UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS
DIVISION

CORY PAUL SMITS Plaintiff, v. DEPUY ORTHOPAEDICS, INC.; DEPUY PRODUCTS, INC.; JOHNSON & JOHNSON SERVICES, INC.; and JOHNSON & JOHNSON, INC., Defendants.	MDL Docket No. 3:11-MD-2244-K Civil Action No. _____

COMPLAINT FOR DAMAGES

Plaintiff CORY PAUL SMITS, hereafter referred to as "Plaintiff," alleges against DePuy Orthopaedics, Inc., Johnson & Johnson Services, Inc. and Johnson & Johnson, Inc. ("Defendants"), the following:

I. SUMMARY OF ACTION

1. Defendants manufactured the Pinnacle Metal-on-Metal Hip Implant System ("Pinnacle Device"), and launched it in 2001. The Pinnacle Device was designed, developed, and sold for human hip joints damaged or diseased due to fracture, osteoarthritis, rheumatoid arthritis, avascular necrosis, and/or other degenerative conditions. Defendants marketed the Pinnacle Device as having significant advantages over other hip devices and hip replacement systems. Defendants marketed and described the Pinnacle Device as "[u]niquely designed to meet the demands of active patients like you - and help reduce pain" and advertised it with

pictures of a young woman trying on sneakers in an athletic shoe store. Defendants advertised the Pinnacle Device as a superior device featuring TrueGlide technology, allowing the body to create a thin film of lubrication between surfaces, which enables "a more fluid range of natural motion."

2. Defendants also advertised and sold the Pinnacle Device as the best surgical option that "[r]ecreates the natural ball-and-socket joint of your hip, increasing stability and range of motion."

3. Defendants have stated in promotional materials that "99.9% of Pinnacle Hip components are still in use today."

4. Defendants are or should be aware that the Pinnacle Device may result in metallosis, biologic toxicity, and is susceptible to loosening and/or dislocation; all of which may contribute to a high failure rate and lead to revision surgery to explant the Pinnacle Device. Plaintiff further alleges that use of the Pinnacle Device results in an unsafe release of toxic metal ions into a hip implant recipient's tissue and bloodstream. Plaintiff further alleges that Defendants are aware that metal particles from the Pinnacle Device result in metallosis, tissue death, bone resorption, and development of cysts.

5. Particulate debris from the Pinnacle Device causes inflammation, pain, tissue and bone loss, and other related diseases.

6. Defendants are aware that certain Pinnacle Device recipients have cobalt and chromium levels that exceed acceptable safety standards.

II. PARTIES, JURISDICTION AND VENUE

7. Plaintiff Cory Paul Smits is a resident of Mishicot, County of Manitowoc, state of Wisconsin.

8. Defendant DePuy Orthopaedics, Inc. is, and at all times relevant to this Complaint was, an Indiana corporation with its principal place of business at 700 Orthopaedic Drive, Warsaw, Indiana 46581. Defendant DePuy Orthopaedics, Inc. is, and was at all times relevant herein, doing business in and/or directed its business activities at the State of Texas.

9. At all relevant times to this Complaint, DePuy Orthopaedics, Inc. designed, manufactured, tested, marketed, distributed and sold the metal-on-metal Pinnacle Device, either directly or indirectly, to customers throughout the United States, including Plaintiff, in the State of Texas.

10. Defendant DePuy Products, Inc. is, and at all times relevant to this Complaint was, an Indiana corporation with its principal place of business at 700 Orthopaedic Drive, Warsaw, Indiana 46581, and is a wholly owned subsidiary of DePuy Orthopaedics. Defendant DePuy Products, Inc. is, and was at all times relevant herein, doing business in and/or directed its business activities at the State of Texas.

11. At all relevant times to this Complaint, DePuy Products, Inc. designed, manufactured, tested, marketed, distributed and sold the metal-on-metal Pinnacle Device, either directly or indirectly, to customers throughout the United States, including Plaintiff, in the State of Texas.

