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UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

JOYCE ULRICH,

Plaintiff,

v.

HOWMEDICA OSTEONICS CORP., STRYKER ORTHOPAEDICS, a New Jersey Corporation; STRYKER CORPORATION, a Michigan Corporation; and DOES 1-10, inclusive,

Defendants.

Case No.:

COMPLAINT FOR MONEY DAMAGES

1) Negligence;
2) Strict Products Liability (Manufacturing Defect);
3) Strict Products Liability (Design Defect);
4) Strict Products Liability (Inadequate Warning);
5) Strict Products Liability (Failure to Conform to Representations);
6) Strict Products Liability (Failure to Adequately Test);
7) Breach of Express Warranty;
8) Breach of Implied Warranty of Merchantability;
9) Negligent Misrepresentation;
10) Fraud; and
11) Punitive Damages

DEMAND FOR JURY TRIAL

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Plaintiff Joyce Ulrich ("Plaintiff") alleges on information and belief, by and through her undersigned attorneys, against Defendants Howmedica Osteonics Corp., Stryker Orthopaedics, a New Jersey Corporation, Stryker Corporation, a Michigan Corporation, and DOES 1-10 Inclusive, (collectively "Defendants"), the following:

I. INTRODUCTION

1. This is an action for damages suffered by Plaintiff Joyce Ulrich, as a direct and proximate result of Defendants' wrongful conduct in connection with developing, designing, testing, assembling, manufacturing, packaging, labeling, preparing, distribution, marketing, supplying, and/or selling the Accolade TMZF® Hip Stem ("Accolade Hip Stem") and the LFIT™ Anatomic V40™ Femoral Head ("LFIT Femoral Head"), (hereinafter collectively "Defective Devices.")

2. Defendants knew or should have known that the Defective Devices implanted in Plaintiff can cause fretting and corrosion at the junction between the femoral stem and the femoral head. Fretting and corrosion is known by Defendants to cause personal injury, significant pain, disability, dislocation, and loss of movement, and these injuries can only be partially remedied through revision surgeries.

3. Defendants mislead healthcare professionals and the public into believing its femoral hip stem was safe and effective for use in total hip arthroplasty procedures; engaged in deceptive, misleading and unconscionable promotional or sales methods to convince healthcare professionals to utilize Defendants' femoral hip stem, even though Defendants knew or should have known its femoral hip stem was unreasonably dangerous; and failed to warn healthcare professionals and the public about the safety risk of its femoral hip stem, including Plaintiff and her physicians.

II. PARTIES

4. Plaintiff Joyce Ulrich is, and at all times relevant to this Complaint was, a resident of Rancho Mirage, California, County of Riverside.

5. Defendant Stryker Orthopaedics is, and at all times relevant to this Complaint was, a New Jersey Corporation with its principle place of business at 325

Corporate Drive, Mahwah, NJ 07430. Defendant Howmedica Osteonics Corp. is, and was at all times relevant herein, doing business in and/or having directed its activities in California, specifically this judicial district. Defendant Howmedica Osteonics Corp. is a wholly owned subsidiary of parent corporation, Stryker Corporation.

6. Defendant Stryker Corporation is the parent corporation organized and existing under the laws of Michigan, with its principal place of business in Kalamazoo, Michigan. Defendant Howmedica Osteonics Corp., is, and was at all times relevant herein, doing business in and/or having directed its activities in California, specifically this judicial district. Defendant Stryker Corporation is a medical technology company creating orthopedic implants as well as medical and surgical equipment to healthcare professionals.

7. Plaintiff is unaware of the true names and capacities, whether individual, corporate, associate, or otherwise, of Defendants DOES 1-10, inclusive, or any of them, and therefore sues these Defendants, and each of them, by such fictitious names. Plaintiff will seek leave of this Court to amend this Complaint when the status and identities of these Defendants are ascertained.

8. Upon information and belief, at all times relevant herein, the employees of Defendants, their subsidiaries, affiliates, and other related entities were the agents, servants, and employees of Defendants, and were acting within the purpose and scope of said agency and employment. Whenever referenced in this Complaint is made to any act or transaction of Defendants, such designation shall be deemed to mean that the principals, officers, employees, agents and/or representatives of the Defendants committed, knew of, performed, authorized, ratified and/or directed such transactions on behalf of Defendants while actively engaged in the scope of their duties.

