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34-2018-00244214

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IN THE SUPERIOR COURT OF CALIFORNIA

IN AND FOR SACRAMENTO COUNTY

DENISE DEROSA; ROBERT GREENLEE; and JOHN WOODS;

Plaintiffs,

v.

BIOMET, INC.; BIOMET ORTHOPEDICS, LLC; BIOMET U.S. RECONSTRUCTION, LLC; BIOMET MANUFACTURING, LLC; ZIMMER BIOMET HOLDINGS, INC.; GLEN PANGILINAN; UDO GESSNER; SYNERGY ORTHOPAEDIC SYSTEMS, INC.; HARRY J. FEGAN, III; ZIMMER BIOMET FEGAN, INC.; and DOES 1 THROUGH 100, inclusive;

Defendants.

Case No. _____

CIVIL COMPLAINT FOR DAMAGES

"Amount in controversy exceeds the jurisdictional minimum of this Court"

COME NOW Plaintiffs, DENISE DEROSA; ROBERT GREENLEE; and JOHN WOODS; ("Plaintiffs"), bring suit against Defendants; BIOMET, INC.; BIOMET ORTHOPEDICS, LLC; BIOMET U.S. RECONSTRUCTION, LLC; BIOMET MANUFACTURING, LLC; and ZIMMER BIOMET HOLDINGS, INC. (hereafter collectively referred to as "Biomet") and GLEN PANGILINAN; UDO GESSNER; SYNERGY ORTHOPAEDIC SYSTEMS, INC.; HARRY J. FEGAN, III; and ZIMMER BIOMET FEGAN, INC. (hereafter collectively referred to as "Distributors"); and DOES 1 through 100, inclusive, and state as follows:

PARTIES, VENUE AND JURISDICTION

1. This is a lawsuit regarding a defective metal on metal hip replacement system implanted in Plaintiffs DENISE DEROSA; ROBERT GREENLEE; and JOHN WOODS which was designed, developed, manufactured, labelled, promoted, marketed, sold, and supplied by Defendants.

2. The particular hip replacement system at issue in this case is the "Biomet M2a Magnum Metal on Metal Hip Replacement System" (hereafter referred to as the "Magnum").

3. Plaintiffs DENISE DEROSA; ROBERT GREENLEE; and JOHN WOODS were implanted with the Biomet Magnum hip replacement system in the State of California.

4. At all times relevant to this Complaint, Defendant BIOMET, INC. was and is an Indiana-based multinational corporation, with its corporate headquarters in Warsaw, Indiana, and facilities world-wide. Further, at all times relevant to this Complaint, Defendants BIOMET ORTHOPEDICS, LLC; BIOMET U.S. RECONSTRUCTION, LLC; and BIOMET MANUFACTURING, LLC each are and have been wholly owned subsidiaries of Defendant BIOMET, INC. In June of 2015, BIOMET, INC, was purchased by ZIMMER BIOMET HOLDINGS, INC, also having its world-wide corporate headquarters in Warsaw, Indiana. From June of 2015 to present, all activities of the subsidiary companies relating to the product at issue in this case were directed and controlled by ZIMMER BIOMET HOLDINGS, INC. Hereafter, these defendants are referred to collectively as "Biomet Defendants" or simply "Biomet."

5. At all times relevant to this Complaint, GLEN PANGILINAN was a citizen of the State of California.

6. At times relevant to this Complaint, UDO GESSNER was a citizen of the State of California, but is presently a citizen of the state of Colorado.

7. From January 1, 2007 until approximately June of 2015, GLEN PANGILINAN and UDO GESSNER had an agreement with the Biomet Defendants to serve as their exclusive distributor for hip replacement systems in large parts of California.

8. Pursuant to industry practice and contractual agreement, the exclusive distributor for the Biomet Defendants was responsible for educating orthopedic surgeons about Biomet hip replacement systems and the advantages, benefits, indications, templating, surgical implantation, follow-up care, servicing, and addressing any post-surgical questions or concerns regarding those Biomet hip replacement systems.

9. GLEN PANGILINAN and UDO GESSNER operated their distributorship through their corporation, SYNERGY ORTHOPAEDIC SYSTEMS, INC.

10. At all times relevant to this Complaint, SYNERGY ORTHOPAEDIC SYSTEMS, INC. was a California corporation with its principal place of business at 2795 East Bidwell Street, Folsom, California, and a citizen of the State of California.

11. GLEN PANGILINAN and UDO GESSNER, operating through their corporation, SYNERGY ORTHOPAEDIC SYSTEMS, INC, were responsible for promoting the Magnum hip replacement to Plaintiffs' surgeons, distributed the actual Magnum hip replacements that were implanted in Plaintiffs' bodies, had sales representatives present at the surgeries to implant the Magnum hip replacements into Plaintiffs' bodies, and serviced the Magnum hip replacements implanted in Plaintiffs' bodies.

