SECOND JUDICIAL DISTRICT
COUNTY OF BERNALILLO
STATE OF NEW MEXICO

MICHAEL BRIAN McDONALD, Ph.D.,

Plaintiff,

v. **No. D-202-CV-2013-04060**

ZIMMER, INC., and
ZIMMER HOLDINGS, INC.;

Defendants.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

This case came before the Court for trial from December 12th through December 23rd 2017. Plaintiff Michael Brian McDonald, Ph.D. ("Plaintiff") appeared through his counsel of record, McGinn, Carpenter, Montoya & Love, PA, and Osborne & Associates. Defendants Zimmer, Inc. and Zimmer Holdings, Inc. ("Defendants") appeared through their counsel of record, Rodey, Dickason, Sloan, Akin & Robb, P.A. and Faegre Baker Daniels LLP. The Court being fully informed hereby enters its Findings of Fact and Conclusions of Law.

FINDINGS OF FACT

Stipulated Facts

1. This Court has jurisdiction over the parties and the subject matter.

2. Plaintiff was implanted with Defendants' M/L Taper Hip Prosthesis with Kinectiv Technology ("MLTK") and a cobalt-chromium head on June 11, 2010 by Dr. Joshua Carothers at Presbyterian Hospital.

3. The implanted MLTK was a "modular" design which consisted of a stem and neck component, both composed of titanium alloy.

4. On October 4, 2011, Plaintiff underwent a revision surgery wherein the MLTK was

removed and a new Kinectiv modular neck and a new ceramic head were implanted. The Kinectiv stem base component was not replaced.

5. On November 18, 2011, Plaintiff underwent a second revision surgery wherein the MLTK was again removed and a new Kinectiv modular neck and a new ceramic head were implanted. The Kinectiv stem base component was not replaced.

6. Plaintiff's Complaint, with the remaining counts of Strict Products Liability – Failure to Warn, Strict Products Liability – Unreasonably Dangerous Design, Negligence, Breach of Express Warranty and Breach of Implied Warranty of Merchantability, was tried to the bench.

Background (Plaintiff)

7. In February 2010, Plaintiff was suffering from severe right hip pain. Plaintiff's hip had bothered him for the prior five years but by 2010 the pain was interfering with his normal activities which included playing tennis and golf several times per week.

8. Plaintiff consulted with Joshua Carothers, M.D. ("Carothers") who ordered an x-ray evaluation of the hip. The evaluation revealed severe osteoarthritis with flattening of the femoral head, osteophyte formation and cystic formation.

9. Plaintiff and Carothers discussed the available treatment options, and Plaintiff determined to have total hip replacement surgery. Plaintiff voiced concerns regarding the risks of metallosis[1] during their discussion.

10. At the time of Plaintiff's surgery, metallosis was known to have come from the metal on metal articulation in the hip replacement (ball and acetabular cup). This problem had been addressed by manufacturers through the use of polyethylene liners in the acetabular cup, so Carothers assured Plaintiff that metallosis would not be an issue.

11. Carothers planned to use the traditional Zimmer M/L Taper[2], with a fixed neck for

[1] Metallosis is also referred to as adverse tissue reaction, metal poisoning and/or trunionosis.

[2] Carothers did not express any concern about using Defendant's products during his testimony but did note that the surgery was to be performed at Presbyterian Hospital and Presbyterian has a sole source contract with Defendants. Therefore Carothers was restricted to using a Zimmer product for Plaintiff's hip replacement.

Plaintiff's total hip replacement. However, during the surgery Carothers needed extra offset for Plaintiff's anatomy and switched to the MLTK[3]. Carothers chose an anteverted neck for Plaintiff.

12. The MLTK allowed Carothers to recreate Plaintiff's leg length, offset and stability, and Carothers believed that the benefits of the MLTK outweighed any risks.

13. The MLTK implanted into Plaintiff was provided by Defendants' sales agent, was not altered by the surgeon, and was in the same condition as when it was manufactured and sold.

14. Plaintiff's initial recovery went well, however, by early May 2011 Plaintiff was experiencing hip pain, groin pain and loss of flexibility.

15. Plaintiff returned to Carothers who initially suspected that the pain was due to Plaintiff's activity level.

16. When Plaintiff's pain did not decrease, Carothers began an established series of tests over the next several months to determine why Plaintiff was continuing to have pain, including:

A. An x-ray (May 2011);

B. A SED rate and C-reactive protein[4] check (June 2011);

C. A hip aspiration to check the synovial fluid and rule out infection (July 2011). Plaintiff's synovial fluid was not normal but it did not indicate infection;

D. A bone scan, which was normal (late July 2011);

E. A "metal artifact reduction sequence" MRI to qualitatively assess metal and which showed that a psudotumor was forming (August 2011).

17. On September 2, 2011, Christopher Beauchamp, M.D. ("Beauchamp") saw Plaintiff at the

[3] Carothers specifically implanted a 56 mm Trilogy Acetabular Shell with cluster holes; a 32 mm Longevity Crosslinked Polyethylene Liner; a Size 10 Zimmer M/L Taper; a 32 mm +0 VerSys Hip System Co-alloy Femoral Head; and an R2 extended offset Kinectiv.

