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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CARL F. WARD, Plaintiff, vs. DEPUY ORTHOPAEDICS, INC. and JOHNSON & JOHNSON, Defendants.	Civil Action No._____ **COMPLAINT and** **DEMAND FOR JURY TRIAL**

Plaintiff Carl F. Ward, by way of Complaint against Defendants, says:

SUMMARY OF PLAINTIFF'S ALLEGATIONS

1. This is an action for damages suffered by Carl F. Ward as a direct and proximate result of Defendants' wrongful conduct in connection with the development, design, testing, manufacture, distribution, and sale of the DePuy ASR™ XL Acetabular Hip Replacement System and ASR™ Hip Resurfacing System (collectively the "ASR Hip"). As a result of the inadequate testing of the ASR Hip that was sold by Defendants and implanted in Plaintiff, Plaintiff has suffered, and continues to suffer, serious bodily

injury and has incurred, and continues to incur, medical expenses to treat his injuries and condition.

PARTIES

2. Plaintiff Carl F. Ward is a citizen of the State of Illinois and resides in Chicago, Illinois.

3. On information and belief, Defendant DePuy Orthopaedics, Inc. ("DePuy") is a corporation organized and existing under the laws of Indiana with its primary place of business in Warsaw, Indiana. DePuy designed, manufactured, and sold the ASR Hip that is the subject of this lawsuit.

4. On information and belief, Defendant Johnson & Johnson ("J&J") is a corporation organized and existing under the laws of New Jersey with its primary place of business in New Brunswick, New Jersey. As DePuy's parent company, J&J was involved in the design, manufacture, and sale of the ASR Hip that is the subject of this lawsuit.

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

6. DePuy and J&J are collectively referred to herein as "Defendants."

JURISDICTION AND VENUE

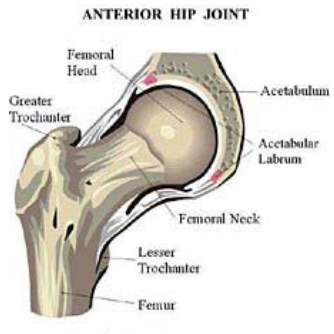
7. This action is a civil action of which this Court has original jurisdiction under 28 U.S.C. section 1332 because it is a civil action between citizens of different states and the amount in controversy exceeds the sum or value of $75,000, exclusive of costs and interest.

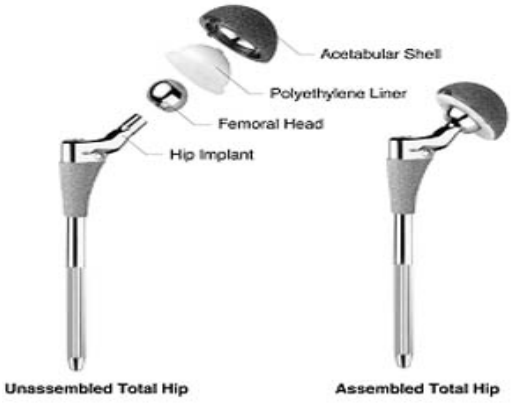
8. Venue is proper in this Court because Defendant Johnson & Johnson resides in New Brunswick, New Jersey and the actions of the Defendants that give rise to this Complaint took place, in part, in New Jersey.

FACTUAL BACKGROUND

A. DePuy's ASR Hip Has Not Been Adequately Tested

9. The hip joint is where the femur connects to the pelvis. The joint is made up of the femoral head (a ball-like structure at the very top of the femur) rotating within the acetabulum (a cup-like structure at the bottom of the pelvis.) In a healthy hip, both the femur and the acetabulum are strong and the rotation of the bones against each other is cushioned and lubricated by cartilage and fluids.





10. A total hip replacement replaces the body's natural joint with an artificial one, usually made out of metal and plastic. A typical total hip replacement system consists of four separate components: (1) a femoral stem (labeled as "hip implant" in the diagram to the left), (2) a femoral head, and (3) a liner, and (4) an acetabular shell. After the surgeon hollows out a patient's femur bone, the femoral stem is implanted. The

femoral head is a metal ball that is fixed on top of the femoral stem. The femoral head forms the hip joint when it is placed inside the polyethylene liner and acetabular shell.

11. The ASR Hip has a different design, one that puts the metal femoral ball directly in contact with a metal acetabular cup. The design of the ASR Hip was not sufficiently tested by the Defendants, and it was never approved by the FDA as being safe or effective for the products' intended purpose.

12. The ASR Hip 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.

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

14. 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.

15. 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.

16. 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.

17. In addition, a medical device marketed *after* the MDA's effective may bypass the rigorous premarket approval process if the device is "substantially equivalent" to a "grandfathered" pre-MDA device (*i.e.*, a device approved prior to May 28, 1976). This exception to premarket approval is known as the "510(k)" process and simply requires the manufacturer to notify the FDA under section 510(k) of the MDA of its intent to market a device at least 90 days prior to the device's introduction on the market, and to explain the device's substantial equivalence to a pre-MDA predicate device. The FDA may then approve the new device for sale in the United States.

18. Most new Class III devices enter the market through the 510(k) process.

19. In 2005, the year when the ASR Hip was approved for sale, the FDA authorized the marketing of 3,148 devices under section 510(k) and granted premarket approval to just 32 devices. P. Hutt, R. Merrill, & L. Grossman, Food and Drug Law 992 (3d ed. 2007).

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

21. Instead of assuring the safety of the ASR Hip through clinical trials, DePuy sought to market its ASR Hip without conducting any clinical trials by obtaining

FDA approval under section 510(k). To that end, in 2005, Defendants submitted a section 510(k) premarket notification of intent to market the ASR Hip.

22. By telling the FDA that the ASR Hip's design was "substantially equivalent" to other hip products on the market, DePuy was able to avoid the safety review required for premarket approval under FDA regulations including clinical trials.

23. In August 2005, the FDA approved the ASR Hip for sale by means of the abbreviated 510(k) process and consequently, the FDA did not require the ASR Hip to undergo clinical trials.

24. The 510(k) notification for the ASR Hip includes only Defendant DePuy's assertion that it "believes the DePuy ASR™ Modular Acetabular Cup System to be substantially equivalent…based upon the similarities in design, material composition, and intended use/indications for use" to devices that themselves had never been reviewed for safety and effectiveness.

25. 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.

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

27. This point is forcefully underscored by the FDA's August 25, 2005 letter to DePuy, which says nothing about the safety and effectiveness of the ASR Hip; finds only that the device was "substantially equivalent to devices introduced into interstate commerce prior to May 28, 1976"; and concludes by stressing that the agency's determination of substantial equivalence "does not mean that FDA has made a

determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies."

28. Thus, the FDA's finding of "substantial equivalence" had nothing to do with reviewing the ARS Hip's safety and effectiveness, but rather only a determination of equivalence to devices that themselves underwent no safety and effectiveness review.

29. The acronym "ASR" stands for "Articular Surface Replacement." ASR is a surgical procedure that is an alternative to a total hip replacement procedure. In an ASR procedure, only the articular surface of the hip (the acetabular cup and the femoral ball) is replaced. On the other hand, a total hip replacement includes not only the acetabular cup and femoral ball, but also a large piece of metal (known as a femoral stem) that is implanted deep into the patient's femur and on which the femoral ball is affixed.

30. To market the ASR Hip for use in ASR surgery, the FDA would have required DePuy to undergo premarket approval, which would have required DePuy to conduct clinical trials, prove that the product is both safe and effective, and monitor the long-term safety and performance of the product once it was placed on the market.

31. DePuy told the FDA that the components of the ASR Hip would be indicated for use in "total hip replacement procedures" and in patients with congenital hip dysplasia, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques", ***not for ASR surgeries***.

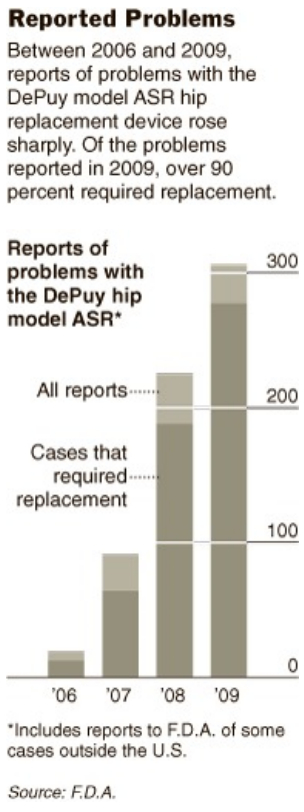
32. In short, Defendants were able to put the ASR Hip on the market in the United States ostensibly for use in an application for which it was not designed, a total hip replacement. To this day, despite being implanted in the bodies of thousands of

Americans who believed that the devices are safe, DePuy's ASR Hip has never been approved by the FDA as being safe or effective for ASR procedures and it never conducted a typical safety review of the ASR Hip.

33. While most hip replacements use a polyethylene ***plastic*** acetabular cup, DePuy's ASR Hip has a critical difference: it uses a ***metal*** acetabular cup. By using a metal acetabular cup and a metal femoral ball, the ASR Hip forces metal to rub against metal with the full weight and pressure of the human body. Because of Defendants' defective design for the ASR Hip, hundreds of patients have been forced to undergo surgeries to replace the failed hip implants.

B. After Hundreds of Failures, DePuy and the FDA Finally Recalled the ASR Hip

34. It wasn't long after DePuy launched the ASR Hip that reports of failures began flooding into DePuy. DePuy would go on to receive hundreds of similar complaints reporting that the ASR Hip had failed due to premature loosening of the acetabular cup and that the failure had forced patients to undergo painful and risky surgeries to remove and replace the failed hip component. As the *New York Times* chart to the right shows, by 2007 over 100 reports had been sent to DePuy. By the end of 2008, that had skyrocketed to well over 300 reports.



35. Consequently, DePuy was fully aware that the ASR Hip was defective and that hundreds of patients already had been injured by that defect. This is confirmed by Dr. Stephen Graves, the Director of the Australian Orthopaedic Association's National Joint

Replacement Registry. Dr. Graves believes that the data available to DePuy had shown for some time that the ASR had been failing early at a significantly higher rate than its competitors' devices.

36. The defect in the ASR Hip appears to be design-related. Several orthopedic specialists have opined that the design of the ASR acetabular cup, which is shallower than acetabular cups made by other companies, is at the heart of the ASR Hip's problems. For example, Dr. Harlan C. Amstutz, an orthopedic surgeon in Los Angeles who designs hip implants said that she believed that the design of the ASR Hip is prone to problems.

37. Even the surgeon who designed the ASR Hip, Dr. Thomas Schmalzried, admitted that DePuy had known since 2008 that the ASR Hip's cup may have problems. *The New York Times* reported in March 2010 that "Dr. Schmalzried said in an interview last month that she and DePuy officials realized within the last two years that the [ASR Hip's] cup might be more of a challenge to implant properly than competing cups." According to Dr. Schmalzried, "The window for component position that is consistent for good, long-term clinical function is smaller for the [ASR Hip]," than other cups.

38. Despite its knowledge that the ASR Hip had a defect and that it had failed hundreds of times, causing hundreds of patients to undergo the agony of another surgery, DePuy continued selling the defective hip implant. In so doing, DePuy actively concealed the known defect from doctors and patients—including Mr. Ward and his doctor—and misrepresented that that the ASR Hip was a safe and effective medical device.

39. In 2009 alone, DePuy brought in more than $5.4 billion in sales. Hip implant sales are critically important to DePuy's parent company, Johnson & Johnson, and DePuy is one of Johnson & Johnson's most profitable business groups.

40. In March 2010, DePuy finally began to disclose some of the alarming information about the ASR Hip. It sent a letter to doctors warning them of the increased failure rate associated with the ASR Hip. DePuy admitted that the ASR Hip suffered from a "higher than expected revision rate," and that data compiled by the Australian National Joint Replacement Registry showed that 5.4 percent of the ASR Hips implanted had been surgically replaced after only three years and that the expected failure rate could be as high as 10 percent. The letter also stated that DePuy was planning to stop selling the ASR Hip, allegedly because of "declining demand."

41. On July 17, 2010, the FDA announced a nationwide recall related to the DePuy ASR Hip. The FDA classified this recall as a Class 2 Recall. A Class 2 Recall includes situations where exposure to a violative product could cause a situation in which use of or exposure to a violative product may cause medically reversible adverse health consequences.

42. DePuy, on August 25, 2010, confirmed that in the first five years after implantation, approximately 12% of patients (1 in 8) who had received the ASR resurfacing device and 13% of patients (1 in 8) who had received the ASR total hip replacement needed to have a revision surgery.

43. DePuy also confirmed that at least 90,000 people have had ASR Hips implanted in their bodies, meaning that over time, at least ***11,700 people*** will have an ASR Hip failure and be forced to undergo a painful surgery to remove and replace it.

44. Most recently, on August 26, 2010, DePuy issued a worldwide recall of its ASR™ XL Acetabular Hip Replacement System and ASR™ Hip Resurfacing System and all components for these devices due to the high percentage of patients who needed to undergo a complex, risky, and painful surgery (known as a "revision surgery").

C. The Defective ASR Hip And The Defendants' Conduct Caused Injuries And Substantial Damages to Mr. Ward

45. In September 2006, Mr. Ward underwent a surgical procedure to implant an ASR Hip.

46. By September 2006, Defendants were on notice that the ASR Hip was defective. It would be approximately another three and a half years before DePuy would disclose the safety issue to Mr. Ward, his physician, or the public, and recall the ASR Hip due to its high failure rate.

47. Within six to seven months after his surgery, Mr. Ward began suffering from discomfort and pain in his hip and loosening of his hip. Mr. Ward is currently in severe pain, currently walks with a cane and has been prescribed pain medication by his primary care physician.

48. Mr. Ward's recovery from his surgery has been long and painful. To this day, he continues to suffer from persistent pain caused by the failure of his ASR Hip. These injuries may be permanent, and they may cause additional complications in the future. Mr. Ward intends to undergo revision surgery to remove his failed ASR Hip and replace it with a new hip implant system, if indicated by his doctor.

49. In the event that Mr. Ward requires revision surgery, he will suffer additional pain and an increased risk of complications. Revision surgeries are generally

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

50. Having to go through a revision surgery will subject Mr. Ward to much greater risks of future complications than he had before a revision surgery. For example, several studies have found that revision surgery has a much higher risk of dislocation compared with an original hip replacement surgery. In one study conducted by Charlotte Phillips and her colleagues at Brigham and Women's Hospital in Boston, 14.4 percent of patients who underwent a revision surgery suffered from a dislocation compared with 3.9 percent of patients who underwent a original hip replacement surgery. In other words, hip replacement patients who have undergone a revision surgery are almost ***four times more likely*** to suffer from a hip dislocation than those who have not. (Phillips CB, *et al*. Incidence rates of dislocation, pulmonary embolism, and deep infection during the first six months after elective total hip replacement. *American Journal of Bone and Joint Surgery* 2003; 85:20–26.)

51. As a direct and proximate result of the failure of his defective ASR Hip and the Defendants' wrongful conduct, Mr. Ward sustained and continues to suffer economic damages (including medical and hospital expenses), severe and possibly permanent injuries, pain, suffering and emotional distress. As a result, Mr. Ward has sustained and will continue to sustain damages in an amount to be proven at trial, but which will far exceed the $75,000 jurisdictional minimum of this Court.

COUNT I

(Products Liability Act – Failure to Warn)

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

53. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the ASR Hip and, in the course of same, directly advertised or marketed the product to the FDA, health care professionals, and consumers, or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of the ASR Hip.

54. Defendants failed to adequately warn health care professionals and the public, including Plaintiff and his physician, of the true risks of the ASR Hip, including that the ASR Hip could loosen and separate from the hip socket, causing severe pain and injury, and requiring further treatment, including revision surgery and/or replacement.

55. Defendants failed to provide timely and reasonable warnings regarding the safety and efficacy of the ASR Hip. Had they done so, proper warnings would have been heeded and no health care professional, including Plaintiff's physician, would have used the ASR Hip and no patient, including Plaintiff, would have had the ASR Hip implanted.

56. Defendants failed to provide timely and reasonable instructions and training concerning safe and effective use of the ASR Hip to either Plaintiff or his physician.

57. The ASR Hip, which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendants, was defective due to inadequate

post-marketing warnings and/or instruction because Defendants failed to provide adequate warnings to health care professionals and the consuming public, including Plaintiff, and continued to aggressively promote the ASR Hip.

58. Defendants failed to perform or otherwise facilitate adequate testing, failed to reveal or concealed testing and research data, or selectively and misleadingly revealed or analyzed testing and research data.

59. 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.

COUNT II

(Products Liability Act – Defective Design)

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

61. Defendants are the researcher, developer, manufacturer, distributor, marketer, promoter, supplier and seller of the ASR Hip, which is defective and unreasonably dangerous.

62. The ASR Hip 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 ASR Hip 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.

63. If the design defects were known at the time of manufacture, a reasonable person would have concluded that the utility of the ASR Hip did not outweigh its risks.

64. The defective condition of the ASR Hip rendered it unreasonably dangerous and/or not reasonable safe, and the ASR Hip was in this defective condition at the time it left the hands of the Defendants. The ASR Hip was expected to and did reach Plaintiff and his 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 ASR Hip. The ASR Hip was unreasonable 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 ASR Hip, it was being utilized in a manner that was intended by Defendants. At the time Plaintiff had the ASR Hip implanted it was represented to be safe and free from latent defects.

66. Defendants are strictly liable to Plaintiff for designing, manufacturing, and placing into the stream of commerce the ASR Hip, 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 ASR Hip, as well as the defective nature of the ASR Hip, but has continued to design, manufacture, sell, distribute, market, promote and/or supply the ASR Hip 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 ASR Hip.

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.

COUNT III
(Breach of Express Warranty)

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

70. Defendants advertised, labeled, marketed and promoted its product, the ASR Hip, representing the quality to health care professionals, the FDA, Plaintiff, and the public in such a way as to induce its purchase or use, thereby making an express warranty that the ASR Hip would conform to the representations. More specifically, Defendants represented that the ASR Hip was safe and effective for use by individuals such as Plaintiff or that it was safe and effective to treat Plaintiff's condition.

71. The representations, as set forth above, contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

72. The ASR Hip did not conform to the representations made by Defendant in that the ASR Hip was not safe and effective, was not safe and effective for use by individuals such as Plaintiff, and/or was not safe and effective to treat in individuals, such as Plaintiff.

73. At all relevant times, Plaintiff used the ASR Hip for the purpose and in the manner intended by Defendants.

74. Plaintiff and Plaintiff's physician, by the use of reasonable care, would not have discovered the breached warranty and realized its danger.

75. The breach of the warranty was a substantial factor in bringing about Plaintiff's injuries.

76. 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.

COUNT IV

(Products Liability Act - Breach of Implied Warranty)

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

78. The ASR Hip was not reasonably fit for the ordinary purposes for which such goods are used and did not meet the expectations for the performance of the product when used in the customary, usual and reasonably foreseeable manner. Nor was the ASR Hip minimally safe for its intended purpose.

79. At all relevant times, Plaintiff used the ASR Hip for the purpose and in the manner intended by Defendants.

80. Plaintiff and Plaintiff's physician, by the use of reasonable care would not have discovered the breached warranty and realized its danger.

81. Defendants' breach of the implied warranty was a substantial factor in bringing about Plaintiff's injuries.

82. 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.

COUNT V

(Punitive Damages under Common Law and the Products Liability Act)

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

84. Plaintiff is entitled to punitive damages because the Defendants' wrongful acts and/or omissions were wanton or in conscious disregard of the rights 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 ASR Hip and by failing to provide adequate instructions and training concerning its use.

85. Defendants downplayed, understated, and/or disregarded their knowledge of the serious and permanent side effects and risks associated with the use of the ASR Hip despite available information demonstrating that the ASR Hip could loosen and separate, causing serious harm to patients. Such risks and adverse effects could easily have been avoided had Defendant not concealed knowledge of the serious risks associated with the ASR Hip or provided proper training and instruction to physicians regarding use of the ASR Hip.

86. Defendants' misrepresentations included knowingly withholding material information from the FDA, the medical community and the public, including Plaintiff, concerning the safety of the ASR Hip.

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

88. Defendants failed to provide warnings that would have dissuaded health care professionals from using the ASR Hip, thus preventing health care professionals and consumers, including Plaintiff, from weighing the true risks against the benefits of using the ASR Hip.

89. Defendants failed to provide adequate training and instructions to physicians that could have prevented failure of the ASR Hip causing serious harm and suffering to patients, including Plaintiff.

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

WHEREFORE, Plaintiff demands judgment in his favor against Defendants as follows:

A. Awarding Plaintiff past and future medical and incidental expenses, according to proof;

B. Awarding Plaintiff past and future loss of earnings and/or earning capacity, according to proof;

C. Awarding Plaintiff past and future general damages, according to proof;

D. Awarding punitive and exemplary damages in an amount to be determined at trial;

E. Awarding disbursements and expenses of this action, including reasonable counsel fees and other appropriate relief;

F. Awarding prejudgment and post judgment interest; and

G. Granting such other and further relief as is just and proper.

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Dated: September 23, 2010

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury as to all issues so triable.

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Dated: September 23, 2010