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III. JURISDICTION AND VENUE

9. This Court has diversity jurisdiction over the parties pursuant to 28 U.S.C. §1332(a). Plaintiff and Defendants are citizens of different states, and the amount in controversy exceeds $75,000, exclusive of interest and costs.

10. This Court has in personam jurisdiction pursuant to 28 U.S.C. §1391 because Defendants conducted substantial business within the State of California and had continuous and systematic contacts with the State of California, and they have consented to jurisdiction in this state. Upon information and belief, Defendants also advertised in this district, made material omissions and representations in this district, and breached warranties in this district.

11. Venue is proper in the Central District of California pursuant to 28 U.S.C. § 1391(a) and (b) because a substantial part of the events, acts and omissions giving rise to these claims occurred in the Central District of California.

IV. FACTUAL BACKGROUND

A. Total Hip Arthroplasty Procedure

12. The Accolade® TMZF® Hip Stem and LFIT™ Anatomic V40™ Femoral Head devices were developed in order to reconstruct human hip joints that are diseased due to conditions such as osteoarthritis, rheumatoid arthritis, avascular necrosis, or fracture. The hip joint connects the thigh (femur) bone of a patient's leg to the patient's pelvis. The hip joint is similar to a ball that fits in a socket. The socket portion of the hip is called the acetabulum. The femoral head at the top of the femur bone rotates within the curved surface of the acetabulum.

13. A total hip replacement typically consists of four separate components: (1) a femoral stem; (2) a femoral head; (3) an acetabular liner; and (4) an acetabular shell. After the surgeon hollows out a patient's femur bone, the metal femoral stem is implanted. The femoral head, usually manufactured from metal or ceramic, is fixed on the top of the femoral stem. The femoral head forms the hip joint that can rotate when it is placed inside a plastic or ceramic acetabular liner attached to the interior portion of the

metal acetabular shell comprised of metal on its outer surface. When the surgery is complete, the femoral stem anchors the femoral head that rotates within the acetabular liner sitting inside the acetabular shell.

14. A hip replacement system containing a metal femoral stem and a metal femoral head, such as the hip replacement system implanted in Plaintiff, is known to cause fretting, corrosion, and can generate particulate debris at the modular junction between the stem and the head. Fretting and corrosive debris in a joint area can lead to multiple complications, including but not limited to, pain, adverse local tissue reaction, pseudotumors, osteolysis and/or spontaneous dissociation—fracture of the femoral neck or trunnion of the prosthesis.

15. Failure of a hip replacement system at the junction between the stem and the femoral head requires the patient to undergo subsequent revision surgery to replace the failed hip replacement system.

B. FDA Process

16. The Medical Device Amendments to the Food, Drug, and Cosmetics Act of 1938 ("MDA"), in theory, requires Class II medical devices, including the Accolade Hip Stem and LFIT Femoral Head, to undergo premarket approval by the FDA, a process which obligates the manufacturer to design and implement a clinical investigation and then submit the results of that investigation to the FDA.

17. Premarket approval is a rigorous process that requires a manufacturer to submit what is typically a multivolume application that includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a full statement of the device's components, ingredients, and properties and of the principle or principles of operation; a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device; samples or device components required by the FDA; and a specimen of the proposed labeling.

18. The FDA may grant premarket approval only if it finds that there is reasonable assurance that the medical devices is safe and effective and must weigh any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

19. A medical device on the market prior to the effective date of the MDA—a so-called "grandfathered" device—was not required to undergo pre-market approval. In addition, a medical device marketed after the MDA's effective date may bypass the rigorous premarket approval process if the device is "substantially equivalent" to a "grandfathered" pre-MDA device (i.e., a device approved prior to May 28, 1976). This exception to premarket approval is known as the "510(k)" process and simply requires the manufacturer to notify the FDA under section 510(k) of the MDA of its intent to market a device at least 90 days prior to the device's introduction on the market, and to explain the device's substantial equivalence to a pre-MDA predicate device. The FDA may then approve the new device for sale in the United States.

20. Through the 510(k) clearance process, a product will be cleared if the manufacturer establishes that the new device is substantially equivalent to a predicate device; one that is already on the market.

21. Rather than being approved for use by the FDA pursuant to the rigorous premarket approval process, Defendants' Defective Devices were sold on the basis that, under section 510(k) of the MDA, they were "substantially equivalent" to older hip implant devices that Defendants sold and implanted prior to the enactment of the MDA in 1976.

22. As such, Defendants were able to market the Defective Devices with virtually no clinical or non-clinical trials or FDA review of the implants for safety and effectiveness.

