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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS

SHANNON BAKER, Personal Representative of the Estate of MICHAEL F. BAKER, deceased,	)	
	)	Court File No.
Plaintiff,	)	
v.	)	
	)	COMPLAINT
DEPUY ORTHOPAEDICS, INC. an Indiana corporation; JOHNSON & JOHNSON SERVICES, INC., a New Jersey corporation; JOHNSON & JOHNSON; THOMAS P. SCHMALZRIED, M.D., a professional corporation; THOMAS P. SCHMALZRIED, M.D.,	)	JURY TRIAL DEMAND
Defendants.	)	

Plaintiff Shannon Baker, Personal Representative of the Estate of Michael F. Baker, deceased ("Plaintiff"), alleges on information and belief against DEPUY ORTHOPAEDICS, INC; JOHNSON &JOHNSON SERVICES, INC; JOHNSON & JOHNSON, INC., and THOMAS P. SCHMALZRIED, M.D. ("Defendants"), the following:

I
INTRODUCTION AND SUMMARY OF ACTION

1. Defendants designed and manufactured the Pinnacle Hip Implant Device ("Pinnacle Device"). DePuy launched the Pinnacle Acetabular Cup System, including the Ultamet insert

component, in 2001. The Pinnacle Device was designed, developed, and sold for replacement of human hip joints damaged or diseased due to fracture, osteoarthritis, rheumatoid arthritis, avascular necrosis or similar conditions. The Pinnacle Device is designed to be fastened to human bone with adhesive or surgical screws. The Pinnacle Device was designed and sold to provide pain relief and restore consistent and smooth range of motion in the hip. Defendants marketed and described the Pinnacle Device as "[u]niquely designed to meet the demands of active patients like you – and help reduce pain" and advertised it with pictures of a young person trying on sneakers in an athletic shoe store. Defendants advertised the Pinnacle Device as superior devices featuring True Glide technology, allowing the body to create a thin film of lubrication between surfaces, which enables "a more fluid range of natural motion."

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

3. On information and belief, Plaintiff alleges that Defendants sold approximately 150,000 Pinnacle Devices. Defendants have stated in promotional materials that "99.9% of the Pinnacle Hip components are still in use today."

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

5. On information and belief, Plaintiff alleges that Defendants are aware that Pinnacle Devices may result in metallosis, biologic toxicity, and high failure rate. Plaintiffs further allege that the Pinnacle Devices result in unsafe release of toxic metal ions into hip implant recipients'

tissue and bloodstream. Plaintiff further alleges that Defendants are aware that metal particles from Pinnacle Devices result in metallosis, tissue death, bon erosion and development of tumors and pseudo tumors.

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

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

8. Plaintiff's decedent's suffering could easily have been prevented. Plaintiff's decedent and those like him would not have suffered from unnecessary pain and debilitation, and the need to undergo subsequent revision surgery had Defendants warned the public of the dangers of the Pinnacle Device when reports began being made to the F.D.A. regarding the device's failures. Or, even better, had Defendants taken the affirmative step of recalling the Pinnacle Devices at that time. Despite receipt of over 1,300 reports of failures Defendants have yet to recall these devices. Even now recall will come too late for thousands of Americans, including Plaintiffs, who will now live with the consequences of these faulty devices for years, if not the rest of their lives. Plaintiff seeks redress for her decedent's injuries.

II
PARTIES

9. Michael F. Baker was at all times relevant to this Complaint, a resident and citizen of the State of Massachusetts and resided in Somerville, Massachusetts.

10. On March 27, 2014 Michael F. Baker died of causes unrelated to his DePuy Pinnacle hip device.

11. Plaintiff Shannon Baker is the Personal Representative of the Estate of Michael F. Baker, deceased.

12. Defendant DEPUY ORTHOPAEDICS, INC., is, and at all times relevant to this Complaint was, an Indiana Corporation with its principal place of business at 700 Orthopaedic Drive, Warsaw, Indiana 46581. Defendant DEPUY ORTHOPAEDICS, INC., is and was at all times relevant herein doing business in and/or having directed its activities at Texas, and specifically this judicial district.

