UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA

COLEMAN JARRETT and PAULA JARRETT **PlaintiffS,** **v.** **WRIGHT MEDICAL TECHNOLOGY, INC., a Delaware corporation; and WRIGHT MEDICAL GROUP INC., a Delaware corporation,** **Defendants.,**	§	**MDL 2329 IN RE: Wright Medical Technology, Inc., Conserve Hip Implant Products Liability Litigation** **CIVIL ACTION No. 1:12-cv-00625** **FIRST AMENDED COMPLAINT** **JURY TRIAL DEMANDED**

SUMMARY OF PLAINTIFF'S ALLEGATIONS

1. This is a civil action being brought by Plaintiff Coleman and Paula Jarrett, private persons, on their own behalf, against Defendants Wright Medical Technology, Inc. and Wright Medical Group, Inc.

2. This First Amended Complaint is being filed pursuant to Federal Rule of Civil Procedure 15 (a)(1)(B) which provides that "[a] party may amend its pleading once as a matter of course within …21 days after service of a motion under Rule 12(b),(e), or (f)…"

3. Coleman Jarrett ("Plaintiff") has suffered damages as a result of Defendants' wrongful conduct in connection with the development, design, testing, manufacture,

distribution, and sale of the Wright Conserve Cup Hip Replacement System ("Conserve Cup"). Paula has suffered from loss of consortium due to Coleman Jarrett's injuries.

4. As a result of the inadequate testing of the Conserve Cup 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

5. Plaintiffs Coleman and Paula Jarrett are citizens and residents of the State of Indiana.

6. Defendant Wright Medical Technology, Inc. is a corporation incorporated in Delaware with its primary place of business in Arlington, TN. Wright Medical Technology Inc. developed, designed, tested, manufactured, distributed and sold the Conserve Cup that is the subject of this lawsuit.

7. Defendant Wright Medical Group, Inc. is a corporation incorporated in Delaware with its primary place of business in Arlington, TN. As Wright Medical Technology, Inc.'s parent company, Wright Medical Group, Inc. was involved in the development, design, testing, manufacture, distribution and sale of the Conserve Cup that is the subject of this lawsuit.

8. Wright Medical Technology and Wright Medical Group are collectively referred to herein as "Defendants."

JURISDICTION AND VENUE

9. 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.

10. Venue is proper in the Southern District of Indiana because Plaintiff resides in Shelbysville, IN and the actions of the Defendants that gave rise to this complaint took place, in part, in Indiana. This action has been appropriately transferred to the Northern District of Georgia for inclusion in MDL 2329 for purposes of pretrial discovery and motions practice.

FACTUAL BACKGROUND

A. WRIGHT'S CONSERVE CUP HAS NOT BEEN ADEQUATELY TESTED

11. 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.

12. 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, (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. These conventional hip replacements typically last 15-20 years.

13. The Wright Conserve Cup has a different design, one that puts the metal femoral ball directly in contact with a metal acetabular cup when most other hip

replacements use a polyethylene plastic acetabular cup. By using a metal acetabular cup and a metal femoral ball, the Conserve Cup forces metal to rub against metal with the full weight and pressure of the human body. Because of Defendants' defective design for the Conserve Cup, hundreds of patients have been forced to undergo surgeries to replace the failed hip implant after only a few years of receiving the hip implant.

14. The design of the Conserve Cup 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.

15. The Conserve Cup 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.

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

17. 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.

18. 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.

19. 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.

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

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

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

23. Instead of assuring the safety of the Conserve Cup through clinical trials, Defendants sought to market its Conserve Cup without conducting any clinical trials by obtaining FDA approval under section 510(k).

24. By telling the FDA that the Conserve Cup's design was "substantially

equivalent" to other hip products on the market, Defendants were able to avoid the safety review required for premarket approval under FDA regulations including clinical trials.

25. The FDA approved the Metal-on-metal Conserve Cup design for sale by means of the abbreviated 510(k) process and consequently, the FDA did not require the Conserve Cup to undergo clinical trials.

26. 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.

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

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

C. DOCTORS ACKNOWLEDGE DANGERS OF METAL-ON-METAL TOTAL HIP REPLACEMENTS

29. Leading orthopedic surgeons in the United States have virtually stopped using metal-on-metal hip implants because a significant percentage of patients who receive these implants experience early failure, dislocation and disarticulation. Many patients also suffer severe tissue loss, infection and irreversible bone damage caused by the failure of metal-on-metal hip implants, metallosis and biologic toxicity.

30. 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 required doctors 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.

31. Because of the problems associated with the need for almost perfect positioning of the implants and because of demonstrated premature and excessive wear, the Journal of Arthroplasty issued a statement urging doctors to use any metal-on-metal hip replacement only with "great caution, if at all."

32. 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. Despite scientific evidence to the contrary, Defendants continues to misrepresent the Conserve Cup metal-on-metal total hip replacement system as a high-quality, safe and effective hip replacement product.