23. The Accolade Hip Stem, LFIT Femoral Head, and related components were approved under the Food and Drug Administration 510(k) process. A 510(k) medical

device does not have to go through the rigors of a clinical study to gain approval by the FDA.

24. On information and belief, Defendants did not conduct a clinical trial of the Accolade system before putting it into the stream of commerce.

C. The Accolade TMZF® Hip Stem and LFIT™ Anatomic V40™ Femoral Head

25. At all times material hereto, Defendants developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the Defective Devices, Accolade Hip Stem and LFIT Femoral Head, either directly or indirectly, to members of the general public within the state of California, including Plaintiff Joyce Ulrich.

26. On or around March 16, 2000, Defendants received FDA clearance to sell its Accolade Hip Stem in the United States. Then, on or around April 11, 2001, Defendants received FDA clearance to sell its LFIT Femoral Head. These clearances were both obtained through the 510(k) process.

27. The Accolade Hip Stem is a hip replacement prosthesis. The stem is manufactured utilizing a proprietary titanium alloy consisting of titanium, molybdenum, zinc, and iron. It combines the material characteristics of TMZF® alloy (TI-12Mo-6Zr-2Fe) and is also coated in a CP Titanium plasma sprayed coating and PureFix™ HA. It is a single piece artificial hip replacement device that is designed to be implanted into the patient's femur. It is indicated for patients requiring total hip arthroplasty or replacement due to joint disease.

28. Defendants claim in their promotional materials for the Accolade Hip Stem that their alloy is both stronger and less rigid than other titanium alloys. Defendants utilized print, television, internet, and/or e-mail marketing to disseminate information promoting purported advantages of their Accolade Hip Stem and LFIT Femoral Heads. They also claimed that the particular titanium alloy has been tested and proven to resist the effects of corrosion and fretting.

29. Upon information and belief, Defendants have since abandoned the use of TMZF titanium throughout its product line. Instead, Defendants now utilize a different titanium alloy.

30. On or around November 16, 1999, and again on April 11, 2001, Defendants received clearance from the FDA to market the LFIT Femoral Head.

31. The LFIT Femoral Head is one of the modular balls or heads designed to be used with the Accolade Hip Stem and is made from a chromium/cobalt alloy.

32. The Accolade Hip Stem and the LFIT Femoral Head are commonly used together during total hip replacement arthroplasty surgery.

D. Defendants' Defective Products

33. Defendants claimed that laboratory testing demonstrates the compatibility of these materials without concern for fretting and corrosion. In their marketing and sale of the devices, Defendants represented and warranted that proprietary materials alleviate concerns for this problem. Despite Defendants' claims, the Defective Devices have been reported to cause corrosion issues.

34. Had Defendants conducted clinical trials of the Defective Devices before they were first released on the market, they would have discovered at that time what they ultimately learned before and/or around August 2016—that the Defective Devices result in a high percentage of patients developing trunnionosis, osteolysis, bone loss, metallosis, biologic toxicity and an early and high failure rate due to the release of metal particles in the patient's surrounding tissue when the cobalt-chromium metal femoral head rotates within the cobalt-chromium metal acetabular liner.

35. In other words, implantation of the Defective Devices result in the nearly immediate systemic release of high levels of toxic metal cobalt-chromium ions into every hip implant patient's tissue and bloodstream. This is because cobalt-chromium metal particles are released by friction from the metal femoral head rotating within the metal liner. The particles then accumulate in the patient's tissue surrounding the implant giving

rise to metallosis, pseudotumors, trunnionosis, osteolysis, bone loss, and/or other conditions.

36. The formation of trunnionosis, osteolysis, bone loss, metallosis, pseudotumors, and infection and inflammation causes severe pain and discomfort, death of surrounding tissue and bone loss, and lack of mobility.

37. The problems with Defendants' Accolade Hip Stem and LFIT Femoral Head devices are similar to the issues that gave rise to Defendants' recall of the ASR XL Acetabular System and ASR Hip Resurfacing System ("ASR"). Like the Defective Devices, the ASR is also prone to early failure, and causes trunnionosis, osteolysis, bone loss, metallosis, and cobalt and chromium toxicity resulting in serious health problems and the need for subsequent revision surgery. As a result, Defendants, in acknowledging the high failure rate of the ASR, recalled countless ASR devices worldwide. Defendants also recalled the LFIT Femoral Heads for the same reasons.

