UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
NORTHERN DIVISION

IN RE:	§	MDL Docket No.
DEPUY ORTHOPAEDICS, INC.	§	
PINNACLE HIP IMPLANT	§	3:11-MD-2244-K
PRODUCTS LIABILITY	§	
LITIGATION	§	

FIRST AMENDED COMPLAINT

Plaintiff GERALD CAGLE ("Plaintiff"), alleges on information and belief against DEPUY ORTHOPAEDICS, INC., DEPUY INC., DEPUY, DEPUY ORTHOPAEDICS, JOHNSON & JOHNSON, JOHNSON & JOHNSON SERVICES INC., JOHNSON & JOHNSON INTERNATIONAL, AND DOES 1-10, Inclusive ("Defendants"), the following:

I.

1. Defendants manufactured the Pinnacle Acetabular Cup System ("Pinnacle Device"), and launched it in 2001. The Pinnacle Device was designed, developed , and sold for human hip joints damaged or deceased due to fracture, osteoarthritis, rheumatoid arthritis, and avascular necrosis. The Pinnacle Device is designed to be fastened to human bone with surgical screws. The Pinnacle Device was designed and sold to provide pain relief and consistent and screws. The Pinnacle Device was designed and sold to provide pain relief and consistent and smooth range of motion. Defendants marketed the Pinnacle Device as having significant advantages over other hip replacement systems. Defendant marketed and described the Pinnacle Devise as "uniquely 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 advertise and sold the Pinnacle Device as the best surgical option that “recreates the natural ball-and-socket joint of your hip, increasing stability and range of motion.

3. On information and belief Plaintiff alleges that Defendants sold approximately 150,000 Pinnacle Devices. Defendants have stated in promotional materials that “99% of Pinnacle Hip components are still in use today.”

4. On information and belief, Plaintiff alleges that over 1,300 adverse reports have been submitted to the U. S. Food and Drug Administration (FDA) regarding failures or complications of the Pinnacle Device.

5. On information and belief, Plaintiff alleges that Defendant are aware that the use of the Pinnacle Device may result in metallosis, biologic toxicity, and a high failure rate. Plaintiff further alleges that use of the Pinnacle Device results in unsafe release of toxic metal ions into hip implant recipients’ tissue and bloodstream. Plaintiff further alleges that Defendants are aware that metal particles from the Pinnacle Device results in metallosis, tissue death, bone erosion, and development of tumors.

6. On information and belief, Plaintiff alleges that particulate debris from the Pinnacle Device causes severe inflammation, severe pain, tissue and bone loss, and other related diseases.

7. Plaintiff further alleges that Defendants are aware that certain Pinnacle Device recipients have elevated cobalt and chromium levels greatly exceeding acceptable safety standards.

II.

Parties

8. Plaintiff GERALD CAGLE is, and at all times relevant to this Complaint was, a resident of the city of Fort Worth, in the State of Texas.

9. Defendant DEPUY ORTHOPAEDICS, INC. is an Indiana corporation with its principal place of business located at 700 Orthopaedic Drive, Warsaw, Indiana 46581. Upon information and belief, Defendant DePuy Orthopaedics, Inc. is a wholly owned subsidiary of Defendant DePuy, Inc.

10. Defendant DEPUY INC. is a foreign corporation organized under the laws of the State of Delaware and qualified to do business in Texas, and doing business in Dallas and Tarrant County with its principal place of business located at 700 Orthopaedic Drive, Warsaw, Indiana 76581. Defendant DEPUY INC.'S registered agent for service of process is Mark T. Piazza, DePuy, Inc., 700 Orthopaedic Drive, Warsaw, Indiana 76581.

11. Defendant DEPUY, 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.

12. Defendant DEPUY ORTHOPAEDICS, 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.

13. Defendant JOHNSON & JOHNSON is a foreign corporation organized under the laws of the State of Delaware and qualified to do business in Texas, and doing business in Dallas and Tarrant County. Johnson & Johnson upon information and belief, at all times relevant advertised, marketed, promoted and sold and/or distributed DEPUY HIP IMPLANTS AND THE COMPONENT PARTS ("the produce") throughout the State of Texas, including Dallas and

Tarrant Counties. For service of process Defendant Johnson & Johnson may be served by Certified Mail at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

14. 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.

