UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

IN RE: DEPUY ORTHOPAEDICS, INC. PINNACLE DEVICE IMPLANT PRODUCTS LIABILITY LITIGATION	**MDL Case No. 3:11-MD-2244-K**
NANCY POWERS,	
Plaintiff,	
v.	**Civil Action No.: _____**
DEPUY ORTHOPAEDICS, INC., DEPUY INC., DEPUY INTERNATIONAL LIMITED, JOHNSON & JOHNSON, JOHNSON & JOHNSON SERVICES, INC., JOHNSON & JOHNSON INTERNATIONAL,	**JURY TRIAL DEMANDED**
Defendants.	

COMPLAINT

Plaintiff, by and through the undersigned attorneys, files this Complaint against the Defendants and in support thereof would show as follows:

I. PARTIES

1. Plaintiff, Nancy Powers, is an adult resident of Lapeer, Michigan.

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

3. Defendant DePuy, Inc. is a Delaware corporation with its principal place of business located at 700 Orthopaedic Drive, Warsaw, Indiana 46581. Upon information and

belief, Defendant DePuy Inc. is a wholly owned subsidiary of Defendant Johnson & Johnson International.

4. Defendant DePuy International Limited is a corporation organized and existing pursuant to the laws of the United Kingdom, with its principal place of business located at St. Anthonys Road, Leeds, West Yorkshire, LS11 8DT.

5. Defendant Johnson & Johnson is a New Jersey corporation with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

6. Defendant Johnson & Johnson Services, Inc., is a New Jersey corporation with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

7. Defendant, Johnson & Johnson International, is a New Jersey Corporation with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Upon information and belief, Defendant Johnson & Johnson International is a wholly owned subsidiary of Defendant Johnson & Johnson.

8. At all relevant times, each Defendant was the representative, agent, employee or alter ego of the other Defendant, and in doing the things alleged herein was acting within the scope of its authority as such.

II. JURSIDICTION AND VENUE

9. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. § 1332.

10. Venue is proper pursuant to 28 U.S.C. § 1407 and Case Management Order 1 entered by Hon. Ed Kineade, on June 29, 2011, by which this matter may be filed directly in the MDL proceedings in the Northern District of Texas.

III. BACKGROUND

A. THE DEPUY PINNACLE® ACETABULAR CUP SYSTEM IS DEFECTIVE, UNSAFE AND HAS NOT BEEN ADEQUATELY TESTED

11. The hip joint connects the thigh (femur) bone of a patient's leg to the patient's pelvis. The hip joint is often characterized as a ball and socket joint. The acetabulum is the cup shaped socket portion of the hip and the femoral head (ball) at the top of the femur bone rotates within the curved surface of the acetabulum.

12. A total hip system replaces the body's natural joint with an artificial one, usually made out of metal, plastic or ceramic. A typical hip replacement system consists of four separate components: (1) a femoral stem, (2) a femoral head, (3) a liner (bearing surface), and (4) an acetabular shell. After the surgeon hollows out a patient's femur bone, the metal femoral stem is implanted. The femoral head is usually a metal ball that is fixed on top of the femoral stem. The femoral head forms the hip joint that can rotate when it is placed inside a plastic, ceramic or metal liner that is attached to the interior portion of the metal acetabulum cup (socket) comprised of metal on its outer shell. When complete, the femoral stem anchors the metal femoral head that rotates within the liner sitting inside the acetabular cup.

13. Defendants developed, designed, tested, manufactured, distributed, and sold the Pinnacle Acetabular Cup System ("Pinnacle Device") which is a hip bearing system to be used in a total hip replacement or revision surgery. The Pinnacle Device system includes two component parts: the liner and acetabular cup. Defendants developed, designed, tested, manufactured, and distributed at least four different metal acetabular cups and three different liners to be used as the Pinnacle Device. The acetabulum cup is comprised of titanium metal on its outer shell and can be fixed to the bone with screws or without screws by growing into the bone with Defendants Gripton™ porous technology. The Pinnacle Device has three different

liners to choose from made of cobalt-chromium metal, polyethylene plastic or ceramic. One of the cobalt-chromium metal liners is the Ultamet® XL.

14. The Pinnacle Device is critically different than most hip replacement devices because a metal acetabular liner may be used instead of a polyethylene plastic acetabular liner. The Pinnacle Device with a metal liner, such as the Ultamet® XL, is a "metal-on-metal" device due to the fact that both articulating surfaces - the femoral head (ball) and acetabulum liner (socket) - are comprised of cobalt-chromium (CoCr) metal. Therefore, the metal-on-metal design forces metal to rub against metal with the full weight and pressure of the human body creating metallic debris to be released into the Plaintiff's hip socket and blood stream. Because of Defendants' defective design for the Pinnacle Device, hundreds of patients – including Plaintiff – have been forced to undergo surgeries to replace the failed hip implants.