13. Defendant JOHNSON & JOHNSON SERVICES, INC., is, and at all times relevant to this Complaint was, a New Jersey Corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Defendant JOHNSON & JOHNSON SERVICES, INC., is and was at all times relevant herein doing business in and/or having directed its activities at Florida, Virginia, and specifically this judicial district.

14. Defendant JOHNSON & JOHNSON, INC., is a corporation formed in the State of New Jersey with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Defendant JOHNSON & JOHNSON, INC., is, and was at all relevant times herein, engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products including the PINNACLE METAL-ON-METAL system. Defendant JOHNSON & JOHNSON, INC., is and was at all times relevant herein doing business in and/or having directed its activities at Florida, Virginia, and specifically this judicial district.

15. Defendants DEPUY ORTHOPAEDICS, INC., JOHNSON & JOHNSON SERVICES, INC., and JOHNSON & JOHNSON, INC., will be collectively referred to in this Complaint as the "DePuy," "DePuy Defendants," or "Defendants."

16. On information and belief, Defendant THOMAS P. SCHMALZRIED, M.D., A PROFESSIONAL CORPORATION, is a corporation organized and existing under the laws of California with its primary place of business at 2200 W. Third Street #400, Los Angeles, California 90057. THOMAS P. SCHMALZRIED, M.D., A PROFESSIONAL CORPORATION, designed the hip implant that is the subject of this lawsuit. THOMAS P. SCHMALZRIED, M.D., A PROFESSIONAL CORPORATION, collects royalties for each hip implant sold, and in the last two years alone, it has collected more than $3.4 million in such royalty payments. In addition to designing the hip implant components that were implanted in Plaintiff Dan Lee Heinrichs and collecting royalties for the sale of Plaintiff's implant, THOMAS P. SCHMALZRIED, M.D., A PROFESSIONAL CORPORATION, remained actively involved in promoting and marketing the PINNACLE METAL-ON-METAL System.

17. On information and belief, Defendant THOMAS P. SCHMALZRIED, M.D., is an individual. THOMAS P. SCHMALZRIED, M.D., resides in Los Angeles County in the State of California.

18. Defendants THOMAS P. SCHMALZRIED, M.D., A PROFESSIONAL CORPORATION, and THOMAS P. SCHMALZRIED, M.D., will hereafter be referred to as "Schmalzried," "TPS Corp." or "Defendants."

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

III
JURISDICTION, VENUE, AND INTRADISTRICT ASSIGNMENT

20. Venue of this case is appropriate in The United States District Court for the District of Colorado. Plaintiff states that but for the Order permitting direct filing into the Northern District of Texas pursuant to Case Management Order No. 5, Plaintiff would have filed in the United States District Court for the District of Massachusetts. Therefore, Plaintiff respectfully requests that at the time of transfer of this action back to the trial court for further proceedings that this case be transferred to the above referenced District Court.

21. This Court has original jurisdiction pursuant to 28 U.S.C. §1332(d)(2)(A). The amount in controversy in this action is well over $100,000.

22. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(a). A substantial portion of the events and omissions giving rise to this lawsuit occurred in this District and the Court has personal jurisdiction over each of the parties as alleged throughout this Complaint.

IV
FACTUAL ALLEGATIONS

A. The Pinnacle Device with an "Ultamet" Liner.

23. The Pinnacle Device was developed for the purpose of reconstructing human hip joints damaged or diseased 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 into a

socket. The socket portion of the hip is called the acetabulum. The femoral head at the top of the femur bone is rounded and rotates within the curved surface of the acetabulum.