12. Defendant Johnson & Johnson Services, Inc. is, and at all times relevant to this Complaint was, a New Jersey corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933, and was the parent company of DePuy Orthopaedics, Inc. Defendant Johnson & Johnson Services, Inc. is, and was at all times relevant herein, doing business in and/or directed its business activities at the State of Texas.

13. At all relevant times to this Complaint, Defendant Johnson & Johnson Services, Inc., as the parent company of DePuy Orthopaedics, Inc. designed, manufactured, tested, advertised, marketed, distributed and sold the Johnson & Johnson/DePuy Pinnacle Device

("Pinnacle Device"), either directly or indirectly, to customers throughout the United States, including Plaintiff, in the State of Texas.

14. Defendant Johnson & Johnson, Inc. is, and at all times relevant to this Complaint was, a New Jersey corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933, and was the parent company of DePuy Orthopaedics, Inc. Defendant Johnson & Johnson, Inc. is, and was at all times relevant herein, doing business in and/or directed its business activities at the State of Texas.

15. At all relevant times to this Complaint, Defendant Johnson & Johnson, Inc., as the parent company of DePuy Orthopaedics, Inc., designed, manufactured, tested, advertised, marketed, distributed and sold the metal-on-metal Pinnacle Device, either directly or indirectly, to customers throughout the United States, including Plaintiff, in the State of Texas.

16. At all times relevant herein, Defendants were the agents of each other, and in doing the things alleged herein, each Defendant was acting within the course and scope of its agency and was subject to and under the supervision of its co-Defendants.

17. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C.

§ 1332(a) because Plaintiff and Defendants are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

18. Venue of this case is appropriate in the United States District Court for the Eastern District of Texas. Plaintiff states that but for the Order permitting direct filing into the Northern District of Texas pursuant to Case Management Order No. 1, filed on June 29, 2011, permitting direct filing into this Court, Plaintiff would have filed in the United States District Court for the Eastern District of Texas. Therefore, Plaintiff respectfully requests that at the time of transfer of this action back to the trial court for further proceedings that this case be transferred to the above referenced District Court.

IV. FACTUAL ALLEGATIONS

A. The Pinnacle Device

19. The Pinnacle Device was developed to compete with other orthopedic devices that reconstruct or replace diseased human hip joints in patients with conditions such as osteoarthritis, rheumatoid arthritis, avascular necrosis (AVN), fracture, and other degenerative conditions. The hip joint connects the thigh (femur) bone of a patient's leg to the patient's pelvis. The hip joint is like 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.

20. The Pinnacle Device is made up of four components: the metal femoral stem is inserted inside the femur bone, the metal femoral head (or ball) connects to the top of the stem and then makes contact with a liner that is attached to the interior portion of the metal acetabulum shell (socket). The acetabulum shell is comprised of titanium metal. A cobalt- chromium metal liner is then placed on the inside of the acetabulum shell. The metal femoral head rotates within the metal liner. The cobalt-chromium metal liner is branded as the "Ultamet" and also known as the "Pinnacle Metal Insert." The Pinnacle Device with an Ultamet liner is a "metal-on-metal" device due to the fact that both articulating surfaces - the femoral head (ball) and acetabulum liner (socket) - are comprised of cobalt-chromium metal.

B. 510(k) Notice

21. The Pinnacle Device is a Class III medical device. Class III devices are those that operate to sustain human life, are of substantial importance in preventing impairment of human health, or pose potentially unreasonable risks to patients.

22. The Medical Device Amendments to the Food, Drug and Cosmetics Act of 1938 ("MDA"), in theory, require Class III medical devices, including the Pinnacle Device, to undergo premarket approval by the FDA, a process which obligates the manufacturer to design and implement a clinical investigation and to submit the results of that investigation to the FDA.

23. 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.