38. On information and belief, Plaintiff alleges that many recipients of Defendants' Defective Devices are suffering from elevated levels of chromium and cobalt. Plaintiff further alleges on information and belief that Defendants are aware that certain recipients of the Defective Devices have significantly elevated levels of chromium and cobalt in amounts many times higher than acceptable or recommended safety levels.

39. In January 2014, the Bone and Joint Journal published an article titled *Raised Levels of Metal Ions in the Blood in Patients Who Have Undergone Uncemented Metal-On-Metal Polyethylene Trident-Accolade Total Hip Replacement* finding high concentrations of metal in the blood of patients that had an Accolade implanted in their body.[1] The authors discontinued the use of the products and notified Defendants of the results.

[1] Paul Craig, et al., *Raised Levels of Metal Ions in the Blood in Patients Who Have Undergone Uncemented Metal-On-Metal Polyethylene Trident-Accolade Total Hip Replacements*, 96-B BONE & JOINT J. 43, 43-47 (2004).

40. On information and belief, Defendants failed to notify patients of the results of this study or dangers of their Defective Devices.

E. Defendants' LFIT™ Anatomic V40™ Femoral Head Recall

41. On or around August 29, 2016, Defendants recalled thousands of their LFIT Femoral Heads. The recall cites gross trunnion failure, metal wear, adverse tissue reaction and the need for revision surgery as causes for recalling the heads. Plaintiff Ulrich suffered one and/or a combination of the above reactions resulting in the need to surgically remove her Accolade TMZF Hip Stem and LFIT Anatomic LFIT Femoral Head.

42. The recall notice states that Defendants are recalling certain lots of LFIT V40 Femoral Heads as a result of several "Potential Hazards." The hazards identified include, but are not limited to:

a. Disassociation of femoral head from hip stem
b. Fractured hip stem trunnion
c. Excessive metallic debris
d. Excessive wear debris

43. The recall notice further states that the problems caused by the LFIT™ Anatomic V40™ Femoral Head include "revision" surgery, "loss of mobility," "dislocation," "adverse local tissue reaction," and "periprosthetic fracture."

44. The recall notice fails to instruct surgeons to contact patients with the LFIT Femoral Heads to undergo a simple, inexpensive blood test that can be used to determine whether a patient is experiencing the corrosive process that can lead to catastrophic failure. Specifically, the presence of elevated levels of cobalt, chromium, or titanium in the blood is a definitive sign that a prosthetic hip is corroding.

45. Plaintiff is informed and believes, and thereon alleges, that the problems with Defendants' Accolade Hip Stem and LFIT Femoral Head products are much larger than those referenced in Defendants' recall notice. Plaintiffs allege that all LFIT™ Anatomic V40™ Femoral Heads sold by Defendants are defective and should be

recalled. Defendants have intentionally downplayed the risk of harm and limited the scope of its recall in an effort to hide from surgeons, patients, and the FDA the true extent of the problems with their defective hips.

F. Plaintiff Joyce Ulrich's Experience Illustrates a Tragic But Not Uncommon or Unforeseeable Risk Associated with Defendants' Defective Devices

46. Defendants placed their Defective Devices into the stream of interstate commerce and they were implanted in Plaintiff Joyce Ulrich on February 11, 2009.

47. On or about February 11, 2009, Plaintiff Joyce Ulrich, a then 68 year-old female, had a right total hip replacement with the Stryker system, consisting of the Accolade Hip Stem and LFIT Femoral Head.

48. After implantation of the Defective Devices, Plaintiff Joyce Ulrich began experiencing discomfort and complications in her hip.

49. Due to elevated risk and instability in her right hip, Plaintiff underwent revision surgery to her right hip on May 17, 2016.

50. During surgery, it was discovered that, in fact, there was significant evidence of trunnionosis around the proximal femur at the junction between the head and neck. The operative report also noted areas of osteolysis, bone loss, and loosening of the femoral component. Once her surgeon removed the acetabulum, he noticed "a severe amount of bone loss and osteolysis in the space behind the patient's acetabular dome."

51. Plaintiff has endured extensive rehabilitation since undergoing revision of her right hip prosthesis.

52. Had Plaintiff Joyce Ulrich known that the Defective Devices caused pain, swelling, inflammation, damage to the surrounding bone and tissue, problems walking, and the need for revision surgery to replace the devices, she would not have elected to have the Defective Devices implanted.