15. Defendants describe the Pinnacle Device as "the only product available that provides the option of choosing a polyethylene or metal insert for use with the same outer titanium cup that replaces the socket of the natural hip."

16. Defendants developed, designed, tested, manufactured, and distributed the metal and ceramic femoral heads that are used with the Pinnacle Device that directly contact the liner. The Articul/eze-M Spec Femoral Head and the aSphere M-Spec Femoral Head are metal femoral heads commonly used with the Pinnacle Device.

17. The Pinnacle Device is fully compatible with DePuy's complete line of advanced femoral stems that Defendants develop, design, test, manufacture, and distribute such as the AML®, Prodigy®, Summit™, Corail®, Tri-Lock®, and S-ROM femoral stems and sleeves.

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

19. The Medical Device Amendments to the Food, Drug, and Cosmetics Act of 1938 ("MDA"), in theory, require Class III medical devices, including the Pinnacle Device, to undergo premarket approval by the FDA. Premarket approval is a process which obligates the manufacturer to design and implement a clinical investigation and submit the results of the investigations to the FDA.

20. Premarket approval is a rigorous process that requires a manufacturer to submit what is typically a multivolume application that includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a full statement of the device's components, ingredients, and properties, and of the principle or principles of operation; a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of such device; samples or device components required by the FDA; and, a specimen of the proposed labeling.

21. The FDA may grant premarket approval only if it finds that there is reasonable assurance that the medical device is safe and effective and must weigh any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

22. A medical device on the market prior to the effective date of the MDA – a so-called "grandfathered" device – was not required to undergo premarket approval.

23. 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

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 at least 90 days prior to the device's introduction on the market of the manufacturer's intent to market a device, and to explain the device's substantial equivalence to a pre-MDA predicate device. The FDA may then approve the new device for sale in the United States.

24. The MDA does not require an FDA determination that the device is in fact substantially equivalent to a grandfathered device.

25. Instead of assuring the safety of the Pinnacle Device through clinical trials, Defendants sought to market the Pinnacle Device without conducting any clinical trials by obtaining FDA approval under section 510(k). To that end, Defendants submitted a section 510(k) premarket notification of intent to market the Pinnacle Device.

26. By telling the FDA that the Pinnacle Device's design was "substantially equivalent" to other hip components and products on the market, Defendants were able to avoid the safety review required for premarket approval under FDA regulations, which includes clinical trials.

27. The FDA cleared the Pinnacle Device for sale by means of the abbreviated 510(k) process and consequently the FDA did not require the Pinnacle Device to undergo clinical trials.

28. The 510(k) notification for the Pinnacle Device includes Defendants assertion that it believes the Pinnacle Device to be substantially equivalent to grandfathered devices - devices that were never required to be reviewed for safety and effectiveness.

29. Significantly, unlike the premarket approval process, the 510(k) notification process does not call for scrutiny – or even clinical testing – of a device's safety and effectiveness.

30. A finding of substantial equivalence is not equivalent to a finding of a device's safety and effectiveness.

31. Thus, the FDA's finding of "substantial equivalence" had nothing to do with reviewing the Pinnacle Device's safety and effectiveness, but rather only a determination of equivalence to grandfathered devices that never underwent safety and effectiveness review.

32. Defendants sold approximately 150,000 Pinnacle Devices.

B. AFTER RECEIVING OVER 1,300 REPORTED ADVERSE EVENTS, DEFENDANTS SHOULD HAVE RECALLED OR NOTIFIED THE PUBLIC AND HEALTH CARE INDUSTRY OF THE DEFECTIVE PROBLEMS. INSTEAD, DEFENDANTS HAVE CONTINUED TO MARKET THE PINNACLE DEVICE.

33. Defendants have received over 1,300 reports associated with the Pinnacle Device since 2002, and the number is expected to grow. From January 1, 2011 to March 31, 2011, the FDA received over 250 self-reported adverse events regarding the Pinnacle Device (metal-on-metal). Reported symptoms range from pain, infection, inflammation, feeling as if hip is dislocating, heavy metal poisoning (metallosis) confirmed by blood tests resulting in eventual revision, ALVAL fluid (Aseptic Lymphocytic Vasculitis Associated Lesion) and necrotic tissue in and around the hip joint, catastrophic failure, premature wear, disarticulation, and disassembly.

34. In May 2002, shortly after Defendants began selling the Pinnacle Device, Defendants received two complaints. One reported that a patient had to undergo revision surgery to remove and replace the Pinnacle Device because the liner disassociated with the cup. The

other reported revision surgery because the acetabular cup had loosened. DePuy closed their investigation of the filed complaints finding that "corrective action is not indicated."

35. Defendants have continued to receive hundreds of similar complaints since 2002 reporting that the Pinnacle Device had failed and forced patients to undergo painful and risky surgery to remove and replace the failed hip. By June 2006, Defendants had received 50 complaints related to the Pinnacle Device.