24. A medical device on the market prior to the effective date of the MDA - a so-called "grandfathered" device - was not required to undergo premarket 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 new device's substantial equivalence to a pre-MDA predicate device. The FDA may then approve the new device for sale in the United States.

25. Rather than being approved for use by the FDA pursuant to the rigorous premarket approval process, the Pinnacle Device was certified to be sold on the basis of Defendants' claim that, under section 510(k) of the MDA, it was "substantially equivalent" to another older metal-on-metal hip implant device that Defendants sold and implanted prior to the enactment of the MDA in 1976.

C. Inadequate Clinical Testing

26. Had Defendants conducted clinical trials of the Pinnacle Device before it was first released on the market in the early 2000's, they would have discovered at that time what they ultimately learned in and around 2007 - that the Pinnacle Device results in a high percentage of patients developing metallosis, biologic toxicity and loosening of their implant – failure of the device requiring revision surgery.

27. In other words, implantation of the Pinnacle Device results 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 and corrosion.

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

29. Many recipients of the Pinnacle Device are suffering from elevated levels of chromium and cobalt. Further, Defendants are aware that certain recipients of the Pinnacle Device have significantly elevated levels of chromium and cobalt in amounts many times higher than acceptable or recommended safety levels.

30. A number of governmental regulatory agencies have recognized the problems that are caused by metal-on-metal implants such as the ASR and Pinnacle Device. For instance, The Medicines and Healthcare Products Regulatory Agency ("MHRA") in Britain investigated

Defendants' metal-on-metal total hip replacement system after receiving widespread reports of soft tissue reactions and tumor growth in thousands of patients who had received these implants. MHRA has required physicians to establish a system to closely monitor patients known to have metal-on-metal hips by monitoring the cobalt and chromium ion levels in their blood and to evaluate them for related soft tissue reactions.

31. Similarly, the Alaska Department of Health issued a bulletin warning of the toxicity of Defendants' metal-on-metal total hip replacement systems. The State of Alaska, like the MHRA, identified the need for close medical monitoring, surveillance and treatment of all patients who had received these and similar metal-on-metal implants.

32. Of note, the designer of this device stated publicly at the American Academy of Orthopaedic Surgeons ("AAOS") Annual Meeting that there is no indication for the use of metal- on-metal total hip replacement devices.

D. Plaintiff's Injuries

33. Plaintiff underwent a left-sided total hip arthroplasty on February 29, 2016 during which a DePuy Pinnacle hip implant device was implanted into his body by Dr. Kirk D. Dimitris, M.D. at Holy Family Medical Center in Manitowoc, Wisconsin.

34. Due to the defective DePuy Pinnacle hip implant Plaintiff received, he has suffered significant discomfort, pain, stiffness, and loss of motion and he has been or is at risk for, as well as suffered damage to his hip joint manifesting as implant loosening, soft tissue damage, muscle damage, and other injuries from the Pinnacle implant, requiring multiple revision surgeries.

35. Due to the defective DePuy hip implant, Plaintiff was required to undergo a left hip revision surgery on March 1, 2016, performed by Dr. Thomas J. Sylvester, M.D. at Holy Family Medical Center in Manitowoc, Wisconsin.

36. Due to the defective DePuy hip implant, Plaintiff was required to undergo a

second left hip revision surgery on March 8, 2016, performed by Dr. Michael P. Kennedy, M.D. at Holy Family Medical Center in Manitowoc, Wisconsin.

37. Due to the defective DePuy hip implant, Plaintiff was required to undergo a third left hip revision surgery on April 6, 2016, performed by Dr. Kirk D. Dimitris, M.D. at Holy Family Medical Center in Manitowoc, Wisconsin.

38. Due to the defective DePuy hip implant, Plaintiff was required to undergo a fourth left hip revision surgery on November 16, 2016, performed by Dr. Kirk D. Dimitris, M.D. at Holy Family Medical Center in Manitowoc, Wisconsin.

