UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

RAMON ALICEA and CAROLE ALICEA, 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. 3:15-cv-03489-K Honorable Ed Kinkeade

AMENDED COMPLAINT AND JURY TRIAL DEMAND

Plaintiffs Ramon Alicea and Carole Alicea, 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 Ramon Alicea is a citizen of the State of New York and resides in West Islip, Suffolk County, New York. On or about June 22, 2010, Ramon Alicea underwent a left total hip arthroplasty procedure and was implanted with a DePuy Pinnacle hip implant device with a metal-on-metal Ultamet liner ("Pinnacle MoM Device").

2. Plaintiff Carole Alicea is a citizen of the State of New York and resides in West Islip, Suffolk County, New York. Carole Alicea is the wife of Ramon Alicea.

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 Eastern District of New York, in Suffolk County as well as 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 Eastern District of New York, in Suffolk County as well as 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 Eastern District of New York, in Suffolk County as well as 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 Eastern District of New York, in Suffolk County as well as 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 Eastern District of New York, in Suffolk County as well as 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 Eastern District of New York, in Suffolk County as well as 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 Plaintiffs 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(b) 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 Ramon Alicea of the 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 Ramon Alicea 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 Ramon Alicea.

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, Defendants were at all relevant times aware that 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." At all relevant times 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. Defendants were also aware at all relevant times that Pinnacle MoM Device recipients often have elevated cobalt and chromium levels greatly exceeding acceptable safety standards.

17. Plaintiff Ramon Alicea 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 the requirement of 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. 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, infection, inflammation, and other adverse reactions.

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

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

35. Defendants failed to warn Plaintiff Ramon Alicea 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 and that 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 each of the foregoing risks and dangers, but failed to disclose them to, and concealed them from, Plaintiff and/or his doctor, the medical community, and the public at large.

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, including Plaintiffs and the public at large.

40. Plaintiff Ramon Alicea, his doctor, and Plaintiff Carole Alicea were unaware of the risks and dangers of the Pinnacle MoM Device at the time the device was implanted in Ramon Alicea.

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

47. 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.

48. 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, including Plaintiffs and the public at large.

Plaintiff Ramon Alicea Was Implanted with a Pinnacle MoM Device and as a Direct Result Has Suffered Injuries

49. On or about June 22, 2010, Plaintiff Ramon Alicea underwent a total hip arthroplasty procedure performed by Jonathan Mallen, M.D., at South Nassau Communities Hospital in Oceanside, New York. A Pinnacle Device with an Ultamet liner was implanted in place of his left hip. After the surgery, friction and wear between the cobalt-chromium metal head and cobalt-chromium metal liner caused large amounts of toxic cobalt-chromium metal ions and particles to be released into Ramon Alicea's blood and tissue and bone surrounding the implant. As a result, Plaintiff Ramon Alicea has been experiencing severe pain and discomfort and inflammation in and around his implant.

50. Because of his chronic pain and discomfort and other symptoms, Plaintiff Ramone Alicea was required to undergo revision surgery to replace his left hip implant. On or about October 15, 2015, Plaintiff Ramon Alicea underwent a left hip revision procedure performed by James Germano, M.D., at South Nassau Communities Hospital in Oceanside, New York.

51. Plaintiff Carole Alicea was at all times relevant hereto the spouse of Ramon Alicea, and as such lives and cohabitates with him. For the reasons set forth herein, Plaintiffs have necessarily paid and have become liable to pay for medical aid, treatment and for medications, and will necessarily incur further expenses of a similar nature in the future. Plaintiff Carole Alicea has been caused, presently and in the future, to suffer the loss of her spouse's companionship, services, society and the ability of her spouse have in those respects been impaired and depreciated, and the marital association between husband and wife has been altered, and accordingly, Plaintiff Carole Alicea has been caused great mental anguish.