24. The Pinnacle Device is made up of four components: the metal femoral stem is inserted inside the femur bone, the femoral head (or ball) connects to the top of the stem and then makes contact with a liner that is attached to the interior portion of the metal acetabulum cup (socket). The Pinnacle Devices include a ceramic femoral head and a cobalt-chromium head. The Pinnacle Device with the cobalt-chromium head are branded by the Defendants as "Articul/eze" and "Ultamet". The acetabulum cup is comprised of titanium metal on its outer shell and is secured in place on the pelvis with screws or adhesive or press fit. The outer surface of the Acetabular shell is rough to encourage bone growth and adhesion to the pelvis. Once the shell is in place a polyethylene plastic, ceramic or cobalt- chromium liner is placed on the inside of the acetabulum cup selected by the surgeon based on the specific patient's needs. The femoral head and the selected liner comprise the "bearing surface" of the hip system. The cobalt-chromium metal liner is branded by Defendants as the "Ultamet". The Pinnacle device with an Ultamet liner is a "metal-on-metal" device due to the fact that both articulating surfaces – the femoral head (ball) and the Acetabular linter (socket) are both comprised of cobalt-chromium metal.

B. Defendants Do Not Seek Premarket Approval From the FDA, and Thus the FDA Makes No Finding That the Pinnacle Device is Safe or Effective.

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

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

premarket approval by the FDA, a process which obligates the manufacturer to design and implement a clinical investigation and to submit the results of that investigation to the FDA.

27. 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.

28. The FDA may grant premarket approval only if it finds that there is a 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.

29. A medical device on the market prior to the effective date of the MDA – a so-called "grandfathered" device – was not required to undergo premarket approval. In addition, a medical device marketed after the MDA's effective date may bypass the rigorous premarket approval process if the device is "substantially equivalent" to a "grandfathered" pre-MDA device (i.e., a device approved prior to May 28, 1976). This exception to premarket approval is known as the "510(k)" process and simply requires the manufacturer to notify the FDA under section 510(k) of the MDA of its intent to market a device at least 90 days prior to the device's introduction on the market, and to explain the device's substantial equivalent to a pre-MDA predicate device. The FDA may then approve the new device for sale in the United States.

30. Rather than being approved for use by the FDA pursuant to the rigorous premarket approval process, the Pinnacle Device metal-on-metal total hip replacement system was certified to be sold on the basis of Defendants' claim that, under section 510(k) of the MDA, it was "substantially equivalent" to another older hip implant that Defendants sold and implanted prior to the enactment of the MDA in 1976. As such, under the 510(k) process, Defendants were able to market the Pinnacle Device with virtually no clinical or non-clinical trials or FDA review of the implant for safety and effectiveness.

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

31. Had Defendants conducted clinical trials of the Pinnacle Device before it was first released on the market in the early 2000's, they would have discovered at that time what they ultimately learned in or around 2007 – that the Pinnacle Device results in a high percentage of patients developing metallosis, biologic toxicity and an early and high failure rate due to the release of metal particles in the patient's surrounding tissue when the cobalt-chromium metal femoral head rotates within the cobalt-chromium metal Acetabular liner.

32. In other words, implantation of the Pinnacle Device results in a nearly immediate systemic release of high levels of toxic metal cobalt-chromium ions into the patient's tissue and bloodstream. This is because cobalt-chromium metal particles are released by the friction from the metal femoral head contacting the metal Acetabular liner. The particles that accumulate in the tissues surrounding the patient's implant giving rise to metallosis, pseudo tumors, infection or other conditions.

33. The formation of metallosis, pseudo tumors and infection and inflammation causes severe pain and discomfort, death of surrounding tissue, bone loss and loss of mobility.

34. The problems with the pinnacle Device are similar to the issues that gave rise to the Defendants' recall of the ASR XL Acetabular System. Like the Pinnacle Device, the ASR is also prone to early failure, and causes metallosis and cobalt toxicity resulting in serious health problems and the need for subsequent revision surgery. As a result, in August 2010, Defendants, in acknowledging the high failure rate of the ASR, recall more than 93,000 ASRs worldwide. It is anticipated that Defendants will at some point recall the Pinnacle Device for the same reasons.

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

36. On information and belief, Plaintiff alleges that many recipients of the Pinnacle 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 Device have significantly elevated levels of chromium and cobalt in amounts many times higher than acceptable or recommended safety levels. Notable, the ASR XL Acetabular System and the Pinnacle Device were both designed by Defendant Thomas Schmalzried.

