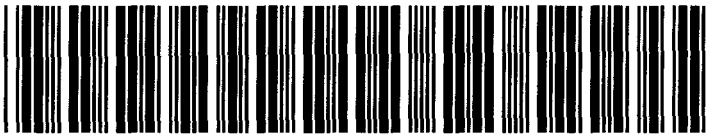

SUPERIOR COURT OF CALIFORNIA

COUNTY OF SAN FRANCISCO

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COMPLAINT

MICKEY REED VS. BIOMET, INC. ET AL

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SUPERIOR COURT OF CALIFORNIA

COUNTY OF SAN FRANCISCO, CIVIC CENTER COURTHOUSE

MICKEY REED, an individual, and NANCY REED, an individual,

as Plaintiffs,

vs.

BIOMET, INC.; BIOMET ORTHOPEDICS, LLC.; BIOMET U.S. RECONSTRUCTION, LLC.; BIOMET MANUFACTURING, LLC.; ZIMMER BIOMET HOLDINGS, INC.; EDWARD J. BORACCHIA, an individual; BORACCHIA & ASSOCIATES, a California corporation; SYNERGY ORTHOPAEDIC SYSTEMS, INC.; ZIMMER BIOMET FEGAN, INC.; and DOES 1 through 100, inclusive,

as Defendants.

Case No.: CGC-18-565909

CIVIL COMPLAINT FOR DAMAGES

1. **Strict Products Liability**
2. **Negligence – Failure to Warn**
3. **Products Liability – Failure to Warn**
4. **Products Liability – Design Defect**
5. **Breach of Implied Warranty**
6. **Intentional Misrepresentation**
7. **Negligent Misrepresentation**
8. **Violation of Cal. Bus. & Prof. Code Sec. 17200 et seq.**
9. **Products Liability – Negligence**
10. **Loss of Consortium**

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

COMES NOW, Plaintiffs MICKEY REED and NANCY REED for Causes of Action against Defendants BIOMET, INC.; BIOMET ORTHOPEDICS, LLC.; BIOMET U.S. RECONSTRUCTION, LLC.; BIOMET MANUFACTURING, LLC.; ZIMMER BIOMET HOLDINGS, INC.; EDWARD J. BORACCHIA, an individual; BORACCHIA & ASSOCIATES, a California corporation; SYNERGY ORTHOPAEDIC SYSTEMS, INC.; ZIMMER BIOMET FEGAN, INC.; and DOES 1 through 100, inclusive, hereby complain and allege as follows:

PARTIES, VENUE, JURISDICTION

1. This is a lawsuit regarding a defective metal on metal hip replacement system implanted in Plaintiff MICKEY REED which was designed, developed, manufactured, labelled, promoted, marketed, sold, supplied, and distributed by Defendants.

2. The particular hip replacement system at issue in this case is the "Biomet M2a-38 Metal on Metal Hip Replacement System" (hereafter referred to as the "M2a").

3. Plaintiff MICKEY REED had a M2a surgically implanted into his body in the State of California. Later, the M2a right total hip arthroplasty failed with metalosis. The M2a had to be surgically removed from MICKEY REED's body. The M2a completely failed, and surgeons diagnosed MICKEY REED with extensive metalosis and destruction of greater trochanter, proximal femur and the acetabulum, and the entire anterior column and most of the posterior column.

4. Defendant BIOMET, INC. is and, at all times relevant herein, was an Indiana-based multinational corporation, with its corporate headquarters in Warsaw, Indiana and facilities throughout the world.

5. Defendants BIOMET ORTHOPEDICS, LLC., BIOMET U.S. RECONSTRUCTION, LLC., and BIOMET MANUFACTURING, LLC. are, and, at all times relevant herein, were wholly owned subsidiaries of Defendant BIOMET, INC.

6. Plaintiffs are informed and believe that in June 2015, BIOMET, INC. was purchased by ZIMMER BIOMET HOLDINGS, INC.

7. Defendant ZIMMER BIOMET HOLDINGS, INC. is and, at all times relevant herein, was a publicly traded medical device company with its headquarters in Warsaw, Indiana. ZIMMER BIOMET HOLDINGS, INC. advertises they operate in California as well as 25 other countries and

sells products in more than 100 countries. employs sales representatives, advertises to and employs sales representatives and

8. Plaintiffs are informed and believe that from June 2015 to present, all activities of BIOMET, INC.'s subsidiary companies being BIOMET ORTHOPEDICS, LLC., BIOMET U.S. RECONSTRUCTION, LLC., and BIOMET MANUFACTURING, LLC. (hereinafter referred to as "BIOMET") relating to hip replacement systems and the M2a product were directed, supervised, and controlled by ZIMMER BIOMET HOLDINGS, INC.

9. Defendant EDWARD J BORACCHIA is and, at all times relevant herein, was a citizen of the State of California.

10. Defendant BORACCHIA & ASSOCIATES is and, at all times relevant herein, was a citizen and/or a California corporation.