[4] Plaintiff's C-reactive protein was elevated reflecting tissue necrosis.

Mayo clinic in Phoenix, AZ. Beauchamp diagnosed Plaintiff with adverse reaction to metal debris associated with the MLKT and scheduled him for revision surgery. Beauchamp believed that the problem stemmed from one of the MLTK's modular junctions.

18. Beauchamp also ordered blood cobalt and chromium serum levels. Both were elevated, however, the cobalt level was significantly elevated[5].

19. Beauchamp performed revision surgery on Plaintiff's hip on October 4, 2011. During the revision Beauchamp discovered corrosion and metal debris at the taper junction, burnishing on the neck component at the second junction, necrotic tissue[6] and turbid joint fluid.

20. Beauchamp's pre-operative and post-operative diagnosis was a failed total hip replacement secondary to adverse reaction to metal debris caused by the cobalt-chromium head articulating with the titanium trunnion (neck).

21. Beauchamp left the original M/L Taper intact but replaced the cobalt-chromium head component with a ceramic head. He also replaced the Kinectiv modular neck and the polyethylene liner.

22. Beauchamp was unable to resect all of Plaintiff's necrotic tissue. The remaining necrotic tissue, because it has no blood supply, left Plaintiff with a greater risk for post-surgical infection[7].

23, Plaintiff developed an infection after Beauchamp's revision.

24. On November 18, 2011, Carothers performed a second revision surgery, irrigation and a debridement for infection. He replaced the polyethylene liner, the ceramic femoral head and the Kinectiv neck.

25. Plaintiff did nothing post-original surgery or post-revision surgery which lead to the

[5] Beauchamp did not believe the chromium level was elevated and testified that the cobalt level was not an unusual level for patients with metal on metal implants.
[6] Dead tissue associated with adverse reaction to metal debris.
[7] Surgeons must balance the risk of leaving necrotic tissue in the patient with the risk of instability that results from removing too much tissue.

corrosion and failure of the MLKT.

26. Plaintiff developed metallosis around his implant and his implant failed due to the corrosion caused by the cobalt chromium femoral head articulating with the titanium trunnion.

27. Following the second revision, Plaintiff was treated with a six-week course of IV antibiotics.

28. Plaintiff's continued risk for infection resulting from Beauchamp's inability to remove all of the necrotic tissue, has forced Plaintiff to a permanent course of antibiotics because of the possibility that an infection will recur.

29. Plaintiff has recovered for the most part, is relatively pain free and has no future appointments scheduled with either of his surgeons.

30. It is more probable than not that Plaintiff will need a third, more complicated revision surgery in future. This surgery will cost approximately $250,000 and will involve removal of all of the implant components for a period of 2-3 months to try and kill the infection, during which Plaintiff will be wheelchair bound. If the infection can be successfully eradicated, another hip prosthesis will be implanted, necessitating the same type of physical therapy and recovery period as the first two revision surgeries.

31. Plaintiff may need a revision based upon other circumstances that are unrelated to the infection such as replacement of the polyethylene liner, loosening of a component or instability.

Background (Defendants)

32. Defendants design and manufacturer medical devices, including hip implants such as the MLTK implant Plaintiff received.

33. In 2001, Defendants initiated the G-2 project when "minimally invasive" hip surgery was getting increased attention. The G-2 Project developed the MLTK, a duel modular hip system.

34. Duel modular refers to the implant having separate modules for the trunnion (neck) and taper (stem) as opposed to a fixed taper (neck and stem as one solid unit).

35. The head (ball) is a separate component on a modular system and on a fixed system.[8]

36. A duel modular system allows the surgeon to select the modular neck-head combination to match the patient's anatomy with the implant to alleviate impingement and improve range of motion and position of the components. It also allows the surgeon to adjust leg length and offset.

37. Prior to initiating the G-2 Project, Defendant had a successful clinical history of using metal heads on fixed titanium tapers.

38. The MLKT stem and neck are both made of titanium.

39. The MLKT was designed to be used with either a metal femoral head or a ceramic femoral head. Typically, the surgeon decides which head to use.

40. The MLKT design team included about twenty consulting surgeons, with different skill sets, to provide the clinical expertise[9]. The consulting surgeons are paid for their work.

41. The first MLTK was implanted in 2007.

42. Defendants continue to market the MLTK to be paired with either a metal femoral head or a ceramic femoral head.

Strict Products Liability – Unreasonably Dangerous Design

43. It is never appropriate to design a hip implant system that would create an unreasonable risk of injury to the health or safety of a patient. Defendants recognize this design principle and recognize that patient safety is paramount.

[8] The head is the portion of the implant that interfaces with the acetabular cup of the hip. The head had been a separate component of the implant for some years prior to Plaintiff's surgery and the modularity of the head is not an issue presently. The use of a cobalt-chromium head versus a ceramic head is an issue presently.

[9] Defense expert witness Joshua Jacobs, M.D. was a consulting surgeon on the MLTK and has consulted with Defendants for a number of years.

44. If a device is throwing off or creating so much metal debris and corrosion that it causes metallosis, that is not an acceptable risk of harm.