37. A number of governmental regulatory agencies have recognized the problems that are caused by metal-on-metal implants such as the ASR and the Pinnacle Device. For instance, The Medicines and Healthcare Products Regulatory Agency ("MHRA") in Britain investigated Defendants' metal-on-metal total hip replacement system after receiving widespread reports of soft tissue reactions and tumor growth in thousands of patients who had received these implants.

MHRA has required physicians in Great Britain to establish a system to closely monitor patients known to have metal-on-metal hips by monitoring the cobalt and chromium ion levels and to evaluate them for related soft tissue reactions.

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

39. Despite the public knowledge to the contrary, Defendants continue to misrepresent the Pinnacle Device as a high quality, safe and effective hip replacement product in their marketing and promotional materials. This despite the fact that Defendants have known for years that the Pinnacle Device poses a danger to patients that have it implanted.

40. As a result, Defendants continue to sell the Pinnacle Device to doctors who implant them in countless numbers of patients with an unreasonably high percentage of those patients being forced to endure serious injury from metallosis, pseudo tumors, biologic toxicity and other complications. These patients are reporting severe pain and discomfort and the need for one or more complicated revision surgeries resulting in life-long health problems caused by the device.

D. As a Direct and Proximate Result of Defendants' Failure to Recall the Pinnacle Devices, Michael F. Baker received a Hip Implant Device, and Suffered Debilitating Pain and the Need for Revision Surgery to Replace the Implant.

41. On October 21, 2002, Michael F. Baker underwent a surgical procedure performed by St. George T. Aufranc, M.D.., at New England Baptist Hospital, Boston, Massachusetts, to implant a Pinnacle Hip in his right hip.

42. Several years after receiving the implant, he began to experience pain in the groin area and an increase in cobalt levels. This pain and swelling persisted and Mr. Baker's orthopedic surgeon, Sumon Nandi, M.D. decided Mr. Baker needed to have his hip implant surgically removed and replaced.

43. On June 21, 2012, Mr. Baker underwent a painful, complex and risky surgery (known as a "revision surgery") performed by Sumon Nandi, M.D.., at New England Baptist Hospital, Boston, Massachusetts, to remove and replace the Pinnacle Hip that had failed.

44. In performing the Mr. Baker's revision surgery Dr. Nandi found a large encapsulated fluid collection demonstrating significant metallosis.

45. Revision surgeries are generally more complex than the original hip replacement surgery, often because there is a reduced amount of bone in which to place the new hip implants. Revision surgeries also usually take longer than the original hip replacement surgery and the revision surgery has a higher rate of complications.

46. As a direct and proximate result of the failure of his defective Pinnacle Hip and the Defendants' wrongful conduct, Mr. Baker sustained and suffered economic damages (including medical and hospital expenses), severe and possibly permanent injuries, pain, suffering and emotional distress.

47. As a result, Mr. Baker sustained damages in an amount to be proven at trial, but which will far exceed the jurisdictional minimum of this court.

48. At no time prior to June 21, 2012 did Michael F. Baker know or have reason to know of the injury and its cause, the defective Pinnacle Hip. Had Michael F. Baker known that the DePuy Pinnacle Metal-on-Metal Hip Implant caused pain, swelling, inflammation, infection, and damage

to surrounding bone and tissue, problems walking, and the potential need for a revision surgery to explant the device, Michael F. Baker would not have elected to have had the surgery.

V
FIRST CAUSE OF ACTION
CLAIMS FOR RELIEF

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

50. Defendants had a duty to exercise reasonable care in the design, manufacture, testing, marketing and distribution into the stream of commerce of the Pinnacle Metal-on-Metal Hip Implant Devices, including a duty to insure that the Pinnacle Metal-on-Metal Hip Implant Devices did not pose a significantly increased risk of adverse events.

51. Defendants failed to exercise reasonable care in the design, manufacture, testing, marketing and distribution into the stream of commerce of the Pinnacle Metal-on-Metal Hip Implant Devices. Defendants knew or should have known that the Pinnacle Metal-on-Metal hip Implant Devices could fail early in patients therefore giving rise to 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, and therefore was not safe for use by Michael F. Baker.