52. Plaintiffs only became aware shortly before they commenced this action 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 adequately warn Ramon Alicea and/or his physicians about the Pinnacle MoM Device's defective and unsafe nature. Plaintiffs were unable to make an earlier discovery of the causal link despite reasonable diligence because of Defendants' failure to adequately warn Plaintiffs or Ramon Alicea's physicians, or the medical community, or the public at large about the Pinnacle MoM Device's defective and unsafe nature, and their failure to issue any recall or to take any other timely action with respect to the injuries being caused to patients implanted with a Pinnacle MoM Device.

53. All of the injuries and complications suffered by the Plaintiffs were caused by the defective design, warnings, construction, and unreasonably dangerous character of the Pinnacle MoM Device that was implanted in Plaintiff Ramon Alicea, and by the

negligence and other wrongful conduct of Defendants. Had Defendants disclosed, and 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, Ramon Alicea would not have consented to the Pinnacle MoM Device being permanently implanted in his body.

54. Plaintiffs have been harmed as a direct and proximate result of the Defendants' wrongful acts and omissions and file this suit to recover fair compensation for their injuries, as described below.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

Negligence

(Plaintiff Ramon Alicea)

55. Plaintiff Ramon Alicea adopts by reference and incorporates herein the allegations set forth above.

56. Defendants had a duty to Plaintiff Ramon Alicea 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 unreasonable, dangerous side effects, including those suffered by Plaintiff Ramon Alicea.

57. Defendants failed to exercise ordinary 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 of unreasonable, dangerous side effects, including those suffered by Plaintiff Ramon Alicea.

58. The negligence of Defendants included but was not limited to the following acts and/or omissions:

a. Designing the Pinnacle MoM Device in a manner which was not reasonably safe to those individuals who had the device surgically implanted;

b. Designing, manufacturing, producing, creating and promoting the Pinnacle MoM Device without adequately testing its safety;

c. Failing to conduct an adequate testing program to determine whether the Pinnacle MoM Device was safe;

d. Marketing and selling the Pinnacle MoM Device when Defendants knew or should have known that it was not reasonably safe and fit for use;

e. Selling the Pinnacle MoM Device without having conducted adequate testing to determine if the device was reasonably safe;

f. Failing to adequately and correctly warn Plaintiff Ramon Alicea and/or his physicians, the medical community, and the public at large of the dangers of the Pinnacle MoM Device;

g. Failing to recall their defective Pinnacle MoM Device at the earliest date that it became known that the device was, in fact, not reasonably sale;

h. Failing to provide adequate instructions regarding safety precautions to be observed by surgeons who would reasonably and foreseeably treat their patients with the Pinnacle MoM Device;

i. Advertising and recommending the use of the Pinnacle MoM Device despite the fact that Defendants knew or should have known that it is not reasonably safe;

j. Representing that the Pinnacle MoM Device was safe for use for its intended purpose, when, in fact, it was not reasonably safe;

k. Representing that the Pinnacle MoM Device offered low wear and high stability, when, in fact, Defendants knew or should have known that neither statement was true;

l. Manufacturing the Pinnacle MoM Device in a manner that was not reasonably safe to those individuals who had it implanted;

m. Producing the Pinnacle MoM Device in a manner that was not reasonably safe to those individuals who had it implanted;

n. Assembling the Pinnacle MoM Device in a manner, that was not reasonably safe to those individuals who had it implanted;

o. Under-reporting, underestimating, and downplaying the risks associated with of the Pinnacle MoM Device.

59. 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 unreasonable risks to individuals that had the devices surgically implanted;

b. Failed to accompany their product with adequate warnings;

c. Failed to accompany their product with adequate 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.

60. 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 to consumers, including Plaintiff Ramon Alicea

61. Defendants knew or should have known that consumers, such as Plaintiff Ramon Alicea, would foreseeably suffer injury and be at increased risk of suffering an injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

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

63. As a direct and proximate result of Defendants' negligence, Plaintiff Ramon Alicea experienced and/or will experience severe personal injuries, 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, a risk of future revisions, any and all life complications caused by Plaintiff Ramon Alicea's revision surgery as well as the need for lifelong medical treatment, monitoring and/or other medications. Plaintiff Ramon Alicea also needed a revision surgery to replace the device, and had to undergo the recovery therefrom, which caused him additional pain and suffering and carried the attendant risks of complications and death from such further surgery. Plaintiff Ramon Alicea also suffered a loss of earnings as a result on Defendants' wrongdoing.