33. In May of 2011 the FDA demanded that medical device companies which manufacture and deliver metal-on-metal devices conduct post-marketing studies regarding the safety of metal-on-metal devices due to concerns about metal poisoning.

D. KNOWN DANGERS OF THE WRIGHT CONSERVE CUP METAL-ON-METAL SYSTEM

34. Defendants have known for years that implantation of their Conserve Cup metal-on-metal total hip replacement system results in metallosis, biologic toxicity and an early and high failure rate.

35. Implantation of defendants' metal-on-metal total hip replacement systems, including the Conserve Cup, results in the release of high levels of toxic metal ions into every hip implant patient's tissue and bloodstream.

36. Particles released by friction of the metal-on-metal surfaces also results in metallosis, tissue death and the growth of tumors. This friction wear is especially pronounced in the early "wear in" period particularly on the leading edge of the metal acetabular cup. In the industry this is commonly referred to as "edge wear" or "edge loading."

37. Defendants' metal-on-metal total hip replacement systems are also defective in that because of their design, "proper" placement is exceedingly difficult for even experienced and competent surgeons to successfully accomplish. Without near perfect placement, the problems of edge wear and edge loading are exacerbated making metallosis more severe and early failure even more common.

38. Once the body is exposed to and absorbs the toxic metallic ions and particulate debris from the Conserve Cup metal-on-metal total hip replacement system, inflammation occurs, causing severe pain, infection, death of the surrounding tissue and bone loss. Tumors also develop.

39. It is estimated that perhaps only 5% of Class III medical device failures are ever reported to the FDA. Despite this fact, the FDA has received notice of hundreds of self-reported cases of critical failures and physical harm to patients implanted with the Conserve Cup metal-on-metal total hip replacement system implanted in Ms. Garrett. The reports of the harm caused by the defective Conserve Cup include catastrophic

failures, premature wear, dislocation, disarticulation, disassembly, metallosis and serum toxicity.

E. THE DEFECTIVE CONSERVE CUP AND THE DEFENDANTS' CONDUCT CAUSED INJURIES AND SUBSTANTIAL DAMAGE TO PLAINTIFF

40. On July 17, 2006 Mr. Jarrett underwent a left hip replacement operation at the IUH Methodist Hospital in Indianapolis, IN performed by Dr. Andrew Parr. During the operation a Conserve Cup hip component was implanted into Mr. Jarrett's left hip. Dr. Parr, acting as Mr. Jarrett's agent, and upon Mr. Jarrett's consent and instruction, purchased the Conserve Cup, or instructed his employer hospital to purchase, the Conserve Cup directly from Defendants.

41. In May of 2009, Mr. Jarrett presented to his surgeon with complaints of pain from his left hip. Dr. Parr took x-rays of the hip replacement and told Mr. Jarrett that the x-rays did not show any problem with his hip replacement. Dr. Parr also did a work up to see if the hip was infected. This work up showed that there was no infection in the left hip. Mr. Jarrett's doctors were unable to determine the source of the pain and sent him home. At this time Mr. Jarrett had no knowledge that the Conserve Cup hip was defective and his pain was reduced for a time being.

42. In July of 2010, Mr. Jarrett began suffering extreme pain and was admitted to the hospital where he was diagnosed with a gross loosening of the Conserve Cup component. On July 12, 2010 a revision surgery was conducted to remove and replace the Conserve Cup. During the surgery, the Surgeon found a copious amount of brown and grayish material and a pseudotumor which was caused by metal ions being released

from the Conserve Cup. Additionally the pseudotumor had eroded part of Mr. Jarrett's hip bone.

43. By 2006, Defendants were on notice that the Conserve Cup was defective. However, it was not until a time after August 2010, that Plaintiff discovered that the Conserve was defective when media reports began to highlight the dangers of metal-on-metal hip implants in the wake of the recall of the DePuy ASR. In no event could the Plaintiff have reasonably discovered that the Conserve Cup implanted in him was defective until after his July 2010 revision surgery when evidence of metallosis and the gross loosening of the acetabular component were first discovered by his surgeons.

44. 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.

45. Further revision surgery will subject Mr. Jarrett to much greater risks of future complications than he had before the 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 his 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.)

46. As a direct and proximate result of the failure of his defective Conserve Cup Hip Replacement and the Defendants' wrongful conduct, Mr. Jarrett sustained and continues to suffer economic damages (including medical and hospital expenses), severe and possibly permanent injuries, disability, disfigurement, pain, suffering and emotional distress. As a result, Mr. Jarrett has sustained and will continue to sustain damages in an amount to be proven at trial.

F. DEFENDANTS FRAUDULENTLY CONCEALED THE DEFECTS IN THE CONSERVE CUP.

47. Since 2006, Defendants have had actual knowledge that the Conserve Cup Implant could fail early due to metal debris 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.