52. Despite the fact that Defendants knew or should have known that the Pinnacle Metal-on-Metal Hip Implant Devices could fail early in patients therefore giving rise to 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 continued to market the Pinnacle Metal-on-Metal Hip Implant Devices as a safe and effective hip replacement system.

53. As a direct and proximate result of Defendants' negligence, Michael F. Baker suffered significant damages, including but not limited to physical injury, economic loss, pain and suffering, and the need for further surgery to replace the faulty device.

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

VI
SECOND CAUSE OF ACTION
STRICT LIABILITY (MANUFACTURING DEFECT)
(Against All Defendants)

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

56. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Pinnacle Metal-on-Metal Hip Implant Devices.

57. The Pinnacle Metal-on-Metal Hip Implant Device that was surgically implanted in Michael F. Baker was defective in their manufacture when they left the hands of Defendants in that they deviated from product specifications, posing a serious risk that they could fail early in patients therefore giving rise to physical injury, pain and suffering, debilitation, and the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

58. As a direct and proximate result of Defendants' placement of the defective Pinnacle Metal-on-Metal Hip Implant Devices into the stream of commerce, Michael F. Baker suffered significant damages, including but not limited to physical injury, economic loss, pain and suffering, and the need for further surgery to replace the faulty device.

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

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

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

61. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Pinnacle Metal-on-Metal Hip Implant Devices.

62. The Pinnacle Metal-on-Metal Hip Implant Devices that was surgically implanted in Michael F. Baker was defective in design when they left the hands of Defendants in that their design was flawed thereby posing a serious risk that the device could fail early in patients therefore giving rise to physical injury, pain and suffering, debilitation, and the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

63. As a direct and proximate result of Defendants' placement of the defective Pinnacle Metal-on-Metal Hip Implant Devices into the stream of commerce, Michael F. Baker suffered significant damages, including but not limited to physical injury, economic loss, pain and suffering, and the need for further surgery to replace the faulty device.

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

VIII
FOURTH CAUSE OF ACTION
STRICT PRODUCTS LIABILITY (INADEQUATE WARNING)
(Against All Defendants)

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

66. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Pinnacle Metal-on-Metal Hip Implant Devices.

67. The Pinnacle Metal-on-Metal Hip Implant Devices placed into the stream of commerce by Defendants were defective due to inadequate warning, because Defendants knew or should have known that the Pinnacle Metal-on-Metal Hip Implant Devices could fail early in patients therefore giving rise to physical injury, pain and suffering, debilitation, and the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery, but failed to give consumers adequate warning of such risks. Further, the Pinnacle Metal-on-Metal Hip Implant Devices placed into the stream of commerce by Defendants were surgically implanted in a manner reasonably anticipated by Defendants.

68. As a direct and proximate result of Defendants' placement of the defective Pinnacle Metal-on-Metal Hip Implant Devices into the stream of commerce, Michael F. Baker suffered significant damages, including but not limited to physical injury, economic loss, pain and suffering, and the need for further surgery to replace the faulty device.

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

IX
FIFTH CAUSE OF ACTION
STRICT PRODUCTS LIABILITY
(FAILURE TO CONFORM TO REPRESENTATIONS)
(Against all Defendants)

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

71. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Pinnacle Metal-on-Metal Hip Implant Devices.

72. Defendants made representations to consumers regarding the character or quality of Pinnacle Metal-on-Metal Hip Implant Devices, including but not limited to statements that the Pinnacle Metal-on-Metal Hip Implant Devices were a safe and effective hip replacement system. For example, Defendants claimed that the device was based on a "strong clinical history", and that the devices would allow patients to "return to their more active lifestyles."

73. The Pinnacle Metal-on-Metal Hip Implant Devices placed into the stream of commerce by the Defendants were defective in that, when they left the hands of the Defendants, they did not conform to Defendants' representations.

74. Michael F. Baker justifiably relied upon Defendants' representations regarding the Pinnacle Metal-on-Metal Hip Implant Devices.