64. 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, including the public at large, so as to justify an award of punitive damages.

65. By reason of the foregoing, Plaintiff Ramon Alicea demands judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deem proper.

66. The limitations on liability set forth in CPLR § 1601 do not apply to this action by reason of one or more of the exceptions set forth in CPLR § 1602.

SECOND CLAIM FOR RELIEF

Strict Liability – Failure to Warn

(Plaintiff Ramon Alicea)

67. Plaintiff Ramon Alicea adopts by reference and incorporates herein the allegations set forth above.

68. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce, and in the course of same, directly advertised or marketed the Pinnacle MoM Device to consumers or persons responsible for consumers, and therefore, had a duty to both Plaintiff Ramon Alicea directly and to his physician to warn of risks associated with the use of Pinnacle MoM Device.

69. Defendants had a duty to warn of adverse effects which they knew or had reason to know could be caused by the use of the Pinnacle MoM Device and/or were associated with the use of the Pinnacle MoM Device.

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

71. 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. Defendants knew, or should have known, that 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 pain, suffering, and risks of complications and death from such further surgery. Defendants failed to give consumers and physicians adequate warning of such risks.

72. Defendants' failure to adequately warn Plaintiff Ramon Alicea and/or his treating physicians of the above risks prevented Plaintiff Ramon Alicea's treating

physicians and Plaintiff Ramon Alicea from correctly and fully evaluating the risks and benefits of the Pinnacle MoM Device.

73. Had Plaintiff Ramon Alicea's physicians and Plaintiff Ramon Alicea been adequately warned of the serious side effects of the Pinnacle MoM Device, Plaintiff Ramon Alicea's physicians would have materially changed the information communicated to Plaintiff Ramon Alicea, including but not limited to, recommending a different device, or, even if they recommended the Pinnacle MoM Device, passing on the risks of that device to Plaintiff Ramon Alicea and discussing the risks with Plaintiff Ramon Alicea at the time of surgery and throughout the treatment of Plaintiff Ramon Alicea. Plaintiff Ramon Alicea would not have consented to the implantation of the Pinnacle MoM Device had he been adequately informed of the risks of the Pinnacle MoM Device.

74. Due to the inadequate warning, the Pinnacle MoM device was in a defective condition and not reasonably safe at the time that it left the control of the Defendants.

75. The Pinnacle MoM Device placed into the stream of commerce by Defendants was surgically implanted in Plaintiff Ramon Alicea in a manner reasonably anticipated by Defendants.

76. As a foreseeable and proximate result of Defendants' placement of the defective Pinnacle MoM Device into the stream of commerce, Ramon Alicea experienced and/or will experience the injuries described above.

77. 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, including the public at large, so as to justify an award of punitive and exemplary damages.

78. By reason of the foregoing, Plaintiff Ramon Alicea demands judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deem proper.

79. The limitations on liability set forth in CPLR § 1601 do not apply to this action by reason of one or more of the exceptions set forth in CPLR § 1602.

THIRD CLAIM FOR RELIEF

Strict Liability - Design Defect

(Plaintiff Ramon Alicea)

80. Plaintiff Ramon Alicea adopts by reference and incorporates herein the allegations set forth above.

81. At the time it left Defendants hands, the Pinnacle MoM Device implanted in Plaintiff Ramon Alicea was defective because it was in a condition not reasonably contemplated by the ultimate consumer and was unreasonably dangerous for its intended use, and its utility did not outweigh the danger inherent in its introduction into the stream of commerce.

82. Defendants breached their duty to market safe products when they marketed a product designed so that it was not reasonably safe.

83. The defective design of Defendants' Pinnacle MoM Device was a substantial factor in causing Plaintiff Ramon Alicea's injuries described above.