36. Consequently, Defendants were fully aware that the Pinnacle Device was defective and that dozens of patients already had been injured by the Pinnacle Device. Based on this information, Defendants should have recalled the Pinnacle Device as early as 2006. At a minimum, Defendants should have stopped selling the defective implant when it became aware that it had catastrophically failed in patients. Over the next two years, patients continued to report failures of the Pinnacle Device. By the end of 2008, Defendants received more than 430 reports, and by the end of 2009, that number skyrocketed to almost 750.

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

38. The metallic particulates released by friction of the metal-on-metal surfaces can become toxic causing metallosis or cobaltism giving rise to pseudotumors or other conditions.

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

39. Despite the knowledge of the Pinnacle Device's defect and that it had failed hundreds of times, causing hundreds of patients to undergo the agony of another surgery, Defendants continued to market and sell the defective Pinnacle Device implant. In so doing, DePuy actively concealed the known defect from doctors and patients – including Plaintiff and her doctor – and misrepresented that the Pinnacle Device was a safe and effective medical device.

40. Despite this knowledge, Defendants failed to warn medical providers and/or their customers of the unreasonable dangers associated with the Pinnacle Device and allowed for the continued sale and implantation into patients' bodies.

41. To this day, Defendants continue to sell the defective Pinnacle Device to unsuspecting patients without any warning about the risks or the failures that have been reported over the years.

42. Defendants tout the metal-on-metal Pinnacle Device in brochures saying "the DePuy metal-on-metal (MoM) articulation system is leading the way in advanced technology. Through years of careful engineering, research and expertise, we've created a total hip replacement solution that offers low wear and high stability." [1]

43. Defendants claim "DePuy Orthopaedics remains the leader in metal-on-metal technology, offering several advantages, including larger diameter bearings that can improve hip range of motion and stability. In fact, one study conducted since the device was approved in

[1] "Advancing High Stability and Low Wear" Brochure. The study was presented at the AAOS 2007 Annual Meeting by at least one of the Pinnacle Device designers, William P. Barrett. (Kirk Kindsfater, William Barrett, James Dowd, Carleton Southworth, Marilyn Cassell. Poster #P077, "Midterm Survival of the Pinnacle Multi-Liner Acetabular Cup in a Prospective Multi Center Study," 2007 AAOS Annual Meeting.)

2002 observed that an estimated 99.9 percent of Pinnacle Device components remain in use." [2] One of the Pinnacle Device designers, William P. Barrett, MD, of Valley Orthopaedic Associates/Proliance Surgeons in Renton, WA, has been quoted in Defendants' marketing materials saying "the Pinnacle cup exhibited 99% survivorship at five years and, significantly, differences between patients, surgeons, femoral stems, head size, and articulation types did not affect survival."

44. Defendants advertised that "only Pinnacle Hip Solutions feature TrueGlide™ technology, allowing the body to create a thin film of lubrication between surfaces. The result is a smooth, more fluid range of natural motion." Defendants distributed a press release stating "the aSphere head, combined with DePuy's exclusive TrueGlide technology, facilitates a more fluid range of natural motion and up to 159 degrees range of motion."

45. Defendants advertised that "the Pinnacle™ Acetabular Cup System is DePuy's premium product for acetabular indications and can address all existing pathologies."

46. Defendants advertised that "for the first time surgeons have the choice between high performance bearings which all work within the Pinnacle™ Acetabular Cup System."

47. Other Pinnacle Device advertisements and brochures included pictures of a man on the beach in wet suit carrying a surf board and a man playing tennis (which specifically describes him as a bilateral replacement). There are pictures of women stretching outside before a job or yoga, and a woman riding a stationary bike.

48. Defendants marketed the Pinnacle Device as high performance hip replacements and as superior products that would allow patients to return to their more active lifestyles.

[2] Pinnacle® Acetabular Cup System (48mm-66mm) Product Overview, http://www.depuy.com/healthcare-professionals/product-details/pinnacle-acetabular-cup-system-48mm-66mm (last visited Sept. 1, 2011).

Defendants also advertised the Pinnacle Device would last longer than other hip replacement products.

49. A number of governmental regulatory agencies have recognized the problems that are caused by metal-on-metal implants such as 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 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.

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

51. Defendants have known for years that implantation of their Pinnacle Device and other metal-on-metal total hip replacement systems results in metallosis, biologic toxicity, and an early and high failure rate. Once the body is exposed to and absorbs the toxic metallic ions and particulate debris from the Pinnacle Device, inflammation occurs causing severe pain, necrosis (death) of the surrounding tissue and bone loss. Pseudotumors also develop and grow as a direct and proximate result of the toxic metallic particles and ions released from the metal-on-metal hip components.

