

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION**

JAY CHRISTOPHER and
JACQUELINE CHRISTOPHER,

Plaintiffs,

VS.

DEPUY ORTHOPAEDICS, INC.; DEPUY
PRODUCTS, INC.; DEPUY SYNTHES,
INC.; JOHNSON & JOHNSON; JOHNSON
& JOHNSON SERVICES, INC.; and
JOHNSON & JOHNSON
INTERNATIONAL,

Defendants.

MDL 2244

Case No. 3-14-cv-1994

Honorable Ed Kinkeade

**AMENDED COMPLAINT
AND JURY TRIAL DEMAND**

Plaintiffs Jay Christopher and Jacqueline Christopher, by and through their undersigned counsel, for their Amended Complaint against DePuy Orthopaedics, Inc., DePuy Products, Inc., DePuy Synthes, Inc., Johnson & Johnson, Johnson & Johnson Services, Inc., and Johnson & Johnson International (“Defendants”), allege on personal knowledge as to themselves and on information and belief as to all other matters as follows:

PARTIES

1. Plaintiff Jay Christopher is a citizen of the State of Texas and resides in or near Beaumont, in Jefferson County. On or about December 7, 2006, Jay Christopher underwent a right hip arthroplasty procedure and was implanted

with a DePuy Pinnacle MoM Device.

2. Plaintiff Jacqueline Christopher is a citizen of the State of Texas and resides in or near Beaumont, in Jefferson County. Jacqueline Christopher is the wife of Jay Christopher.

3. Defendant DePuy Orthopaedics, Inc. is a corporation organized and existing under the laws of the State of Indiana with its principal place of business located at 700 Orthopaedics Drive, Warsaw, IN 46581. At all times relevant to this action, defendant DePuy Orthopaedics has conducted business in the Northern District of Texas, and in Dallas County, Texas.

4. Defendant DePuy Products, Inc. is a corporation organized and existing under the laws of the State of Indiana, with its principal place of business located at 700 Orthopaedics Drive, Warsaw, IN 46581. At all times relevant to this action, defendant DePuy Products, Inc. has conducted business in the Northern District of Texas, and in Dallas County, Texas.

5. Defendant DePuy Synthes, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 700 Orthopaedics Drive, Warsaw, IN 46581. At all times relevant to this action, defendant DePuy Synthes, Inc. has conducted business in the Northern District of Texas, and in Dallas County, Texas.

6. Defendant Johnson & Johnson is a corporation organized and

existing under the laws of the State of New Jersey, with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, NJ 08933. Defendant Johnson & Johnson is the parent company of Defendants DePuy Synthes, Inc., Johnson & Johnson Services, Inc., and Johnson & Johnson International. At all times relevant to this action, Defendant Johnson & Johnson, Inc. has conducted business in the Northern District of Texas, and in Dallas County, Texas.

7. Defendant Johnson & Johnson Services, Inc. is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, NJ 08933. Defendant Johnson & Johnson Services, Inc. is a subsidiary of Defendant Johnson & Johnson. At all times relevant to this action, Defendant Johnson & Johnson Services, Inc. has conducted business in the Northern District of Texas, and in Dallas County, Texas.

8. Johnson & Johnson International is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, NJ 08933. Defendant Johnson & Johnson International is a subsidiary of Defendant Johnson & Johnson. At all times relevant to this action, Defendant Johnson & Johnson International has conducted business in the Northern District of Texas, and in

Dallas County, Texas.

9. With respect to the allegations in this Amended Complaint and the conduct leading to Plaintiffs' injuries, the Defendants acted in concert with one another, pursuant to a common design, provided substantial assistance and/or encouragement to the tortious conduct of the others, and participated in their tortious conduct.

JURISDICTION AND VENUE

10. This Court has diversity jurisdiction over the parties pursuant to 28 U.S.C. §1332(a). At least one defendant is a citizen of a different state as the Plaintiff and the amount in controversy exceeds \$75,000.00, exclusive of interest and costs.

11. Venue is proper in this Court under 28 U.S.C. § 1391(c) and also under this Court's Case Management Order #1, dated June 29, 2011, permitting direct filing into this Court and for consideration for transfer into MDL No. 3:11 MD 2244 K.

ALLEGATIONS COMMON TO ALL CLAIMS

12. In this action, Plaintiffs seek compensation for injuries resulting from implantation in Jay Christopher of the defective Pinnacle hip implant device with a metal-on-metal liner ("Pinnacle MoM Device").