84. Plaintiff Ramon Alicea's injury resulted when the defectively designed product was used for its intended purpose or for an unintended but reasonably foreseeable purpose.

85. 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.

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 Ramon Alicea's injuries without substantially impairing the device's utility.

87. At the time the Pinnacle MoM Device was implanted in him, Plaintiff Ramon Alicea was unaware of its defects, and Plaintiff Ramon Alicea could not, by the reasonable exercise of care, have discovered its defects.

88. Defendants are strictly liable to Plaintiff Ramon Alicea for the injuries he suffered due to the defective design of the Pinnacle MoM Device.

89. 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, including the public at large, so as to justify an award of punitive damages.

90. By reason of the foregoing, Plaintiff Ramon Alicea demands judgment against each Defendant, individually, jointly and severally for compensatory damages in

a sum in excess of $75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deem proper.

91. The limitations on liability set forth in CPLR § 1601 do not apply to this action by reason of one or more of the exceptions set forth in CPLR § 1602.

FOURTH CLAIM FOR RELIEF

Strict Liability - Manufacturing Defect

(Plaintiff Ramon Alicea)

92. Plaintiff Ramon Alicea adopts by reference and incorporates herein the allegations set forth in the paragraphs above.

93. 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.

94. 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.

95. The Pinnacle MoM Device that was surgically implanted in Plaintiff Ramon Alicea 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.

96. As a direct and proximate result of Defendants' placement of the defective and unreasonably dangerous Pinnacle Devices into the stream or commerce, Ramon Alicea has suffered and will continue to suffer the substantial injuries described above.

97. 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, including the public at large, so as to justify an award of punitive damages.

98. By reason of the foregoing, Plaintiff Ramon Alicea demands judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deem proper.

99. The limitations on liability set forth in CPLR § 1601 do not apply to this action by reason of one or more of the exceptions set forth in CPLR § 1602.

FIFTH CLAIM FOR RELIEF

Fraud and Fraudulent Concealment

(Plaintiff Ramon Alicea)

100. Plaintiff Ramon Alicea 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.

101. 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.

102. 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.

103. Defendants knowingly, intentionally, and with reckless disregard of the true facts made material representations and material omissions and/or concealments to Plaintiff Ramon Alicea 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.

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

105. Defendants knew or should have known that their representations were false or misleading and/or knew that Defendants were concealing and/or omitting material information from the medical and healthcare community at large, the general public, Plaintiff Ramon Alicea's healthcare provider(s), and/or Plaintiff Ramon Alicea.

106. Plaintiff Ramon Alicea 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. Ramon Alicea 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 Ramon Alicea known the risks associated with the use of the Pinnacle MoM Device,

he would not have consented to the Pinnacle MoM Device being permanently implanted in his body.

107. Plaintiff Ramon Alicea and/or his doctor justifiably relied on the information provided by Defendants in deciding whether to obtain, implant, and retain the Pinnacle MoM Device.

108. As a direct and proximate result of reliance on the Defendants' misrepresentations, Ramon Alicea has suffered and will suffer the injuries described above.

109. 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, including the public at large, so as to justify an award of punitive damages.

110. By reason of the foregoing, Plaintiff Ramon Alicea demands judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deem proper.

111. The limitations on liability set forth in CPLR § 1601 do not apply to this action by reason of one or more of the exceptions set forth in CPLR § 1602.

SIXTH CLAIM FOR RELIEF

Negligent Misrepresentation

(Plaintiff Ramon Alicea)

112. Plaintiff Ramon Alicea adopts by reference and incorporates herein the allegations set forth above.

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

a. That Plaintiff Ramon Alicea's Pinnacle MoM implant was fit for its intended use;

b. That Plaintiff Ramon Alicea's Pinnacle MoM implant was of merchantable quality;

c. That Plaintiff Ramon Alicea's Pinnacle MoM implant was safe and effective in the treatment of Plaintiff Ramon Alicea's medical condition; and

d. That Plaintiff Ramon Alicea's Pinnacle MoM implant would function as intended when necessary;

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

a. That Plaintiff Ramon Alicea's Pinnacle MoM implant was defective, such that it would fail to function as intended;

b. That Plaintiff Ramon Alicea's Pinnacle MoM implant presented a risk of injury and harm in its ordinary and intended use; and

c. That Plaintiff Ramon Alicea's Pinnacle MoM implant was not reasonably safe.