52. There is no non-surgical solution for elevated cobalt levels.

C. THE DEFECTIVE PINNACLE DEVICE AND THE DEFENDANTS' CONDUCT CAUSED INJURIES AND SUBSTANTIAL DAMAGES TO PLAINTIFF.

53. On or about April 27, 2010, Plaintiff underwent a left total hip arthroplasty at Lapeer Regional Medical Center in Lapeer, MI performed by Gordon McClimans, M.D. Plaintiff's surgeon implanted a Pinnacle Device with an Ultamet (metal) liner in place of Plaintiff's left hip joint.

54. Shortly before undergoing revision surgery, Plaintiff suffered from severe pain and discomfort as well as elevated metal ions in her body.

55. On or about July 8, 2016, Plaintiff underwent a painful, complex and risky surgery known as a "revision surgery" to remove and replace the metal lining of Plaintiff's Pinnacle Acetabular shell. Revision surgeries normally take longer than the original hip replacement and the revision surgery has a higher rate of complications.

56. Had Plaintiff known that the Pinnacle Device caused the symptoms she is experiencing, Plaintiff would not have elected to have the Pinnacle Device implanted.

57. As a direct and proximate result of the failure of her defective Pinnacle Device system, Plaintiff sustained and continues to suffer damages, including, but not limited to, past, present, and future pain and suffering, severe and possibly permanent injuries, emotional distress, disability, disfigurement, economic damages (including medical and hospital expenses) monitoring, rehabilitative and pharmaceutical costs, and lost wages and loss of future earnings capacity. As a result, Plaintiff has sustained and will continue to sustain damages in an amount to be proven at trial.

58. All of the injuries and complications suffered by Plaintiff were caused by the defective design, warnings, construction and unreasonably dangerous character of the Pinnacle Device that was implanted in her. Had Defendants not concealed the known defects, the early

failure rate, the known complications and the unreasonable risks associated with the use of the Pinnacle Device, Plaintiff would not have consented to the Pinnacle Device being used in her total hip arthroplasty.

IV. FRAUDULENT CONCEALMENT

59. Any applicable statutes of limitations have been tolled by the knowing and active concealment and denial of the facts as alleged herein by Defendants. Plaintiff has been kept in ignorance of vital information essential to the pursuit of these claims, without any fault or lack of diligence on her part. Plaintiff could not reasonably have discovered the dangerous nature of and unreasonable adverse side effects associated with the Pinnacle Device prior to the filing of this Complaint.

60. The Defendants are and were under a continuing duty to disclose the true character, quality and nature of their Pinnacle Device to Plaintiff. Because of Defendants' concealment of the true character, quality and nature of the Pinnacle Device, the Defendants are estopped from relying on any statute of limitations defense.

V. CAUSES OF ACTION

COUNT I
STRICT PRODUCTS LIABILITY – DEFECTIVE DESIGN

61. Plaintiff incorporates by references all preceding paragraphs and allegations of this Complaint as though fully set forth therein.

62. Defendants are the researcher, developer, manufacturer, distributor, marketer, promoter, supplier and seller of the Pinnacle Device, which is defective and unreasonably dangerous.

63. The Pinnacle Device is defective in its design or formulation in that it is not reasonably fit, suitable or safe for its intended purpose and/or its foreseeable risks exceed the

benefits associated with its design. The Pinnacle Device is defective in design in that it lacks efficacy, poses a greater likelihood of injury and is more dangerous than other available devices indicated for the same conditions and uses. If the design defects were known at the time of manufacture, a reasonable person would have concluded that the utility of the Pinnacle Device did not outweigh its risks.

64. The defective condition of the Pinnacle Device rendered it unreasonably dangerous and/or not reasonably safe, and the Pinnacle Device was in this defective condition at the time it left the hands of Defendants. The Pinnacle Device was expected to and did reach Plaintiff and her physician without substantial change in the condition in which it was designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied and otherwise released into the stream of commerce.

65. Plaintiff was unaware of the significant hazards and defects in the Pinnacle Device. The Pinnacle Device was unreasonably dangerous and/or not reasonably safe in that it was more dangerous than would be reasonably contemplated by the ordinary patient or physician. During the period that Plaintiff used the Pinnacle Device, it was being utilized in a manner that was intended by Defendants. At the time Plaintiff had the Pinnacle Device implanted, it was represented to be safe and free from latent defects.

66. Defendants are liable to Plaintiff for designing, manufacturing, and placing into the stream of commerce the Pinnacle Device, which was unreasonably dangerous for its reasonably foreseeable uses because of its design defects.

67. Defendants knew or should have known of the danger associated with the use of the Pinnacle Device, as well as the defective nature of the Pinnacle Device, but have continued to design, manufacture, sell, distribute, market, promote and/or supply the Pinnacle Device so as to

maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by the Pinnacle Device.

68. As a direct result of Defendants' conduct, Plaintiff has suffered and continues to suffer serious and permanent non-economic and economic injuries and Defendants are liable to Plaintiff in an amount to be determined at trial.

WHEREFORE, the Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages and punitive damages where applicable, together with costs and interest, and any further relief as the court deems proper, as well as a trial by jury of all issues to be tried.

COUNT II
STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

69. Plaintiff incorporates by reference all preceding paragraphs and allegations of this Complaint as though fully set forth herein.

70. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Pinnacle Devices.

71. The Pinnacle Device that were surgically implanted in Plaintiff was defective in its 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.

72. As a direct and proximate result of Defendants' placement of the defective Pinnacle Devices into the stream of commerce, Plaintiff experienced and/or will experience severe harmful effects including but not limited to partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are permanent and lasting in

nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

73. As a direct result of Defendants' conduct, Plaintiff has suffered and continues to suffer serious and permanent non-economic and economic injuries and Defendants are liable to Plaintiff in an amount to be determined at trial.

WHEREFORE, the Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages and punitive damages where applicable, together with costs and interest, and any further relief as the court deems proper, as well as a trial by jury of all issues to be tried.

COUNT III
STRICT PRODUCTS LIABILITY-FAILURE TO WARN

74. Plaintiff incorporates by reference all preceding paragraphs and allegations of this Complaint as though fully set forth herein.

75. Defendants are manufacturers, distributors, sellers, and suppliers of the Pinnacle Device.

76. The Pinnacle Device was not accompanied by proper warnings and instructions to physicians and the public regarding potential adverse side effects associated with the implantation of the Pinnacle Device and the comparative severity and duration of such adverse side effects.

77. The warnings, instructions, and information provided to the medical community and the public did not accurately reflect the symptoms, scope, or severity of potential side effects, specifically the risk of increased metal ions.

78. Defendants failed to perform adequate testing which would have demonstrated that the Pinnacle Device had potentially serious side effects about which Defendants should have provided full and proper warnings.

79. The Pinnacle Device was defective due to inadequate warnings, information, and instructions that failed to convey to physicians and the public accurate information about the scope and severity of potential side effects.

80. As a direct result of Defendants' conduct, Plaintiff has suffered and continues to suffer serious and permanent non-economic and economic injuries and Defendants are liable to Plaintiff in an amount to be determined at trial.

WHEREFORE, the Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages and punitive damages where applicable, together with costs and interest, and any further relief as the court deems proper, as well as a trial by jury of all issues to be tried.

COUNT IV
NEGLIGENCE

81. Plaintiff incorporates by reference all preceding paragraphs and allegations of this Complaint as though fully set forth herein.

82. At all material times, Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control and/or distribution of the Pinnacle Device into the stream of commerce, including a duty to assure that the device would not cause those who had it surgically implanted to suffer adverse harmful effects from it.

83. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control

and/or distribution of the Pinnacle Device into interstate commerce in that Defendants knew or should have known that this product created a high risk of unreasonable, dangerous side effects, thereby breaching their duty to consumers, including Plaintiff.

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

(a) Negligently designing the Pinnacle Device in a manner which was dangerous to those individuals who had the device surgically implanted;

(b) Designing, manufacturing, producing, creating and/or promoting the Pinnacle Device without adequately, sufficiently, or thoroughly testing it;

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

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

(e) Selling the Pinnacle Device without making proper and sufficient tests to determine the danger to its users;

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

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

(h) Failing to provide adequate instructions regarding the safety precautions to be observed by surgeons who would reasonably and foreseeably come into contact with, and more particularly, implant the Pinnacle Device into their patients;

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

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

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

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

(m) Negligently assembling the Pinnacle Device in a manner which was dangerous to those who had it implanted; and

(n) Defendants under-reported, underestimated and downplayed the serious danger of the Pinnacle Device.

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

(a) Failed to use due care in designing and manufacturing the Pinnacle Device so as to avoid the aforementioned risks to individuals that had the devices surgically implanted;

(b) Failed to accompany their product with proper warnings;

(c) Failed to accompany their product with proper instructions for use;

(d) Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of the Pinnacle Device; and

(e) Were otherwise careless and/or negligent.

86. Upon information and belief, Defendants continued to market, manufacture distribute and/or sell the Pinnacle Device to consumers, including Plaintiff, despite the fact that Defendants knew or should have known that the Pinnacle Device caused unreasonable, dangerous side effects which many users would be unable to remedy by any means, when there were safer alternative methods of hip replacements.

87. Defendants knew or should have known that consumers such as Plaintiff would suffer foreseeable injuries as a result of Defendants' failure to exercise ordinary care as described above.

88. At all material times, Defendants knew of the defective nature of the Pinnacle Device as set forth herein, and continued to design, manufacture, market and sell the drug so as to maximize sales and profits at the expense of public health and safety, and as such Defendants' conduct exhibited a wanton and reckless disregard for human life; and further, upon information and belief, Defendants exhibited such an entire want of care as to establish that their actions were a result of fraud, evil motive, actual malice and a conscious and deliberate disregard of foreseeable harm to Plaintiff herein.

WHEREFORE, the Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory and punitive damages where applicable, together with costs and interest, and any further relief as the court deems proper, as well as a trial by jury of all issues to be tried.

COUNT V
NEGLIGENCE *PER SE*

89. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

90. The Pinnacle Device supplied by Defendants is adulterated and/or misbranded product as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§331(a) and 333(a)(2) ("FD&C Act").

91. Plaintiff is within the class of persons the FD&C Act and regulations promulgated pursuant to it by the FDA are designed to protect, and the Plaintiff's injuries are the type of harm these statutes and regulations are designed to prevent.

92. Defendants were negligent per se in supplying the Pinnacle Device to the Plaintiff, because it is an adulterated and/or misbranded product. As a direct and proximate result of Defendants'' negligence, Plaintiff has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, the Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages and punitive damages where applicable, together with costs and interest, and any further relief as the court deems proper, as well as a trial by jury of all issues to be tried.

COUNT VI
NEGLIGENT MISREPRESENTATION

93. Plaintiff incorporates by reference all preceding paragraphs and allegations of this Complaint as though fully set forth herein.

94. At the time Defendants manufactured, designed, marketed, sold and distributed the Pinnacle Device for use by Plaintiff, Defendants knew or should have known of the use for which the Pinnacle Device was intended and the serious risks and dangers associated with such use of the Pinnacle Device.

95. Defendants owed a duty to treating physicians and to the ultimate end-users of the Pinnacle Device, Plaintiff, to accurately and truthfully represent the risks of the Pinnacle Device. Defendants breached that duty by misrepresenting and/or failing to adequately warn Plaintiff's physicians, the medical community, Plaintiff and the public about the risks of the Pinnacle Device, which Defendants knew or in the exercise of diligence should have known.

96. As a direct result of Defendants' conduct, Plaintiff has suffered and continues to suffer serious and permanent non-economic and economic injuries and Defendants are liable to Plaintiff in an amount to be determined at trial.

WHEREFORE, the Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages and punitive damages where applicable, together with costs and interest, and any further relief as the court deems proper, as well as a trial by jury of all issues to be tried.

COUNT VII
FRAUDULENT CONCEALMENT

97. Plaintiff incorporates by reference all preceding paragraphs and allegations of this Complaint as though fully set forth herein.

98. Defendants fraudulently concealed information with respect to the Pinnacle Device in the following particulars:

(a) Defendants represented through the labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Pinnacle Device was safe and fraudulently withheld and concealed information about the substantial risks of using the Pinnacle Device; and

(b) Defendants represented that the Pinnacle Device was safer than other alternative medications and fraudulently concealed information which demonstrated that the Pinnacle Device was not safer than alternatives available on the market.

99. Defendants had sole access to material facts concerning the dangers and unreasonable risks of the Pinnacle Device.

100. The concealment of information by Defendants about the risks of the Pinnacle Device was intentional, and the representations made by Defendants were known by Defendants to be false.

101. The concealment of information and the misrepresentations about the Pinnacle Device were made by Defendants with the intent that doctors and patients, including Plaintiff, rely upon them.

102. Plaintiff and her physicians relied upon the representations and were unaware of the substantial risks of the Pinnacle Device which Defendants concealed from the public, including Plaintiff and her physicians.

103. Plaintiff was injured as a direct and proximate result of Defendants' actions, omissions, and misrepresentations. Plaintiff has incurred, and will continue to incur expenses as a result of using the Pinnacle Device.

WHEREFORE, the Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages and punitive damages where applicable, together with costs and interest, and any further relief as the court deems proper, as well as a trial by jury of all issues to be tried.

COUNT VIII
BREACH OF EXPRESS WARRANTY

104. Plaintiff incorporates by reference all preceding paragraphs and allegations of this Complaint as though fully set forth herein.

105. Defendants expressly warranted to Plaintiff by and through Defendants and/or their authorized agents or sales representatives, in publications, package inserts, the internet, and other communications intended for physicians, patients, Plaintiff, and the general public, that the Pinnacle Device was safe, effective, fit and proper for its intended use.

106. The Pinnacle Device does not conform to those express representations because the Pinnacle Device is not safe and has serious, life-threatening side effects.

107. In allowing the implantation of the Pinnacle Device, Plaintiff and her physician relied on the skill, judgment, representations, and express warranties of Defendants. These warranties and representations were false in that the Pinnacle Device was not safe and was unfit for the uses for which it was intended.

108. Defendants breached their warranty of the mechanical soundness of the Pinnacle Device by continuing sales and marketing campaigns highlighting the safety and efficacy of their product, while they knew of the defects and risk of product failure and resulting patient injuries.

109. As a direct result of Defendants' conduct, Plaintiff has suffered and continues to suffer serious and permanent non-economic and economic injuries and Defendants are liable to Plaintiff in an amount to be determined at trial.

WHEREFORE, the Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages and punitive damages where applicable, together with costs and interest, and any further relief as the court deems proper, as well as a trial by jury of all issues to be tried.

COUNT IX
BREACH OF IMPLIED WARRANTY

110. Plaintiff incorporates by references all preceding paragraphs and allegations of this Complaint as though fully set forth therein.

111. Defendants impliedly warranted to prospective purchasers and users, including Plaintiff, that the Pinnacle Device was safe, merchantable, and fit for the ordinary purposes for which said product was to be used.

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

113. Upon information and belief, and contrary to such implied warranties, the Pinnacle Device was not of merchantable quality or safe and fit for its intended use, because the product was and is unreasonably dangerous and unfit for the ordinary purposes for which it was used, as described above.

114. As a direct and proximate result of the breach of implied warranties by Defendants, Plaintiff suffered and will continue to suffer harm and economic loss as described above.

WHEREFORE, the Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages and punitive damages where applicable, together with costs and interest, and any further relief as the court deems proper, as well as a trial by jury of all issues to be tried.

COUNT X
FRAUD

115. Plaintiff incorporates by references all preceding paragraphs and allegations of this Complaint as though fully set forth therein.

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

117. Before they marketed the Pinnacle Device that was implanted in Plaintiff, Defendants knew or should have known of the unreasonable dangers and serious health risks that such a metal-on-metal total hip replacement system posed to patients like Plaintiff.

118. As specifically described in detail above, Defendants knew that the Pinnacle Device subjected patients to early failure, painful and harmful physical reactions to toxic metallic particles and ions, death of tissue, bone loss and the need for explants and revision surgery.

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

120. Defendants concealed their knowledge of the unreasonable risks and dangers associated with the use of the Pinnacle Device to induce Plaintiff and many thousands of others to purchase the system for surgical implantation in their bodies.

121. Neither Plaintiff nor her physicians knew of the falsity of Defendants' statements regarding the Pinnacle Device.

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

123. Plaintiff and her physicians had a right to rely on Defendants' representations and in fact did rely upon such representations. Had Plaintiff known of the high risks associated with the Pinnacle Device, she would not have purchased or allowed the Pinnacle Device to have been surgically implanted in her.

124. Any applicable statutes of limitation have been tolled by Defendants' knowing and active concealment and misrepresentations alleged here. Plaintiff and others were kept in ignorance of vital information, without any fault or lack of diligence on their part, had no knowledge of the above facts and could not reasonably have discovered the fraudulent nature of Defendants' conduct.

WHEREFORE, the Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages and punitive damages where applicable, together with costs and interest, and any further relief as the court deems proper, as well as a trial by jury of all issues to be tried.

COUNT XI
UNFAIR AND DECEPTIVE TRADE PRACTICES/CONSUMER FRAUD

125. Plaintiff incorporates by references all preceding paragraphs and allegations of this Complaint as though fully set forth therein.

126. Defendants are the researchers, developers, manufacturers, distributors, marketers, promoters, suppliers and sellers of the Pinnacle Device, which they represented would be free from defects and fit for its intended purpose.

127. Defendants advertised, labeled, marketed and promoted its product, the Pinnacle Device, representing the quality to health care professionals, the FDA, Plaintiff, Plaintiff's surgeon, and the public in such a way as to induce its purchase or use. More specifically, Defendants represented that the Pinnacle Device was safe and effective for use by individuals such as Plaintiff or that it was safe and effective to treat Plaintiff's condition.

128. Defendants knew or should have known that the Pinnacle Device did not or would not conform to Defendants' representations and promises.

129. Defendants' concealed knowledge of the serious risks associated with the Pinnacle Device and concealed testing and research data, or selectively and misleadingly revealed or analyzed testing and research data.

130. Defendants' representations, actions and conduct regarding the Pinnacle Device were in or affecting commerce.

131. Defendants' actions and conduct, as alleged in this Complaint, constitute deceptive trade practices in the course of Defendants' business in violation of the provisions of *Va. Code Ann.* § 59.1-200. *et seq.* and/or New Jersey Consumer Fraud Act, *N.J.S.A.* 56:8-1 *et seq.* and/or Indiana Deceptive Consumer Sales Act, *Ind. Code* §§ 24-5-0.5-1 to 24-5-0.5-12

and/or other applicable statutory provisions concerning deceptive trade practices or consumer fraud.

132. As a direct and proximate result of Defendants' unfair and/or deceptive conduct, in or affecting commerce, Plaintiff is entitled to recover damages from Defendants, pursuant to the provisions of the Virginia Consumer Protection Act, *Va. Code Ann.* § 59.1-200. *et seq*. and/or New Jersey Consumer Fraud Act, *N.J.S.A.* 56:8-1 *et seq.* and/or Indiana Deceptive Consumer Sales Act, *Ind. Code* §§ 24-5-0.5-1 to 24-5-0.5-12 and/or other applicable statutory provisions concerning deceptive trade practices or consumer fraud..

WHEREFORE, the Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages and punitive damages where applicable, together with costs and interest, and any further relief as the court deems proper, as well as a trial by jury of all issues to be tried.