45. The MLTK was a new design and new product for Defendants[10].

46. The MLTK had three component parts: the stem also known as the taper, which is inserted into the femur; the head, which acts as the ball and fits into the acetabular cup[11] and provides for the rotation and movement of the hip; and the neck also known as the trunnion, which provides the bridge and connects the stem and the head.

47. The MLTK therefore had two junctions between the component parts: the stem/neck junction, which was a titanium/titanium junction and the neck/head junction which was either titanium/cobalt-chromium or titanium/ceramic depending on the type of head the surgeon chose. These junctions are where the metals interfaced and where corrosion occurred.

48. There are three primary product design considerations for a new product: strength, corrosion fatigue and junction stability. These design considerations cannot be addressed in isolation.

49. Hip implants can fail for a variety of reasons including but not limited to dislocation, infection, loosening and metallosis.

50. The risk of corrosion is that it will cause metallosis. Metallosis from this sort of an implant was a rare diagnosis in 2010, when Plaintiff received his first implant.

51. There is no consensus in the medical community as to why patients react differently to corrosion.

[10] During the design of the MLTK and since, almost all hip implant systems involve the use of modular heads. Modular heads have been used for thirty years. The new design was not a component system but a three component system.

[11] This is the cup of the pelvis.

52. Corrosion can occur with any hip implant system, with mixed metal or similar metal pairings. Corrosion is seen from retrieved implants in patients that have had no adverse local tissue reaction.

53. Corrosion can occur with metal heads and ceramic heads.

54. Zero risk is unattainable but the occurrence rate must be low.

55. In creating a new product, the manufacturer must mitigate known risks to patient safety through design and testing, as best possible.

56. Before it set out to design the MLTK through its G-2 project in 2001, Defendants knew of the danger to human beings if too much metal debris from an implant was released into the body through corrosion, micro-motion, or fretting[12]. The risk of fretting and corrosion had been known since the early 1980s.

57. There are two types of corrosion that can occur. Galvanic corrosion occurs when the electropotential of two contacting metals does not match and the more active metal corrodes. The electropotential of titanium and cobalt chromium is virtually the same, so galvanic corrosion was not an issue that Defendants needed to address in the development of the MLTK.

58. Very simply put, fretting corrosion occurs when two metals move against each other. Fretting corrosion occurs because one metal is rubbing of the oxide coating of the other and exposing new material in a chemical environment[13].

59. In designing the MLTK, Defendants knew that the use of dissimilar metals can result in a higher potential for corrosion and that wear debris from a junction of two dissimilar metals had been documented to be toxic and harmful to the human body.

[12] Fretting is the micro-motion of one metal surface against another. Fretting corrosion is corrosion that occurs due to this movement.

[13] Fretting corrosion can occur at the junction of dissimilar metals or similar metals.

60. Before placing the MLTK on the market, Defendants were required to mitigate the risks of this known danger by minimizing the risk of corrosion and metal debris at the head-neck junction where the titanium neck interfaced with the cobalt-chromium head.

61. Initially, the MLKT model was designed with a cobalt-chromium neck coupled with a titanium stem. Cobalt-chromium was selected for its strength. The cobalt-chromium neck did not pass Defendants' internal fretting corrosion testing, so it was abandoned.

62. In 2004, Defendants moved to a design that included a titanium stem and titanium neck. Defendants' decision to change the materials in the MLKT was prompted by its corrosion fatigue testing which revealed that a titanium neck produced less metal wear and corrosion than a cobalt-chromium neck.

63. Changing from the cobalt-chromium neck to the titanium neck extended the G-2 Project time frame.

64. The five year development of the MLTK was longer than the normal three year development time frame. The longer time frame resulted in additional cost to Defendants.

65. Defendants knew that characteristics of the MLTK, including elasticity, taper geometry, and flexural rigidity all play a role in causing fretting and corrosion. Specifically, the more flexible the taper, the greater the risk of micro-motion, corrosion and fretting.

66. The type of testing Defendants used to determine corrosion and/or metal debris generation was called "accelerated corrosion fatigue testing ('ACF')."

67. Defendants chose to conduct ACF testing on the two separate junctions of the MLTK – the head-neck junction and the neck-stem junction. The purpose of the separate tests was to isolate and measure metal debris liberated at each isolated junction.

68. Defendants then added the amounts of debris from the separate ACF tests to determine

the total amount of expected metal debris from the MLTK.

69. Defendants used the metal debris levels of a clinically successful product, the 6-degree M/L taper with the VerSys head and VerSys stem, as its benchmark for acceptable levels of metal debris. Defendants developed a bench mark they wanted to meet in the ACF test of the MLTK based upon the worst case liberated metal (5.62 milligrams) from the 6-degree M/L taper.

70. The M/L taper with VerSys head and VerSys stem included a titanium monoblock taper[14] and cobalt-chromium head. It had been the "gold standard" in total hip replacement for about thirty years.

71. The changes in design of the MLTK which were different from the M/L Taper were: (a) the introduction of a modular neck and (b) variation in the geometry of available components of the neck, both longer and shorter with different angles of anteversion. The dual-modular MLTK design doubled the places where micro-motion and fretting can occur, not only at each individual junction, but stemming from the dynamic created by two junctions.