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

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

117. Defendants did not exercise reasonable care or competence in obtaining or communicating this information, but rather negligently and carelessly made the foregoing misrepresentations.

118. When Defendants made the foregoing representations, they intended to induce Plaintiff Ramon Alicea and/or his doctor to select the Pinnacle MoM Device for use in Ramon Alicea's hip replacement surgery.

119. The relationship between Defendants and Plaintiff Ramon Alicea was one of privity, or approaching that of privity, so as to give rise to a duty of reasonable care in their representations and disclosures regarding the Pinnacle MoM Device implanted in Plaintiff Ramon Alicea.

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

121. As a direct and proximate result of the foregoing negligent misrepresentations by Defendants, Plaintiff Ramon Alicea suffered the injuries previously described.

122. Defendants' conduct as described herein was so grossly negligent as to indicate a wanton disregard of the rights of others, including the public at large, so as to justify an award of punitive damages.

123. By reason of the foregoing, Plaintiff Ramon Alicea demands judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deem proper.

124. The limitations on liability set forth in CPLR § 1601 do not apply to this action by reason of one or more of the exceptions set forth in CPLR § 1602.

SEVENTH CLAIM FOR RELIEF
Breach of Express Warranty
(Plaintiff Ramon Alicea)

125. Plaintiff Ramon Alicea 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.

126. Defendants expressly warranted that the Pinnacle MoM Device was safe and effective for its intended use as otherwise described in this complaint. The Pinnacle MoM device did not conform to these express representations.

127. The express warranties represented by the Defendants were a part of the basis for Plaintiff Ramon Alicea's use of the Pinnacle MoM Device and Plaintiff Ramon

Alicea relied on these warranties in deciding to have the Pinnacle MoM Device implanted.

128. At the time of the making of the express warranties, the Defendants had knowledge of the purpose for which the Pinnacle MoM Device was to be used, and warranted same to be in all respects safe and effective for such purpose.

129. 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 Ramon Alicea'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.

130. As a direct and proximate result of Defendants' breach of express warranties, Plaintiff Ramon Alicea has suffered and will continue to suffer the injuries described above.

131. 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, including the public at large, so as to justify an award of punitive damages.

132. By reason of the foregoing, Plaintiff Ramon Alicea demands judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deem proper.

133. The limitations on liability set forth in CPLR § 1601 do not apply to this action by reason of one or more of the exceptions set forth in CPLR § 1602.

EIGHTH CLAIM FOR RELIEF

Breach of Implied Warranty of Merchantability

(Plaintiff Ramon Alicea)

134. Plaintiff Ramon Alicea 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.

135. 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.

136. By placing the Pinnacle MoM Device into the stream of commerce, Defendants impliedly warranted that it was merchantable and fit for the ordinary purpose for which it was intended.

137. The Pinnacle MoM Device placed into the stream of commerce by Defendants was defective and, accordingly, was not merchantable or fit for the ordinary purpose for which it was intended.

138. 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.

139. Defendants breached the implied warranty for the Pinnacle MoM Device.

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

141. As a direct and proximate result of Defendants' breach of implied warranties, Plaintiff Ramon Alicea suffered, and will continue to suffer the injuries previously described, rendering Defendants liable for said damages.

142. 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, including the public at large, so as to justify an award of punitive damages.

143. By reason of the foregoing, Plaintiff Ramon Alicea demands judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deem proper.

144. The limitations on liability set forth in CPLR § 1601 do not apply to this action by reason of one or more of the exceptions set forth in CPLR § 1602.

NINTH CLAIM FOR RELIEF
General Business Law § 349
(Plaintiff Ramon Alicea)

145. Plaintiff Ramon Alicea 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.

146. Defendants' engaged in deceptive acts and practices in the conduct of their business, trade, or commerce in violation of New York General Business Law § 349.

