UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

MARGARET AOKI, Plaintiff, 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. 3-13-cv-1071 Honorable Ed Kinkeade **AMENDED COMPLAINT AND JURY TRIAL DEMAND**

Plaintiff Margaret Aoki, by and through her undersigned counsel, for her Amended Complaint against DePuy Orthopaedics, Inc., DePuy Products, Inc., DePuy Synthes, Inc., Johnson & Johnson, Johnson & Johnson Services, Inc., and Johnson & Johnson International ("Defendants"), alleges on personal knowledge as to herself and on information and belief as to all other matters as follows:

PARTIES

1. Plaintiff Margaret Aoki is a citizen of the State of Texas and resides in or near Austin, in Travis County. On or about September 20, 2010, Margaret Aoki underwent a left total hip arthroplasty procedure and was implanted with a DePuy Pinnacle MoM Device.

2. 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.

3. 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.

4. 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.

5. 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.

6. 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.

7. 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.

8. With respect to the allegations in this Amended Complaint and the conduct leading to Plaintiff's 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

9. 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.

10. 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

11. In this action, Plaintiff seeks compensation for injuries resulting from implantation in Margaret Aoki of the defective Pinnacle hip implant device with a metal-on-metal liner ("Pinnacle MoM Device").

12. 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."

13. 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 Margaret Aoki 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 Margaret Aoki.

14. 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.

15. 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.

16. Plaintiff Margaret Aoki was implanted with the Pinnacle MoM Device and has suffered substantial injuries and damage.

The Pinnacle MoM Device

17. 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.

18. 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

19. 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.

20. 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.

21. 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.

22. 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.

23. 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.

24. 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.

25. 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

26. 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.

27. 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.

28. 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.

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

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

31. 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 or chromium and cobalt in amounts many times higher than acceptable or recommended safety levels.

32. 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.

33. 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

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

35. 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.

36. 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.

37. 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.

38. 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.

39. Plaintiff Margaret Aoki, and/or her doctor, was not aware of the risks and dangers of the Pinnacle MoM Device at the time the device was implanted in Aoki.

Defendants Misrepresented the Benefits of the Pinnacle MoM Device

40. 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."

41. 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.

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

43. 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.

44. 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.

45. 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.

46. 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 Margaret Aoki Was Implanted with a Pinnacle MoM Device and as a Result Has Suffered Injuries

47. On or about September 20, 2010, Plaintiff Margaret Aoki underwent a left total hip arthroplasty procedure. A Pinnacle MoM Device was implanted in place of her left 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 Aoki's tissue surrounding the implant. After her surgery Aoki began experiencing pain and difficulty with her implant.

48. Plaintiff Margaret Aoki had to undergo a revision surgery to remove the "metal on metal" hip implant and replace it with "metal on polyethylene" implant. Her left hip was revised on February 22, 2013.

49. Plaintiff only recently became aware of the causal link between the injuries she has suffered and any wrongdoing on the part of Defendants due to the faulty and defective nature of the Pinnacle MoM Device and to the failure of Defendants to properly warn Aoki and/or her physicians about the Pinnacle MoM Device's defective and faulty nature. Plaintiff was unable to make an earlier discovery of the causal link despite reasonable diligence because of Defendants' failure to properly warn Aoki'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.

50. 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 Margaret Aoki, 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, Aoki would not have consented to the Pinnacle MoM Device being used in her total hip arthroplasty.

51. Plaintiff was unaware of any causal link between the injuries she has suffered and any wrongdoing on the part of Defendants due to the faulty and defective nature of the Pinnacle MoM Device and due in part to the failures of Defendants to properly warn Plaintiff Margaret Aoki, and/or her physicians about the Pinnacle MoM Device's defective and faulty nature.

52. Plaintiff has been harmed as a result of the Defendants' wrongful acts and omissions and files this suit to recover her damages, as described below.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

Negligence

(Plaintiff Margaret Aoki)

53. Plaintiff Margaret Aoki adopts by reference and incorporates herein the allegations set forth above.

54. 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.

55. 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.

56. 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 Margaret Aoki and/or her 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.

57. 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.

58. 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.

59. Defendants knew or should have known that consumers, such as Plaintiff Margaret Aoki, 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.