11. Plaintiffs are informed and believe that from February 23, 1979 through June 9, 2006, Defendant EDWARD J. BORACCHIA, in his individual capacity and through his company,

12. Defendant BORACCHIA & ASSOCIATES, a California corporation, had an agreement with BIOMET to serve as its exclusive distributor for hip replacement systems in Northern California. Defendant BORACCHIA & ASSOCIATES advertises itself as diversified supplier of specialty medical products across California and the United States.

13. As the exclusive distributor for BIOMET, Defendants EDWARD J. BORACCHIA and BORACCHIA & ASSOCIATES, by industry custom and practice and by contractual agreement, were responsible for educating orthopedic surgeons about BIOMET hip replacement systems which included, but not limited to, the advantages and benefits of the hip replacement systems; templating, indications, and surgical implantation of the hip replacement systems; servicing of the hip replacement systems; and follow-up care and post-surgical issues.

14. Plaintiffs are informed and believe that from June 9, 2006, until approximately June 2015, Defendant SYNERGY ORTHOPAEDIC SYSTEMS, INC., became the exclusive distributor for BIOMET in Northern California. Defendant SYNERGY ORTHOPAEDIC SYSTEMS, INC. is and, at all times relevant herein, 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.

15. Plaintiffs are informed and believe that from June 2015 until present, Defendant ZIMMER BIOMET FEGAN, INC. became the exclusive distributor for the Biomet Defendants in Northern California. Defendant ZIMMER BIOMET FEGAN, INC. is and, at all times relevant herein, was a California corporation and citizen of the State of California.

16. Hereafter, Defendants EDWARD J. BORACCHIA, BORACCHIA & ASSOCIATES SYNERGY ORTHOPAEDIC SYSTEMS, INC., ZIMMER BIOMET FEGAN, INC. will be referred to collectively as "Distributors".

17. Plaintiffs are informed and believe that the information provided by the Distributors regarding BIOMET hip replacement systems was much more extensive than the information found on the M2a packaging, and/or labeling.

18. Plaintiffs are informed and believe that the Distributors' sales representatives and other personnel selected the components, tools, and other accessories that would be and were present in the operating room when MICKEY REED had the M2a surgically implanted in his body.

19. Plaintiffs are informed and believe that at all relevant times herein that MICKEY REED's surgeon relied upon information, facts, and other representations provided by sales representatives, agents, employees, and/or other personnel of the Distributors in selecting the M2a hip replacement system as the one that would be surgically implanted into MICKEY REED's body.

20. The Distributors profited from the promotion, sale, and servicing of the M2a hip replacement system at issue before and at the time the M2a was implanted into MICKEY REED's body.

21. Following the implantation of the M2a hip replacement system into MICKEY REED's body, the Distributors continued to promote, sell, and profit from the servicing of and the addressing of any questions or concerns regarding BIOMET hip replacement systems including, but not limited to, the M2a hip replacement system.

22. Jurisdiction is proper in the courts of the State of California because the Distributors are all citizens of California, Plaintiffs are citizens of California, MICKEY REED's surgical implantation of the M2a hip replacement system was conducted in Northern California, and MICKEY REED surgical removal of the M2a hip replacement system was conducted in Northern California.

23. Venue is proper in this jurisdiction in that the acts giving rise to this lawsuit, which are described more fully below, occurred within this court's jurisdictional area. Further, the relief sought through this Civil Complaint is within the jurisdiction of this Court as damages in excess of $25,000.

STATEMENT OF FACTS & GENERAL ALLEGATIONS

A. The Biomet M2a is different than the typical hip replacement

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

25. 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.

26. The Biomet M2a instead uses a metal replacement head interfacing directly with a metal shell; there is no plastic liner in the M2a. Accordingly, this type of hip system is commonly referred to as a metal on metal hip replacement system.

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

27. In the 1960s and early 1970s, hip replacement manufacturers first began to market metal on metal hip replacements to surgeons. Unfortunately, these early metal on metal hip replacements experienced a high rate of heavy metal poisoning and failure. When the metal shell and metal head of these implants rubbed together, it released toxic cobalt and chromium debris into the body.

28. The cobalt and chromium debris resulted in patients suffering heavy metal poisoning, causing tissue death and bone destruction.

29. 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 M2a

30. 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.

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31. The M2a hip replacement implanted in MICKEY REED was created by Biomet and began being sold in the United States in 2001.

D. Biomet employed a loophole to avoid testing M2a

32. Despite their knowledge that earlier metal on metal hip replacements were a failure and resulted in heavy metal poisoning, Biomet conducted no testing of the M2a in real world conditions before selling it for implantation into the bodies of patients.

33. To avoid comprehensive testing of the M2a, Biomet claimed to United States regulators that the M2a was "grandfathered-in" because it was substantially similar to hip replacements sold prior to May 28, 1976.

34. This loophole allowed there to be no testing for safety or efficacy.

E. Defendants claimed that the M2a was a "lifetime hip" and suitable for use in younger, more active patients

35. Defendants claimed that without the plastic liner to wear out, the Biomet M2a should last a patient's lifetime. Defendants claimed that the Biomet M2a was suitable for implantation in younger, more active patients.

36. Defendants promoted the M2a as a "lifetime hip."

F. Biomet falsely claimed it conducted extensive testing of M2a

37. Despite the fact that Biomet conducted no clinical testing of the M2a, it claimed "[t]he patent pending one-piece design of the M2a incorporates a 38mm articulating surface with metal-on-metal to achieve maximum range of motion, stability and minimal wear."