147. Defendants have represented deceptive, inaccurate, false and misleading material information as to the safety of the Pinnacle MoM Device to Plaintiff Ramon Alicea's physicians, Plaintiff, and other consumers with the intent that they rely thereon.

148. Defendants knew or reasonably should have known that the Pinnacle MoM Device carried the risk of serious adverse effects described above.

149. Defendants failed to disclose material facts in the conduct of their business, trade, or commerce in that they did not disclose the risk of serious adverse effects to the intended users of the Pinnacle MoM Device.

150. Plaintiff Ramon Alicea has been injured by reason of Defendants' violation of New York General Business Law § 349(a).

151. Defendants' violation of § 349(a) was willful and knowing.

152. Plaintiff Ramon Alicea is entitled to actual damages, treble damages, costs, and, should he prevail in this action, reasonable attorney's fees pursuant to § 349(h).

TENTH CLAIM FOR RELIEF

Loss of Consortium

(Plaintiff Carole Alicea)

153. Plaintiff Carole Alicea adopts by reference and incorporates herein the allegations set forth above.

154. Plaintiff Carole Alicea was and is the lawful spouse of Ramon Alicea, and as such, was and is entitled to his support, society and services, including, but not limited to, love, companionship, affection, sexual relations, and solace.

155. As a direct and proximate result of Defendants' wrongdoing, Plaintiff Carole Alicea was deprived of the society and services of her spouse; her comfort and happiness have been impaired; she has suffered and will continue to suffer economic loss; and she has otherwise been emotionally and economically injured. Plaintiff Carole Alicea's injuries and damages are permanent and will continue into the future.

156. 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, including the public at large, so as to justify an award of punitive damages.

157. By reason of the foregoing, Plaintiff Carole Alicea demands judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deem proper.

158. The limitations on liability set forth in CPLR § 1601 do not apply to this action by reason of one or more of the exceptions set forth in CPLR § 1602.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants on each of the above-referenced claims as follows:

A. Awarding compensatory damages to Plaintiffs for past and future damages including but not limited to pain and suffering for severe and permanent personal injuries sustained by the Plaintiffs, health care costs, medical monitoring, loss of earnings, together with interest and costs as provided by law;

B. Awarding punitive and/or treble damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiffs in an amount sufficient to punish Defendants and deter future similar conduct;

C. Awarding Plaintiffs attorney fees;

D. Awarding Plaintiffs the costs of these proceedings; and

E. Awarding such other and further relief as this Court deems just and proper.

JURY DEMAND

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

Dated: February 3, 2017

Respectfully submitted:

W. Mark Lanier
THE LANIER LAW FIRM
6810 FM 1960 Rd W
Houston, TX 77069-3804
(713) 659-5200
(713) 659-2204 Fax
E-mail: wml@lanierlawfirm.com

Wayne Fisher
FISHER, BOYD, JOHNSON
& HUGUENARD, LLP
2777 Allen Parkway, 14th Floor
Houston, Texas 77019

Telephone: (713) 400-4000
Fax: (713) 400-4050
Email: wfisher@fisherboyd.com
Email: justinp@fisherboyd.com

Richard J. Arsenault
NEBLETT, BEARD & ARSENAULT
2220 Bonaventure Court
P.O. Box 1190
Alexandria, Louisiana 71301
Telephone: (800) 256-1050
Fax: (318) 561-2591
E-mail: rarsenault@nbalawfirm.com

Jayne Conroy
SIMMONS HANLY CONROY
112 Madison Avenue
New York, NY 10016
Telephone: (212) 784-6402
Fax: (212) 213-5949
E-mail: jconroy@simmonsfirm.com

Jerrold S. Parker
PARKER WAICHMAN LLP
6 Harbor Park Drive
Port Washington, NY 11050
516.466.6500 | Tel.
jerry@yourlawyer.com

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 February 3, 2017.

/s/ *W. Mark Lanier*
W. Mark Lanier