12. At all times relevant to this Complaint, HARRY J. FEGAN, III was a citizen of the State of California.

13. In June of 2015, HARRY J. FEGAN, III became the exclusive distributor for the Biomet Defendants in large parts of California and his role as the exclusive distributor for those areas continues to this day.

14. At all times relevant to this Complaint, HARRY J. FEGAN, III operated his distributorship through his corporation, ZIMMER BIOMET FEGAN, INC., a California corporation and a citizen of the State of California.

15. In June of 2015, HARRY J. FEGAN, III, operating through his corporation ZIMMER BIOMET FEGAN, INC., became responsible for servicing the surgeons responsible for implanting the Magnum hip replacement systems in Plaintiffs and thus responsible for servicing the Magnum hip replacement systems implanted in Plaintiffs.

16. Hereafter, these defendants will be referred to collectively as "Distributors."

17. The information that Distributors provided about Biomet hip replacement systems far exceeded the information provided on Magnum packaging or labeling.

18. Distributors' sales representatives selected the components and tools to have present in the operating room when DENISE DEROSA; ROBERT GREENLEE; and JOHN WOODS was surgically implanted with the Biomet Magnum.

19. At all times relevant to this Complaint, Plaintiffs' surgeons relied upon information provided by Distributors' sales representatives in selecting the Magnum hip replacement for implantation into Plaintiffs' bodies.

20. Distributors profited from the promotion, sale, and servicing of the Magnum hip replacement systems at issue in the instant case at the time they were implanted in the bodies of DENISE DEROSA; ROBERT GREENLEE; and JOHN WOODS.

21. Following the Magnum hip replacement being implanted in the bodies of DENISE DEROSA; ROBERT GREENLEE; and JOHN WOODS, Distributors continued to profit from the servicing of and the addressing of any questions or concerns regarding Biomet hip replacement systems.

22. Jurisdiction is proper in the courts of the State of California because GLEN PANGILINAN; SYNERGY ORTHOPAEDIC SYSTEMS, INC.; HARRY J. FEGAN, III; and ZIMMER BIOMET FEGAN, INC. are all citizens of the State of California and Plaintiffs were all implanted with the Biomet Magnum hip replacement in the State of California.

23. Venue is proper in the Superior Court of California in and for Sacramento County in that GLEN PANGILINAN resides in Sacramento County and the principal place of business of Defendant SYNERGY ORTHOPAEDIC SYSTEMS, INC. is located in Sacramento County.

24. Suit is brought on behalf of the Plaintiffs to this matter for damages greatly in excess of $75,000.

STATEMENT OF FACTS

A. The Biomet Magnum is different than the typical hip replacement

25. A hip replacement surgery replaces the natural head and socket of the hip joint with artificial components.

26. The majority of hip replacements implanted world-wide over the past several decades have utilized a replacement hip joint consisting of a metal head making contact with an ultra-heavy duty plastic cup inside a metal shell.

27. This typical hip replacement consisting of a metal-plastic interface has been refined to the point that ultra-heavy duty plastic hip replacements have a greater than 99.5 percent success rate per year.

28. The Biomet Magnum instead uses a metal replacement head interfacing directly with a metal shell; there is no plastic liner in the Magnum. Accordingly, this type of hip system is commonly referred to as a metal on metal hip replacement.

B. Metal on metal hip replacements were tried decades ago, failed, and abandoned

29. In the 1960s and early 1970s, hip replacement manufacturers first began to market metal on metal hip replacements to surgeons.

30. Unfortunately, these early metal on metal hip replacements experienced a high rate of heavy metal poisoning and failure.

31. When the metal shell and metal head of these implants rubbed together, they released toxic cobalt and chromium debris into the body.

32. The release of the cobalt and chromium debris resulted in patients suffering heavy metal poisoning, causing tissue death and bone destruction.

33. As a result, the medical community abandoned metal on metal hip replacements in the 1970s.

C. Biomet revived abandoned metal on metal hip replacements with the Magnum

34. Despite the prior failure of metal on metal hip replacements to perform as intended, Biomet began designing metal on metal hip replacements in the 1990s.

35. The Magnum hip replacement implanted in Plaintiffs was created by Biomet and began being sold in the United States in 2004.

D. Biomet employed loophole to avoid testing Magnum

36. Despite their knowledge that early metal on metal hip replacements were a failure and resulted in heavy metal poisoning, Biomet conducted no testing of the Magnum in real world conditions before selling it for implantation into the bodies of patients.