72. The MLTK called for a neck designed to be thinner in both planes as compared to the M/L Taper. The MLTK has a thinner neck than other designs. The neck was narrowed to create more flexibility so as to optimize range of motion and reduce impingement[15].

73. The MLTK is in the top third of flexibility for implant devices, so it is more flexible than most. This increased flexural rigidity may account for increased fretting corrosion[16].

74. The MLTK also introduced a different angle of anteversion which introduced another variable into the flexibility and relative motion at the neck-head junction.

75. The MLTK has two junctions rather than one where there can be micromotion, (1)

[14] The monoblock taper included a single neck-stem as opposed to the modular parts of the MLTK.
[15] Impingement occurs when the neck of the implant hits the acetabulum (hip cup) and interferes with range of motion. Surgeons avoid impingement whenever possible.
[16] This was the subject of a clinical research report published by Defense expert Gilbert in 2014 entitled "Modern Trunnions are More Flexible: A Mechanical Analysis of THA Taper Designs.".

between the CoCr head and the neck and (2) between the titanium neck and titanium stem.

76. When Defendants conducted ACF testing on the MLKT, it did not run the test on the entire device with both junctions.

77. Defendants used a metal head for the ACF testing at the head-neck junction.

78. Defendants used a ceramic head for the ACF testing at the neck-stem junction. The use of a ceramic head allowed Defendants to isolate the metal debris to that produced at the neck-stem junction.

79. ACF testing is conducted in a way to mimic the conditions of the human body. The component part is tested in solution with a similar PH to what it will be subjected to in the human body and subjected to a load, calculated to mimic the activity load a normal human would exert on the joint.

80. Defendants created a "worst case scenario" for the ACF testing in which they made the PH of the testing solution more acidic that it would be in the body and raised the temperature of the solution above the body temperature to accelerate chemical reactions. Defendants used a +8 leg length, extra-extended offset straight neck to produce the greatest bending moment. Defendants believed that these adjustments would cause the greatest micromotion, fretting and potential for corrosion.

81. Defendants' ACF testing on the separate MLTK components resulted in 4.4 mg of metal debris loss.

82. Because the MLTK components ACF metal debris was less than the benchmark M/L taper metal debris Defendants determined that the MLTK was safe and ready to market.

83. Defendants never conducted ACF testing with both the head-neck junction and the neck-stem junction together on the MLTK.

84. Defendants never conducted ACF testing on the MLTK configuration that was implanted into Plaintiff.

85. Defendants never conducted ACF testing on the anteverted neck that was implanted into Plaintiff[17]. Defendants chose a neck that was longer than the anteverted neck because the longer straight neck generated the most fretting.

86. Defendants never conducted ACF testing on the titanium neck juncture with a cobalt-chromium head.

87. Nothing prevented Defendants from conducting this additional testing.

88. Spectrum Accelerated Corrosion Fatigue ("SACF") Testing was available to Defendants when testing the MLTK and would have applied side loads in a variable way that might be more similar to how a patient would actually load the part.

89. During a February 9, 2006, G2 test development meeting held to discuss what testing might be appropriate, the group suggested that the team consider SACF testing as it would provide "nice to know" information.

90. Defendants did not conduct SACF testing on the MLTK.

91. The best way to evaluate a product is to use laboratory testing combined with clinical information. Defendants never conducted a clinical study on the MLTK even though one of the consulting surgeons, Dr. Joshua Jacobs ("Jacobs"), recommended one in 2003[18].

92. While Defendants used consulting surgeons, the final decisions on the design and testing of the MLTK were made by Defendants.

[17] Defendants did not specifically, physically test the 32 millimeter cobalt chromium head and anteverted titanium neck that was Plaintiff's first implant.

[18] The MLTK model under consideration in 2003 was the prior model with a cobalt-chromium neck. It is not well established in the record whether Dr. Jacobs would have recommended a clinical trial with the MLTK model with a titanium neck. Dr. Jacob's renewed proposal for a clinical trial in 2011 suggests that his proposal for clinical trials extended to both models.

93. The MLTK was cleared by the Food & Drug Administration ("FDA") through the 510(k) process on January 24, 2007. The FDA granted Defendants market clearance for the MLTK through the 510(k) process because the MLTK was substantially similar to a device that had already been on the market and used prior to marketing the MLTK.

94. The FDA 510(k) process cannot be used as evidence that the MLTK was safe for use.

95. Defendants conduct world-wide post market surveillance of their hip products. This includes looking at complaints, clinical data, relevant publications and national join registries to review the safety and performance of their products.

96. Typically complaints come to Defendants through their sales representative, at the time of a revision surgery. Defendants have an electronic system that the sales representative will populate and email to when they become aware of a problem. The report goes to a quality engineer who completes the investigation and follows up.

97. Complaints may also be communicated through surgeons, patients, legal complaints or Defendants' employees.

98. In the U.S. adverse events are required to be tracked and reported to the FDA and made public through the Manufacturer and User Facility Device Experience ("MAUDE") database by manufacturers.

99. The adverse reports become part of a correlated electronic database where Defendants can assess patterns and react to the level of occurrence.

100. Because reported data is primarily controlled by the manufacturer, the MAUDE does not permit manufacturers to use statistical data from the MAUDE database to justify or try to prove that a particular device is safe or not defective.