13. Defendants designed, manufactured, marketed, and sold the

Pinnacle MoM Device. The Pinnacle MoM Device was designed, developed, marketed, and sold for human hip joints damaged or diseased due to, *inter alia*, fracture, osteoarthritis, rheumatoid arthritis, and avascular necrosis. The Pinnacle MoM Device was designed and sold to provide pain relief and consistent and smooth range of motion. Defendants marketed the Pinnacle MoM Device as having significant advantages over other hip devices and hip replacement systems. Defendants marketed and described the Pinnacle MoM 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 MoM Devices as superior devices featuring "TrueGlide technology," allowing the body to create a thin film of lubrication between surfaces, which enables "a more fluid range of natural motion." Defendants also advertised and sold the Pinnacle MoM Device as the best surgical option that "[r]ecreates the natural ball-and-socket joint of your hip, increasing stability and range of motion."

14. Defendants sold approximately 150,000 Pinnacle MoM Devices, each with the "Johnson & Johnson" logo on the package. In marketing and advertising the Pinnacle MoM Devices, Defendants made use of the "Johnson & Johnson" name and the familiarity of doctors and the public at large with Johnson & Johnson and its products. DePuy refers to itself as "a Johnson &

Johnson Company” on letterhead and logos. When problems became apparent with DePuy’s “ASR” hip implant, another metal-on-metal design, DePuy relied on its status as “a Johnson & Johnson Company” in an attempt to restore confidence among surgeons, and to encourage them to use the Pinnacle MoM Device in place of the ASR hip after it was recalled. All of these actions were taken with the knowledge, approval and encouragement of Johnson & Johnson. Johnson & Johnson directly participated in promotional and marketing efforts to promote the use of metal-on-metal hips in general, and the Pinnacle MoM Device in particular. Johnson & Johnson personnel approved specific marketing and promotional messages, approved Defendants’ marketing of devices, including the Pinnacle MoM Device, and directly participated in “damage control” in the wake of the ASR recall, including efforts to convince surgeons that the Pinnacle MoM Device was still safe for use. In addition, Johnson & Johnson specifically undertook to perform certain services for Defendants that it knew or should have known were necessary for the protection of patients implanted with Defendants’ Pinnacle MoM Devices, Johnson & Johnson failed to exercise reasonable care in performing those services, patients such as Plaintiff Jay Christopher relied on Johnson & Johnson’s performance and reputation, and Johnson & Johnson’s performance of those services increased the risk of harm to patients, including Plaintiff Jay Christopher.

15. Defendants have stated in promotional materials that “99.9% of Pinnacle hip components are still in use today.” Plaintiff has learned, however, that over 1,300 adverse reports have been submitted to the U.S. Food and Drug Administration (FDA) regarding failures or complications of Pinnacle MoM Devices.

16. Despite their marketing of the Pinnacle MoM Device as a safe and superior device, Defendants were at all relevant times aware that Pinnacle MoM Devices may result in metallosis, biologic toxicity, and unreasonably high, early failure rates. Moreover, the Pinnacle MoM Device may result in unsafe release of toxic metal wear debris and metal ions into hip implant recipients' tissue and bloodstream. At all relevant times, Defendants were aware that metal particles from Pinnacle MoM Devices result in metallosis, tissue death, bone erosion, and the development of “pseudotumors.” Defendants further were aware that particulate debris from the Pinnacle MoM Devices can cause severe inflammation, severe pain, tissue and bone loss, and other related diseases. Finally, Defendants were also aware Pinnacle MoM Device recipients often have elevated cobalt and chromium levels greatly exceeding acceptable safety standards.

17. Plaintiff Jay Christopher was implanted with the Pinnacle MoM Device and has suffered substantial injuries and damage.

The Pinnacle MoM Device

18. The Pinnacle hip implant system was developed by Defendants 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.

19. The Pinnacle implant system is made up of four components: the metal femoral stem, which is inserted inside the femur bone; the metal femoral head (or ball), which connects to the top of the stem; the metal acetabular cup or shell (socket), which attaches to the pelvis; and the liner, which sits inside the acetabular cup. The acetabular cup is made of titanium. The liner may be polyethylene (plastic), ceramic, or cobalt-chromium metal. The metal femoral head articulates within the liner. The Pinnacle MoM Device -- the Pinnacle implant system when used with a metal liner -- is a "metal-on-metal" device because both articulating surfaces -- the femoral head (ball) and acetabular liner (socket) -- are comprised of cobalt-chromium metal.

Defendants Did Not Seek Premarket Approval from the FDA, and Thus the FDA Made No Finding That the Pinnacle MoM Device Is Safe or Effective

20. The Pinnacle MoM 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.

21. The Medical Device Amendments to the Food, Drug, and Cosmetics Act of 1938 ("MDA"), in theory, require Class III medical devices, including the Pinnacle MoM 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.

22. 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.

23. 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.

24. A medical device on the market prior to the effective date of the MDA -- a so-called "grandfathered" device -- is 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 § 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 "clear" the new device for marketing and sale in the United States.

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

26. Accordingly, under the 510(k) process, Defendants were able to

market the Pinnacle MoM Device with virtually no clinical or non-clinical trials or FDA review of the implant for safety and effectiveness.

Defendants Did not Adequately Test the Pinnacle MoM Device and They Should Have Discovered That It Leads to Metallosis and Other Complications Before Releasing It into the Market

27. Defendants failed adequately to test the Pinnacle MoM Device before releasing it into the market. Had Defendants properly tested the Pinnacle MoM Device, they would have discovered the dangers of the device before bringing it to market.

28. Defendants knew or should have known that the Pinnacle MoM Device results in an unreasonably 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 femoral head articulates against the cobalt-chromium metal acetabular liner and implant components corrode inside the body.

29. In other words, implantation of the Pinnacle MoM Device results in the nearly immediate systemic release of high levels of toxic cobalt-chromium metal wear particles and metal 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 articulating within the metal liner, in addition to particles and ions being released by corrosion reactions. The particles

and ions then accumulate in the patient's tissue surrounding the implant giving rise to metallosis, pseudotumors or other conditions.

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

31. FDA has received more than 1,300 adverse reports regarding problems associated with or attributed to the Pinnacle MoM Device.

32. Many recipients of the Pinnacle MoM Device 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 Pinnacle MoM Device have significantly elevated levels of chromium and cobalt in amounts many times higher than acceptable or recommended safety levels.

33. A number of governmental regulatory agencies have recognized and cautioned against the problems that are caused by metal-on-metal implants such as the ASR and Pinnacle MoM Device. For instance, the United Kingdom's Medicines and Healthcare products Regulatory Agency ("MHRA") 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.

34. Similarly, the Alaska Department of Health recently 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.

Defendants Failed Adequately to Disclose and/or Warn About the Dangers of the Pinnacle MoM Device

35. Defendants failed to warn Plaintiff and/or his doctor, the medical community, and the public at large about the dangers of the Pinnacle MoM Device.

36. In particular, Defendants failed to warn that metal-on-metal implants, such as the Pinnacle MoM Device, could experience unusual, premature, or increased friction and/or wear and tear, and that such wear and tear could damage surrounding tissues and/or cause premature failure of the implant.

37. Defendants also failed to warn that metal-on-metal implants, such as the Pinnacle MoM Device, generated unusually high amounts of metal wear debris and metal ions over time due to the premature and/or increased friction and/or wear and tear of the device. This debris and ions can spread throughout

the surrounding bone and tissue and cause serious complications and damage, including possible development of conditions commonly referred to in the medical community as ARMD (adverse reaction to metal debris), ALTR (adverse local tissue reaction), ALVAL (aseptic lymphocyte-dominated vasculitis-associated lesion), metallosis, and pseudotumors.

38. Defendants knew or should have known of these risks and dangers, but failed to disclose them, and, in particular, failed to warn the medical community, including Plaintiff's doctor, of these risks and dangers.

39. In concealing, and failing to disclose, the risks and dangers of the Pinnacle MoM Device, Defendants' conduct was fraudulent, malicious, oppressive, willful, and/or so grossly negligent as to indicate a wanton disregard of the rights of others.

40. Plaintiff Jay Christopher, and/or his doctor, and Plaintiff Jacqueline Christopher were not aware of the risks and dangers of the Pinnacle MoM Device at the time the device was implanted in Christopher.

Defendants Misrepresented the Benefits of the Pinnacle MoM Device

41. Defendants advertised the Pinnacle MoM 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."

42. This representation was false and/or misleading, and Defendants knew that it was false and/or misleading because Defendants knew that fluid film lubrication occurs rarely and is not present during the majority of movements of the Pinnacle MoM Device.

43. Defendants have stated in promotional materials that “99.9% of Pinnacle hip components are still in use today.”

44. This representation was false and/or misleading, and Defendants knew that it was false and/or misleading. Defendants knew that the actual survival rate of the device was lower and knew that the data they cited in support of the 99.9% statistic did not in fact support that representation.

45. Defendants marketed the Pinnacle MoM Device as especially suitable for younger and/or more active patients because of the claimed survivability rate of the device.

46. In 2013, the FDA announced it would no longer allow Defendants to market metal-on-metal hip implants, including the Pinnacle MoM Device, under the “grandfather”/510(k) method, and would instead require a Pre-market Application for any such devices. In response, Defendants announced they were discontinuing sales of the Pinnacle MoM Device in August of 2013.

47. In misrepresenting the benefits of the Pinnacle MoM Device, Defendants’ conduct was fraudulent, malicious, oppressive, willful, and/or so

grossly negligent as to indicate a wanton disregard of the rights of others.

Plaintiff Jay Christopher Was Implanted with a Pinnacle MoM Device and as a Result Has Suffered Injuries

48. On or about December 7, 2006, Plaintiff Jay Christopher underwent a right total hip arthroplasty procedure. A Pinnacle MoM Device was implanted in place of his right hip. Over time, the known and common problem of corrosion and friction wear is believed to have caused amounts of toxic cobalt-chromium metal debris to be released into Christopher's tissue surrounding the implant. After his surgery Christopher began experiencing pain and difficulty with his implant.

49. Plaintiff Jay Christopher had to undergo a revision surgery to remove the "metal on metal" hip implant and replace it with "metal on polyethylene" implant. His right hip was revised on December 19, 2013.

50. Plaintiffs only recently became aware of the causal link between the injuries they have suffered and any wrongdoing on the part of Defendants due to the faulty and defective nature of the Pinnacle MoM Device and to the failure of Defendants to properly warn Christopher and/or his physicians about the Pinnacle MoM Device's defective and faulty nature. Plaintiffs were unable to make an earlier discovery of the causal link despite reasonable diligence because of Defendants' failure to properly warn Plaintiffs or Christopher's physicians about the Pinnacle MoM 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.

51. All of the injuries and complications suffered by Plaintiff were caused by the defective design, warnings, construction and unreasonably dangerous character of the Pinnacle MoM Device that was implanted in Plaintiff Jay Christopher, and by the negligence and other wrongful conduct of Defendants. 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 MoM Device, Christopher would not have consented to the Pinnacle MoM Device being used in his total hip arthroplasty.

52. Plaintiffs were unaware of any causal link between the injuries they have suffered and any wrongdoing on the part of Defendants due to the faulty and defective nature of the Pinnacle MoM Device and due in part to the failures of Defendants to properly warn Plaintiff Jay Christopher, his physicians, and Plaintiff Jacqueline Christopher about the Pinnacle MoM Device's defective and faulty nature.

53. Plaintiffs have been harmed as a result of the Defendants' wrongful acts and omissions and file this suit to recover their damages, as described below.

CLAIMS FOR RELIEF
FIRST CLAIM FOR RELIEF
Negligence
(Plaintiff Jay Christopher)

54. Plaintiff Jay Christopher adopts by reference and incorporates herein the allegations set forth above.

55. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control and distribution of the Pinnacle MoM 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.

56. Defendants failed to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control and distribution of the Pinnacle MoM Device into interstate commerce. 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. Additionally, Defendants knew or should have known about the harmful effects from the need for a revision

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

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

- a. Negligently designing the Pinnacle MoM Device in a manner which was dangerous to those individuals who had the device surgically implanted;
- b. Designing, manufacturing, producing, creating and promoting the Pinnacle MoM Device without adequately, sufficiently or thoroughly testing it;
- c. Not conducting a sufficient testing program to determine whether or not the Pinnacle MoM Device was safe for use;
- d. Marketing and selling the Pinnacle MoM Device when Defendants knew or should have known that it was unsafe and unfit for use because of the dangers to its users;
- e. Selling the Pinnacle MoM Device without making proper and sufficient tests to determine the dangers to its users;
- f. Negligently failing to adequately and correctly warn Plaintiff Jay Christopher and/or his physicians, hospitals and healthcare providers of the dangers of the Pinnacle MoM Device;

- g. Negligently failing to recall their dangerous and defective Pinnacle MoM Device at the earliest date that it became known that the device was, in fact, unreasonably dangerous and defective;
- h. Failing to provide adequate instructions regarding safety precautions to be observed by surgeons who would reasonably and foreseeably come in contact with, and more particularly, implant the Pinnacle MoM Device into their patients;
- i. Negligently advertising and recommending the use of the Pinnacle MoM Device despite the fact that Defendants knew or should have known of its dangerous propensities;
- j. Negligently representing that the Pinnacle MoM Device was safe for use for its intended purpose, when, in fact, it was unsafe;
- k. Negligently representing that the Pinnacle MoM Device offered low wear and high stability, when, in fact, the opposite was true;
- l. Negligently manufacturing the Pinnacle MoM Device in a manner that was dangerous to those individuals who had it implanted;
- m. Negligently producing the Pinnacle MoM Device in a manner that was dangerous to those individuals who had it implanted;
- n. Negligently assembling the Pinnacle MoM Device in a manner, that was dangerous to those individuals who had it implanted;

- o. Negligently under-reporting, underestimating and downplaying the serious dangers of the Pinnacle MoM Device.

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

- a. Failed to use due care in designing and manufacturing the Pinnacle Device so as to avoid the 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 MoM Device; and
- e. Were otherwise careless and negligent.

59. Despite the fact that Defendants knew or should have known that the Pinnacle MoM Device caused harm to individuals in whom the device was surgically implanted, Defendants continued to market, manufacture, distribute and sell the Pinnacle MoM Device.

60. Defendants knew or should have known that consumers, such as

Plaintiff Jay Christopher, would suffer foreseeable injury and be at increased risk of suffering an injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

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

62. By reason of the foregoing, Plaintiff Jay Christopher 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. Christopher also needed a revision surgery to replace the device, which carried the attendant risks of complications and death from such further surgery.

63. Defendants' conduct as described herein was fraudulent, malicious, oppressive, willful, and/or so grossly negligent as to indicate a wanton disregard of the rights of others, so as to justify an award of punitive and exemplary damages.

SECOND CLAIM FOR RELIEF

Strict Liability - Failure to Warn

(Plaintiff Jay Christopher)

64. Plaintiff Jay Christopher adopts by reference and incorporates

herein the allegations set forth above.

65. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Pinnacle MoM Device. The Pinnacle MoM Device that was implanted in Plaintiff was in substantially the same condition at the time it was implanted as it was when it left Defendants' possession and entered into the stream of commerce.

66. The Pinnacle MoM Device placed into the stream of commerce by Defendants and implanted in Plaintiff was defective because it was not accompanied by an adequate warning.

67. In particular, Defendants knew or should have known that the Pinnacle MoM Device was subject to early failure and could cause elevated blood levels of cobalt and/or chromium, metallosis, damage to surrounding tissues, and other complications. Such failure or complications in turn may 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. Defendants failed to give consumers and physicians adequate warning of such risks.

68. The Pinnacle MoM Device placed into the stream of commerce by Defendants was surgically implanted in Plaintiff Jay Christopher in a manner reasonably anticipated by Defendants.

69. As a direct and proximate result of Defendants' placement of the defective Pinnacle MoM Device into the stream of commerce, Christopher 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. Plaintiff Jay Christopher also needed revision surgeries to replace the devices, which carried the attendant risks of complications and death from such further surgeries.

70. Defendants' conduct as described herein was fraudulent, malicious, oppressive, willful, and/or so grossly negligent as to indicate a wanton disregard of the rights of others, so as to justify an award of punitive and exemplary damages.

THIRD CLAIM FOR RELIEF
Strict Liability - Design Defect
(Plaintiff Jay Christopher)

71. Plaintiff Jay Christopher adopts by reference and incorporates herein the allegations set forth above.

72. At all times herein mentioned, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed the Pinnacle MoM Devices as hereinabove described that were surgically

implanted in the Plaintiff Jay Christopher.

73. At all times herein mentioned, the Pinnacle MoM Device designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed by Defendants was in an unsafe, defective, and unreasonably dangerous condition, which was dangerous to users such as Christopher who had the devices surgically implanted. In particular, the Pinnacle MoM Device was defectively designed in that the design of the implant was prone to friction between the metal surfaces and to early failure, causing serious and permanent injuries. At all times herein mentioned, the Pinnacle MoM Device designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed by Defendants was in an unsafe, defective and unreasonably dangerous condition at the time it left Defendants' possession.

74. At all times herein mentioned, the Pinnacle MoM 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.

75. At all times herein mentioned, the Pinnacle MoM Device's unsafe, defective, and unreasonably dangerous condition was a producing cause of injuries and damages to Plaintiff Jay Christopher.

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

77. The design of the Pinnacle MoM Device was defective at the time the device was first offered for sale in the United States and remained defective throughout the entire time the product was sold in the United States.

78. Jay Christopher's injuries resulted from use of the Pinnacle MoM Device that was both intended and reasonably foreseeable by Defendants.

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

80. At all times herein mentioned, the Pinnacle MoM 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.

81. Defendants knew, or should have known, that at all times herein mentioned the Pinnacle MoM Device was in a defective condition as a result of its design, and was and is unreasonably dangerous and unsafe.

82. At the time of the implantation of the Pinnacle MoM Device into the Plaintiff Jay Christopher, the product was being used for the purposes and in a

manner normally intended, namely for use as a hip replacement device.

83. Defendants, with this knowledge, voluntarily designed its Pinnacle MoM Device in a dangerous condition for use by the public and, in particular, Jay Christopher.

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

85. 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 Jay Christopher, in particular, and Defendants are therefore strictly liable for the injuries sustained by Christopher.

86. At all times material to these claims, there was a safer alternative design that was both technologically and economically feasible which would have prevented or substantially reduced the risk of Plaintiff Jay Christopher's injuries without substantially impairing the device's utility.

87. As a direct and proximate result of Defendants' placement of the defective Pinnacle MoM 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. Plaintiff also needed revision surgeries to replace the devices, which carried the attendant risks of complications and death from such further surgeries.

88. Defendants' conduct as described herein was fraudulent, malicious, oppressive, willful, and/or so grossly negligent as to indicate a wanton disregard of the rights of others, so as to justify an award of punitive and exemplary damages.

FOURTH CLAIM FOR RELIEF
Strict Liability - Manufacturing Defect
(Plaintiff Jay Christopher)

89. Plaintiff Jay Christopher adopts by reference and incorporates herein the allegations set forth in the paragraphs above.

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

91. At all times herein mentioned, the Pinnacle MoM Device designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was in an unsafe, defective and unreasonably dangerous condition at the time it left Defendants' possession.

92. At all times herein mentioned, the Pinnacle MoM 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.

93. The Pinnacle MoM Device that was surgically implanted in Plaintiff Jay Christopher 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 thereby 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.

94. As a direct and proximate result of Defendants' placement of the defective and unreasonably dangerous Pinnacle Devices into the stream or commerce, Christopher has suffered and will continue to suffer substantial damages.

FIFTH CLAIM FOR RELIEF

Fraud

(Plaintiff Jay Christopher)

95. Plaintiff Jay Christopher hereby restates and re-alleges each and every allegation set forth above, with the same force and effect as if herein repeated and set forth in full.

96. At the time Defendants manufactured, designed, marketed, sold and distributed the Pinnacle MoM Device, they had knowledge of the dangers metal-on-metal hip implant devices posed to their recipients. Further, Defendants had

knowledge of the physical injury, pain and suffering, debilitation, and need for revision surgeries and subsequent complications that the Pinnacle MoM Device imposed on patients receiving the devices.

97. The dangers associated with the use of metal-on-metal and the subsequent physical injury, pain and suffering, debilitation, and the need for revision surgeries and the subsequent complications were, and are, material facts.

98. Defendants knowingly, intentionally, and with reckless disregard of the true facts made false representations of material facts and omitted material facts to Plaintiff and/or his doctor, including, but not limited to, claims that the Pinnacle MoM Device was safe, effective and fit for use as a hip replacement device.

99. Defendants' misrepresentation and omission of known facts were intended to induce Christopher and/or his doctor to purchase and use the Pinnacle MoM Device.

100. Plaintiff Jay Christopher and/or his doctor relied on Defendants' misrepresentations of material facts regarding the safety, effectiveness and fitness of the Pinnacle MoM Device for use as a hip replacement device. Christopher and/or his doctor further relied on Defendants to provide them with information about the dangers of the Pinnacle MoM Device, and not to

conceal information they had about such dangers. Had Christopher known the risks associated with the use of the Pinnacle MoM Device, he would not have agreed to the use of the device to treat his condition.

101. Plaintiff Jay Christopher and/or his doctor reasonably relied on the information provided by Defendants in deciding whether to obtain, implant, and retain the Pinnacle MoM Device.

102. As a direct and proximate result of reliance on the Defendants' misrepresentations, Christopher has suffered and will suffer damages as described herein.

103. Defendants' conduct as described herein was fraudulent, malicious, oppressive, willful, and/or so grossly negligent as to indicate a wanton disregard of the rights of others, so as to justify an award of punitive and exemplary damages.

SIXTH CLAIM FOR RELIEF
Negligent Misrepresentation
(Plaintiff Jay Christopher)

104. Plaintiff Jay Christopher adopts by reference and incorporates herein the allegations set forth above.

105. Defendants made misrepresentations of material facts in the course of their business, including, but not limited to:

- a. That Plaintiff Jay Christopher's Pinnacle MoM implant was fit for its

intended use;

- b. That Plaintiff's Pinnacle MoM implant was of merchantable quality;
- c. That Plaintiff's Pinnacle MoM implant was safe and effective in the treatment of Plaintiff's medical condition; and
- d. That Plaintiff's Pinnacle MoM implant would function as intended when necessary;

106. Defendants omitted to reveal material facts, including, but not limited to:

- a. That Plaintiff Jay Christopher's Pinnacle MoM implant was defective, such that it would fail to function as intended;
- b. That Plaintiff Jay Christopher's Pinnacle MoM implant presented a risk of injury and harm in its ordinary and intended use; and
- c. That Plaintiff's implant was unreasonably dangerous.

107. These representations and/or omissions were false and misleading at the time they were made.

108. False information about the characteristics and safety of the Pinnacle MoM implant was supplied by Defendants for the guidance of others.

109. Defendants did not exercise reasonable care or competence in obtaining or communicating this information, but rather negligently and carelessly made the foregoing misrepresentations without a basis.

110. Defendants were aware that they did not possess information on which to accurately base the foregoing representations and concealed from Jay Christopher that there was no reasonable basis for making said representations herein.

111. When Defendants made the foregoing representations, they knew or should have known them to be false.

112. When Defendants made the foregoing representations, they intended to induce Plaintiff Jay Christopher and/or his doctor to select the Pinnacle metal-on-metal hip device for use in Christopher's arthroplasty surgery.

113. In reliance upon the foregoing misrepresentations by the Defendants, Plaintiff Jay Christopher was induced to and did subject himself to the use of the Pinnacle MoM Device. If Jay Christopher had known of the true facts, he would not have taken such action and risk. Plaintiff's reliance on Defendants' misrepresentations and omissions was reasonable because said representations were made by individuals and entities in a position to know the true facts.

114. As a result of the foregoing negligent misrepresentations by Defendants, Plaintiff Jay Christopher was injured and damaged, and will continue to suffer injury, expense and economic loss as previously described.

SEVENTH CLAIM FOR RELIEF

Breach of Express Warranty

(Plaintiff Jay Christopher)

115. Plaintiff Jay Christopher restates each and re-alleges every allegation set forth above with the same force and effects as it set forth herein and repeated in full.

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

117. Defendants expressly warranted that the Pinnacle MoM Device was safe and effective hip replacement systems.

118. The Pinnacle MoM Devices placed into the stream of commerce by Defendants did not conform to these express representations because they failed early, as did Christopher's, 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.

119. As a direct and proximate result of Defendants' breach of express warranties regarding the safety and effectiveness of the Pinnacle MoM Device, Plaintiff Jay Christopher has suffered and will continue to suffer personal injury and substantial damages.

120. Defendants' conduct described herein was fraudulent, malicious,

oppressive, willful, and/or so grossly negligent as to indicate a wanton disregard of the rights of others, so as to justify an award of punitive and exemplary damages.

EIGHTH CLAIM FOR RELIEF
Breach of Implied Warranty of Merchantability
(Plaintiff Jay Christopher)

121. Plaintiff Jay Christopher restates and re-alleges each and every allegation set forth above with the same force and effects as it set forth herein and repeated in full.

122. Defendants are in the business of designing, manufacturing, and/or supplying and/or placing into the stream of commerce the Pinnacle MoM Device for consumers.

123. By placing the Pinnacle MoM Device into the stream of commerce, Defendants impliedly warranted that it was merchantable and fit and safe for its intended use.

124. The Pinnacle MoM Device placed into the stream of commerce by Defendants was defective and accordingly, was not fit, safe, or merchantable for its intended use.

125. The defects in the Pinnacle MoM Device designed, manufactured and/or supplied and/or placed into the stream of commerce by Defendants, were present at the time the product left Defendant's control.

126. Defendants breached the implied warranty for the Pinnacle MoM Device because said product was defective and unmerchantable.

127. Plaintiff Jay Christopher was a foreseeable user of the Pinnacle MoM Device designed, manufactured and/or supplied and placed into the stream of commerce by Defendants.

128. As a direct and proximate result of Defendants' breach of implied warranties, Plaintiff Jay Christopher will continue to suffer injury, expense and economic loss as previously described, rendering Defendants liable for said damages.

129. Defendants' conduct described herein was fraudulent, malicious, oppressive, willful, and/or so grossly negligent as to indicate a wanton disregard of the rights of others, so as to justify an award of punitive and exemplary damages.

NINTH CLAIM FOR RELIEF

Loss of Consortium

(Plaintiff Jacqueline Christopher)

130. Plaintiff Jacqueline Christopher adopts by reference and incorporates herein the allegations set forth above.

131. As a further result of Defendants' breach of duties as described and alleged above, Plaintiff Jacqueline Christopher's relationship with her husband has been impaired, and she has in the past and will in the future suffer damages

resulting from the loss of companionship, aid, comfort, society, services, protection and consortium. She hereby brings suit to recover her damages that were caused by Defendants' wrongful and tortious conduct as described herein.

ACTUAL AND EXEMPLARY DAMAGES

132. Plaintiffs Jay Christopher and Jacqueline Christopher adopt by reference and incorporate herein the allegations set forth above.

133. As described herein, Plaintiffs Jay Christopher and Jacqueline Christopher have sustained damages and losses as a result of the wrongful and tortious conduct of Defendants, for which Defendants are jointly and severally liable. Plaintiffs hereby request the Court and Jury to determine the amount of loss they have incurred in the past and will incur in the future, not only from a financial standpoint but also in terms of good health and freedom from pain and worry. There are certain elements of damages, provided by law, that Plaintiffs are entitled to have the Jury in this case separately consider to determine the sum of money for each element that will fairly and reasonably compensate Plaintiffs for their injuries, disabilities, damages, and losses incurred and, in reasonable probability, to be incurred in the future. From the date of the incident until the time of trial, those elements of past damages to be considered separately and individually are as follows:

- a. The physical pain that Jay Christopher has suffered from the date of

his injury until the time of trial;

- b. The mental anguish that Jay Christopher has suffered from the date of his injury until the time of trial;
- c. The amount of reasonable medical expenses, necessarily incurred in the care and treatment of Jay Christopher's injuries from the date of his injury until the time of trial;
- d. The physical incapacities, disabilities and impairments suffered by Jay Christopher, and the resulting inability to do those tasks and services that he would have ordinarily been able to perform, from the date of his injury until the time of trial;
- e. The disfigurement of Jay Christopher from the date of his injury until the time of trial;
- f. Jay Christopher's loss of earnings or earning capacity from the date of his injury until the time of trial; and
- g. Loss of consortium sustained by Jacqueline Christopher from the date of Jay Christopher's injury until the time of trial.

134. From the time of the trial of this case, those elements of future damages to be separately considered which Plaintiffs Jay Christopher and Jacqueline Christopher will, in reasonable probability, sustain in the future beyond trial are the following:

- a. The physical pain that Jay Christopher will suffer beyond the time of trial;
- b. The mental anguish that Jay Christopher will suffer beyond the time of trial;
- c. The reasonable value of medical expenses that will necessarily be incurred in the care and treatment of Jay Christopher's injuries beyond the time of trial;
- d. The physical incapacities, disabilities and impairments suffered by Jay Christopher, and the resulting inability to do those tasks and services that he would have ordinarily been able to perform, beyond the time of trial;
- e. The disfigurement of Jay Christopher beyond the time of trial;
- f. Jay Christopher's loss of earnings or earning capacity beyond the time of trial; and
- g. The loss of consortium sustained by Jacqueline Christopher beyond the time of trial.

135. Plaintiffs Jay Christopher and Jacqueline Christopher are also entitled to recover pre-judgment and post-judgment interest as allowed by law, for which Plaintiffs hereby bring suit to recover together with court costs and any other relief to which they are entitled.

136. In addition to their actual damages, as outlined above, Plaintiffs Jay Christopher and Jacqueline Christopher are also entitled to recover exemplary damages from Defendants under Chapter 41 of the Texas Civil Practice and Remedies Code.

137. Specifically, the acts and omissions of Defendants described herein constituted, fraud, malice, and/or gross negligence as those terms are defined under Texas law. Consequently, Plaintiffs are entitled to have the Jury consider and award exemplary damages against Defendants.

PRAYER

For the reasons stated herein, Plaintiffs Jay Christopher and Jacqueline Christopher pray that upon final trial of this case, they be awarded a judgment against Defendants, jointly and severally, for actual damages as specified herein, exemplary damages as specified herein, costs of court, pre-judgment and post judgment interest as allowed by law, attorneys' fees and expenses as allowed by law, and such other and further relief, general and special, at law and in equity, to which they may be justly entitled.

JURY DEMAND

Plaintiffs hereby demand a trial by jury as to all claims in this action.

Dated: August 21, 2015

Respectfully submitted,
THE LANIER LAW FIRM

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and Jacqueline Christopher*

CERTIFICATE OF SERVICE

I certify that the foregoing instrument was served on all counsel of record by the Court's CM/ECF system, and was also forwarded to counsel for the DePuy Defendants by electronic mail, on August 21, 2015.

/s/ W. Mark Lanier
W. Mark Lanier