37. To avoid comprehensive testing of the Magnum hip replacement, Biomet claimed to United States regulators that the Magnum was "grandfathered-in" because it was substantially similar to hip replacements sold prior to May 28, 1976. [1]

38. This loophole required no testing for safety or efficacy.

E. Defendants claimed that the Magnum was a "lifetime hip" and suitable for use in younger, more active patients

39. Defendants claimed that without the plastic liner to wear out, the Biomet Magnum should last a patient's lifetime.

40. Defendants claimed that the Biomet Magnum was suitable for implantation in younger, more active patients.

41. Defendants promoted the Magnum as a "lifetime hip."

F. Biomet falsely claimed it conducted extensive testing of Magnum

42. Despite the fact that Biomet conducted no clinical testing of the Magnum hip replacement, it has continuously claimed "[t]he Magnum-Magnum™ Large Metal Articulation System offers optimal joint mechanic restoration and ultra low-wear rates in vivo" citing to a 1996 article about previously abandoned types of metal on metal hip replacements.[2]

43. In a 2004 publication titled "Metal Ions – A Scientific Review," Biomet falsely concludes that: "Extensive research and years of clinical trials have failed to prove any cause for concern associated with the ion levels exhibited from metal-on-metal implants."[3]

44. In fact, in a heading on page 7 of the publication, Biomet goes so far as to claim that: "Cobalt and Chromium may be beneficial to the body as established by research and listed

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[1] *See,* https://www.accessdata.fda.gov/cdrh_docs/pdf4/K042037.pdf containing Biomet Manufacturing Corp.'s 510(k) Summary of Safety and Effectiveness (Last accessed Nov. 11, 2018).

[2] *See,* http://www.biomet.com/campaign/trueAlternativeBearings/BOI03400MagnumDesignRationale.pdf (Last accessed Nov. 11, 2018).

[3] *See* http://www.grossortho.com/images/stories/pdf/currenttopics/MetalIonWhitePaper.pdf. (Last accessed Nov. 11, 2018).

by the US government."[4]

45. The 2004 publication by "Biomet Orthopedics, Inc., the Most Responsive Company in Orthopedics," is still available to physicians and the public online today at http://www.grossortho.com/images/stories/pdf/currenttopics/MetalIonWhitePaper.pdf. (Last accessed Nov. 11, 2018).

G. Biomet had surgeons conduct secret Magnum marketing campaign in exchange for millions of dollars

46. In conjunction with the promotion of the Magnum hip replacement, Biomet paid surgeons to give speeches and publish articles such as "The Rationale for Metal-on-Metal Total Hip Arthroplasty" published in 2005, claiming that there were "no adverse physiologic effects" to metal on metal hip replacements.

47. At the time the author published the above article, Biomet was paying the author a percentage of the sale price of Magnum metal on metal hip replacement systems sold in the United States, something Biomet and the author failed to mention in the article promoting such hip replacements.

H. Thousands of Biomet Magnum metal on metal hip replacement systems are presently implanted in the bodies of California citizens

48. Defendants' promotion of the Magnum hip replacement was extremely successful.

49. Upon information and belief, in the State of California alone, thousands of Biomet metal on metal hip replacements were sold by Defendants and remain surgically implanted in the bodies of patients.

I. Defendants continue to claim that the Magnum is safe and successful

50. Defendants sold the Magnum metal on metal hip replacement for implantation into the bodies of patients up to the year 2014.

51. Defendants ceased selling Biomet Magnum metal on metal hip replacement in 2014, claiming that the decision to cease selling it was unrelated to reports of heavy metal poisoning and tissue death caused by the Magnum received by Defendant from around the world.

52. However, Defendants have continued to reassure California physicians and the public that the heavy metal poisoning seen with other metal on metal hip replacements is not an

[4] *Id.*

issue with the Magnum.

53. To this day, Defendants continue to claim to physicians and the public that the Magnum is a safe and successful product.

J. In 2010, Johnson & Johnson voluntarily recalled their version of the Magnum

54. Approximately the same time as Defendants began selling the Magnum, Johnson & Johnson began selling the DePuy ASR.

55. The Biomet Magnum was very similar to the ASR in its primary design features.

56. Like the Magnum, the ASR was a monoblock metal on metal hip replacement system with its cobalt chromium alloy head articulating against its cobalt chromium alloy shell.

57. In the summer of 2010, in response to "higher than expected revision rates," Johnson & Johnson conducted a world-wide recall of the ASR hip replacement.

58. Johnson & Johnson advised physicians to conduct detailed testing and follow-up of patients with ASR hip replacements.

59. As a result of the testing and follow-up, dangerously high heavy metal levels were discovered in a significant percentage of patients necessitating surgery to remove the metal on metal hip replacements.

60. Heavy metal poisoning and tissue death from the toxic heavy metals released by the ASR was widely reported in the medical literature.

61. The Defendants were aware of the reports and studies discussing the injuries suffered by metal on metal patients as a result of this very similar product.

K. Defendants' response to the recall of the almost identical product: Sell more Magnums!

62. In response to the 2010 voluntary world-wide recall of an almost identical hip replacement, Defendants did not:

a. Recall Defendants' almost identical Magnum hip replacement.
b. Suspend the sales of their very similar hip replacement pending a full investigation.
c. Conduct comprehensive testing of the Magnum to ensure it was not prone to causing heavy metal poisoning.
d. Warn physicians of the design similarities and the need to inform and carefully follow-up their patients.