39. Due to the defective DePuy hip implant, Plaintiff was required to undergo a fifth left hip revision surgery on December 27, 2016, performed by Dr. Kirk D. Dimitris, M.D. at Holy Family Medical Center in Manitowoc, Wisconsin.

40. Several studies have found that a revision surgery causes a much higher risk of dislocation compared with an original hip replacement surgery. In one study conducted by Charlotte Phillips and her colleagues at Brigham and Women's Hospital in Boston, 14.4% of patients who underwent a revision surgery suffered from a dislocation compared with 3.9% of patients who underwent an original hip replacement surgery. In other words, hip replacement patients who undergo a revision surgery are almost four times more likely to suffer from a hip dislocation than those who have not. (Phillips, CV, et al., Incidence Rates of Dislocation, Pulmonary Embolism, and Deep Infection During the First Six Months After Elective Total Hip Replacement. *American Journal of Bone and Joint Surgery* 2003; 85:20-26.)

41. As a direct and proximate cause of the defective Pinnacle Device that was implanted into Plaintiff, and the Defendants' wrongful conduct, Plaintiff has undergone and will continue to undergo medical treatment, and has sustained and continues to suffer economic damages (including medical expenses), injury, pain, suffering and emotional distress.

42. All of the injuries and complications suffered by Plaintiff related to the Pinnacle

Device that was implanted into Plaintiff were caused by the defective design, warnings, construction and unreasonably dangerous character of the Pinnacle Device. Had Defendants not concealed the known defects, the early failure rate, the known complications and the unreasonable risks associated with the use of the Pinnacle Device, Plaintiff would not have consented to the Pinnacle Device being used in his total hip arthroplasty.

CAUSES OF ACTION
FIRST CAUSE OF ACTION
NEGLIGENCE
(Against All Defendants)

43. Plaintiff incorporates by reference, as if fully set forth herein, each and every factual allegation set forth in the preceding paragraphs and further allege as follows:

44. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control, and/or distribution of the Pinnacle Device into the stream of commerce, including a duty to assure that the device would not cause those who had it surgically implanted to suffer adverse harmful effects from it.

45. Defendants failed to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control, and/or distribution of the Pinnacle Device into interstate commerce in that Defendants knew or should have known that those individuals that had the device surgically implanted were at risk for suffering harmful effects from it, including, but not limited to, partial or complete loss of mobility, loss of range of motion, as well as other personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for a revision

surgery to replace the device with the attendant risks of complications and death from such further surgery.

46. The negligence of Defendants, their agents, servants, and/or employees, included, but was not limited to, the following acts and/or omissions:

a. Negligently designing the Pinnacle Device in a manner which was dangerous to those individuals who have the device surgically implanted;

b. Negligently designing the Pinnacle Device in a manner which it was susceptible to the loosening of implant which can result in the early failure of the device and required surgery to explant the device;

c. Designing, manufacturing, producing, creating, and/or promoting the Pinnacle Device without adequately, sufficiently, or thoroughly testing it;

d. Not conducting sufficient testing programs to determine whether the aforesaid Pinnacle Device was safe for use;

e. Defendants herein knew or should have known that the Pinnacle Device was unsafe and unfit for use by reason of the dangers to its users;

f. Selling the Pinnacle Device without making proper and sufficient tests to determine the dangers to its users;

g. Negligently failing to adequately and correctly warn Plaintiff or his physicians, hospitals and/or healthcare providers of the dangers of the Pinnacle Device;

h. Negligently failing to recall the dangerous and defective Pinnacle Device at the earliest date that it became known that the Pinnacle Device was, in fact, dangerous and defective;

i. Failing to provide adequate instructions regarding safety precautions to be observed by surgeons who would reasonably and foreseeably come into contact with, and more particularly, implant the Pinnacle Device into their patients;

j. Negligently advertising and recommending the use of the Pinnacle Device despite those Defendants knew or should have known of its dangerous propensities;

k. Negligently representing that the Pinnacle Device offered was safe for use for its intended purpose, when, in fact, it was unsafe;

l. Negligently manufacturing the Pinnacle Device in a manner which was dangerous to those individuals who had it implanted;

m. Negligently producing the Pinnacle Device in a manner which was dangerous to those individuals who had it implanted;

n. Negligently assembling the Pinnacle Device in a manner which was dangerous to those individuals who had it implanted;

o. Defendants under-reported, underestimated and downplayed the serious danger of the Pinnacle Device.