53. As a direct and proximate cause of the implantation of the Defective Devices, Plaintiff Joyce Ulrich has suffered sufficient harm, including, but not limited to, physical injury and bodily impairment, debilitating lack of mobility, and conscious pain

and suffering. In addition, because of the faulty nature of Defendants' products, Plaintiff Joyce Ulrich endured severe pain and suffering.

54. As a result of the foregoing, Plaintiff Joyce Ulrich has suffered symptoms including severe pain, swelling, inflammation and damage to surrounding bone and tissue, including granulomatous, trunnionosis, and lack of mobility. These symptoms are the result of possible loosening of the implant, where the bone around the implant may have broken, dislocation, where the two parts of the implant that move against each other are no longer aligned; or the spread of metal debris from the metal femoral head and metal acetabulum cup rubbing and rotating against each other. For these reasons, revisions surgery was necessary to remove the faulty Defective Devices from Plaintiff Joyce Ulrich's right hip.

55. All of the injuries and complications suffered by Plaintiff Joyce Ulrich were caused by the defective design, manufacturing defect, warnings, construction, and/or unreasonably dangerous character of the Defective Devices that were implanted in her. Had Defendants not concealed the known defects, the early failure rate, the known complications, and the unreasonable risk associated with the use of the Defective Devices, Plaintiff Joyce Ulrich and Plaintiff's healthcare providers would not have consented to the Defective Devices being used in Plaintiff's total right hip arthroplasty surgery. Had Plaintiff not been implanted with the Defective Devices, Plaintiff would not have experienced the failure of her hip system, requiring her to have a premature revision surgery.

56. The Defective Devices reached Plaintiff without substantial change in their condition when they left the possession of Defendants and were used in the manner for which they were intended. The Defective Devices were defective and unreasonably dangerous when Defendants placed them into the stream of commerce.

57. Defendants continue to misrepresent the Defective Devices as high-quality, safe and effective hip replacement products in their marketing and promotional materials.

This is despite the fact that Defendants have known for years that the Defective Devices pose a danger to patients that have it implanted.

58. As a result, Defendants continue to sell the Defective Devices to doctors who implant them in countless numbers of patients with an unreasonably high percentage of those patients being forced to endure serious injury from trunnion, osteolysis, bone loss, metallosis, pseudotumors, and biologic toxicity, among other complications. These patients are reporting severe pain and discomfort and the need for one or more complicated revision surgeries resulting in life-long health problems.

59. As a directl result of Defendants placing the Defective Devices into the stream of commerce, Plaintiff Joyce Ulrich has suffered and continues to suffer both injuries and damages, including but not limited to: past, present, and future physical and mental pain and suffering; past, present, and future medical, hospital, rehabilitative, and pharmaceutical expenses, and other related damages.

60. Plaintiff Joyce Ulrich was unaware of any causal link between the injuries she has suffered and any wrongdoing on the part of Defendants due to the faulty and defective nature of the Defective Devices, due in part to the failures of Defendants to properly warn her and her physicians about the Defective Devices and their faulty nature. In and around August 2016, Plaintiff Joyce Ulrich first became aware of a causal link when Defendants released an urgent recall notice. Plaintiff was unable to make an earlier discovery of a causal link despite reasonable diligence because of Defendants' failure to properly warn her and her physicians about Defendants' Defective Devices, their faulty nature, and Defendants' failure to issue a timely recall or take any other proactive action with respect to the injuries being caused to patients that have been implanted with the Defective Devices.

61. Plaintiff exercised reasonable diligence in investigating potential causes of her injury by discussing her injuries with healthcare providers. None of Plaintiff's conversations with her healthcare providers gave Plaintiff any reason to suspect, or reasonably should have given Plaintiff a reason to suspect, that the hip implant was

defective. Under the facts of this case, Plaintiff's suit was filed well within the applicable statute of limitations period.

62. Defendants fraudulently concealed relevant facts from Plaintiff and the medical community about the true risks of harm associated with its Defective Devices and fraudulently advised the medical community that instances of corrosion were non-existent and/or extremely rare. As a result, Plaintiff, Plaintiff's physicians, nurses, and/or healthcare staff were deprived of vital information essential to the pursuit of these claims, without any fault or lack of diligence on their part.