63. Instead, Defendants increased promotion of Magnum, attempting to capture

market share lost by Johnson & Johnson due to its voluntary recall.

64. Defendants employed marketing tactics to differentiate the Magnum from the recalled ASR hip replacement and other metal on metal hip replacements.

65. Defendants promoted these marketing tactics to physicians and the public to reassure them that the Magnum did not cause heavy metal poisoning.

L. In 2010, Netherlands hospital warns Biomet of high rate of pseudotumors with Magnum

66. At the same time that Defendants were reassuring orthopedic surgeons and the public of the safety of the Magnum, they were receiving reports of just the opposite.

67. Isala Klinieken ("Isala") located in Zwolle, The Netherlands, has historically had a long and close relationship with Biomet.

68. From 2005 to 2007, Isala implanted patients with Biomet Magnum metal on metal hip replacements.

69. Prior to and during this time period, Isala was in fact a Biomet funded study site, paid by Biomet to conduct research on Biomet products.

70. In 2010, Isala reported to Biomet that when it performed CT scans of over 100 patients' hips, more than a third had pseudotumors adjacent to their Biomet metal on metal hip replacements.

M. Biomet warned that CT/MRI scanning was necessary to see tissue death from Magnum heavy metal poisoning

71. Isala reported to Biomet that the necessity for revision surgery was not identified until Isala conducted the CT scanning of their Biomet Magnum metal on metal hip replacement patients.

72. Isala warned that by the time that swelling, pain, and clicking indicating tissue death resulting from the heavy metal poisoning became apparent; the patient may have already suffered extensive injury.

73. In 2010, Isala informed Biomet that it had ceased implanting Biomet metal on metal hip replacements in its patients.

74. Isala encouraged Biomet to adopt a comprehensive screening protocol using CT and MRIs of all patients with Biomet metal on metal hip replacements implanted in their bodies and warned that without such an enhanced protocol, patients may be at risk.

75. The Isala Klinieken reported some of its findings regarding the Biomet metal on metal hip replacements in a British medical journal.[5]

76. Despite all of these critical warnings provided by the Isala Klinieken, Defendants failed to inform physicians or patients in the State of California of the study, ignored the need for follow-up screening, and instead continued to promote the Magnum for implantation into the bodies of patients.

N. Finland university reports severe adverse reactions from Biomet metal on metal hip replacements

77. Likewise, Turku University in Turku, Finland has historically had a long and close relationship with Biomet.

78. Turku University was also a Biomet funded study site.

79. From 2005 to 2012, Biomet metal on metal hip replacements were the most commonly implanted hip replacement at Turku University.

80. In 2013, Turku University reported to Biomet that when the University examined a sample of their patients implanted with Biomet Magnum metal on metal hip replacements, over half of the patients were experiencing ARMD or "Adverse Reaction to Metal Debris" from the devices.

81. MRIs of the sample of Turku University Magnum patients revealed that over half had a psuedotumor or fluid collection in their hip.

82. Despite its close relationship and funding from Biomet, in a 2013 publication of the Nordic Orthopedic Federation, Turku University stated that "ARMD is common after ... Magnum total hip arthroplasty, and we discourage the use of this device." [6]

83. Defendants failed to inform physicians or patients in the State of California of this study, that Turku University had discouraged use of Biomet metal on metal hip replacements, the need for physicians to screen their patients for Adverse Reaction to Metal Debris, and instead continued to promote their metal on metal hip replacements for implantation into the bodies of patients.

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[5] Bosker B, Ettema H, Boomsma M, et al. High incidence of pseudotumour formation after large-diameter metal-on-metal total hip replacement: a prospective cohort study. *J Bone Joint Surg Br.* 2012 Jun;94(6):755-61.

[6] Mokka J, Junnila M, Seppänen M, et al. Adverse reaction to metal debris after ReCap-M2a-Magnum large-diameter-head metal-on-metal total hip arthroplasty. *Acta Orthopaedica.* 2013;84(6):549-554.

O. Biomet used Olympic gymnast Mary Lou Retton as Magnum spokesperson

84. As part of the promotion of the Magnum hip replacement, Biomet hired Olympic gold-metal gymnast, Mary Lou Retton, as a spokesperson.

85. Mary Lou Retton had received a Biomet metal on metal hip replacement in 2005.

86. Biomet heavily promoted to surgeons and the public that the Magnum metal on metal hip allowed "younger, more active patients, like Mary Lou" to "return to her normal activities, including her workout schedule."[7]

87. Mary Lou Retton was used by Defendants to promote the Magnum in brochures, in newspapers, on radio and television, and in-person to orthopedic surgeons and the public. [8]

88. A heading on Biomet's website proclaims "Mary Lou lives pain-free, and so should you."[9]

P. Mary Lou Retton has sued Biomet over defective Magnum hip replacements

89. Unfortunately, Mary Lou Retton, like Plaintiffs, is a Biomet metal on metal hip replacement victim.

90. While initially "pain-free," Mary Lou Retton suffered heavy-metal poisoning from her Magnum hip replacement necessitating the surgical removal and replacement of the metal on metal hip replacement.