38. 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."

39. 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 by the US government."

40. 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 March 15, 2018).

G. Biomet had surgeons conduct secret M2a marketing campaign in exchange for millions of dollars

41. In conjunction with the promotion of the M2a 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.

42. At the time that the author published the above article, Biomet was paying the author a percentage of the sale price of M2a 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 M2a-38 and Biomet Magnum metal on metal hip replacement systems are presently implanted in the bodies of California citizens

43. Defendants' promotion of the M2a hip replacement was extremely successful.

44. 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 M2a is safe and successful

45. Defendants sold the M2a metal on metal hip replacement for implantation into the bodies of patients up to the year 2012.

46. Defendants ceased selling Biomet M2a metal on metal hip replacement in 2012, claiming that the decision to cease selling it was unrelated to reports of heavy metal poisoning and tissue death caused by the M2a received by Defendant from around the world.

47. 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 issue with the M2a.

48. To this day, Defendants continue to claim to physicians and the public that the M2a is a safe and successful product.

J. In 2010, Johnson & Johnson voluntarily recalled their version of the M2a

49. A few years after Defendants began selling the M2a, Johnson & Johnson began selling the DePuy ASR. The Biomet M2a was very similar to the ASR in its primary design features.

50. Like the M2a, the ASR was a monoblock metal on metal hip replacement system with its cobalt chromium alloy head articulating against its cobalt chromium alloy shell.

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

52. 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.

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

54. 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 Johnson & Johnson recall of the almost identical product was to sell more M2as!

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

a. Recall Defendants' almost identical M2a hip replacement.

b. Suspend the sales of their very similar hip replacement pending a full investigation.

c. Conduct comprehensive testing of the M2a 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.

56. Instead, Defendants increased promotion of M2a, attempting to capture market share lost by Johnson & Johnson due to its voluntary recall.

///

57. Defendants employed marketing tactics to differentiate the M2a from the recalled ASR hip replacement and other metal on metal hip replacements.

58. Defendants promoted these marketing tactics to physicians and the public to reassure them that the M2a did not cause heavy metal poisoning.

L. In 2010, Netherlands hospital warns Biomet of high rate of pseudotumors with M2a

59. At the same time that Defendants were reassuring orthopedic surgeons and the public of the safety of the M2a, they were receiving reports of just the opposite.

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

61. From 2005 to 2007, Isala implanted patients with Biomet M2a metal on metal hip replacements.

62. 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.

63. 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 M2a heavy metal poisoning

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

65. 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.

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

67. 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.

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

69. 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 M2a for implantation into the bodies of patients.

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

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

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

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

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

74. MRIs of the sample of Turku University M2a patients revealed that over half had a psuedotumor or fluid collection in their hip.

75. 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."

76. 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.

O. Biomet used Olympic gymnast Mary Lou Retton as M2a spokesperson

77. As part of the promotion of the M2a hip replacement, Biomet hired Olympic gold-medal gymnast, Mary Lou Retton, as a spokesperson. Mary Lou Retton had received a M2a hip replacement in 2005.

78. Biomet heavily promoted to surgeons and the public that the M2a metal on metal hip allowed "younger, more active patients, like Mary Lou" to "return to her normal activities, including her workout schedule."

79. Mary Lou Retton was used by Defendants to promote the M2a in brochures, in newspapers, on radio and television, and in-person to orthopedic surgeons and the public.

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

P. Mary Lou Retton has sued Biomet over defective M2a hip replacements

81. Unfortunately, Mary Lou Retton, like Mickey Reed, is a Biomet metal on metal hip replacement victim. While initially "pain-free," Mary Lou Retton suffered heavy metal poisoning from her M2a hip replacement necessitating the surgical removal and replacement of the metal on metal hip replacement.

82. Mary Lou Retton was so severely injured by the M2a 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 M2a in Mary Lou Retton for years, Biomet continues to claim her a success story

83. Biomet has failed to inform physicians and the public that Mary Lou Retton suffered heavy metal poisoning and had to have her M2a surgically removed.

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

85. 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. Biomet M2a recalled in Australian, United Kingdom, and Europe

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

87. Biomet ceased selling the Biomet M2a metal on metal hip replacements in Australia in 2011.

88. In 2014, the Australian government communicated to Biomet that it was seeing excessive failure rates of the M2a in Australian patients.

89. In 2015, the Australian government issued a "Hazard Alert" recalling the Biomet M2a due to a "higher than expected revision rate."

90. Because Biomet had already ceased selling the M2a in Australia, the Australian government's recall of the M2a consisted of the "Hazard Alert" and mandating Biomet notify implanting surgeons in Australia of the recall and excessive revision rate.

91. Defendants have failed to disclose to orthopedic physicians or the public in the State of California that the M2a hip replacement had been recalled in Australia and that the Australian government issued a "Hazard Alert" regarding the M2a.

92. Likewise, in April of 2016, Biomet was forced to issue a "Urgent Field Safety Notice" for the M2a to surgeons in the United Kingdom and throughout Europe.