101. Defendants' internal report reflect a total of 47 MLTK devices that were revised

due to metallosis between July 9, 2009 and June 20, 2016.[19] It is unknown whether any of the devices included the same configuration as Plaintiff's implant, because Defendants' internal reports do not track that information.

102. Not all doctors report problems that appear through revisions to Defendants.

103. During the time period of 2007 through 2016, 148,470 MLKTs were sold worldwide[20].

104. Using those two figures there were .032 MLTK devices that were revised due to metallosis during this time period for every one thousand MLTK devices implanted. This percentage reflects the number of known MLTK devices that were revised due to metallosis divided by the number sold.

105. During the same time period, using that same criteria, with the same limitations, the M/L Taper has had a metallosis revision rate of .025.

106. The Australian Registry is an independent data base compiled by the Australian National Health Service. This Registry provides information regarding how a product is performing in comparison to other products, including publishing medical device revision results.

107. According to the 2013 Australian Registry, in Australia, the MLTK has a revision rate of 4.6 percent after four years, which is higher than the average revision rate of 2.9 percent for all other hip implants.[21]

108. According to the Australian Registry, in Australia, the MLTK has a nine times higher rate of revision due to metal-related pathology compared to all other systems being used in Australia.[22]

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[19] These represent implants that were implanted between July 10, 2007 and November 19, 2011 and that were reported to Defendants between September 7, 2010 and August 2, 2016.

[20] While this was the number of MLTKs sold, Defendants does not know how many of these were actually implanted.

[21] These are total revisions for all reasons, not simply those revisions due to metallosis.

[22] The Registry is not specific as to which MLTK combinations were revised.

109. The United Kingdom ("U.K.") (England, Wales and Northern Ireland) has a National Joint Registry that encompasses all patients receiving implants in the U.K.

110. The National Joint Registry publishes a Postmarket Surveillance Report to inform companies how their products are performing in the U.K..

111. The National Joint Registry reports that between 2006 and 2016 1,074 MLTK were implanted in the U.K. with 23 total revisions[23], for a total revision rate of .021.

112. The National Joint Registry additionally reports that the number of MLTKs sold in the UK has dropped precipitously since 2012. No explanation for the drop was contained in the National Joint Registry or testified to at trial.

113. In 2010, Jacobs submitted a research proposal from Rush Medical Center to Defendants proposing a clinical study of fretting corrosion on the MLTK. Jacob's proposal titled "Fretting Corrosion Testing of Head-Neck-Body (Kinectiv) Modular Junctions" proposed to test the wear potential of both junctions (head-neck and neck-stem) at the same time.

114. Jacobs proposed that such testing was needed because "[p]resently, the amount of metal released from newer dually modular head-neck total arthroplasty components is not well characterized and thus the biological impact of this is not known." He concluded that a clinical data was needed as "concerns with the potential modular junctions to produce biolactic degradation products requires well characterized surveillance of new modular junction configurations."

115. While Defendants' lead engineer on the MLTK, Steven Meulink met with Jacobs and agreed with his concerns, Defendants did not fund Jacob's proposal because they "did not have funding for the project at this time."

[23] The National Joint Registry only reflects one revision due to adverse soft tissue reaction (metallosis). During this time period the registry predicted there would be 4.58 revisions for this reason.

116. In April 2011, Defendants performed a Quality Investigation Report ("QIR-12014") based on "external, trending, product surveillance." QIR-12014 contains the following "problem statement and description":

> It has been reported by Dr. Josh Jacobs at RUSH Medical that he and his colleagues are publishing the results of a series of analyses on approximately 10 metal-on-polyethylene (MoP) primary total hip arthroplasties (THAs) in which patients presented with pain and in several cases abductor deficiency. These patients were found to have elevated Co and/or Cr serum ion levels as part of their diagnostic workup. Head-neck taper corrosion was visually observed at the time of revision in all cases. Adverse tissue reactions similar to those observed in revised metal-on-metal systems were also observed in several of the cases at the time of revision.**"**

Eight of the ten THAs were Defendants' products.

117. QIR-12014 reviewed and evaluated internal complaint and sales data, product specification revisions, manufacturing process revisions, inspections method revisions, registry data, the Zimmer outcomes database, literature implant corrosion, Zimmer Instructions for Use for QIR scope and Device history records.

118. QIR-12013 noted a substantial rise in "[c]orrosion complaint rates" in the past five (5) years with "the majority of corrosion complaints had in-vivo times of less than 4 years." The highest number of complaints arose from combinations of the 12/14 legacy CoCr heads with the MLTK stems (7) and the12/14 legacy CoCr head with VerSys Beaded Full Coat Stems (8).

119. In April 2011, Defendants undertook a parallel Quality Investigation Report, ("QIR-12060") "investigating an increase in complaints pertaining to head-stem taper corrosion involving the VerSys 12/14 femoral heads."

120. In 2012, Dr. Paul Dewilius, one of Defendants' MLTK consulting surgeons published a peer-reviewed article warning of the use of modular hip implants like the MLTK with a cobalt-chromium head because they posed an unreasonable risk of harm to patients. The article

describes metal corrosion and trunionosis occurring not just at the junction of the cobalt-chromium head and titanium neck, but also at the second junction between the titanium neck and titanium stem. Dr. Dewilius indicated that he "now almost exclusively uses nonmodular stems and ceramic femoral heads to decrease the possibility of corrosion." Defendants reviewed this article as part of their post market surveillance.

121. In 2012, Dr. Richard Berger, another MLTK design team surgeon, wrote an article about corrosion at the head-neck taper as a cause of adverse local tissue reaction. Dr. Berger has stopped using the MLTK with a metal head.

122. Plaintiff's first revision surgeon, Beauchamp has stopped using the MLTK with a metal head because of the excessive corrosion and metal debris that causes toxic adverse tissue reaction.

123. Defense expert Jeremy Gilbert, Ph.D., has written two articles warning about the increased risk of corrosion and metal debris by using a cobalt-chromium head on a titanium neck and has indicated that the possible source of this problem is a neck design that decreases the flexural rigidity of the neck-stem module.[24]

124. A hip implant should not cause metallosis to a patient in which it is implanted. Although a small amount of non-toxic corrosion or metal debris may occur with a hip implant, an implant that causes an excessive amount of corrosion or metal debris sufficient to cause toxic metal poisoning creates an unreasonable risk of injury.

125. Plaintiff's metallosis was caused by a defective condition of the MLTK implant, which resulted in him having a significant amount of metallic debris at the taper junction.

[24] "Do Ceramic Femoral Heads Reduce Taper Fretting Corrosion in Hip Arthroplasty?," (2013) and "Ceramic Heads Decrease Metal Release Caused by Head-Taper Fretting and Corrosion." (2016)

126. The defective nature of the MLTK system is not that the components in isolation are defective, it is what happens when you put the components together.

127. Testing the function of a device requires testing with all components. It is not enough to test individual components of a system in isolation when it is known that there is an interaction between components of the system and performance of that system.

128. Defendant did not fully or adequately test the configuration of this new, dual-modular design with two metal-to-metal junctions that was implanted into Plaintiff with a CoCr head and an anteverted neck.

129. While Defendants did not know of the defective condition of the MLTK at the time of Plaintiff's first surgery, over time it has been shown to be defective.

130. The unreasonable risk of metallosis, whether from corrosion, micro-motion, fretting or some other mechanism, makes the MLTK with a metal CoCr head a defective product, even though all possible care was used by Defendants.

131. The MLTK created an unreasonable risk of harm to Plaintiff as it allowed the liberation of sufficient quantities of cobalt debris to be harmful to Plaintiff's hip joint.

Strict Products Liability – Failure to Warn

132. If a manufacturer is unable to mitigate a risk to an acceptable safety level, the manufacturer must warn the consumer about the risk.

133. Defendants marketed its hip implants, including the MLTK, to orthopedic surgeons and hospitals rather than end-user patients.

134. No evidence was presented that Plaintiff was told, prior to this total hip replacement surgery, about the device that would be implanted or about Carothers' alternate plan for using the MLTK if needed.

135. No evidence was presented that Plaintiff saw any of Defendants' literature or spoke to anyone at Zimmer about the total hip replacement products.

136. Plaintiff's orthopedic surgeon, Carothers, chose the MLTK implant during surgery.

137. Carothers choses an implant based upon his training, what he is familiar with, what is available in the local market and different design factors and outcomes "that may be better or worse based upon the design philosophy or the specifics of the design that may produce a better outcome for a different patient."

138. No evidence was presented that Carothers saw any of Defendants' sales literature about the MLTK.

139. Carothers mainly uses Defendants' products for his total hip replacements because Defendants have a sole-source contract with Presbyterian Hospital where he conducts his surgeries.

140. Carothers worked with Defendants' sales representative Richard Herrin on Plaintiff's case. Herrin would have helped with templating and would have been in the operating room. He would not have been involved in any preoperative conversations with Plaintiff.

141. It is important for surgeons to know of defects in or problems with implant devices.

142. Sometimes problems with devices are reported to surgeons through the peer-reviewed literature.[25] Sometimes problems with devices are presented through continuing medical education seminars or meetings.

143. Defendants could also have their sales representatives inform surgeons about problems with devices.

[25] Medical journal articles or other literature will report through a series of cases that have demonstrated a problem with a particular device or a lack of an optimal outcome.

144. If there is a product recall, surgeons receive a FedEx letter or a registered letter announcing the recall.

145. Product package inserts, otherwise known as "Instructions for Use", play a minimal role in informing Carothers about products. They are typically filled with information he already knows and that trained orthopedic surgeons already know.

146. The product insert accompanying Plaintiff's MLTK and available to Carothers contained a section entitled "Adverse Effects" which warned that "The following adverse effects have been reported:..Metal sensitivity, Inflammatory reactions and osteolysis . . . Corrosion of metal implants."

147. Defendants' product insert was consistent with industry product inserts and warnings.

148. Carothers does not look to product package inserts for descriptions of new problems with a device.

149. Defendants would not communicate problems with a device through product package inserts. They do use the product package insert to communicate warnings and contraindications.

150. Carothers did not read the package insert before Plaintiff's surgery. He finds the inserts to be "essentially useless in the daily use and understanding of implants."