91. Mary Lou Retton was so severely injured by the Magnum metal on metal hip replacement, that despite her status as a celebrity spokesperson for the product, she too has sued the company.

Q. Despite knowing of the failure of the Magnum in Mary Lou Retton for years, Biomet continues to claim her as a success story

92. Biomet has failed to inform physicians and the public that Mary Lou Retton suffered heavy metal poisoning and had to have her Magnum surgically removed.

93. Biomet continues to cite to Mary Lou Retton as a patient success story.

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[7] *See*, http://www.biomet.com/fileLibrary/Patient_Education/PatientEdBrochures/Hip/English/Mary%20Lou%20Retton%20-%20Magnum%20Magnum.pdf (Last accessed Nov, 11, 2018).

[8] *See*, http://www.biomet.com/news/getFile.cfm?id=113&rt=inline&type=pr (Last accessed Nov. 11, 2018).

[9] *See*, http://www.biomet.com/fileLibrary/Patient_Education/PatientEdBrochures/Hip/English/Mary%20Lou%20Retton%20-%20Magnum%20Magnum.pdf (Last accessed Nov. 11, 2018).

94. Biomet has known of the failure of Mary Lou Retton's hip replacement for years, but has continued to promote to physicians and the public a false story.

R. Australian government required Biomet to recall Magnum

95. Australia has a world-leading implant registry which keeps track of every orthopedic hip replacement sold, implanted, and replaced in Australia.

96. Biomet ceased selling the Biomet Magnum metal on metal hip replacements in Australia in 2011.

97. In 2014, the Australian government communicated to Biomet that it was seeing excessive failure rates of the Magnum in Australian patients.

98. In 2015, the Australian government issued a "Hazard Alert" recalling the Biomet Magnum due to a "higher than expected revision rate."

99. Because Biomet had already ceased selling the Magnum in Australia, the Australian government's recall of the Magnum consisted of the "Hazard Alert" and mandating Biomet notify implanting surgeons in Australia of the recall and excessive revision rate.

100. Defendants have failed to disclose to orthopedic physicians or the public in the State of California that the Magnum hip replacement had been recalled in Australia and that the Australian government issued a "Hazard Alert" regarding the Magnum.

S. Since 2012 Biomet has had false Magnum failure rate data posted on its website

101. From 2012 until today, Biomet had posted on its website under the heading "Important information regarding metal-on-metal hips" data purporting to show the success of Biomet's metal on metal hip replacements at http://www.biomet.com/wps/portal/internet/Biomet/Healthcare-Professionals/products/orthopedics/important-information-mom-hips (Last accessed Nov. 11, 2018.)

102. The "Important information regarding metal-on-metal hips" is clearly intended to reassure patients and surgeons that Biomet's metal on metal hip replacements are safe and performing as intended.

103. The "Important information regarding metal-on-metal hips" states "Biomet has been closely monitoring the available data regarding its [metal on metal] hip devices."

104. The "Important information regarding metal-on-metal hips" claims that there is

no statistically significant difference between survivorship of the Biomet Magnum and hip replacements generally in the Australian National Joint Registry and the England and Wales National Joint Registry.

105. By 2015, at the latest, Biomet was aware that the Biomet Magnum was failing at a statically significantly higher rate than hip replacements generally in the Australian National Joint Registry.

106. Likewise, for years Biomet has been aware that the Magnum was failing at a significantly significant higher rate in the England and Wales National Joint Registry than hip replacements generally.

107. Despite knowing that it would mislead orthopedic surgeons and the public concerning the safety of its metal on metal hip replacements, Biomet has continued to promote false information regarding the safety of its Magnum hip replacement.

T. Biomet metal on metal hips are a ticking time-bomb implanted in thousands of California citizens' bodies

108. The Biomet Magnum metal on metal hip replacement is inherently defective.

109. When implanted in patients, it is prone to release toxic levels of cobalt and chromium.

110. Patients thus can suffer heavy metal poisoning, resulting in elevated levels of cobalt and chromium in the blood, pseudotumors, tissue necrosis, muscle wasting, bone loss, and other severe injuries.

111. The Defendants' failure to warn physicians and patients that the Biomet Magnum metal on metal hip replacements that were surgically implanted in patients' bodies may be releasing toxic heavy metals has left thousands of California patients with ticking time-bombs in their hips.

112. Based on the studies discussed above and others, hundreds, if not thousands, of California patients have already suffered undiagnosed pseudotumors, tissue death, bone death, etc. as a result of poisoning from the toxic heavy metals released from the Biomet Magnum.