93. The notice stated that the reason it was being sent was to warn surgeons that the M2a-38 hip replacements implanted "have a higher than expected revision rate."

94. Despite the April 2016 "Urgent Field Safety Notice" regarding the M2a being sent to surgeons in the UK and across Europe, no such warning has been provided to physicians or patients in the United States.

S. Biomet metal on metal hips are a ticking time-bomb implanted in thousands of California's citizens' bodies

95. The Biomet M2a metal on metal hip replacement is inherently defective.

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

97. 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.

98. The Defendants' failure to warn physicians and patients that the Biomet M2a 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.

99. 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 M2a.

T. California is facing a public health disaster from unmonitored M2as

100. As a result of Defendants' failure to warn physicians and patients of the necessity for immediate testing and screening of implanted Biomet M2a hip replacements, the number of patients poisoned and severely injured by the M2a will greatly increase.

101. California is facing a public health disaster from unmonitored Biomet M2a metal on metal hip replacements.

U. Mickey Reed suffered heavy metal poisoning from the M2a

102. Mickey Reed was implanted with the Biomet M2a metal on metal hip replacement on December 28, 2005.

103. Unknown to Mr. Reed and his physicians, during the next twelve years the Biomet M2a hip replacement continuously released toxic heavy metals into his body, gradually poisoning him.

V. Heavy metal poisoning from the Biomet M2a killed Mickey Reed's tissue and destroyed his pelvis

104. The silent release of the toxic heavy metal from the M2a hip replacement into Mr. Reed's body slowly killed the tissue surrounding the hip replacement.

105. As the toxic heavy metal continued to be released, it then began to kill his bone in addition to his tissue.

106. The Biomet M2a released so much toxic heavy metal that it severely destroyed Mr. Reed's pelvis.

W. The M2a had to be surgically removed from Mickey Reed's body, but due to the severe bone destruction, could not be replaced

107. On July 19, 2017, Mr. Reed underwent a surgery to remove his Biomet M2a metal on metal hip replacement.

108. Unfortunately, when the surgeon surgically opened Mr. Reed, he discovered the incredible extent of the tissue death and bone destruction.

109. The surgeon was forced to perform surgery to remove the M2a hip replacement, but with the extent of the damage, it was not possible to substitute the hip replacement with one that would not poison Mr. Reed.

110. Instead, Mr. Reed was left with no hip joint.

X. Damage to Mickey Reed's pelvis was so severe that he now has no hip joint

111. Since the July 2017 surgery, Mr. Reed has been left without a hip joint.

112. He has thus lost the ability to walk and has been left in tremendous pain.

FIRST CAUSE OF ACTION
(Strict Products Liability Against All Defendants)

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

114. Defendants, as the designers, manufacturers, promoters, marketers, sellers, suppliers, distributors, wholesalers, retailers, makers, and/or servicers of the M2a hip replacement system, owed a duty to use reasonable care in the design, manufacture, promotion, marketing, selling, supplying, distribution, and service of Plaintiff MICKEY REED's M2a hip replacement system.

115. Plaintiffs are informed and believe, and thereupon allege, that the M2a hip replacement system had design and/or manufacturing defects, and in fact, did cause serious life-altering injuries to the users and consumers thereof, including Plaintiffs, while being used in a manner reasonably foreseeable, thereby rending the M2a hip replacement system unsafe and dangerous. Defendants also failed to provide adequate warnings or instructions to consumers and users of the M2a hip replacement system concerning the significant dangers associated with it and/or its component parts, or to instruct consumers and users regarding the use of it, and failed to warn and/or instruct, anticipated consumers concerning defects with the M2a hip replacement system.

116. Plaintiffs are informed and believe, and thereupon allege, the M2a hip replacement system was defective when placed on the market by Defendants and was of such a nature that the defects would not be discovered in the normal course of inspection and use by users thereof. At all times relevant herein, the M2a hip replacement system was in substantially the same condition as when it was originally placed into the stream of commerce by Defendants.

117. Defendants are strictly liable for designing, testing, manufacturing, making, distributing, selling, and/or placing a defective product that was unreasonable dangerous product into the stream of commerce.

118. Further, Defendants owed Plaintiff MICKEY REED a duty to provide reasonable complete and accurate information to him, his orthopedic surgeon, and the orthopedic community regarding Plaintiff MICKEY REED's M2a hip replacement system.

119. Defendants, in breach of the duties described above, negligently and carelessly designed, manufactured, promoted, marketed, sold, supplied, distributed and serviced the M2a hip replacement system and components implanted in Plaintiff MICKEY REED.

120. Defendants, in breach of the duties described above, negligently and carelessly failed to provide reasonable complete and accurate information to Plaintiff MICKEY REED, his orthopedic surgeon, and the orthopedic community regarding Plaintiff MICKEY REED's M2a hip replacement system.

121. As a direct and proximate result of Defendants' breaches of duty, Plaintiff MICKEY REED needlessly suffered injuries as described above.

SECOND CAUSE OF ACTION
(Failure to Warn Against All Defendants)

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

123. Defendants had a duty to give adequate and appropriate warnings to Plaintiff MICKEY REED regarding particular risks about the M2a hip replacement system that Defendants knew or should have known were involved in Plaintiff MICKEY REED's reasonably foreseeable use of the product.

124. Plaintiff MICKEY REED's use of the M2a hip replacement system was reasonably foreseeable by Defendants.

125. Defendants knew or should have known of particular risks involved in Plaintiff MICKEY REED's reasonably foreseeable use of the product.

126. Breaching this duty, Defendants failed to provide adequate or appropriate warnings to Plaintiff MICKEY REED relating to the M2a hip replacement system,

127. As a direct and proximate result of the conduct of Defendants, Plaintiff MICKEY REED needlessly suffered injuries as described specifically above.

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THIRD CAUSE OF ACTION
(Strict Liability Failure to Warn Against All Defendants)

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

129. At the time that Defendants promoted, marketed, sold, supplied, distributed and serviced the M2a hip replacement system implanted in Plaintiff MICKEY REED, such system contained defects that made them unreasonably dangerous beyond the expectations of the ordinary consumer, and were unfit for their intended use.

130. The M2a hip replacement system reached Plaintiff MICKEY REED without substantial change in the condition in which they were sold.

131. At the time and on the occasions in question, the M2a 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.

132. The foreseeable risk of harm from the defects in the M2a hip replacement system could have been reduced or avoided by providing adequate instructions or warnings.

133. Defendants failed to provide adequate instructions or warnings regarding the defects in the M2a hip replacement system which were known by Defendants or should have been known by Defendants.

134. As a direct and proximate result of the lack of reasonable and adequate instructions or warnings regarding the defects in the M2a hip replacement system, Plaintiff MICKEY REED suffered injuries as described above.

FOURTH CAUSE OF ACTION
(Strict Liability for Design Defect Against All Defendants)

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

136. At the time that Defendants designed, manufactured, promoted, marketed, sold, supplied, distributed and serviced the M2a hip replacement system implanted in Plaintiff MICKEY

REED, such system contained design defects that made it unreasonably dangerous beyond the expectations of the ordinary consumer, and were unfit for its intended use.

137. The hip replacement system reached Plaintiff MICKEY REED without substantial change in the condition in which it was sold.

138. At the time and on the occasions in question, the M2a 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.

139. The M2a hip replacement system, for the reasons stated herein, was defective and unreasonably dangerous in design.

140. As a direct and proximate result of the design defects in the M2a hip replacement system, Plaintiff MICKEY REED suffered injuries as described above.

FIFTH CAUSE OF ACTION
(Breach of Implied Warranty Against All Defendants)

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

142. Defendants designed, manufactured, promoted, marketed, distributed, supplied, sold, and serviced the M2a hip replacement system at issue in this case.

143. Defendants impliedly warranted that the M2a hip replacement system was reasonably fit for its intended use as a hip replacement system.

144. Plaintiff MICKEY REED was a foreseeable user of the M2a hip replacement system.

145. Plaintiff MICKEY REED purchased the M2a hip replacement system from Defendants, through his orthopedic surgeon.

146. The M2a hip replacement components failed while being used for their intended purpose, causing serious injury to Plaintiff MICKEY REED.

147. As a direct and proximate cause of this breach, Plaintiff MICKEY REED suffered injuries as described above.

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SIXTH CAUSE OF ACTION

(Intentional Misrepresentation Against Biomet Defendants - BIOMET, INC.; BIOMET ORTHOPEDICS, LLC.; BIOMET U.S. RECONSTRUCTION, LLC.; BIOMET MANUFACTURING, LLC.; ZIMMER BIOMET HOLDINGS, INC.)

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

149. BIOMET defendants represented to Plaintiff MICKEY REED and his agents that the M2a metal on metal hip replacement system had been shown to be safe through extensive testing and that it continued to be safe during the entirety of the time that the device remained in his body.

150. The representations made by BIOMET defendants to Plaintiff MICKEY REED were false.

151. BIOMET defendants knew these representations were false when they were made or made the representations recklessly without regard to the truth of those representations.

152. BIOMET defendants intended for Plaintiff MICKEY REED and his agents to rely on these representations.

153. Plaintiff MICKEY REED and his agents did in fact reasonably rely on these representations, to his detriment.

154. Plaintiff MICKEY REED's reliance on representations made by BIOMET defendants was a substantial factor in causing the harm suffered, as described above.

155. 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 Plaintiff MICKEY REED 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 M2a 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 M2a 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 M2a 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 M2a 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.

156. 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 Plaintiff Mickey Reed, 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
(Negligent Misrepresentation Against All Defendants)

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

158. Defendants represented to Plaintiff MICKEY REED, and his agents, that the M2a hip replacement system was safe and effective and not defective.

159. Defendants representations to Plaintiff MICKEY REED and his agents were false.

160. Although Defendants may have believed, in good faith, that the representations were true, Defendants had no reasonable grounds for believing the representations were true at the time they were made to Plaintiff MICKEY REED and his agents.

161. Defendants intended for Plaintiff MICKEY REED and his agents to rely on these representations.

162. Plaintiff MICKEY REED and his agents did in fact reasonably rely on these

representations, to his detriment.

163. Plaintiff MICKEY REED's reliance on Defendants' representations was a substantial factor in causing the harm suffered, as described above.

EIGHTH CAUSE OF ACTION
(Unlawful, Unfair, and Fraudulent Business Practices in Violation of California Business & Professions Code Sec. 17200, et Seq. Against All Defendants)

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

165. 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."

166. Defendants have made numerous misrepresentations to Plaintiff MICKEY REED, his agents, and to the general public. Among those misrepresentations are Defendants' claims that the Biomet M2a hip replacement system was a safe and effective hip replacement system.

167. Defendants' business practices relating to the M2a hip replacement systems are unlawful because they constitute false advertising, intentional misrepresentation, and fraudulent concealment.

168. As a direct and proximate result of Defendants' unlawful business practices and false advertising, Plaintiff MICKEY REED has 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.

169. Plaintiff MICKEY REED hereby requests 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
(Products Liability Negligence Against All Defendants)

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

171. Defendants, as the designers, manufacturers, promoters, marketers, sellers, suppliers, distributors, and servicers of the M2a hip replacement system, owed a duty to use reasonable care in the

design, manufacture, promotion, marketing, selling, supplying, distribution, and service of Plaintiff MICKEY REED's M2a hip system.

172. Further, Defendants owed Plaintiff Mickey Reed a duty to provide reasonable complete and accurate information to him, his orthopedic surgeon, and the orthopedic community regarding Plaintiff MICKEY REED's M2a system.

173. Defendants, in breach of the duties described above, negligently and carelessly designed, manufactured, promoted, marketed, sold, supplied, distributed and serviced the M2a hip replacement components implanted in Plaintiff MICKEY REED.

174. Defendants, in breach of the duties described above, negligently and carelessly failed to provide reasonable complete and accurate information to Plaintiff MICKEY REED, his orthopedic surgeon, and the orthopedic community regarding Plaintiff MICKEY REED's M2a hip system.

175. As a direct and proximate result of Defendants' breaches of duty, Plaintiff MICKEY REED needlessly suffered injuries as described above.

TENTH CAUSE OF ACTION
(Loss of Consortium Against All Defendants)

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

177. Plaintiff, NANCY REED, was and is currently the lawful wife of Plaintiff, MICKEY REED.

178. As a direct and proximate result of the conduct of Defendants as set forth above, and of the injuries and damages suffered by Plaintiff MICKEY REED, Plaintiff NANCY REED suffered and will continue to suffer the loss of care, services, companionship, counsel, advice, assistance, comfort, and consortium of her husband, Plaintiff MICKEY REED, and has incurred, and will continue to incur in the future, expenses for the care and treatment of her husband, Plaintiff MICKEY REED, and has provided and will continue to provide extraordinary services in order to care for her husband, all to her loss and damage.

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PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendants, and each of them, as follows:

1. For special damages incurred by Plaintiffs;
2. For general damages incurred by Plaintiffs;
3. For prejudgment interest;
4. For costs of suit herein incurred;
5. For exemplary and punitive damages against Defendants;
6. Damages, restitution, attorneys' fees and costs, and all other relief allowed under California Business and Professions Code Section 17200 et seq.;
7. For such other and further relief as this Court may deem just and proper.

DATED: 4/19/18

HAMPARYAN INJURY LAWYERS

Robert Hamparyan, Esq,
David R. Loeffler, Esq.
Attorney for Plaintiff

CM-010

ATTORNEY OR PARTY WITHOUT ATTORNEY (Name, State Bar number, and address):
Robert Hamparyan (SBN 181934) David R. Loeffler (269263)
Hamparyan Injury Lawyers
275 West Market Street
San Diego, CA 92101
TELEPHONE NO.: 6195501355 FAX NO.: 6195501356
ATTORNEY FOR (Name):

FOR COURT USE ONLY

FILED
San Francisco County Superior Court

APR 19 2018

CLERK OF THE COURT
BY: Ekalene Robinson
Deputy Clerk

SUPERIOR COURT OF CALIFORNIA, COUNTY OF San Francisco
STREET ADDRESS: 400 McAllister
MAILING ADDRESS: 400 McAllister
CITY AND ZIP CODE: San Francisco 94102
BRANCH NAME: Civic Center Courthouse

CASE NAME: MICKEY REED v. BIOMET, INC., et al.

CIVIL CASE COVER SHEET
[✓] **Unlimited** (Amount demanded exceeds $25,000) [ ] **Limited** (Amount demanded is $25,000 or less)

Complex Case Designation
[ ] **Counter** [ ] **Joinder**
Filed with first appearance by defendant (Cal. Rules of Court, rule 3.402)

CASE NUMBER: CGC-18-565909
JUDGE:
DEPT:

Items 1–6 below must be completed (see instructions on page 2).

1. Check **one** box below for the case type that best describes this case:

Auto Tort
[ ] Auto (22)
[ ] Uninsured motorist (46)

Other PI/PD/WD (Personal Injury/Property Damage/Wrongful Death) Tort
[ ] Asbestos (04)
[✓] Product liability (24)
[ ] Medical malpractice (45)
[ ] Other PI/PD/WD (23)

Non-PI/PD/WD (Other) Tort
[ ] Business tort/unfair business practice (07)
[ ] Civil rights (08)
[ ] Defamation (13)
[ ] Fraud (16)
[ ] Intellectual property (19)
[ ] Professional negligence (25)
[ ] Other non-PI/PD/WD tort (35)

Employment
[ ] Wrongful termination (36)
[ ] Other employment (15)

Contract
[ ] Breach of contract/warranty (06)
[ ] Rule 3.740 collections (09)
[ ] Other collections (09)
[ ] Insurance coverage (18)
[ ] Other contract (37)

Real Property
[ ] Eminent domain/Inverse condemnation (14)
[ ] Wrongful eviction (33)
[ ] Other real property (26)

Unlawful Detainer
[ ] Commercial (31)
[ ] Residential (32)
[ ] Drugs (38)

Judicial Review
[ ] Asset forfeiture (05)
[ ] Petition re: arbitration award (11)
[ ] Writ of mandate (02)
[ ] Other judicial review (39)

Provisionally Complex Civil Litigation (Cal. Rules of Court, rules 3.400–3.403)
[ ] Antitrust/Trade regulation (03)
[ ] Construction defect (10)
[ ] Mass tort (40)
[ ] Securities litigation (28)
[ ] Environmental/Toxic tort (30)
[ ] Insurance coverage claims arising from the above listed provisionally complex case types (41)

Enforcement of Judgment
[ ] Enforcement of judgment (20)

Miscellaneous Civil Complaint
[ ] RICO (27)
[ ] Other complaint *(not specified above)* (42)

Miscellaneous Civil Petition
[ ] Partnership and corporate governance (21)
[ ] Other petition *(not specified above)* (43)

2. This case [ ] is [✓] is not complex under rule 3.400 of the California Rules of Court. If the case is complex, mark the factors requiring exceptional judicial management:
   a. [ ] Large number of separately represented parties
   b. [ ] Extensive motion practice raising difficult or novel issues that will be time-consuming to resolve
   c. [ ] Substantial amount of documentary evidence
   d. [ ] Large number of witnesses
   e. [ ] Coordination with related actions pending in one or more courts in other counties, states, or countries, or in a federal court
   f. [ ] Substantial postjudgment judicial supervision
3. Remedies sought *(check all that apply)*: a. [X] monetary b. [ ] nonmonetary; declaratory or injunctive relief c. [X] punitive
4. Number of causes of action *(specify)*: 10
5. This case [ ] is [✓] is not a class action suit.
6. If there are any known related cases, file and serve a notice of related case. *(You may use form CM-015.)*

Date: April 19, 2018
Robert Hamparyan
(TYPE OR PRINT NAME)
(SIGNATURE OF PARTY OR ATTORNEY FOR PARTY)

NOTICE
- Plaintiff must file this cover sheet with the first paper filed in the action or proceeding (except small claims cases or cases filed under the Probate Code, Family Code, or Welfare and Institutions Code). (Cal. Rules of Court, rule 3.220.) Failure to file may result in sanctions.
- File this cover sheet in addition to any cover sheet required by local court rule.
- If this case is complex under rule 3.400 et seq. of the California Rules of Court, you must serve a copy of this cover sheet on all other parties to the action or proceeding.
- Unless this is a collections case under rule 3.740 or a complex case, this cover sheet will be used for statistical purposes only.

Form Adopted for Mandatory Use
Judicial Council of California
CM-010 [Rev July 1, 2007]

CIVIL CASE COVER SHEET

Cal. Rules of Court, rules 2.30, 3.220, 3.400–3.403, 3.740;
Cal. Standards of Judicial Administration, std. 3.10
www.courtinfo.ca.gov

ORIGINAL FAXED

INSTRUCTIONS ON HOW TO COMPLETE THE COVER SHEET

To Plaintiffs and Others Filing First Papers. If you are filing a first paper (for example, a complaint) in a civil case, you **must** complete and file, along with your first paper, the *Civil Case Cover Sheet* contained on page 1. This information will be used to compile statistics about the types and numbers of cases filed. You must complete items 1 through 6 on the sheet. In item 1, you must check **one** box for the case type that best describes the case. If the case fits both a general and a more specific type of case listed in item 1, check the more specific one. If the case has multiple causes of action, check the box that best indicates the **primary** cause of action. To assist you in completing the sheet, examples of the cases that belong under each case type in item 1 are provided below. A cover sheet must be filed only with your initial paper. Failure to file a cover sheet with the first paper filed in a civil case may subject a party, its counsel, or both to sanctions under rules 2.30 and 3.220 of the California Rules of Court.

To Parties in Rule 3.740 Collections Cases. A "collections case" under rule 3.740 is defined as an action for recovery of money owed in a sum stated to be certain that is not more than $25,000, exclusive of interest and attorney's fees, arising from a transaction in which property, services, or money was acquired on credit. A collections case does not include an action seeking the following: (1) tort damages, (2) punitive damages, (3) recovery of real property, (4) recovery of personal property, or (5) a prejudgment writ of attachment. The identification of a case as a rule 3.740 collections case on this form means that it will be exempt from the general time-for-service requirements and case management rules, unless a defendant files a responsive pleading. A rule 3.740 collections case will be subject to the requirements for service and obtaining a judgment in rule 3.740.

To Parties in Complex Cases. In complex cases only, parties must also use the *Civil Case Cover Sheet* to designate whether the case is complex. If a plaintiff believes the case is complex under rule 3.400 of the California Rules of Court, this must be indicated by completing the appropriate boxes in items 1 and 2. If a plaintiff designates a case as complex, the cover sheet must be served with the complaint on all parties to the action. A defendant may file and serve no later than the time of its first appearance a joinder in the plaintiff's designation, a counter-designation that the case is not complex, or, if the plaintiff has made no designation, a designation that the case is complex.

CASE TYPES AND EXAMPLES

Auto Tort
- Auto (22)–Personal Injury/Property Damage/Wrongful Death
- Uninsured Motorist (46) *(if the case involves an uninsured motorist claim subject to arbitration, check this item instead of Auto)*

Other PI/PD/WD (Personal Injury/ Property Damage/Wrongful Death) Tort
- Asbestos (04)
  - Asbestos Property Damage
  - Asbestos Personal Injury/ Wrongful Death
- Product Liability *(not asbestos or toxic/environmental)* (24)
- Medical Malpractice (45)
  - Medical Malpractice–Physicians & Surgeons
  - Other Professional Health Care Malpractice
- Other PI/PD/WD (23)
  - Premises Liability (e.g., slip and fall)
  - Intentional Bodily Injury/PD/WD (e.g., assault, vandalism)
  - Intentional Infliction of Emotional Distress
  - Negligent Infliction of Emotional Distress
  - Other PI/PD/WD

Non-PI/PD/WD (Other) Tort
- Business Tort/Unfair Business Practice (07)
- Civil Rights (e.g., discrimination, false arrest) *(not civil harassment)* (08)
- Defamation (e.g., slander, libel) (13)
- Fraud (16)
- Intellectual Property (19)
- Professional Negligence (25)
  - Legal Malpractice
  - Other Professional Malpractice *(not medical or legal)*
- Other Non-PI/PD/WD Tort (35)

Employment
- Wrongful Termination (36)
- Other Employment (15)

Contract
- Breach of Contract/Warranty (06)
  - Breach of Rental/Lease Contract *(not unlawful detainer or wrongful eviction)*
  - Contract/Warranty Breach–Seller Plaintiff *(not fraud or negligence)*
  - Negligent Breach of Contract/ Warranty
  - Other Breach of Contract/Warranty
- Collections (e.g., money owed, open book accounts) (09)
  - Collection Case–Seller Plaintiff
  - Other Promissory Note/Collections Case
- Insurance Coverage *(not provisionally complex)* (18)
  - Auto Subrogation
  - Other Coverage
- Other Contract (37)
  - Contractual Fraud
  - Other Contract Dispute

Real Property
- Eminent Domain/Inverse Condemnation (14)
- Wrongful Eviction (33)
- Other Real Property (e.g., quiet title) (26)
  - Writ of Possession of Real Property
  - Mortgage Foreclosure
  - Quiet Title
  - Other Real Property *(not eminent domain, landlord/tenant, or foreclosure)*

Unlawful Detainer
- Commercial (31)
- Residential (32)
- Drugs (38) *(if the case involves illegal drugs, check this item; otherwise, report as Commercial or Residential)*

Judicial Review
- Asset Forfeiture (05)
- Petition Re: Arbitration Award (11)
- Writ of Mandate (02)
  - Writ–Administrative Mandamus
  - Writ–Mandamus on Limited Court Case Matter
  - Writ–Other Limited Court Case Review
- Other Judicial Review (39)
  - Review of Health Officer Order
  - Notice of Appeal–Labor Commissioner Appeals

Provisionally Complex Civil Litigation (Cal. Rules of Court Rules 3.400–3.403)
- Antitrust/Trade Regulation (03)
- Construction Defect (10)
- Claims Involving Mass Tort (40)
- Securities Litigation (28)
- Environmental/Toxic Tort (30)
- Insurance Coverage Claims *(arising from provisionally complex case type listed above)* (41)

Enforcement of Judgment
- Enforcement of Judgment (20)
  - Abstract of Judgment (Out of County)
  - Confession of Judgment *(non-domestic relations)*
  - Sister State Judgment
  - Administrative Agency Award *(not unpaid taxes)*
  - Petition/Certification of Entry of Judgment on Unpaid Taxes
  - Other Enforcement of Judgment Case

Miscellaneous Civil Complaint
- RICO (27)
- Other Complaint *(not specified above)* (42)
  - Declaratory Relief Only
  - Injunctive Relief Only *(non-harassment)*
  - Mechanics Lien
  - Other Commercial Complaint Case *(non-tort/non-complex)*
  - Other Civil Complaint *(non-tort/non-complex)*

Miscellaneous Civil Petition
- Partnership and Corporate Governance (21)
- Other Petition *(not specified above)* (43)
  - Civil Harassment
  - Workplace Violence
  - Elder/Dependent Adult Abuse
  - Election Contest
  - Petition for Name Change
  - Petition for Relief From Late Claim
  - Other Civil Petition