ _____ ~~Overruled:~~ _____ WITHDRAWN by Defendant (*see* Dkt. No. 112)

This Order terminates Dkt. No. 62, 63, and 67. **IT IS SO ORDERED**.

Dated: February 27, 2013

YVONNE GONZALEZ ROGERS
UNITED STATES DISTRICT COURT JUDGE