U. California is facing a public health disaster from unmonitored Magnums

113. As a result of Defendants' failure to warn physicians and patients of the necessity for immediate testing and radiographic screening of implanted Biomet Magnum hip

replacements, the number of patients poisoned and severely injured by the Magnum will greatly increase.

114. California is facing a public health disaster from unmonitored Biomet Magnum metal on metal hip replacements.

V. Denise Derosa suffered heavy metal poisoning from the Magnum requiring nine follow-up procedures

115. Denise Derosa was implanted with the Biomet Magnum metal on metal hip replacement in her right hip on August 15, 2007, and her left hip on December 19, 2007, with both surgeries occurring at Mercy Hospital of Folsom in Sacramento County, California.

116. Unknown to Ms. Derosa and her physicians, during the ensuing years, the Biomet Magnum hip replacement continuously released toxic heavy metals into her body, gradually poisoning her.

W. Heavy metal poisoning from the Biomet Magnum killed Denise Derosa's muscles, ligaments, and bone

117. The silent release of the toxic heavy metal from the Magnum hip replacement into Ms. Derosa's body slowly killed the muscles and ligaments surrounding the hip replacements.

118. In addition to the death of her tissue surrounding the hip replacements, the toxic heavy metal killed her bone surrounding the hip replacement.

X. Both Magnums had to be surgically removed from Denise Derosa's body, but due to the muscle and ligament destruction, the revision surgeries have failed

119. On May 11, 2017, and October 12, 2017, Ms. Derosa underwent revision surgeries to remove each of the Biomet Magnum metal on metal hip replacements.

120. Due to the extent of the bone killed by the metal poisoning, she had to receive bone grafts.

121. Unfortunately, due to the extent of the muscle and ligament death, both revision surgeries failed.

122. Since the revision surgeries, Ms. Derosa has had repeated dislocations of her hip sockets, procedures to put the hip socket back in place, and additional re-revision surgeries.

Y. Robert Greenlee has failed bilateral Magnum hip replacements

123. Robert Greenlee was implanted with the Biomet Magnum metal on metal hip replacement in his left hip on July 29, 2008, and his right hip on September 16, 2008, with both

surgeries occurring at Mercy Hospital of Folsom in Sacramento County, California.

124. The Magnum hip replacements have poisoned Mr. Greenlee, releasing extreme levels of toxic cobalt and chromium into this body.

125. Both hip replacements have now failed, Mr. Greenless will be forced to undergo revision surgery in the near future.

Z. John Woods had failed Magnum hip replacement that required surgical removal

126. John Woods was implanted with the Biomet Magnum metal on metal hip replacement in his right hip on November 7, 2011.

127. The Biomet Magnum subsequently failed and components of the Biomet Magnum had to be surgically removed from Mr. Woods' body on May 24, 2018.

DAMAGES AND CAUSES OF ACTION

128. As a direct and proximate result of the defective Magnum hip replacement, Plaintiffs suffered injuries, including but not limited to significant pain, tissue destruction, bone destruction, metal wear, metal poisoning, loss of enjoyment of life, and limitation of daily activities.

129. Plaintiffs expect to continue suffering such injuries in the future as a result of the injuries received from the Magnum.

130. As a direct and proximate result of the defective Magnum, Plaintiffs incurred medical expenses and expects to incur additional medical expenses in the future.

131. As a direct and proximate result of the defective Magnum, Plaintiffs experienced emotional trauma and distress and are likely to experience emotional trauma and distress in the future.

FIRST CAUSE OF ACTION FOR NEGLIGENCE
(Against All Defendants)

132. Plaintiffs re-allege and incorporate by reference the paragraphs above as if fully stated herein.

133. Defendants, as the designers, manufacturers, promoters, marketers, sellers, suppliers, distributors, and servicers of the Magnum hip replacement system, owed a duty to use reasonable care in the design, manufacture, promotion, marketing, selling, supplying, distribution, and service of Plaintiffs' Magnum hip replacement systems.

134. Further, Defendants owed Plaintiffs a duty to provide reasonable complete and

accurate information to each of them, their orthopedic surgeons, and the orthopedic community regarding Plaintiffs Magnum hip replacement systems.

135. Defendants, in breach of the duties described above, negligently and carelessly designed, manufactured, promoted, marketed, sold, supplied, distributed and serviced the Magnum hip replacement systems implanted in Plaintiffs.

136. Defendants, in breach of the duties described above, negligently and carelessly failed to provide reasonable complete and accurate information to Plaintiffs, their orthopedic surgeons, and the orthopedic community regarding the Magnum hip replacement system.

137. As a direct and proximate result of Defendants' breaches of duty, Plaintiffs needlessly suffered injuries as described above.

SECOND CAUSE OF ACTION FOR NEGLIGENT FAILURE TO WARN
(Against All Defendants)

138. Plaintiffs re-allege and incorporate by reference the paragraphs above as if fully stated herein.

139. Defendants had a duty to give adequate and appropriate warnings to Plaintiffs regarding particular risks about the Magnum hip replacement system that Defendants knew or should have known were involved in Plaintiffs' reasonably foreseeable use of the product.

140. Plaintiffs' use of the Magnum hip replacement system was reasonably foreseeable by Defendants.

141. Defendants knew or should have known of particular risks involved in Plaintiffs' reasonably foreseeable use of the product.

142. Breaching this duty, Defendants failed to provide adequate or appropriate warnings to Plaintiffs.

143. As a direct and proximate result of the conduct of Defendants, Plaintiffs needlessly suffered injuries as described specifically above.

THIRD CAUSE OF ACTION FOR STRICT LIABILITY FAILURE TO WARN
(Against All Defendants)

144. Plaintiffs re-allege and incorporate by reference the paragraphs above as if fully stated herein.

145. At the time that Defendants promoted, marketed, sold, supplied, distributed and serviced the Magnum hip replacement system implanted in Plaintiffs, such system contained defects that made them unreasonably dangerous beyond the expectations of the ordinary consumer, and were unfit for their intended use.

146. The hip replacement system reached Plaintiffs without substantial change in the condition in which they were sold.

147. At the time and on the occasions in question, the Magnum hip replacement system was being properly used for the purpose for which it was intended, and such system was in fact defective, unsafe and unreasonably dangerous.

148. The foreseeable risk of harm from the defects in the Magnum hip replacement system could have been reduced or avoided by providing adequate instructions or warnings.

149. Defendants failed to provide adequate instructions or warnings regarding the defects in the Magnum hip replacement system which were known by Defendants or should have been known by Defendants.

150. As a direct and proximate result of the lack of reasonable and adequate instructions or warnings regarding the defects in the Magnum hip replacement system, Plaintiffs suffered injuries as described above.

FOURTH CAUSE OF ACTION FOR STRICT LIABILITY DESIGN DEFECT
(Against All Defendants)

151. Plaintiffs re-allege and incorporate by reference the paragraphs above as if fully stated herein.

152. At the time that Defendants designed, manufactured, promoted, marketed, sold, supplied, distributed and serviced the Magnum hip replacement system implanted in Plaintiffs, such system contained design defects that made it unreasonably dangerous beyond the expectations of the ordinary consumer, and were unfit for its intended use.

153. The hip replacement system reached Plaintiffs without substantial change in the condition in which it was sold.

154. At the time and on the occasions in question, the Magnum hip replacement system was being properly used for the purpose for which it was intended, and such system was in fact defective, unsafe, and unreasonably dangerous.

155. The hip replacement system, for the reasons stated herein, was defective and unreasonably dangerous in design.

156. As a direct and proximate result of the design defects in the Magnum hip replacement system, Plaintiffs suffered injuries as described above.

FIFTH CAUSE OF ACTION FOR BREACH OF IMPLIED WARRANTY
(Against All Defendants)

157. Plaintiffs re-allege and incorporate by reference the paragraphs above as if fully stated herein.

158. Defendants designed, manufactured, promoted, marketed, distributed, supplied, sold, and serviced the Magnum hip replacement system at issue in this case.

159. Defendants impliedly warranted that the Magnum hip replacement system was reasonably fit for its intended use as a hip replacement system.

160. Plaintiffs were foreseeable user of the Magnum hip replacement system.

161. Plaintiffs purchased the Magnum hip replacement system from Defendants, through their orthopedic surgeon.

162. The Magnum hip replacement system failed while being used for its intended purpose, causing serious injury to Plaintiffs.

163. As a direct and proximate cause of this breach, Plaintiffs suffered injuries as described above.

SIXTH CAUSE OF ACTION FOR INTENTIONAL MISREPRESENTATION
(Against Biomet Defendants)

164. Plaintiffs re-allege and incorporate by reference the paragraphs above as if fully stated herein.

165. Biomet represented to Plaintiffs and their agents that the Magnum metal on metal hip replacement system had been shown to be safe through extensive testing and that it continued to be safe during the entirely of the time that the device remained in his body.

166. Biomet's representations to Plaintiffs were false.

167. Biomet knew these representations to be false when they were made, or made the representations recklessly without regard to the truth of those representations.

168. Biomet intended for Plaintiffs and their agents to rely on these representations.

169. Plaintiffs and their agents did in fact reasonably rely on these representations, to their detriment.

170. Plaintiffs' reliance on Biomet's representations was a substantial factor in causing the harm suffered, as described above.