60. Defendants' negligence was the proximate cause of Aoki's physical, mental and emotional injuries and harm, and economic loss, which she has

suffered and/or will continue to suffer.

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

62. 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 Margaret Aoki)

63. Plaintiff Margaret Aoki adopts by reference and incorporates herein the allegations set forth above.

64. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Pinnacle MoM Device. The Pinnacle MoM Devices that were 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.

65. 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.

66. 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.

67. Additionally and alternatively, Defendants entered into a contractual relationship with the orthopaedic surgeon who implanted Margaret Aoki's Pinnacle MoM hips, Dr. Eric Matthew Heinrich, whereby Dr. Heinrich was paid (and continues to be paid) substantial sums of money to promote DePuy's products and to assist DePuy with marketing efforts to other surgeons. Because of this relationship, Dr. Heinrich was not an independent "learned intermediary" as that term is defined under Texas law. As such, Defendants are precluded from invoking the "learned intermediary" doctrine in this case.

68. The Pinnacle MoM Device placed into the stream of commerce by Defendants was surgically implanted in Plaintiff Margaret Aoki 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, Aoki 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 Margaret Aoki 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 Margaret Aoki)

71. Plaintiff Margaret Aoki 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 Margaret Aoki.

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 Aoki 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 Margaret Aoki.

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. Margaret Aoki'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 Margaret Aoki, 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, Margaret Aoki.

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 Margaret Aoki, in particular, and Defendants are therefore strictly liable for the injuries sustained by Aoki.

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 Margaret Aoki'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 Margaret Aoki)

89. Plaintiff Margaret Aoki 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 Margaret Aoki 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 Device into the stream or commerce, Aoki has suffered and will continue to suffer substantial damages.

FIFTH CLAIM FOR RELIEF

Fraud

(Plaintiff Margaret Aoki)

95. Plaintiff Margaret Aoki 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 her 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 Aoki and/or her doctor to purchase and use the Pinnacle MoM Device.

100. Plaintiff Margaret Aoki and/or her 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. Aoki and/or her 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 Aoki known the risks associated with the use of the Pinnacle MoM Device, she would not have agreed to the use of the device to treat her condition.

101. Plaintiff Margaret Aoki and/or her 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, Aoki 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 Margaret Aoki)

104. Plaintiff Margaret Aoki 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 Margaret Aoki'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 Margaret Aoki's Pinnacle MoM implant was defective, such that it would fail to function as intended;

b. That Plaintiff Margaret Aoki'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 Margaret Aoki 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 Margaret Aoki and/or her doctor to select the Pinnacle metal-on-metal hip device for use in Aoki's arthroplasty surgery.

113. Additionally and alternatively, Defendants entered into a contractual relationship with the orthopaedic surgeon who implanted Margaret Aoki's Pinnacle MoM hips, Dr. Eric Matthew Heinrich, whereby Dr. Heinrich was paid (and continues to be paid) substantial sums of money to promote DePuy's products and to assist DePuy with marketing efforts to other surgeons. Because of this relationship, Dr. Heinrich was not an independent "learned intermediary" as that term is defined under Texas law. As such, Defendants are precluded from invoking the "learned intermediary" doctrine in this case.

114. In reliance upon the foregoing misrepresentations by the Defendants, Plaintiff Margaret Aoki was induced to and did subject herself to the

use of the Pinnacle MoM Device. If Margaret Aoki had known of the true facts, she 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.

115. As a result of the foregoing negligent misrepresentations by Defendants, Plaintiff Margaret Aoki 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 Margaret Aoki)

116. Plaintiff Margaret Aoki 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.

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

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

119. The Pinnacle MoM Device placed into the stream of commerce by Defendants did not conform to these express representations because they failed early, as did Aoki'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.

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

121. 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 Margaret Aoki)

122. Plaintiff Margaret Aoki 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.

123. 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.

124. 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.

125. 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.

126. 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.

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

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

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

130. 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.