47. Defendants were negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of the Pinnacle Device in that they:

a. Failed to use due care in designing and manufacturing the Pinnacle Device so as to avoid the aforementioned risks to individuals that had the devices surgically implanted;

b. Failed to accompany their product with proper warnings;

c. Failed to accompany their product with proper instructions for use;

d. Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of the Pinnacle Device; and

e. Were otherwise careless and/or negligent.

48. Despite the fact that Defendants knew or should have known that the Pinnacle Device caused harm to individuals that had the device surgically implanted, Defendants continued to market, manufacture, distribute and/or sell the Pinnacle Device.

49. Defendants knew or should have known that consumers such as Plaintiff would suffer foreseeable injury, and/or be at increased risk of suffering injury as a result of Defendants' failure to exercise ordinary care.

50. Defendant's negligence was the proximate cause of Plaintiff's physical, mental and emotional injuries and harm, and economic loss which they have suffered and will continue to suffer.

51. By reason of foregoing, Plaintiff has experienced and will continue to experience harms, losses, and damages, including, but not limited to, partial or complete loss of mobility, loss of range of motion, as well as other personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for continuing medical treatment and the necessity to undergo revision surgery, subjecting himself to the attendant risks of complications and death from such further surgery and post-operative complications.

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

SECOND CAUSE OF ACTION
STRICT PRODUCTS LIABILITY (DESIGN DEFECT)
(Against All Defendants)

53. Plaintiff incorporates by reference, as if fully set forth herein, each and every factual allegation set forth in the preceding paragraphs and further allege as follows:

54. At all times relevant to this Complaint, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed the Pinnacle

Device that was surgically implanted in Plaintiff.

55. At all times relevant to this Complaint, the Pinnacle Device designed, researched, manufactured, tested, advertising, promoted, marketed, sold and/or distributed by Defendants was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users such as Plaintiff that had the device surgically implanted.

56. At all times relevant to this Complaint, the Pinnacle Device designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed by Defendants was in an unsafe, defective, and inherently dangerous condition at the time it left Defendants' possession.

57. At all times relevant to this Complaint, the Pinnacle Device was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was designed, produced, manufactured, sold, distributed, and marketed by Defendants.

58. At all times relevant to this Complaint, the Pinnacle Device's unsafe, defective, and inherently dangerous condition was a cause of injury to Plaintiff.

59. At all times relevant to this Complaint, the Pinnacle Device failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.

60. Plaintiff's injuries resulted from use of the Pinnacle Device that was both intended and reasonably foreseeable by Defendants.

61. At all times relevant to this Complaint, the Pinnacle Device posed a risk of danger inherent in the design which outweighed the benefits of the design.

62. At all times relevant to this Complaint, the Pinnacle Device was defective and unsafe, and Defendants knew or had reason to know that said product was defective and unsafe, especially when used in the form and manner as provided by Defendants.

63. Defendants knew, or should have known, that at all times herein mentioned the Pinnacle Device was in a defective condition, and was and is, inherently dangerous and unsafe.

64. At all times relevant to this Complaint, the Pinnacle Device implanted into Plaintiff was being used for the purpose intended and in a manner normally intended, namely for use as a hip replacement device.

65. Defendants, with this knowledge, voluntarily designed their Pinnacle Device in a dangerous condition for use by the public and, in particular Plaintiff.

66. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use.

67. Defendants designed, manufactured, advertised, promoted, marketed, sold and distributed a defective product which, when used in its intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers and to, in particular, and Defendants are therefore strictly liable for the injuries sustained by Plaintiff.