75. As a direct and proximate result of Defendants' placement of the defective Pinnacle Metal-on-Metal Hip Implant Devices into the stream of commerce, Michael F. Baker suffered significant damages, including but not limited to physical injury, economic loss, pain and suffering, and the need for further surgery to replace the faulty device.

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

X
SIXTH CAUSE OF ACTION
STRICT PRODUCTS LIABILITY (FAILURE TO ADEQUATELY TEST)
(Against All Defendants)

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

78. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Pinnacle Metal-on-Metal Hip Implant Devices.

79. Defendants advised consumers that the Pinnacle Metal-on-Metal Hip Implant Devices were safe and effective hip replacement devices. Defendants failed to adequately test the Pinnacle Metal-on-Metal Hip Implant Devices to ensure that they would not fail early thereby giving rise to unnecessary physical injury, pain and suffering, debilitation, and the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

80. Had Defendants adequately tested the Pinnacle Metal-on-Metal Hip Implant Devices and disclosed the results of those tests to public, Michael F. Baker would not have elected to have the Pinnacle Metal-on-Metal Hip Implant Devices surgically implanted.

81. As a direct and proximate result of Defendants' placement of the defective Pinnacle Metal-on-Metal Hip Implant Devices into the stream of commerce, Michael F. Baker suffered significant damages, including but not limited to physical injury, economic loss, pain and suffering,

and the need for further surgery to replace the faulty device, and will continue to suffer such damages in the future.

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

XI
SEVENTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY
(Against All Defendants)

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

84. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Pinnacle Metal-on-Metal Hip Implant Devices.

85. Defendants expressly warranted that the Pinnacle Metal-on-Metal Hip Implant Devices were safe and effective hip replacement systems.

86. The Pinnacle Metal-on-Metal Hip Implant Devices placed into the stream of commerce by Defendants did not conform to these express representations because they failed early thereby giving rise to unnecessary physical injury, pain and suffering, debilitation, and the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

87. As a direct and proximate result of Defendants' breach of express warranties regarding the safety and effectiveness of the Pinnacle Metal-on-Metal Hip Implant Devices, Michael F. Baker suffered significant damages, including but not limited to physical injury, economic loss, pain and suffering, and the need for further surgery to replace the faulty device.

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

XII
EIGHTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY
(Against All Defendants)

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

90. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Pinnacle Metal-on-Metal Hip Implant Devices.

91. At the time Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Pinnacle Metal-on-Metal Hip Implant Devices, Defendants knew the use for which the Pinnacle Metal-on-Metal Hip Implant Devices were intended, and impliedly warranted the Pinnacle Metal-on- Metal Hip Implant Devices to be of merchantable quality and safe for such use.

92. Michael F. Baker reasonably relied upon the skill and judgment of Defendants as to whether the Pinnacle Metal-on-Metal Hip Implant Devices were of merchantable quality and safe for its intended use.

93. Contrary to Defendants' implied warranties, the Pinnacle Metal-on-Metal Hip Implant Devices were not of merchantable quality or safe for its intended use, because the Pinnacle Metal-on-Metal Hip Implant Devices were unreasonably dangerous as described above.

94. As a direct and proximate result of Defendants' breach of implied warranties regarding the safety and effectiveness of the Pinnacle Metal-on-Metal Hip Implant Devices,

Michael F. Baker suffered significant damages, including but not limited to physical injury, economic loss, pain and suffering, and the need for further surgery to replace the faulty device

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

XIII
NINTH CAUSE OF ACTION
FRAUDULENT CONCEALMENT
(Against All Defendants)

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

97. Defendants had a duty to inform Michael F. Baker of all material facts about the Pinnacle Metal-on-Metal Hip Implant Devices based upon their assumption of that responsibility by representing to consumers that the Pinnacle Metal-on-Metal Hip Implant Devices were safe and effective hip replacement systems.

98. Since 2008, Defendants have had actual knowledge that the Pinnacle Metal-on-Metal Hip Implant Devices could fail early thereby giving rise to unnecessary 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.