151. Carothers was aware of the metallosis issues that came to light around 2005 through 2007 due to metal-on-metal articulations in acetabular cup/head junction of hip implants[26].

152. Carothers did not remember discussing metallosis concerns with Plaintiff prior to surgery but if Plaintiff had expressed concerns about metallosis[27], Carothers would have assured Plaintiff that it was not going to be an issue because the metallosis issue that Carothers was aware of (the cup/head junction articulation) had been addressed.

[26] The metal-on-metal articulation metallosis is different than what Plaintiff suffered herein.

[27] Plaintiff testified that he was concerned about metallosis and raised the concern with Carothers prior to his first surgery.

153. Carothers was not aware of the MLTK design testing prior to Plaintiff's first surgery.

154. Carothers believed the MLTK was necessary to use in Plaintiff's 2010 surgery.

155. Carothers believed that the benefits of the MLTK with VerSys head outweighed its risks when he implanted it in Plaintiff in 2010.

156. Since Plaintiff's first surgery, Carothers believes that the "occurrence of corrosive changes at the trunnion between a titanium stem and a cobalt-chrome head has become much more widely known." He did not know of these changes in 2010 and 2011.

157. No evidence was presented that Defendants were aware of MLTK revisions necessitated by metallosis prior to Plaintiff's June 11, 2010 surgery. Defendants' internal complaint report indicates that the first MLTK revision, necessitated by metallosis, was reported to them on December 15, 2010, even though it occurred prior to that date.[28]

158. Defendants' 2010 MLTK warnings were adequate.

159. Carothers did not read or rely on Defendants' warnings.

160. Regardless of whether Defendants' warning were adequate or inadequate, Carothers would have utilized the MLTK.

161. Defendants' MLTK warnings did not create an unreasonable risk of harm to Plaintiff.

Negligence

162. Defendants had the duty to use ordinary care in designing and testing the MLTK.

163. Defendant exercised ordinary care in the designing and testing of the MLTK.

164. To a reasonable degree of medical certainty, Plaintiff did nothing post-implantation which led to the corrosion and failure of this device.

[28] The two revision surgeries associated with metalossis that took place before Plaintiff's surgery were done on June 3, 2009 and February 5, 2010. No evidence was presented regarding the delay of reporting these to Defendant's internal report file until January 17, 2012 and December 15, 2010.

Damages

165. At the time Plaintiff had his first implant surgery in 2010 he was suffering from severe hip pain that was interfering with his ability to be active in the way he had in the past. As a result of the two revision surgeries due to metallosis and the subsequent infection he has lost enjoyment of life. He can no longer pay tennis and he cannot golf and fish the way he used to do. He must take daily antibiotics and await a future surgery.

166. As a result of the metallosis caused by the MLTK with Cobalt-Chromium head, Plaintiff has endured pain and suffering and will face pain and suffering in the future.

167. As a result of the two revision surgeries in 2011, Plaintiff lost wages in 2011 and 2012.

168. As a result of the metalossis caused by the MLTK implant, to a reasonable degree of medical certainty, Plaintiff incurred past medical expenses.

169. Because the infection which occurred after the first revision surgery has likely not been eradicated, requiring Plaintiff to take daily antibiotics, it is more probable than not that Plaintiff will need a third, more complicated revision surgery in future. This surgery will cost approximately $250,000 and will involve removal of all of the implant components for a period of 2-3 months to try and kill the infection, during which Plaintiff will be wheelchair bound. If the infection can be successfully eradicated, another hip prosthesis will be implanted, necessitating the same type of physical therapy and recovery period as the first two revision surgeries. Plaintiff will require household services during his recovery period.

170. It is appropriate that the product manufacturer bear the expense of the losses and damages suffered by Plaintiff.

171. Plaintiff suffered the following compensatory damages:

a.)	Lost enjoyment of life	$	480,000.00

b.)	Pain and Suffering, past and future	$	1,000,000.00
c.)	Lost earnings	$	62,629.00
d.)	Past medical expenses	$	174,594.18
e.)	Future medical expenses (3^{rd} revision surgery & in home health care during recovery)	$	287,440.00
f.)	Lost household services	$	16, 896.00
g.)	Out-of-pocket expenses	$	5,865.73
TOTAL DAMAGES		$	2,027,424.91

Punitive Damages

172. Defendant's actions in this case do not give rise to punitive damages.

CONCLUSIONS OF LAW

A. Venue and jurisdiction over the parties are not disputed and are hereby determined to be present.

B. The purpose behind the strict products liability doctrine is to allow an injured user or consumer to recover against a manufacturer without the requirement of proving negligence. *Fernandez v. Ford Motor Company*, 1994-NMCA-063, ¶ 27, 118 N.M. 100, 879 P.2d 101.

C. Policies that support the imposition of strict products liability include "the risk -or cost-distribution" which places the risk of loss on the manufacturer of a defective product because they are in a position to absorb the loss through distributing it as a cost of doing business; relieving Plaintiffs of the burden of proving negligence; and fairness in that manufacturers should bear the risk of an unreasonably dangerous product. *Brooks v. Beech Aircraft Corp.*, 1995-NMSC-043, ¶ 15, 16, 18, 120 N.M. 372, 902 P.2d 54.