COUNT XII
PUNITIVE DAMAGES

133. Plaintiff incorporates by references all preceding paragraphs and allegations of this Complaint as though fully set forth therein.

134. Plaintiff is entitled to punitive damages because Defendants' wrongful acts and/or omissions were willful and wanton conduct and in conscious and intentional disregard of and indifference to the rights and safety of others. Defendants misled both the medical community and the public at large, including Plaintiff, by making false representations about the safety and efficacy of the Pinnacle Device and by failing to provide adequate instructions and training concerning its use.

135. Defendants downplayed, understated, and/or disregarded their knowledge of the serious and permanent side effects and risks associated with the use of the Pinnacle Device

despite available information demonstrating that the Pinnacle Device could cause particles of cobalt and chromium to be deposited into Plaintiff's body and cause the device to loosen and become displaced or separate, causing serious harm to patients. Such risks and adverse effects could easily have been avoided had Defendants not concealed knowledge of the serious risks associated with the Pinnacle Device or provided proper training and instruction to physicians regarding use of the Pinnacle Device.

136. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety of the Pinnacle Device.

137. Defendants were or should have been in possession of evidence demonstrating that the Pinnacle Device caused serious side effects. Nevertheless, Defendants continued to market the Pinnacle Device by providing false and misleading information with regard to its safety and efficacy.

138. Defendants failed to provide warnings that would have dissuaded health care professionals from using the Pinnacle Device, thus preventing health care professionals, including Plaintiff's surgeon, and consumers, including Plaintiff, from weighing the true risks against any benefits of using the Pinnacle Device.

139. Defendants failed to provide adequate training and instructions to surgeons, including Plaintiff's surgeon, who could have prevented failure of the Pinnacle Device causing serious harm and suffering to patients, including Plaintiff.

140. As a result of Defendants' conduct, Defendants are liable to Plaintiff in an amount to be determined at trial.

WHEREFORE, the Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages and punitive damages where applicable, together with costs and interest, and any further relief as the court deems proper, as well as a trial by jury of all issues to be tried.

PRAYER FOR RELIEF AS TO ALL COUNTS

WHEREFORE, Plaintiff, Nancy Powers, prays for judgment against Defendants as follows:

1. Judgment in favor of Plaintiff and against all Defendants, for damages in such amounts as may be proven at trial;
2. Compensation for both economic and non-economic losses, including but not limited to medical expenses, loss of earnings, pain and suffering, mental anguish and emotional distress, in such amounts as may be proven at trial;
3. Punitive and/or exemplary damages in such amounts as may be proven at trial;
4. Attorneys' fees, expenses and costs of this action;
5. Pre- and post-judgment interest as provided by law; and
6. Any and all further relief, both legal and equitable, that the Court may deem just and proper.

Dated: December 5, 2016

/s/ Esther Berezofsky

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Attorneys for Plaintiff

CIVIL COVER SHEET

The JS 44 civil coversheet 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 NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Nancy Powers

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Williams Cuker Berezofsky, LLC, 210 Lake Drive East, Suite 101, Cherry Hill, New Jersey 08002; 856-667-0500

DEFENDANTS

DePuy Orthopaedics, Inc., DePuy, Inc., DePuy International Limited, Johnson & Johnson, Johnson & Johnson Services, Inc., Johnson & Johnson International

County of Residence of First Listed Defendant Warsaw, Indiana
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

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

- ☐ 1 U.S. Government Plaintiff
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☒ 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

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
- ☐ 362 Personal Injury - Med. Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical 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

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus - Alien Detainee (Prisoner Petition)
- ☐ 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
- ☐ 375 False Claims Act
- ☐ 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
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

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

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

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

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

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

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. 1332.

Brief description of cause:
Product Liability/Personal Injury

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 12/05/2016

SIGNATURE OF ATTORNEY OF RECORD /s/Esther Berezofsky

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

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INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading 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. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I. (a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.C.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.

United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.

United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.

Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.

Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; federal question actions take precedence over diversity cases.)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerks in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. Origin. Place an "X" in one of the seven boxes.

Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.

Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.

Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

Appeal to District Judge from Magistrate Judgment. (7) Check this box for an appeal from a magistrate judge's decision.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity**. Example: U.S. Civil Statute: 47 USC 553
Brief Description: Unauthorized reception of cable service

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.

Demand. In this space enter the dollar amount (in thousands of dollars) being demanded or indicate other demand such as a preliminary injunction.

Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference cases that are related to this filing, if any. If a realted case exists, whether pending or closed, insert the docket numbers and the corresponding judge names for such cases. A case is "realted" to this filing if the case: (1) involves some or all of the same parties and is based on the same or similar claim; (2) involves the same property, transaction, or event; (3) involves substantially similar

issues of law and fact; and/or (4) involves the same estate in a bankruptcy appeal.

Date and Attorney Signature. Date and sign the civil cover sheet.