99. The fact that the Pinnacle Metal-on-Metal Hip Implant Devices could fail early thereby giving rise to unnecessary 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 was, and is a material fact.

100. Defendants failed to disclose this material fact to consumers, including Michael F. Baker. Instead, Defendants took affirmative steps to prevent physicians and consumers from learning of this material fact, while aggressively marketing the Pinnacle Metal-on-Metal Hip Implant Devices as safe and effective hip replacement systems. This concealment was done with the intent to induce Michael F. Baker to purchase the Pinnacle Metal-on-Metal Hip Implant Devices so that their physicians could surgically implant the devices into Michael F. Baker.

101. In reliance on Defendants' fraudulent concealment of a material fact, Michael F. Baker purchased the Pinnacle Metal-on-Metal Hip Implant Devices so that their physicians could surgically implant the devices into Michael F. Baker. Had Michael F. Baker known that the Pinnacle Metal-on-Metal Hip Implant Devices could fail early thereby giving rise to unnecessary physical injury, pain and suffering, debilitation, and the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery, he would not have purchased or consumed the Pinnacle Metal-on-Metal Hip Implant Devices.

102. As a result of Defendants' unlawful and fraudulent concealment of the effects of the Pinnacle Metal-on-Metal Hip Implant Devices, the running statute of limitations has been suspended with respect to claims that Plaintiff has brought or could bring. Michael F. Baker had no knowledge of Defendants unlawful conduct, or of any of the facts that might have led to the discovery of Defendants' wrongdoing, until shortly before this Complaint was filed when notice of the recall was sent.

103. As a direct and proximate result of Defendants' fraudulent concealment of the effects of the Pinnacle Metal-on-Metal Hip Implant Devices, Michael F. Baker suffered significant

damages, including but not limited to physical injury, economic loss, pain and suffering, and the need for surgery to replace the faulty device.

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

XIV
TENTH CAUSE OF ACTION
INTENTIONAL MISREPRESENTATION
(Against All Defendants)

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

106. Since at least 2008, Defendants have had actual knowledge that the Pinnacle Metal-on-Metal Hip Implant Devices could fail early thereby giving rise to unnecessary 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.

107. The fact that the Pinnacle Metal-on-Metal Hip Implant Devices could fail early thereby giving rise to unnecessary 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 was, and is, a material fact.

108. Defendants knowingly and intentionally made false representations of material fact to Plaintiffs, including but not limited to claims that the Pinnacle Metal-on-Metal Hip Implant Devices were safe and effective hip replacement systems. For example, Defendants claimed that the device was based on a "strong clinical history", and that the devices would allow patients to "return to their more active lifestyles."

109. These representations were made with the intent to induce Michael F. Baker to obtain the Pinnacle Metal-on-Metal Hip Implant Devices.

110. In reliance on Defendants' misrepresentations of material fact, Michael F. Baker obtained the Pinnacle Metal-on-Metal Hip Implant Devices. Had Michael F. Baker known that the Pinnacle Metal-on-Metal Hip Implant Devices could fail early thereby giving rise to unnecessary 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, he would not have elected to obtain a Pinnacle Metal-on-Metal Hip Implant Device.

111. As a result of Defendants' intentional misrepresentations regarding the effects of the Pinnacle Metal-on-Metal Hip Implant Device, the running statute of limitations has been suspended with respect to claims that Plaintiff has brought or could bring. Michael F. Baker had no knowledge of Defendants' unlawful conduct, or of any of the facts that might have led to the discovery of Defendants' wrongdoing, until shortly before this Complaint was filed when notice of recall was sent.

112. As a direct and proximate result of Defendants' intentional misrepresentations, including but not limited to claims that the Pinnacle Metal-on- Metal Hip Implant Device was safe for use, Michael F. Baker suffered significant damages, including but not limited to physical injury, economic loss, pain and suffering, and the need for further surgery to replace the faulty device.

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

XV
ELEVENTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION
(Against All Defendants)

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

115. Since at least 2008, Defendants have had actual knowledge that the Pinnacle Metal-on-Metal Hip Implant Devices could fail early thereby giving rise to unnecessary 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.