63. At all times relevant, Plaintiff, Plaintiff's physicians, nurses, and/or healthcare staff relied on Defendants' misrepresentations and omissions and therefore could not reasonably have known or become aware of facts that would lead a reasonable, prudent person to make an inquiry to discover Defendants' tortious conduct. Plaintiff diligently filed suit once she discovered the actual facts that would lead a reasonable, prudent person to make an inquiry to discover Defendants' tortious conduct. Defendants' misconduct and fraudulent concealment of relevant facts, as described above, tolls any relevant statute of limitations. Regardless, Plaintiff's suit is filed well within the applicable statutory limitations period.

64. Defendants are and were under a continuing duty to monitor and disclose the true character, quality, and nature of its Defective Devices. Because of Defendants' misconduct and fraudulent concealment of the true character, quality, and nature of its devices, Defendants are estopped from relying on any statute of limitations defense.

V. CAUSES OF ACTION

FIRST CAUSE OF ACTION
NEGLIGENCE

65. Plaintiff incorporates, by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

66. Defendants designed, manufactured, marketed, distributed, and/or advertised both the Accolade Hip Stem and LFIT Femoral head to physicians and consumers.

67. Defendants had a duty to exercise reasonable care in the design, manufacture, testing, marketing, and distribution into the stream of commerce of the Defective Devices, including a duty to insure that the Defective Devices did not pose a significant risk of adverse events.

68. Defendants failed to exercise reasonable care in designing, manufacturing, testing, marketing, and distributing the Defective Devices into the stream of commerce. Defendants knew or should have known that the Defective Devices could fail early in patients, therefore giving rise to pain and suffering, debilitation, and the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery, and therefore were not safe for use by Plaintiff Joyce Ulrich.

69. Despite the fact that Defendants knew or should have known that the Defective Devices could fail early in patients, therefore giving rise to pain and suffering, debilitation, and the need for revision surgeries to replace the device with the attendant risks of complications and death from such further surgeries, Defendants continued to market the Defective Devices as a safe and effective hip replacement system.

70. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered significant damages, including but not limited to physical injury, economic loss, pain and suffering, and the need for further surgeries to replace the faulty devices, and will continue to suffer such damages in the future.

71. In performing the foregoing acts and omissions, Defendants acted despicably, fraudulently, and with malice and oppression so as to justify an award of punitive and exemplary damages.

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SECOND CAUSE OF ACTION
STRICT PRODUCTS LIABILITY (MANUFACTURING DEFECT)

72. Plaintiff incorporates, by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

73. Defendants designed, manufactured, tested, marketed, and distributed into the stream of commerce the Defective Devices.

74. The Defective Devices that were surgically implanted in Plaintiff Joyce Ulrich were defective in their manufacture when the devices left the hands of Defendants in that they deviated from product specifications, posing a serious risk that they could fail early in patients therefore giving rise to physical injury, pain and suffering, deliberation, and the need for revision surgeries to replace the devices with the attendant risks of complications and death from such further surgeries.

75. As a direct and proximate result of Defendants' placement of the Defective Devices into the stream of commerce, Plaintiff has suffered significant damages, including but not limited to physical injury, economic loss, pain and suffering, and the need for further surgery to replace the faulty devices, and will continue to suffer such damages in the future.

THIRD CAUSE OF ACTION
STRICT PRODUCTS LIABILITY (DESIGN DEFECT)

76. Plaintiff incorporates, by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

77. Defendants designed, manufactured, tested, marketed, and distributed into the stream of commerce the Defective Devices.

78. The Defective Devices that were surgically implanted in Plaintiff Joyce Ulrich were defective in their design when they left the hands of Defendants in that the design was flawed, thereby posing a serious risk that the devices could fail early in

patients, giving rise to physical injury, pain and suffering, debilitation, and the need for revision surgeries to replace the devices with the attendant risks of complications and death from such further surgeries.

79. As a direct and proximate result of Defendants' placement of the Defective Devices into the stream of commerce, Plaintiff has suffered significant damages, including but not limited to physical injury, economic loss, pain and suffering, and the need for further surgeries to replace the faulty devices, and will continue to suffer such damages in the future.

FOURTH CAUSE OF ACTION

STRICT PRODUCTS LIABILITY (INADEQUATE WARNING)

80. Plaintiff incorporates, by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

81. Defendants designed, manufactured, tested, marketed, and distributed into the stream of commerce the Defective Devices.