D. Products can present three sorts of defects: manufacturing defects, design defects and warning defects. *Fernandez,* 1994-NMCA-063, ¶ 27. The product designer controls the design decision and is in a better position than the consumer to control the amount of risk that the product contains. *Brooks*, 1995-NMSC-043, ¶ 29.

E. Strict products liability focuses on the defendant's product. Alternatively, negligence focuses on the defendant's conduct. *Brooks* at ¶ 26.

F. The quality of the product may be measured not only by information available to the manufacturer at the time of the design, but also by information available at the time of trial. *Id.* ¶ 35.

G. The product designer is therefore liable for harm caused by an unreasonable risk of injury resulting from a condition of the product. Such a risk makes the product defective. This rule applies even though all possible care has been used by the supplier in putting the product on the market. UJI 13-1406 NMRA.

H. An unreasonable risk of injury is a risk which a reasonably prudent person having full knowledge of the risk would find unacceptable. This means that a product does not present an unreasonable risk of injury simply because it is possible to be harmed by it. UJI 13-1407 NMRA.

I. The design of a product need not necessarily adopt features which represent the ultimate in safety. The manufacturer's ability to eliminate the risk without seriously impairing the usefulness of the product or making it unduly expensive should be considered. UJI 13-1407 NMRA.

J. What is customarily done by those engaged in the supplier's business is evidence of whether a risk of injury would be acceptable to a reasonably prudent person. However, the

acceptability of a risk of injury is determined by the conduct of a reasonably prudent person having full knowledge of the risk. UJI 13-1408 NMRA.

K. Manufacturers also have a duty to warn of a risk of injury that it knew of or should have known of. UJI 13-1415 NMRA.

L. In New Mexico the duty to warn is fulfilled if it warns the physician as opposed to the patient. *Serna v. Roche Laboratories, Div. of Hoffman-LaRoche, Inc.*, 1984-NMCA-078, ¶ 9, 101 N.M. 522, 684 P.2d 1187; *accord Hines v. St. Joseph's Hospital,* 1974-NMCA-110, ¶ 6, 527 P.2d 1075, 86 N.M. 763.

M. The inadequacy or absence of the warning must also have caused Plaintiff's injury, uninterrupted by an independent intervening cause. *Silva v. Smithkline Beecham Corp.,* No. 31,276, slip. op. at 3 (N.M. Ct. App. Feb. 7, 2013); citing *Richards v. Upjohn Co.,* 1980-NMCA-062, 95 N.M. 675, 625 P.2d 1192; UJI 13-1424, 13-1424A and 13-1425 NMRA.

N. The manufacturer of a product must use ordinary care in the design of the product to avoid a foreseeable risk of injury. A manufacture that does not use ordinary care is negligent.

O. Evidence of compliance with applicable regulations is relevant to whether the manufacturer was negligent or reckless, but not conclusive. *Brooks*, 1995-NMSC-043, ¶ 38; *Gonzales v. Surgidev Corp*., 1995-NMSC-036, ¶ 49, 120 N.M. 133, 899 P.2d 576.

P. Punitive damages are warranted in a products liability case where the manufacturer knew that its product was inherently dangerous to persons or property and that its continued use is likely to cause injury or death, but still continued to market the product without feasible modifications to eliminate the danger or making adequate disclosure and

warning of such danger. *Gonzales*, 1995-NMSC-036, ¶ 48, citing *Baker v. Firestone Tire & Rubber Co.,* 793 F.2d 1196 (11th Cir. 1986).[29]

Q. Defendants' MLTK exposed Plaintiff to an unreasonable risk of injury resulting from a condition in the product design, and the product was therefore defective.

R. Defendants' defective product caused damage and injury to Plaintiff.

S. Defendants were the supplier of the MLTK.

T. In 2010, Defendants satisfied their duty to warn doctors of the risk of using a metal rather than a ceramic head with the MLTK.

U. Even if Defendants had not satisfied their duty to warn, Carothers's actions in not reviewing the MLTK instructions for use acted as an independent intervening cause so that any inadequate warnings given by Defendants did not cause Plaintiff's injuries.

V. Defendants did not create and breach an express warranty or an implied warranty of merchantability to Plaintiff. UJI 13-1429; 13-1430.

W. Plaintiff did nothing to cause the injuries he suffered.

X. Compensatory damages should be awarded in this case in the total amount of $ 2,027.424.91.

Y. Punitive damages are not warranted herein**.**

CONCLUSION

1. Plaintiff is entitled to a judgment in his favor on his claim of strict products liability.

2. Defendants are liable to Plaintiff for damages in the amount of $ 2,027,424.91 on his claim for Strict Products Liability – unreasonably dangerous design.

[29] Notably in *Gonzales*, Surgidev had known about the product defect for several years prior to Plaintiffs receiving the defective implant and failed to warn, as opposed to the present case, where Defendants became aware of issues regarding the MLTK several years after Plaintiff's implant.

3. Plaintiff's claims of Strict Products Liability - failure to warn, Negligence, Breach of Express Warranty and Breach of Implied Warranty of Merchantability are denied.

4. Plaintiff's request for punitive damages is denied.

Hon. Nan G. Nash

A copy of these Findings and Conclusions were delivered to all parties of record on the date of filing.