68. As a direct and proximate result of Defendants' placement of the defective Pinnacle Device into the stream of commerce, Plaintiff has experienced and will experience harms, including, but not limited to, partial or complete loss of mobility, loss of range of motion, as well as other personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for continuing medical treatment and the necessity to undergo revision surgery, subjecting himself to the attendant risks of complications and death from such further surgery and post-operative complications.

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

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

70. Plaintiff incorporates by reference, as if fully set forth herein, each and every factual allegation set forth in the preceding paragraphs and further allege as follows:

71. Defendants designed, manufactured, marketed, and placed into the stream of commerce the Pinnacle Device.

72. In the course of business, Defendants designed, manufactured and sold the Pinnacle Device to Plaintiff for hip replacement surgery.

73. At the time of the design, manufacture and sale of the Pinnacle Device, and more specifically at the time Plaintiff received the Pinnacle Device, it was defective and unreasonably dangerous when put to its intended and reasonably anticipated use. Further, the Pinnacle Device was not accompanied by proper warnings regarding significant adverse consequences associated with the Pinnacle Device.

74. Defendants failed to provide any warnings, labels or instructions for the Pinnacle Device's dangerous propensities that were known or reasonably scientifically knowable at the time of distribution. The reasonably foreseeable use of the product involved significant dangers not readily obvious to the ordinary user of the product.

75. Defendants failed to warn of the known or knowable injuries associated with the malfunction of the Pinnacle Device which would require subsequent surgical procedures and result in losses, damages and injuries.

76. The dangerous and defective conditions in the Pinnacle Device existed at the time it was delivered by the manufacturer to the distributor. At the time Plaintiff had his right hip replacement surgery, the Pinnacle Device was in the same condition as when manufactured, distributed and sold.

77. Neither Plaintiff nor Plaintiff's implanting physician knew or had reason to know, at the time of use, or at any time prior thereto, of the existence of the defect(s) within the Pinnacle Device.

78. As a direct and proximate result of Defendants' placement of the defective Pinnacle Device into the stream of commerce, Plaintiff has experienced and will experience harms, losses and damages, including, but not limited to, partial or complete loss of mobility, loss of range of motion, ~~loss of consortium~~, as well as other personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for continuing medical treatment and the necessity to undergo revision surgery, subjecting himself to the attendant risks of complications and death from such further surgery and post-operative complications.

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

FOURTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY
(Against All Defendants)

80. Plaintiff incorporates by reference, as if fully set forth herein, each and every factual allegation set forth in the proceeding paragraphs and further allege as follows:

81. Defendants designed, manufactured, marketed and distributed into the stream of commerce the Pinnacle Device.

82. Plaintiff currently is not in possession of documents relating to all representations, warnings and/or communications made by Defendants in this action. Plaintiff reserves the right to present evidence in support of the claim which is not presently in their possession, but which is not necessarily limited to: instruction for use manuals; all written material or information provided on and/or within any and all packaging associated with Plaintiff's device; manufacturer's labels, package inserts; Adverse Event Reports; clinical trial data; medical literature; medical research findings and opinions; medical publications; advertisements; sales, prescription and adverse event report databases; and communications from Defendants in this action, including said Defendants' employees, officers, directors, agents, representatives, contractors and business associates, to the public, medical community, Plaintiff's prescribing physician and Plaintiff. Plaintiff is not in possession of documents as described herein, however, upon information, knowledge and belief, the documents, instruments and/or evidence stated above are in the possession of Defendants to this action.

83. Moreover, Defendants expressly warranted the Pinnacle Device was a safe and effective hip replacement system, that it was "[u]niquely designed to meet the demands of active patients like you - and help reduce pain", that it was a superior device featuring TrueGlide technology, allowing the body to create a thin film of lubrication between surfaces, which enables "a more fluid range of natural motion", that it was the best surgical option that "[r]ecreates the natural ball-and-socket joint of your hip, increasing stability and range of motion", and that "99.9% of Pinnacle Hip components are still in use today."