82. The Defective Devices that were surgically implanted in Plaintiff Joyce Ulrich were defective due to inadequate warning because Defendants knew or should have known that the Defective Devices could fail early in patients, therefore giving rise to physical injury, pain and suffering, debilitation, and the need for revision surgeries to replace the devices with the attendant risks of complications and death from such further surgeries, but failed to give consumers adequate warning of such risk. Further, the Defective Devices placed into the stream of commerce by Defendants were surgically implanted in a manner reasonably anticipated by Defendants.

83. As a direct and proximate result of Defendants' placement of the Defective Devices into the stream of commerce, Plaintiff has suffered significant damages, including but not limited to physical injury, economic loss, pain and suffering, and the need for further surgeries to replace the faulty devices, and will continue to suffer such damages in the future.

FIFTH CAUSE OF ACTION
STRICT PRODUCTS LIABILITY (FAILURE TO CONFORM TO REPRESENTATIONS)

84. Plaintiff incorporates, by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

85. Defendants designed, manufactured, tested, marketed, and distributed into the stream of commerce the Defective Devices.

86. Defendants made representations to consumers regarding the character or quality of the Defective Devices, including, but not limited to, statements that Stryker hip implant devices were safe and effective hip replacement systems.

87. Defendants' Accolade Hip Stem and LFIT Femoral Head products were placed into the stream of commerce and were defective when they left the hands of Defendants and they did not conform to Defendants' representations.

88. Plaintiff Joyce Ulrich justifiably relied upon Defendants' representations regarding the Defective Devices.

89. As a direct and proximate result of Defendants' placement of the Defective Devices into the stream of commerce, Plaintiff has suffered significant damages, including but not limited to physical injury, economic loss, pain and suffering, and the need for further surgeries to replace the faulty devices, and will continue to suffer such damages in the future.

SIXTH CAUSE OF ACTION
STRICT PRODUCTS LIABILITY (FAILURE TO ADEQUATELY TEST)

90. Plaintiff incorporates, by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

91. Defendants designed, manufactured, tested, marketed, and distributed into the stream of commerce the Defective Devices.

92. Defendants advised consumers that the Defective Devices were safe and effective hip replacement devices. Defendants failed to adequately test the Defective Devices to ensure they would not fail early, thereby giving rise to unnecessary physical injury, pain and suffering, debilitation, and the need for revision surgeries to replace the devices with the attendant risks of complications and death from such further surgery.

93. Had Defendants adequately tested the Defective Devices and disclosed the results of those tests to the public, Plaintiff Joyce Ulrich would not have elected to have the Defective Devices surgically implanted.

94. As a direct and proximate result of Defendants' placement of the Defective Devices into the stream of commerce, Plaintiff has suffered significant damages, including but not limited to physical injury, economic loss, pain and suffering, and the need for further surgeries to replace the faulty devices, and will continue to suffer such damages in the future.

SEVENTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY

95. Plaintiff incorporates, by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

96. Defendants designed, manufactured, tested, marketed, and distributed into the stream of commerce the Stryker hip implant devices.

97. Defendants expressly warranted that the Stryker hip implant devices were safe and effective hip replacement systems.

98. The Stryker hip implant devices placed into the stream of commerce by Defendants did not conform to these express representations because they failed early, thereby giving rise to unnecessary physical injury, pain and suffering, debilitation, and the need for revision surgeries to replace the devices with the attendant risks of complications and death from such further surgeries.

99. As a direct and proximate result of Defendants' placement of the defective Stryker hip implant device into the stream of commerce, Plaintiff has suffered significant damages, including but not limited to physical injury, economic loss, pain and suffering, and the need for further surgeries to replace the faulty devices, and will continue to suffer such damages in the future.

EIGHTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

100. Plaintiff incorporates, by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

101. Defendants designed, manufactured, tested, marketed, and distributed into the stream of commerce the Defective Devices.

102. At the time Defendants designed, manufactured, tested, marketed, and distributed into the stream of commerce the Stryker hip implant devices, Defendants knew the use for which the Defective Devices were intended, and impliedly warranted the Stryker hip implant devices to be of merchantable quality and safe for such use.

103. Plaintiff Joyce Ulrich reasonably relied upon the skill and judgment of Defendants as to whether the Defective Devices were of merchantable quality and safe for their intended use.

104. Contrary to Defendants' implied warranties, the Defective Devices were not of merchantable quality or safe for their intended use, because the Defective Devices implanted in Plaintiff Joyce Ulrich were unreasonably dangerous as described above.