ACTUAL AND EXEMPLARY DAMAGES

131. Plaintiff Margaret Aoki adopts by reference and incorporates herein the allegations set forth above.

132. As described herein, Plaintiff Margaret Aoki has sustained damages and losses as a result of the wrongful and tortious conduct of Defendants, for which Defendants are jointly and severally liable. Plaintiff hereby requests the Court and Jury to determine the amount of loss she has 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 Plaintiff is 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 Plaintiff for her 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 Margaret Aoki has suffered from the date of her injury until the time of trial;

b. The mental anguish that Margaret Aoki has suffered from the date of her injury until the time of trial;

c. The amount of reasonable medical expenses, necessarily incurred in

the care and treatment of Margaret Aoki's injuries from the date of her injury until the time of trial;

d. The physical incapacities, disabilities and impairments suffered by Margaret Aoki, and the resulting inability to do those tasks and services that she would have ordinarily been able to perform, from the date of her injury until the time of trial; and

e. The disfigurement of Margaret Aoki from the date of her injury until the time of trial.

133. From the time of the trial of this case, those elements of future damages to be separately considered which Plaintiff Margaret Aoki will, in reasonable probability, sustain in the future beyond trial are the following:

a. The physical pain that Margaret Aoki will suffer beyond the time of trial;

b. The mental anguish that Margaret Aoki 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 Margaret Aoki's injuries beyond the time of trial;

d. The physical incapacities, disabilities and impairments suffered by Margaret Aoki, and the resulting inability to do those tasks and

services that she would have ordinarily been able to perform, beyond the time of trial; and

e. The disfigurement of Margaret Aoki beyond the time of trial.

134. Plaintiff Margaret Aoki is also entitled to recover pre-judgment and post-judgment interest as allowed by law, for which Plaintiff hereby bring suit to recover together with court costs and any other relief to which she is entitled.

135. In addition to her actual damages, as outlined above, Plaintiff Margaret Aoki is also entitled to recover exemplary damages from Defendants under Chapter 41 of the Texas Civil Practice and Remedies Code.

136. 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, Plaintiff is entitled to have the Jury consider and award exemplary damages against Defendants.

137. Section 41.008(b) of the Texas Civil Practice and Remedies Code provides a limitation on the amount of exemplary damages that may be awarded. However, that limitation is not applicable in this case under Section 41.008(c)(9) of the Code. Specifically, the limitation does not apply because the claims asserted in this case are based, in part, on conduct described as a felony in Section 32.43 of the Texas Penal Code: Commercial Bribery.

138. Section 32.43(b) of the Texas Penal Code prohibits a fiduciary (which

is specifically defined to include a "physician"), without the consent of his beneficiary (here, the patient, Ms. Aoki), from intentionally or knowingly soliciting, accepting, or agreeing to accept any benefit from another person[1] on agreement or understanding that the benefit will influence the conduct of the fiduciary (physician) in relation to the affairs of his beneficiary (patient). Section 32.43(c) prohibits any person from offering, conferring, or agreeing to confer any benefit the acceptance of which is an offense under [Section 32.43(b)]. An offense under this section of the Penal Code is a state jail felony.

139. Upon information and belief, Defendants intentionally and knowingly offered, conferred, or agreed to confer benefits in the form of lucrative consulting agreements on Dr. Heinrich – a fiduciary under the statute – with the agreement or understanding that the benefits would influence the conduct of Dr. Heinrich in the conduct of his treatment of patients – beneficiaries under the statute.

140. In fact, the conduct of Defendants in this regard was so widespread that they were investigated by the United States Attorney's Office in New Jersey. Defendants entered into a Deferred Prosecution Agreement in response to a draft criminal complaint, which alleged Defendants "used consulting agreements with orthopedic surgeons and payments made thereunder, in part as inducements for

[1] Under Texas Penal Code Section 1.07(a)(38), "'Person' means an individual, corporation, or association."

such surgeons' use of DePuy's artificial hip and knee reconstruction and replacement parts." The draft complaint further alleged that, in furtherance of this conspiracy, "DePuy entered into consulting agreements with certain orthopedic surgeons designed, in part, to induce the surgeons to use, and cause the purchase of, DePuy's hip and knee reconstruction and replacement products." In short, the Government alleged that DePuy had in effect paid doctors to use its products, including its hip replacement products.

141. For these reasons, the limitation or "cap" on exemplary damages does not apply to any award of exemplary damages in this case, under the provisions of Section 41.008(c)(9) of the Texas Civil Practice and Remedies Code.

PRAYER

For the reasons stated herein, Plaintiff Margaret Aoki prays that upon final trial of this case, she 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 she may be justly entitled.

JURY DEMAND

Plaintiff hereby demands 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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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