116. The fact that the Pinnacle Metal-on-Metal Hip Implant Devices could fail early thereby giving rise to unnecessary 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 was, and is a material fact.

117. Defendants recklessly and/or negligently made false representations of material fact to Plaintiffs, including but not limited to claims that the Pinnacle Metal-on-Metal Hip Implant Devices were safe and effective hip replacement systems. For example, Defendants claimed that the device was based on a "strong clinical history", and that the devices would allow patients to "return to their more active lifestyles".

118. These representations were made with the intent to induce Michael F. Baker to obtain the Pinnacle Metal-on-Metal Hip Implant Devices.

119. In reliance of Defendants' misrepresentations of material fact, Michael F. Baker obtained the Pinnacle Metal-on-Metal Hip Implant Devices. Had Michael F. Baker known that the Pinnacle Metal-on-Metal Hip Implant Devices could fail early thereby giving rise to unnecessary

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, he would not have elected to obtain a Pinnacle Metal-on-Metal Hip Implant Device.

120. As a result of Defendants' reckless and/or negligent misrepresentations regarding the effects of the Pinnacle Metal-on-Metal Hip Implant Devices, the running statute of limitations has been suspended with respect to claims that Plaintiff has brought or could bring. Michael F. Baker had no knowledge of Defendants' unlawful conduct, or of any of the facts that might have led to the discovery of Defendants' wrongdoing, until shortly before this Complaint was filed when notice of the recall was sent.

121. As a direct and proximate result of Defendants' reckless and/or negligent misrepresentations, including but not limited to claims that the Pinnacle Metal-on-Metal Hip Implant Devices was safe for use, Michael F. Baker suffered significant damages, including but not limited to physical injury, economic loss, pain and suffering, and the need for surgery to replace the faulty device.

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

XVI
PRAYER FOR RELIEF

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

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

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

D. Restitution and disgorgement of all revenue that Defendants have obtained through the manufacture, marketing, sale and administration of the Pinnacle Metal-on-Metal Hip Implant Devices;

E. Attorney's fees and costs;

F. Pre- and post-judgment interest; and,

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

Dated this 22nd day of May 2015.

Warshauer-McLaughlin Law Group, P.C.

/s/ George E. McLaughlin
George E. McLaughlin, #16364
1890 Gaylord Street
Denver, CO 80206
720-420-9800 – telephone
303-322-3423 – facsimile
gem@w-mlawgroup.com

JS 44 (TXND Rev. 2/10)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS
Shannon Baker, Personal Representative of the Estate of Michael F. Baker, deceased

(b) County of Residence of First Listed Plaintiff Middlesex, MA
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)
George E. McLaughlin, Warshauer-McLaughlin Law Group, P.C.
1890 Gaylord Street, Denver, CO 80206
720-420-9899

DEFENDANTS
DePuy Orthopaedics, Inc.; Johnson & Johnson Services, Inc.; Johnson & Johnson; Thomas P. Schmalzried, M.D., P.C.; Thomas P. Schmalzried, M.D.

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☒ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury

PERSONAL INJURY
- ☐ 362 Personal Injury - Med. Malpractice
- ☒ 365 Personal Injury - Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 440 Other Civil Rights

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

FORFEITURE/PENALTY
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs.
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt.Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus - Alien Detainee
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN (Place an "X" in One Box Only)
☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing (**Do not cite jurisdictional statutes unless diversity**):
28 U.S.C. Section 1332
Brief description of cause:
Personal injury and strict product liability against manufacturer

VII. REQUESTED IN COMPLAINT:
☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23
DEMAND $
CHECK YES only if demanded in complaint:
JURY DEMAND: ☑ Yes ☐ No

VIII. RELATED CASE(S) PENDING OR CLOSED: (See instructions)
JUDGE Ed Kinkeade DOCKET NUMBER 3:11-MD-2244-K

DATE 05/22/2015
SIGNATURE OF ATTORNEY OF RECORD /s/ George E. McLaughlin

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE