**UNITED STATES DISTRICT COURT**

**FOR THE SOUTHERN DISTRICT OF TEXAS**

**HOUSTON DIVISION**

**NO. _____**

KATHRYN Y. THOMPSON

Plaintiff,

vs.

DEPUY ORTHOPAEDICS, INC., an Indiana Corporation; JOHNSON & JOHNSON SERVICES, INC., a New Jersey Corporation

Defendants.

**COMPLAINT FOR:**

1) **NEGLIGENCE;**
2) **STRICT PRODUCTS LIABILITY (MANUFACTURING DEFECT);**
3) **STRICT PRODUCTS LIABILITY (DESIGN DEFECT);**
4) **STRICT PRODUCTS LIABILITY (INADEQUATE WARNING);**
5) **STRICT PRODUCTS LIABILITY (FAILURE TO CONFORM TO REPRESENTATIONS);**
6) **STRICT PRODUCTS LIABILITY (FAILURE TO ADEQUATELY TEST);**
7) **BREACH OF EXPRESS WARRANTY;**
8) **BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY;**
9) **FRAUDULENT CONCEALMENT;**
10) **INTENTIONAL MISREPRESENTATION;**
11) **NEGLIGENT MISREPRESENTATION; AND**
12) **VIOLATIONS OF THE TEXAS DTPA. Tex. Bus. & Com. Code §§ 17.41, *ET SEQ.***

**DEMAND FOR JURY TRIAL**

Plaintiff KATHRYN Y. THOMPSON ("Plaintiff"), alleges the following against DEPUY ORTHOPAEDICS, INC., and JOHNSON & JOHNSON SERVICES, INC. ("Defendants"), the following:

## I.

## INTRODUCTION AND SUMMARY OF ACTION

1. For more than two years, Defendants have known that there is a likelihood that their hip replacement prosthesis – the ASR XL Acetabular System ("ASR Hip Implant Device") – may become unstable and fail within months after surgical implantation despite the fact that such hip implant devices are supposed to last more than fifteen years. They have also known that the implant's metal "ball" and "socket" bearings that make up the hip-joint generate metal debris over time from wear and tear that can spread throughout the patient's surrounding bone and tissue. As a result of these defects, patients who have had the device implanted have endured, or will endure, unnecessary severe pain and suffering; debilitation; a partial or complete lack of mobility; inflammation causing damage or death to surrounding tissue and bone; and a subsequent more difficult revision surgery to replace the faulty device giving rise to even more debilitation, a prolonged recovery time, and an increased risk of complications and death from surgery.

2. But rather than immediately recalling the ASR Hip Implant Device upon first receiving notice in 2007/2008 of complaints made to the Food and Drug Administration ("FDA") of the problems discussed above, Defendants continued to aggressively market the ASR Hip Implant Device, claiming that it was a safe and effective hip replacement system that would "maximize[] range of motion", "offer[] low wear and high stability", and that would help patients maintain an active lifestyle and "never stop moving." Defendants continued to make such marketing claims despite their knowledge of evidence showing that a high number of the individuals that received the device, such as Plaintiffs, in fact had little or no range of motion after the device was implanted, that the device had little to no stability and a high rate of wear,

and that patients that received the device had tremendous difficulty maintaining any sort of active lifestyle, and had little or no ability to be able to get up and move.

3. Plaintiff's suffering could easily have been prevented. Had Defendants recalled the devices in 2007/2008 when dozens of complaints began being made to the FDA regarding the device's failures (before such time as Plaintiff had the device surgically implanted), Plaintiff would not have suffered from unnecessary pain, inflammation and infection, debilitation, partial or complete immobility, and the need to undergo subsequent revision surgery. But Defendants' recent recall of these devices has come too late for thousands of Americans, including Plaintiff, who will now live with the consequences of these faulty and defective devices for years, if not the rest of their lives. Plaintiff seeks redress for her injuries.

## II.

## PARTIES

4. Plaintiff KATHRYN Y. THOMPSON is, and at all times relevant to this Complaint was, a resident of the city of Houston, located in the county of Harris, in the state of Texas.

5. 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 in Texas, and specifically this judicial district.

6. 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 in Texas, and specifically this judicial district.

7. 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

8. This Court has original jurisdiction pursuant to 28 U.S.C. § 1332(a)(1). The amount in controversy is well over $75,000,000, and diversity of citizenship exists as Defendants reside, or have their primary places of business, in Indiana and New Jersey.

9. 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. DEFENDANTS DESIGNED, MANUFACTURED, AND MARKETED THE ASR HIP IMPLANT DEVICE TO PHYSICIANS AND THE PUBLIC, EVEN THOUGH THEY KNEW OR SHOULD HAVE KNOWN OF THE DANGER THAT THE ASR HIP IMPLANT DEVICE POSED.

10. The ASR Hip Implant Device was developed for the purpose of reconstructing diseased human hip joints from conditions such as osteoarthritis, rheumatoid arthritis, avascular necrosis (AVN), or fracture. The hip joint connects the thigh (femur) bone of a patient's leg to the patient's pelvis. The hip joint is like a ball that fits in a socket. The socket portion of the hip is called the acetabulum. The femoral head at the top of the femur bone rotates within the curved surface of the acetabulum.

11. The ASR Hip Implant Device is made up of three components: the metal femoral stem is inserted inside the femur, the metal femoral head (or ball) connects to the stem and then

fits inside the metal acetabulum cup (socket). Once implanted, the device is supposed to last on average for 15 or more years before requiring replacement.

12. Defendants aggressively marketed the ASR Hip Implant Device as having many advantages over other hip replacement systems. Defendants described the ASR Hip Implant Device as a "high performance hip replacement" and advertised it with pictures of a young woman running on a sandy beach, a man taking a very aggressive golf swing, women practicing yoga, and a man playing tennis. Defendants advertised the ASR Hip Implant Device as a superior device as the bone in the hip socket was preserved, the hip replacement was subject to reduced wear, the hip replacement matched the hip's natural anatomy, the surgery only required a small incision, and the device was based on a strong clinical history.

13. Defendants further advertised the ASR Hip Implant Device as a superior option "[i]f you have gradually stopped doing the things you enjoy or are adapting your life to cope with reduced mobility hip replacement surgery may be appropriate for you." Defendants further stated that "[f]ortunately, today's advanced techniques and technologies have revolutionized hip replacements. That means more patients can consider treatments at an earlier stage than they could in the past, potentially allowing them to return to their more active lifestyles."

14. Defendants also advertised that the Hip Implant Device is "[d]esigned for active lifestyles." They further asserted that 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." They further touted that "[w]ith DePuy Advanced Bearing options, you can help your patients never stop moving." Defendants also indicated that "[l]arge diameter bearings improve hip range of motion and stability for higher function and a reduction in the occurrence of revision surgery."

15. Contrary to Defendants' marketing campaigns, for more than two years Defendants have known that the ASR Hip Implant Device was becoming unstable and failing early, therefore causing harm in a high number of patients that received the devices. Specifically, for more than two years, the FDA has been receiving complaints that the devices

failed early in some patients due to component loosening, component misalignment, dislocation, and fracture, due to the design of the devices. In addition, reports were received that the implant's "ball" and "socket" that make up the hip-joint – which are both metal bearings – generate metal debris over time from wear which can spread throughout the surrounding bone and tissue and cause severe inflammation and damage. Indeed, since the start of 2008, the FDA has received approximately 400 complaints involving patients in the United States that received the devices, with a substantial number of these patients requiring complicated, expensive and painful revision surgeries with a prolonged recovery time and risk of complications and death that comes with surgery.

16. Further, the Australian Joint Registry issued seven reports to Defendants starting in 2007 that identified problems with the ASR Hip Implant Device. The device was finally withdrawn from the Australian market in December 2009. Professor Stephen Graves, director of the Australian National Joint Replacement Registry, told the Independent, a UK media outlet, that Defendants had behaved "irresponsibly and very badly", and that "[i]t is a complete untruth that DePuy did not have reason to withdraw the ASR before now; we have been telling them since 2007, but they allowed it to be used on thousands of people."

17. Notwithstanding these complaints, Defendants neither halted sales of the ASR Hip Implant Device, nor warned the public until very recently. Instead, throughout 2007, 2008, 2009, and 2010, they aggressively marketed the ASR Hip Implant Device as a safe and effective hip replacement device even though they were on notice of the high number of complaints received by the FDA and the complaints received in the Australian market.

18. Only when faced with even more data regarding the dangers of the ASR Hip Implant Device did Defendants act to recall the device. Specifically, in late August, 2010, Defendants issued a voluntary recall of the ASR Hip Implant Device after "new" data was released confirming the already known dangers of the devices, and corroborating the many complaints received by the FDA from physicians and patients years earlier, and from complaints stemming from the Australian market.

19. The data Defendants have relied on in issuing the recall includes an advisory issued by the British agency that regulates medical devices indicating that metal-on-metal implants, such as the ASR Hip Implant Device, are potentially dangerous because they can generate large amounts of metallic debris as they wear over time. The metallic debris has been shown to cause severe inflammatory responses in some patients that cause pain in the groin, and death of tissue in the hip joint and loss of surrounding bone, requiring a revision surgery to replace the device soon after implant. Such metallic debris have also been linked to potential genotoxicity that can give rise to cancer.

20. The other source is unpublished data from the National Joint Registry (NJR) of England and Wales. The NJR data shows the five year revision rate for the ASR Hip Implant Device is approximately 13 percent. However, Defendants acknowledge that under generally accepted standards, no more than 5 percent of patients should have a revision surgery within five years of implantation. The data released from the NJR shows that the ASR Hip Implant Devices had a revision rate almost three times that of the generally accepted standards.

21. Many surgeons have acknowledged that the culprit for the high number of revision surgeries is due to the design of the acetabulum metal cup which is shallower than other competitor's cups on the market. It is this shallower design which presents a challenge for properly implanting the device at the correct angle which can lead to problems such as loosening of the device, misalignment of the device, and fracture of the device from the bone, all of which can cause severe infection and inflammation in patients.

22. Another design flaw stems from the fact the ASR Hip Implant Device does not use cement or screws to attach the metal components to the patient's bone. Instead, the device's porous shell relies on bone growth to fasten and secure the device's components to the patient's bone. Such a fixation method leads to loosening and instability of the device causing failure and painful symptoms for patients.

23. As a result of the issues with the ASR Hip Implant Device, Plaintiff has suffered symptoms including pain, swelling, inflammation and damage to surrounding bone and tissue, and partial or complete lack of mobility. As noted above, these symptoms are the result of

possible loosening of the implant, where the implant does not stay attached to the bone in the correct position; fracture, where the bone around the implant may have broken; dislocation, where two parts of the implant that move against each other are no longer aligned; or the spread of metal debris from the metal femur head and metal acetabulum cup from rubbing and rotating against each other. For these reasons, revision surgeries have been necessary to remove the faulty ASR Hip Implant Device. However, these revision surgeries present enormous risks to patients because they are technically more difficult than the original implant surgery, the patient is more at risk of complications and death, and the recovery is more prolonged than the original hip replacement surgery.

**B. AS A DIRECT AND PROXIMATE RESULT OF DEFENDANTS' FAILURE TO RECALL THE HIP IMPLANT DEVICES EARLIER, PLAINTIFF RECEIVED A DEFECTIVE ASR HIP IMPLANT DEVICE, AND NOW HAS SUFFERED DEBILITATING PAIN AND OTHER HARM AND THE NEED FOR REVISION SURGERY TO REPLACE THE FAULTY IMPLANT.**

24. Plaintiff is a 74 year old homemaker.

25. On March 4, 2008, Plaintiff Thompson underwent a total hip replacement surgery. An ASR Hip Implant Device was implanted in her hip.

26. Since the surgical implantation of the ASR Hip Implant Device, Plaintiff has suffered symptoms including but not limited to pain, swelling, inflammation, infection, damage to surrounding bone and tissue, and a lack of mobility. As a result, in September 2010, Plaintiff required surgery to remove and replace the ASR Hip Implant Device which was causing her pain and infection.

27. Had Plaintiff known that the ASR Hip Implant Device caused pain, swelling, inflammation, infection, damage to surrounding bone and tissue, problems walking, and the need for a revision surgery to replace the device, she would not have elected to have had the ASR Hip Implant Device implanted.

28. As a direct and proximate result of the implantation of the ASR Hip Implant Device, Plaintiff has suffered significant harm, including but not limited to physical injury and bodily impairment, debilitating lack of mobility, and conscious pain and suffering. In addition, because of the faulty nature of the ASR Hip Implant Devices, Plaintiff was required to undergo revision surgery to replace one of the faulty ASR Hip Implant Devices. As a result, Plaintiff will continue to suffer damages in the future.

29. Plaintiff was unaware of any causal link between the injuries she has suffered and any wrongdoing on the part of Defendants due to the faulty and defective nature of the ASR Hip Implant Devices until on or about August 26, 2010, due in part to the failures of Defendants to properly warn her and her physicians about the ASR Hip Implant Device's defective and faulty nature. On or about August 26, 2010, Plaintiff became aware of said causal link when she was advised of Defendants' actions in issuing a recall of the ASR Hip Implant Device on that date. Plaintiff was unable to make an earlier discovery of said causal link despite reasonable diligence because of Defendants' failure to properly warn her and her physicians about the ASR Hip Implant Device's defective and faulty nature, and their failure to issue a recall of the device any earlier than August 26, 2010.

## V.

## CLAIMS FOR RELIEF

### FIRST CAUSE OF ACTION

### NEGLIGENCE

### (Against All Defendants)

30. 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:

31. 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 ASR Hip Implant 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.

32. Defendants failed to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control, and/or distribution of the ASR Hip Implant Device into interstate commerce in that Defendants knew or should have known that those individuals that had the device surgically implanted were at risk for suffering harmful effects from it including but not limited to partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, 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.

33. 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 ASR Hip Implant 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 ASR Hip Implant Device without adequately, sufficiently, or thoroughly testing it;

c. Not conducting sufficient testing programs to determine whether or not the aforesaid ASR Hip Implant Device was safe for use;

d. Defendants herein knew or should have known that ASR Hip Implant Device was unsafe and unfit for use by reason of the dangers to its users;

e. Selling the ASR Hip Implant Device without making proper and sufficient tests to determine the dangers to its users;

f. Negligently failing to adequately and correctly warn Plaintiffs or their physicians, hospitals and/or healthcare providers of the dangers of ASR Hip Implant Device;

g. Negligently failing to recall their dangerous and defective ASR Hip Implant 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 safety precautions to be observed by surgeons who would reasonably and foreseeably come into contact with, and more particularly, implant the ASR Hip Implant Device into their patients;

i. Negligently advertising and recommending the use of the ASR Hip Implant Device despite the fact that Defendants knew or should have known of its dangerous propensities;

j. Negligently representing that the ASR Hip Implant Device offered was safe for use for its intended purpose, when, in fact, it was unsafe;

k. Negligently representing that the ASR Hip Implant Device offered low wear and high stability, when, in fact, the opposite was true;

l. Negligently manufacturing the ASR Hip Implant Device in a manner which was dangerous to those individuals who had it implanted;

m. Negligently producing the ASR Hip Implant Device in a manner which was dangerous to those individuals who had it implanted;

n. Negligently assembling the ASR Hip Implant Device in a manner which was dangerous to those individuals who had it implanted;

o. Defendants under-reported, underestimated and downplayed the serious danger of the ASR Hip Implant Device.

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

a. Failed to use due care in designing and manufacturing the ASR Hip Implant 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 ASR Hip Implant Device; and

e. Were otherwise careless and/or negligent.

35. Despite the fact that Defendants knew or should have known that the ASR Hip Implant Device caused harm to individuals that had the device surgically implanted, Defendants continued to market, manufacture, distribute and/or sell the ASR Hip Implant Device.

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

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

38. By reason of the foregoing, 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.

39. Further, as a result of the foregoing acts and omissions, Plaintiff suffered a loss of wages and will in the future suffer a diminished capacity to earn wages.

40. In performing the foregoing acts and omissions, Defendants acted despicably, fraudulently, and with malice and oppression so as to justify an award of punitive and exemplary damages.

## SECOND CAUSE OF ACTION

## STRICT PRODUCTS LIABILITY (MANUFACTURING DEFECT)

**(Against All Defendants)**

41. 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:

42. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the ASR Hip Implant Devices.

43. The ASR Hip Implant Device that was surgically implanted in Plaintiff was defective in its manufacture when it left the hands of Defendants in that it deviated from product specifications, posing a serious risk that it could fail early in patients 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.

44. As a direct and proximate result of Defendants' placement of the defective ASR Hip Implant 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.

45. In performing the foregoing acts and omissions, Defendants acted despicably, fraudulently, and with malice and oppression so as to justify an award of punitive and exemplary damages.

## THIRD CAUSE OF ACTION

## STRICT PRODUCTS LIABILITY (DESIGN DEFECT)

**(Against All Defendants)**

46. 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:

47. At all times herein mentioned, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed the ASR Hip Implant Device as hereinabove described that was surgically implanted in Plaintiff.

48. At all times herein mentioned, the ASR Hip Implant Device designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed by Defendants was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users such as Plaintiffs that had the device surgically implanted.

49. At all times herein mentioned, the ASR Hip Implant Device designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed by

Defendants was in an unsafe, defective, and inherently dangerous condition at the time it left Defendants' possession.

50. At all times herein mentioned, the ASR Hip Implant Device was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was designed, produced, manufactured, sold, distributed, and marketed by Defendants.

51. At all times herein mentioned, the ASR Hip Implant Device's unsafe, defective, and inherently dangerous condition was a cause of injury to Plaintiff.

52. At all times herein mentioned, the ASR Hip Implant Device failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.

53. Plaintiff's injuries resulted from use of the ASR Hip Implant Device that was both intended and reasonably foreseeable by Defendants.

54. At all times herein mentioned, the ASR Hip Implant Device posed a risk of danger inherent in the design which outweighed the benefits of that design.

55. At all times herein mentioned, the ASR Hip Implant Device was defective and unsafe, and Defendants knew or had reason to know that said product was defective and unsafe, especially when used in the form and manner as provided by Defendants. Specifically, Defendants knew that the design of the ASR Hip Implant Device was defective for several reasons, including but not limited to, the device's acetabulum cup being too shallow therefore presenting a challenge for properly implanting the device at the correct angle which can lead to problems such as loosening of the device, misalignment of the device, and fracture of the device from the bone, all of which can cause severe infection and inflammation in patients. Another of the several design flaws stems from the fact the ASR Hip Implant Device does not use cement or screws to attach the metal components to the patient's bone. Instead, the device's porous shell relies on bone growth to fasten and secure the device's components to the patient's bone. Such a fixation method leads to loosening and instability of the device causing failure and painful symptoms for patients.

56. Defendants knew, or should have known, that at all times herein mentioned that the ASR Hip Implant Device was in a defective condition, and was and is inherently dangerous and unsafe.

57. At the time of the implantation of the ASR Hip Implant Device into Plaintiff, the aforesaid product was being used for the purposes and in a manner normally intended, namely for use as a hip replacement device.

58. Defendants, with this knowledge, voluntarily designed their ASR Hip Implant Device in a dangerous condition for use by the public and, in particular, Plaintiff.

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

60. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which, when used in its intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers and to Plaintiff, in particular, and Defendants are therefore strictly liable for the injuries sustained by Plaintiff.

61. As a direct and proximate result of Defendants' placement of the defective ASR Hip Implant 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.

62. In performing the foregoing acts and omissions, Defendants acted despicably, fraudulently, and with malice and oppression so as to justify an award of punitive and exemplary damages.

**FOURTH CAUSE OF ACTION**

**STRICT PRODUCTS LIABILITY (INADEQUATE WARNING)**

**(Against All Defendants)**

63. 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:

64. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the ASR Hip Implant Devices.

65. The ASR 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 ASR Hip Implant Devices could fail early in patients therefore give rise to physical injury, pain and suffering, debilitation, and the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery, but failed to give consumers adequate warning of such risks. Further, the ASR Hip Implant Devices placed into the stream of commerce by Defendants were surgically implanted in a manner reasonably anticipated by Defendants.

66. As a direct and proximate result of Defendants' placement of the defective ASR Hip Implant 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.

67. In performing the foregoing acts and omissions, Defendants acted despicably, fraudulently, and with malice and oppression so as to justify an award of punitive and exemplary damages.

**FIFTH CAUSE OF ACTION**

**STRICT PRODUCTS LIABILITY (FAILURE TO CONFORM TO REPRESENTATIONS)**

**(Against All Defendants)**

68. 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:

69. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the ASR Hip Implant Devices.

70. Defendants made representations to consumers regarding the character or quality of ASR Hip Implant Devices, including but not limited to statements that the ASR Hip Implant Devices were a 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." Defendants also advertised that the Hip Implant Device is "[d]esigned for active lifestyles." They further asserted that 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." They further touted that "[w]ith DePuy Advanced Bearing options, you can help your patients never stop moving." Defendants also indicated that "[l]arge diameter bearings improve hip range of motion and stability for higher function and a reduction in the occurrence of revision surgery."

71. The ASR 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.

72. Plaintiffs justifiably relied upon Defendants' representations regarding the ASR Hip Implant Devices.

73. As a direct and proximate result of Defendants' placement of the defective ASR Hip Implant 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.

74. In performing the foregoing acts and omissions, Defendants acted despicably, fraudulently, and with malice and oppression so as to justify an award of punitive and exemplary damages.

## SIXTH CAUSE OF ACTION

## STRICT PRODUCTS LIABILITY (FAILURE TO ADEQUATELY TEST)

**(Against All Defendants)**

75. 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:

76. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the ASR Hip Implant Devices.

77. Defendants advised consumers that the ASR Hip Implant Devices were safe and effective hip replacement devices. Defendants failed to adequately test the ASR 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.

78. Had Defendants adequately tested the ASR Hip Implant Devices and disclosed the results of those tests to the public, Plaintiff would not have elected to have the ASR Hip Implant Devices surgically implanted.

79. As a direct and proximate result of Defendants' placement of the defective ASR Hip Implant 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.

80. In performing the foregoing acts and omissions, Defendants acted despicably, fraudulently, and with malice and oppression so as to justify an award of punitive and exemplary damages.

## SEVENTH CAUSE OF ACTION

## BREACH OF EXPRESS WARRANTY

**(Against All Defendants)**

81. 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:

82. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the ASR Hip Implant Devices.

83. Defendants expressly warranted that the ASR Hip Implant Devices were safe and effective hip replacement systems.

84. The ASR 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.

85. As a direct and proximate result of Defendants' breach of express warranties regarding the safety and effectiveness of the ASR Hip Implant Devices, Plaintiff has 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.

86. 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.

## EIGHTH CAUSE OF ACTION

## BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

**(Against All Defendants)**

87. 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:

88. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the ASR Hip Implant Devices.

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

90. Plaintiffs reasonably relied upon the skill and judgment of Defendants as to whether the ASR Hip Implant Devices was of merchantable quality and safe for its intended use.

91. Contrary to Defendants' implied warranties, the ASR Hip Implant Devices was not of merchantable quality or safe for its intended use, because the ASR Hip Implant Devices were unreasonably dangerous as described above.

92. As a direct and proximate result of Defendants' breach of implied warranties regarding the safety and effectiveness of the ASR Hip Implant Devices, Plaintiff has 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.

93. 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.

## NINTH CAUSE OF ACTION

## FRAUDULENT CONCEALMENT

**(Against All Defendants)**

94. 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:

95. Defendants had a duty to inform Plaintiff of all material facts about the ASR Hip Implant Devices based upon their assumption of that responsibility by representing to consumers that the ASR Hip Implant Devices were safe and effective hip replacement systems.

96. Since 2007/2008, Defendants have had actual knowledge that the ASR 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.

97. The fact that the ASR 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.

98. Defendants failed to disclose this material fact to consumers, including Plaintiff. Instead, Defendants took affirmative steps to prevent physicians and consumers from learning of this material fact, while aggressively marketing the ASR Hip Implant Devices as safe and effective hip replacement systems. This concealment was done with the intent to induce Plaintiff to purchase the ASR Hip Implant Device so that her physician could surgically implant the devices into Plaintiff.

99. In reliance on Defendants' fraudulent concealment of a material fact, Plaintiff purchased the ASR Hip Implant Devices so that her physicians could surgically implant the devices into Plaintiff. Had Plaintiff known that the ASR Hip Implant Device 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, she would not have purchased or consumed the ASR Hip Implant Device.

100. As a result of Defendants' unlawful and fraudulent concealment of the effects of the ASR Hip Implant Devices, the running statute of limitations has been suspended with respect to claims that Plaintiff has brought or could bring. Plaintiff 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.

101. As a direct and proximate result of Defendants' fraudulent concealment of the effects of the ASR Hip Implant Devices, Plaintiff has 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.

102. 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.

## TENTH CAUSE OF ACTION

## INTENTIONAL MISREPRESENTATION

**(Against All Defendants)**

103. 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:

104. Since at least 2007/2008, Defendants have had actual knowledge that the ASR 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.

105. The fact that the ASR 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.

106. Defendants knowingly and intentionally made false representations of material fact to Plaintiff, including but not limited to claims that the ASR 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." Defendants also advertised that the Hip Implant Device is "[d]esigned for active lifestyles." They further asserted that 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." They further touted that "[w]ith DePuy Advanced Bearing options, you can help your patients never stop moving." Defendants also indicated that "[l]arge diameter bearings improve hip range of motion and stability for higher function and a reduction in the occurrence of revision surgery."

107. These representations were made with the intent to induce Plaintiff to obtain the ASR Hip Implant Device.

108. In reliance on Defendants' misrepresentations of material fact, Plaintiff obtained the ASR Hip Implant Device. Had Plaintiff known that the ASR Hip Implant Device 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, she would not have elected to obtain an ASR Hip Implant Device.

109. As a result of Defendants' intentional misrepresentations regarding the effects of the ASR Hip Implant Device, the running statute of limitations has been suspended with respect to claims that Plaintiff has brought or could bring. Plaintiff 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.

110. As a direct and proximate result of Defendants' intentional misrepresentations, including but not limited to claims that the ASR Hip Implant Device was safe for use, Plaintiff

has 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.

111. 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.

## ELEVENTH CAUSE OF ACTION

## NEGLIGENT MISREPRESENTATION

**(Against All Defendants)**

112. 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:

113. Since at least 2007/2008, Defendants have had actual knowledge that the ASR 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.

114. The fact that the ASR 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.

115. Defendants recklessly and/or negligently made false representations of material fact to Plaintiff, including but not limited to claims that the ASR Hip Implant Device was 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." Defendants also advertised that the Hip Implant Device is "[d]esigned for active lifestyles." They further asserted that 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." They further touted that "[w]ith DePuy Advanced Bearing options, you can help your patients never stop moving." Defendants also indicated that "[l]arge diameter bearings improve hip range of motion and stability for higher function and a reduction in the occurrence of revision surgery."

116. These representations were made with the intent to induce Plaintiff to obtain the ASR Hip Implant Device.

117. In reliance on Defendants' misrepresentations of material fact, Plaintiff obtained the ASR Hip Implant Device. Had Plaintiff known that the ASR 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, she would not have elected to obtain an ASR Hip Implant Device.

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

119. As a direct and proximate result of Defendants' reckless and/or negligent misrepresentations, including but not limited to claims that the ASR Hip Implant Devices was safe for use, Plaintiff has 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.

120. 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.

**TWELFTH CAUSE OF ACTION**

**VIOLATIONS OF THE TEXAS DECEPTIVE TRADE PRACTICES ACT**

**TEX. BUS. & COM. CODE §§ 17.41, *ET SEQ***

**(Against All Defendants)**

121. 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:

122. Texas' Deceptive Trade Practices Act (DTPA) creates a cause of action for those harmed by deceptive acts including "false, misleading or deceptive" acts or practices.

123. Defendants, and each of them, have made numerous misrepresentations to Plaintiff and the general public. Among these misrepresentations are Defendants' claims that the ASR 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." Defendants also advertised that the Hip Implant Device is "[d]esigned for active lifestyles." They further asserted that 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." They further touted that "[w]ith DePuy Advanced Bearing options, you can help your patients never stop moving." Defendants also indicated that "[l]arge diameter bearings improve hip range of motion and stability for higher function and a reduction in the occurrence of revision surgery."

124. Defendants have made numerous misleading omissions, including their failure to disclose to Plaintiff and the general public the results of research showing that that the ASR 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

125. Defendants' business practices relating to the ASR Hip Implant Devices are unlawful because they constitute, *inter alia*, false advertising, intentional misrepresentation and

fraudulent concealment. Indeed, Defendants were recently criticized in a warning letter by the FDA for not seeking approval before marketing a hip implant device for an unapproved use.

126. As a direct and proximate result of Defendants' unlawful business practices and false advertising, Plaintiff has suffered significant damages, including but not limited to physical injury and actual loss of money or property, and will continue to suffer such damages in the future.

127. Plaintiff seeks an order of this Court awarding damages, restitution, disgorgement, injunctive relief, attorneys' fees and costs, and all other relief allowed under California Business and Professions Code §17200, *et seq*.

## VII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for the following 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, loss of consortium, 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 ASR Hip Implant Devices;

E. Attorneys' 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: September 24, 2010

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**JURY DEMAND**

Plaintiff demands a trial by jury.

Ken Soh