105. As a direct and proximate result of Defendants' placement of the defective Stryker hip implant device into the stream of commerce, Plaintiff has suffered significant damages, including but not limited to physical injury, economic loss, pain and suffering, and the need for further surgeries to replace the faulty devices, and will continue to suffer such damages in the future.

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NINTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

106. Plaintiff incorporates, by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

107. Defendants supplied false information to the public, to Plaintiff and to her physicians regarding the high-quality, safety and effectiveness of the Defective Devices. Defendants provided this false information to induce the public, Plaintiff, and her physicians to purchase and implant the Defective Devices.

108. Defendants knew or should have known that the information they supplied regarding the purported high-quality, safety and effectiveness of the implant was provided to induce Plaintiff and her physicians to purchase and use the Defective Devices and was false.

109. Defendants were negligent in obtaining or communicating false information regarding the purported high-quality, safety and effectiveness of the Defective Devices.

110. Plaintiff and her physicians relied on false information supplied by Defendants to their detriment by causing the Defective Devices to be purchased and implanted in Plaintiff.

111. Plaintiff and her physicians were justified in their reliance on false information supplied by Defendants regarding the purported high-quality, safety and effectiveness of the Defective Devices.

112. As a direct and proximate result of Defendants' placement of the defective Stryker hip implant device into the stream of commerce, Plaintiff has suffered significant damages, including but not limited to physical injury, economic loss, pain and suffering, and the need for further surgeries to replace the faulty devices, and will continue to suffer such damages in the future.

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TENTH CAUSE OF ACTION
FRAUD

113. Plaintiff incorporates, by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

114. Defendants made representations to Plaintiff and her physicians that their Stryker device was a high-quality, safe and effective hip replacement system.

115. Before they marketed the Defective Devices that were implanted in Plaintiff, Defendants knew or should have known of the unreasonable dangers and serious health risks that such a total hip replacement system posed to patients like Plaintiff.

116. As specifically described in detail above, Defendants knew that the Defective Devices subjected patients to early failure, painful and harmful physical reaction to toxic metallic particles and ions, death of tissue, bone loss, dislocations, and the need for explants and revision surgery.

117. Defendants' representations to Plaintiff and her physicians that their Defective Devices are high-quality, safe and effective were false.

118. Defendants concealed their knowledge of the unreasonable risks and dangers associated with the use of the Stryker device to induce Plaintiff and many thousands of others to purchase the system for surgical implantation in their bodies.

119. Neither Plaintiff nor her physicians knew of the falsity of Defendants' statements regarding the Stryker device.

120. Plaintiff and her physicians relied upon and accepted as truthful Defendants' representations regarding the Stryker device.

121. As a direct and proximate result of Defendants' placement of the defective Stryker hip implant device into the stream of commerce, Plaintiff has suffered significant damages, including but not limited to physical injury, economic loss, pain and suffering, and the need for further surgeries to replace the faulty devices, and will continue to suffer such damages in the future.

ELEVENTH CAUSE OF ACTION
PUNITIVE DAMAGES

122. Plaintiff incorporates, by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

123. Defendants' conduct in marketing, advertising, promoting, manufacturing, distributing, and/or selling the Accolade Hip Stem and LFIT Femoral Heads constitutes gross negligence, reckless, and intentional misconduct as to warrant the award of punitive damages to punish Defendants and to deter Defendants and others from like conduct in the future.

124. In performing the foregoing acts and omissions, Defendants acted despicably, fraudulently, and with malice and oppression as to justify an award of punitive and exemplary damages.

VI. PRAYER FOR RELIEF

Wherefore, Plaintiff Joyce Ulrich prays for the following relief:

A. Judgement in favor of Plaintiff and against all Defendants, for damages in such amounts as may be proven at trial;

B. Award all actual, general, special, incidental, statutory, punitive, and consequential damages and restitution to which Plaintiff is entitled;

C. Compensation for both economic and non-economic losses, including but not limited to medical expenses, loss of earnings, loss of consortium, disfigurement, pain and suffering, mental anguish, and emotional distress, in such amounts as may be proven at trial;

D. Punitive and/or exemplary damages in such amounts as may be proven at trial;

E. Pre-judgement and post-judgement interest on such monetary relief;

F. Reasonable attorneys' fees and costs; and

G. Any and all further relief, both legal and equitable, that the Court may deem just and proper.

VII. DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all issues so triable.

DATED: June 5, 2017

McCune Wright Arevalo, LLP

BY: */s/ Kristy M. Arevalo*
Kristy M. Arevalo
Tuan Q. Nguyen