12. Defendant, JOHNSON & JOHNSON INTERNATIONAL 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.

13. Plaintiff is unaware of the true names and capacities, whether individual, corporate, associates, 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.

III.

JURISDICTION AND VENUE

14. 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.

15. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(a) and (c).

IV.

FACTUAL ALLEGATIONS

A. The Pinnacle Device With An "Ultamet" Liner

16. The Pinnacle Device was developed for the purpose of reconstructing diseased human hip joints from 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.

17. 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 cup (socket). The acetabulum cup is comprised of titanium metal. Either a plastic, ceramic, or cobalt-chromium metal liner is then placed on the inside of the acetabulum cup. The metal femoral head rotates within the plastic, ceramic, or metal liner, depending on which liner the surgeon selects based on the patient's needs. The cobalt-chromium metal liner is branded by Defendants as the "Ultamet." 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. Defendants Do Not Seek Premarket Approval From The FDA, And Thus The FDA Makes No Finding That The Pinnacle Device Is Safe Or Effective

18. 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.

19. 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.

20. 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.

21. The FDA may grant premarket approval only if it finds that there is reasonable assurance that the medical device 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.

22. 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 device's substantial equivalence to a pre-MDA predicate device. The FDA may then approve the new device for sale in the United States.

23. Rather than being approved for use by the FDA pursuant to the rigorous premarket approval process, the Pinnacle Device metal-on-metal total hip replacement system 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.

24. As such, under the 510(k) process, Defendants were able to market the Pinnacle Device with virtually no clinical or non-clinical trials or FDA review of the implant for safety and effectiveness.

C. Defendants Took No Steps To Test The Pinnacle Device Or They Would Have Discovered That It Leads To Metallosis And Other Complications Before Releasing It On The Market

25. 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 an early and high failure rate due to the release of metal particles in the patient's surrounding tissue when the cobalt-chromium metal formal head rotates within the cobalt-chromium metal acetabular liner.

26. 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. The particles than accumulate in the patient's tissue surrounding the implant giving rise to metallosis, pseudotumors, or other conditions.

27. 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.

28. On information and belief, Plaintiff alleges that the FDA has received more than 1,300 adverse reports regarding problems associated with or attributed to the Pinnacle Device.

29. On information and belief, Plaintiff alleges that the ASR and the Pinnacle Device were designed by the same orthopaedic surgeon, Dr. Thomas Schmalzried.

30. Defendants continue to sell the Pinnacle Device 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 metallosis, pseudotumors, and biologic toxicity, among other complications, and represent to the public that they are safe. These patients are reporting severe pain and discomfort and the need for one or more complicated revision surgeries resulting in life-long health problems caused by the defective device.

D. Plaintiff Was Implanted With A Pinnacle Device And As A Result Has Suffered Severe Injuries

31. On or about February 24, 2005, Plaintiff, age 60, underwent a right total hip replacement procedure. A Pinnacle Device with an Ultamet liner was implanted in place of his right hip.

32. After the surgery, friction and wear between the cobalt-chromium metal head and cobalt-chromium metal liner caused large amounts of toxic cobalt-chromium metal ions and particles to be released into Plaintiff's blood and tissue and bone surrounding the implant. As a result, Plaintiff has been experiencing severe pain and discomfort and inflammation

33. Due to Plaintiff's pain and discomfort and other symptoms, on May 15, 2007, Plaintiff underwent removal of the implant and removal of 40cc's of milky white substance.

34. All of the injuries and complications suffered by Plaintiff were caused by the defective design, warnings, construction and unreasonably dangerous character of the Pinnacle Device that was implanted in him. 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.

35. Plaintiff was unaware of any causal link between the injuries he has suffered and any wrongdoing on the part of Defendants due to the faulty and defective nature of the Pinnacle Device, due in part to the failures of Defendants to properly warn him and his physicians about the Pinnacle Device's defective and faulty nature. In and around late fall, 2010, Plaintiff first became aware of said causal link when he became aware of the recall of the ASR and realized that the issues he had had with his Pinnacle Device were eerily similar to that which was being reported regarding the ASR. Plaintiff was unable to make an earlier discovery of said causal link despite reasonable diligence because of Defendants' denial of issues, and failure to properly warn him and his physicians about the Pinnacle Device's defective and faulty nature, and their failure to issue any recall or take any other proactive action to date with respect to the injuries being caused to patients that have been implanted with a Pinnacle Device. Defendants had a duty to inform the public of the problems with the Pinnacle Device and knowingly concealed the problems from the Plaintiff and public.

CAUSES OF ACTION

FIRST CAUSE OF ACTION

NEGLIGENCE

(Against All Defendants)

36. 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:

37. 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.

38. 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 severe and 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.

39. 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 had the device surgically implanted;

b. Designing, manufacturing, producing, creating, and/or promoting the

Pinnacle Device without adequately, sufficiently, or thoroughly testing it;

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

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

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

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

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

h. 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;

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

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

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

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

m. Negligently assembling the Pinnacle Device in a manner which was

dangerous to those individuals who had it implanted;

n. Defendants under-reported, concealed important relevant information, underestimated and downplayed the serious danger of the Pinnacle Device.

40. 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.

41. 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.

42. 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, as set forth above.

43. Defendants' negligence was the proximate cause of Plaintiff's physical, mental and emotional injuries and harm, and economic loss which he has suffered and/or will continue to suffer.

44. By reason of the foregoing, Plaintiff experienced and/or will experience severe

harmful effects including but not limited to partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the past need for a revision surgery to replace the device with the attendant risks of complications and death from such surgery.

45. 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.

SECOND CAUSE OF ACTION

STRICT PRODUCTS LIABILITY (MANUFACTURING DEFECT)

(Against All Defendants)

46. 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:

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

48. The Pinnacle Device that was surgically implanted in Plaintiff was defective in its manufacture when it left the hands of Defendants in that it deviated from product specifications, posing a serious risk that it could fail early in patients therefore giving rise to physical injury, 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.

49. As a direct and proximate result of Defendants' placement of the defective Pinnacle Device into the stream of commerce, Plaintiff experienced and/or will experience severe harmful effects including but not limited to partial or complete loss of mobility, loss of

range of motion, as well as other severe and 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.

50. 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.

THIRD CAUSE OF ACTION

STRICT PRODUCTS LIABILITY (DESIGN DEFECT)

(Against All Defendants)

51. 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:

52. At all times herein mentioned, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed the Pinnacle Device as hereinabove described that was surgically implanted in Plaintiff.

53. At all times herein mentioned, 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, which was dangerous to users such as Plaintiff that had the device surgically implanted.

54. At all times herein mentioned, 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.

55. At all times herein mentioned, 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.

56. At all times herein mentioned, the Pinnacle Device's unsafe, defective, and inherently dangerous condition was a cause of injury to Plaintiff.

57. At all times herein mentioned, the Pinnacle Device failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.

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

59. At all times herein mentioned, the Pinnacle Device posed a risk of danger inherent in the design which outweighed the benefits of that design.

60. At all times herein mentioned, 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.

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

62. At the time of the implantation of the Pinnacle Device into Plaintiff, the aforesaid product was being used for the purposes and in a manner normally intended, namely for use as a hip replacement device.

63. Defendants, with this knowledge, voluntarily designed their Pinnacle Device in a

dangerous condition for use by the public and, in particular, Plaintiff.

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

65. Defendants designed, researched, manufactured, tested, 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 Plaintiff, in particular, and Defendants are therefore strictly liable for the injuries sustained by Plaintiff.

66. As a direct and proximate result of Defendants' placement of the defective Pinnacle Device into the stream of commerce, Plaintiff experienced and/or will experience severe harmful effects including but not limited to partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the past need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

67. 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.

FOURTH CAUSE OF ACTION

STRICT PRODUCTS LIABILITY (INADEQUATE WARNING)

(Against All Defendants)

68. 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:

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

70. The Pinnacle Device placed into the stream of commerce by Defendants was defective due to inadequate warning, because Defendants knew or should have known that the Pinnacle Device could fail early in patients therefore give rise to physical injury, 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, but failed to give consumers adequate warning of such risks. Further, the Pinnacle Device placed into the stream of commerce by Defendants was surgically implanted in a manner reasonably anticipated by Defendants.

71. As a direct and proximate result of Defendants' placement of the defective Pinnacle Device into the stream of commerce, Plaintiff experienced and/or will experience severe harmful effects including but not limited to partial or complete loss of mobility, loss of range of motion, as well as other severe and 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.

72. Further, as a result of the foregoing acts and omissions, Plaintiff suffered a loss of wages and will in the future suffer a diminished capacity to earn wages.

73. 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.

FIFTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

(Against All Defendants)

74. 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:

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

76. Defendants expressly warranted that the Pinnacle Device was a safe and effective hip replacement system.

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

78. As a direct and proximate result of Defendants' breach of express warranties regarding the safety and effectiveness of the Pinnacle Device, Plaintiff has suffered significant damages, including but not limited to physical injury, economic loss, pain and suffering, and the need for past revision surgery to replace the faulty device, and will continue to suffer such damages in the future.

79. In taking the actions and omissions that caused these damages, Defendants were guilty of malice, oppression and fraud, and Plaintiff is therefore entitled to recover punitive damages.

SIXTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

(Against All Defendants)

80. 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:

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

82. At the time Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Pinnacle Device, Defendants knew the use for which the Pinnacle Device was intended, and impliedly warranted the Pinnacle Device to be of merchantable quality and safe for such use.

83. Plaintiff reasonably relied upon the skill and judgment of Defendants as to whether the Pinnacle Device was of merchantable quality and safe for its intended use.

84. Contrary to Defendants' implied warranties, the Pinnacle Device was not of merchantable quality or safe for its intended use, because the Pinnacle Device was unreasonably dangerous as described above.

85. As a direct and proximate result of Defendants' breach of implied warranties regarding the safety and effectiveness of the Pinnacle Device, Plaintiff has suffered significant damages, including but not limited to physical injury, economic loss, pain and suffering, and the need for past revision surgery to replace the faulty device, and will continue to suffer such damages in the future.

86. In taking the actions and omissions that caused these damages, Defendants were guilty of malice, oppression and fraud, and Plaintiff is therefore entitled to recover punitive damages.

SEVENTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

(Against All Defendants)

87. 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:

88. The Defendants supplied false information to the public, to Plaintiff and to his physicians regarding the high-quality, safety and effectiveness of the Pinnacle Device. Defendants provided this false information to induce the public, Plaintiff and his physicians to purchase and implant a Pinnacle Device.

89. 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 his physicians to purchase and use a Pinnacle Device was false.

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

91. Plaintiff and his physicians relied on the false information supplied by the Defendants to his detriment by causing the Pinnacle Device to be purchased and implanted in Plaintiff.

92. Plaintiff and his physicians 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.

93. As a direct and proximate result of Defendants' negligent misrepresentations, Plaintiff has suffered significant damages, including but not limited to permanent physical injury, economic loss, pain and suffering and the need past revision surgery to repair the physical damage to Plaintiff caused by the Pinnacle Device.

EIGHTH CAUSE OF ACTION

FRAUD

(Against All Defendants)

94. 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:

95. Defendants made representations to Plaintiff and his physicians that their Pinnacle Device is a high-quality, safe and effective hip replacement system.

96. 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.

97. 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.

98. Defendants' representations to Plaintiff and his physicians that their Pinnacle Device is high-quality, safe and effective were false.

99. 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 system for surgical implantation in their bodies.

100. Neither Plaintiff nor his physicians knew of the falsity of Defendants' statements regarding the Pinnacle Device.

101. Plaintiff and his physicians relied upon and accepted as truthful Defendants' representations regarding the Pinnacle Device.

102. Plaintiff and his physicians had a right to rely on Defendants' representations and in fact did rely upon such representations. Had Plaintiff known that the Pinnacle Device would fail early and expose him to the unreasonable risk of toxic metals, metallosis, and revision surgeries he would not have purchased or allowed the Pinnacle Device to have been surgically implanted in him.

103. As a direct and proximate result of Defendants' fraudulent representations, Plaintiff has suffered significant damages, including but not limited to permanent physical injury, economic loss, pain and suffering and the need for past revision surgeries to repair the physical damage to Plaintiff caused by the Pinnacle Device.

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, loss of earnings, disfigurement, 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.

Dated: July 11, 2012

/s/Robert Haslam_____
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