171. Defendants acted with "malice" in that they engaged in conduct either constituting willful and wanton misconduct, or despicable conduct in conscious disregard of the safety of Plaintiffs and the public, thereby entitling Plaintiffs to an award of punitive damages pursuant to California Civil Code § 3294. Defendants acted with "malice," by conduct that included, but is not limited to the following:

a. Knowingly, intentionally, and with a conscious and reckless disregard for the safety of others, failed to adequately test the Biomet Magnum metal on metal hip replacement system before promoting and selling it for surgical implantation into the bodies of patients.

b. Knowingly, intentionally, and with a conscious and reckless disregard for the safety of others falsely claiming that the Biomet Magnum metal on metal hip replacement system had been extensively tested.

c. Knowingly, intentionally, and with a conscious and reckless disregard for the safety of others failing to warn physicians and patients that the Biomet Magnum metal on metal hip replacement system was poisoning patients with toxic heavy metals.

d. Knowingly, intentionally, and with a conscious and reckless disregard for the safety of others falsely claiming that the Biomet Magnum metal on metal hip replacement system was not prone to the failures of similar metal on metal hip replacement systems.

e. Were otherwise willful and wanton in their actions.

172. Because the acts and/or omissions of Biomet were committed in a malicious, unlawful, and/or unreasonable manner, as fully set forth above, causing injury and damage to Plaintiffs, and done with a conscious disregard of the rights and safety of Plaintiffs, Plaintiffs request the assessment of punitive damages against Biomet in an amount appropriate to punish or set an example of Biomet.

SEVENTH CAUSE OF ACTION FOR NEGLIGENT MISREPRESENTATION (Against All Defendants)

173. Plaintiffs re-allege and incorporate by reference the paragraphs above as if fully stated herein.

174. Defendants represented to Plaintiffs, and his agents, that the Magnum system was safe and effective and not defective.

175. Defendants representations to Plaintiffs and their agents were false.

176. Although Defendants may have believed, that the representations were true, Defendants had no reasonable grounds for believing the representations were true at the time they were made to Plaintiff and his agents.

177. Defendants intended for Plaintiffs and their agents to rely on these representations.

178. Plaintiffs and their agents did in fact reasonably rely on these representations, to their detriment.

179. Plaintiffs' reliance on Defendants' representations was a substantial factor in causing the harm suffered, as described above.

EIGHTH CAUSE OF ACTION FOR UNLAWFUL, UNFAIR, AND FRAUDULENT BUSINESS PRACTICES IN VIOLATION OF CALIFORNIA BUSINESS & PROFESSIONS CODE SEC. 17200, ET SEQ.
(Against All Defendants)

180. Plaintiffs re-allege and incorporate by reference the paragraphs above as if fully stated herein.

181. California's Unfair Competition Law (UCL) creates a cause of action for those harmed by unfair competition, which includes "any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising."

182. Defendants have made numerous misrepresentations to Plaintiffs, their agents, and to the general public as described above.

183. Defendants' business practices relating to the Magnum System were unlawful because they constitute false advertising, intentional misrepresentation, and fraudulent concealment.

184. As a direct and proximate result of Defendants' unlawful business practices and false advertising, Plaintiffs have suffered significant damages, including but not limited to physical injury and loss of money and property, and will continue to suffer such damages in the future.

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185. Plaintiffs hereby request an order of this Court awarding damages, restitution, attorneys' fees and costs, and all other relief allowed under California Business and Professions Code Section 17200 et seq.

NINTH CAUSE OF ACTION FOR INFORMATION NEGLIGENT SUPPLIED FOR THE GUIDANCE OF OTHERS
(Against All Defendants)

186. Plaintiffs re-allege and incorporate by reference the paragraphs above as if fully stated herein.

187. Plaintiff's purchase of the Magnum was a business transaction.

188. The Defendants all had a pecuniary interest in the design, development, promotion, and testing of the Magnum.

189. The Defendants supplied false information for the guidance of others regarding the selection and retention of the Magnum as a safe and effective hip replacement option, as alleged above.

190. The Defendants failed to exercise reasonable care or competence in obtaining and communicating the information supplied for the guidance of others regarding the Magnum.

191. Plaintiffs, and Plaintiffs' orthopedic surgeon agents, were within the limited group of persons for whose benefit and guidance the Defendants intended to supply the information.

192. The Defendants intended for their information to influence either the transaction in which Plaintiff, through Plaintiff's orthopedic surgeon agent, purchased the Magnum, failed to realize the necessity of the removal of the Magnum, or a substantially similar transaction.

193. Plaintiffs, individually and through Plaintiffs' orthopedic surgeon agents, justifiably relied upon the information provided by Defendants.

194. As a direct and proximate result of the Defendants' false information, Plaintiffs suffered pecuniary loss, as described above.

DEMAND FOR JURY TRIAL

195. Plaintiffs respectfully request that a jury be impaneled to hear this cause of action and to award such damages as the jury finds to be fair and reasonable under the circumstances.

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PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully demand judgment against Defendants for compensatory and punitive damages and any other relief the Court deems just and proper.

Dated November 7, 2018.

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