84. The Pinnacle Device 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 surgery to replace the device with the attendant risks of complications and death from such further surgery.

85. As a direct and proximate result of Defendants' breach of express warranties regarding the safety and effectiveness of the Pinnacle Device, Plaintiff has experienced and will experience harms, losses and damages including, but not limited to, partial or complete loss of mobility, loss of range of motion, as well as other personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for continuing medical treatment and the necessity to undergo revision surgery, subjecting himself to the attendant risks of complications and death from such further surgery and post-operative complications.

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

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

87. Plaintiff incorporates by reference, as if fully set forth herein, each and every factual allegation set forth in the proceeding paragraphs and further allege as follows:

88. At the time the Defendants marketed, sold and/or distributed the Pinnacle Device, they knew that the hip device was intended for human use.

89. At the time the Defendants marketed, sold and/or distributed the Pinnacle Device, Plaintiff was a foreseeable user of the device.

90. At the time the Defendants marketed, sold and/or distributed the Pinnacle Device, they impliedly warranted that the hip, including all of its component parts, was safe and merchantable for their intended use.

91. Plaintiff and his implanting physician(s) reasonably relied upon the representations that the Pinnacle Device was of merchantable quality and safe for their intended

uses.

92. Plaintiff used the Pinnacle Device for its intended purpose.

93. Contrary to the express and implied warranties, at the time the Defendants marketed, sold and/or distributed the Pinnacle Device, it was not of merchantable quality or safe for its intended use as described above.

94. As a direct and proximate result of one or more of the foregoing wrongful acts or omissions in and by the Defendants, the Pinnacle Device caused Plaintiff to suffer and sustain injuries of a permanent nature; Plaintiff was caused to and will in the future be caused to endure pain and suffering in body and mind; in an endeavor to cure his said injuries, Plaintiff was caused to and will in the future be caused to expend money for medical care; furthermore, Plaintiff was unable to and will in the future be unable to attend to their normal affairs and duties for an indefinite period of time.

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

SIXTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION
(Against All Defendants)

96. Plaintiff incorporates by reference, as if fully set forth herein, each and every factual allegation set forth in the proceeding paragraphs and further allege as follows:

97. The Defendants supplied false information to the public, to Plaintiff and to Plaintiff's physician(s) regarding the high-quality, safety and effectiveness of the Pinnacle Device. Defendants provided this false information to induce the public, and physicians to purchase and implant a Pinnacle Device.

98. The Defendants knew or should have known that the information they supplied

regarding the purported high-quality, safety and effectiveness of the implant to induce Plaintiff and Plaintiff's physician(s) to purchase and use a Pinnacle Device was false.

99. The Defendants were negligent in obtaining or communicating false information regarding the purported high-quality, safety and effectiveness of the Pinnacle Device.

100. Plaintiff and Plaintiff's physician(s) relied on the false information supplied by the Defendants to their detriment by causing the Pinnacle Device to be purchased and implanted in Plaintiff.

101. Plaintiff and Plaintiff's physician(s) were justified in their reliance on the false information supplied by the Defendants regarding the purported high-quality, safety and effectiveness of the Pinnacle Device.

102. As a direct and proximate result of defendant's negligent misrepresentations, Plaintiff has experienced and will experience harms, losses and damages, including, but not limited to, partial or complete loss of mobility, loss of range of motion, loss of consortium, as well as other personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for continuing medical treatment and the necessity to undergo revision surgery, subjecting himself to the attendant risks of complications and death from such further surgery and post-operative complications.

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

SEVENTH CAUSE OF ACTION FRAUD
(Against All Defendants)

104. Plaintiff incorporates by reference, as if fully set forth herein, each and every

allegation set forth in the preceding paragraphs and further allege as follows:

105. Defendants made representations to Plaintiff and Plaintiff's physician(s) that their Pinnacle Device is a high-quality, safe and effective hip replacement system.

106. Before they marketed the Pinnacle Device that was implanted in Plaintiff, Defendants knew or should have known of the unreasonable dangers and serious health risks that such a metal-on-metal total hip replacement system posed to patients like Plaintiff.

107. As specifically described in detail above, Defendants knew that the Pinnacle Device subjected patients to early failure, painful and harmful physical reactions to toxic metallic particles and ions, death of tissue, bone loss and the need for explants and revision surgery.

108. Defendants' representations to Plaintiff and Plaintiff's physician(s) that their Pinnacle Device is high-quality, safe, and effective were false.

109. Defendants concealed their knowledge of the unreasonable risks and dangers associated with the use of the Pinnacle Device to induce Plaintiff and many thousands of others to purchase the Pinnacle Device for surgical implantation in their bodies.

110. Neither Plaintiff nor Plaintiff's physician(s) knew of the falsity of Defendants' statements regarding the Pinnacle Device.

111. Plaintiff and Plaintiff's physician(s) had a right to rely on Defendants' representations and in fact did rely upon such representations. Had Plaintiff and Plaintiff's physicians(s) known that the Pinnacle Device would fail early and expose Plaintiff to the unreasonable risk of toxic metals, metallosis, revision surgeries, and post- revision complications, they would not have purchased or allowed the Pinnacle Device to have been surgically implanted in Plaintiff.

112. As a direct and proximate result of Defendants' fraudulent representations, Plaintiff has experienced and will experience harms, losses and damages, including, but not limited to, partial or complete loss of mobility, loss of range of motion, loss of consortium, as

well as other personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for continuing medical treatment and the necessity to undergo revision surgery, subjecting himself to the attendant risks of complications and death from such further surgery and post-operative complications.

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

EIGHTH CAUSE OF ACTION UNJUST ENRICHMENT
(Against All Defendants)

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

115. As the intended and expected result of their conscious wrongdoing, Defendants have profited and benefited from the purchase of Defendants' Pinnacle Device by Plaintiff.

116. Defendants have voluntarily accepted and retained these profits and benefits, derived from Plaintiff, with full knowledge and awareness that, as a result of Defendants' fraud and other conscious and intentional wrongdoing, Plaintiff was not receiving a product of the quality, nature or fitness that had been represented by Defendants or that Plaintiff, as a reasonable consumer, expected.

117. By virtue of the conscious wrongdoing alleged above, Defendants have been unjustly enriched at the expense of Plaintiff, who is entitled to in equity, and hereby seeks, the disgorgement and restitution of Defendants' wrongful profits, revenues and benefits, to the extent and in the amount deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy the Defendants' unjust enrichment.

NINTH CAUSE OF ACTION
PUNITIVE DAMAGES
(Against All Defendants)

118. Plaintiff incorporates by reference, as if fully set forth herein, each and every factual allegation set forth in the preceding paragraphs and further allege as follows:

119. The acts of the Defendants were willful and wanton, malicious, and showed a total disregard for human life and human suffering. Based upon the acts alleged herein, Defendants knew or should have known, in light of the surrounding circumstances that their conduct would naturally and probably result in injury and damage. Defendants continued such conduct with malice and/or in reckless disregard of the consequences, from which malice may be inferred. Plaintiff should be awarded punitive damages against Defendants, based upon the acts herein so as to punish Defendants and deter similar conduct.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for the following relief:

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

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

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

D. Attorneys' fees and costs;

E. Pre-and post-judgment interest; and

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

JURY DEMAND

Plaintiff hereby demands a trial by jury.

Dated: July 31, 2017

Respectfully submitted,

/s/ Bobby Saadian

Bobby Saadian
TX Bar No. 24100275
WILSHIRE LAW FIRM, PLC
3055 Wilshire Blvd., 12th Floor
(213)381-9988
Fax (213)381-9989
masstorts@wilshirelawfirm.com