48. The fact that the Conserve Cup Implant 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.

49. 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 Conserve Cup Implant as safe and effective hip replacement systems that reduces complications from debris material. This concealment was done with the intent to induce Plaintiff and physicians to purchase the Conserve Cup Implant Devices and to prevent patients from filing lawsuits

seeking damages for the defective Conserve Cup Implant. Further Plaintiff and his physicians could have discovered the cause of Plaintiff's pain had Defendants not actively concealed the fact that their product released excessive amounts of metal debris.

50. In reliance on Defendants' fraudulent concealment of a material fact, Plaintiff purchased the Conserve Cup Implant devices so that his physician could surgically implant the devices into Plaintiff. Had Plaintiff known that the Conserve Cup Implant Devices could fail early thereby giving rise to unnecessary physical injury, pain and suffering, debilitation, and the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery, they would not have purchased the Conserve Cup Implant Device.

51. As a result of Defendants' unlawful and fraudulent concealment of the effects of the Conserve Cup Implant Devices, the running statute of limitations has been suspended with respect to claims that Plaintiff have 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 and after public notice that the Depuy ASR, a substantially similar device, was recalled. In no event could the Plaintiff have realized that the Conserve Cup implanted in him was defective until after his July 2010 revision surgery when evidence of metallosis and the gross loosening of the acetabular component were first discovered by his surgeons.

COUNT I

Liability under The Indiana Products Liability Act Ind. Code Ann. § 34-20-1-1, *et seq.*

52. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint and further alleges:

53. Defendants owed a duty to Plaintiff to use reasonable care in the manufacture, design, sale and distribution of the Conserve Cup. Defendant's proper performance of this duty would have eliminated the risk that the device Defendants distributed and sold would become unsafe for its intended use. Defendants breached this duty and are therefore liable under the Indiana Products Liability Act..

54. Defendants had a duty to properly supervise, train, and monitor its employees, agents, and contractors to ensure their compliance with all applicable statutes, laws, regulations, or safety codes pertaining to the manufacture, distribution, storage, and sale of the Conserve Cup, but failed to do so and are therefore liable under the Indiana Products Liability Act.

55. Defendants had a duty to use supplies and other constituent materials that were reasonably safe, free of defects, and in compliance with applicable federal, state, and local laws, ordinances, and regulations. Defendants breached this duty and are therefore liable under the Indiana Products Liability Act.

56. Defendants had a duty to ensure that the Conserve Cup it distributed and sold was safe for implantation in the human body. Defendants failed to do so and are therefore liable under the Indiana Products Liability Act.

57. Defendants had a duty to exercise reasonable care to sell reasonably safe medical devices so as not to subject the ultimate consumer to unreasonable risk of harm.

58. Defendants were strictly liable, negligent, careless, reckless, grossly negligent and wanton, and breached its duties, in the manufacture, design, distribution and sale of the Conserve Cup System in all of the following respects:

a. By manufacturing, designing inspecting, marketing, distributing, selling and/or supplying the Conserve Cup in such a way that persons using the product would be subjected to unreasonable danger;

b. By failing to warn hospitals and patients that the Conserve Cup was defective in that the metal on metal design could lead to a failure for the cup to adhere to bone necessitating a risky and complicated revision surgery;

c. By failing to warn hospitals and patients that the Conserve Cup was defective in that the metal on metal design would release metal ions into the body causing extensive soft-tissue damage and pseudotumors.

d. By failing to warn hospitals and patients that the Conserve Cup was defective in that the metal on metal design increased the risk of early failure and revision surgery over conventional hip replacement designs

e. By placing and/or permitting the placement of the Conserve Cup into the stream of commerce when Defendants knew or should have known the Conserve Cup was defective;

f. By failing to properly and adequately test and inspect the Conserve Cup to determine its safety;

g. By failing to employ corrective safety mechanisms to limit the harm caused by the Conserve Cup;

h. By manufacturing, inspecting, marketing, distributing, selling and/or supplying the Conserve Cup in an unsafe condition;

i. By failing to keep abreast of and/or react appropriately to public, government and/or industry studies, information, documentation and recommendations, consumer complaints and reports and/or other information regarding the Conserve Cup; and

j. By failing to use due care under the circumstances.

59. Plaintiff was in the class of persons that the Defendants' reasonably should have been aware would be harmed by the defects in the Conserve Cup.

60. Defendants were engaged in the business of selling the Conserve Cup.

61. The Conserve Cup was implanted into the Plaintiff without substantial alteration to its condition when sold by the Defendants.

62. As a direct and proximate result of the Defendants' strict liability, negligence, carelessness, recklessness, gross negligence and wantonness, Plaintiff has suffered injury and damages.

COUNT II

Breach of Express Warranty
(Contract Claim)
Pursuant to Ind. Code Ann. § 26-1-2-313

63. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint and further alleges:

64. Defendants made affirmations of fact or promises through the advertisement, labeling, marketing, and promotion of its product, the Conserve Cup, to health care professionals, the FDA, Plaintiff, and the public, representing that the Conserve Cup was

safe, effective, fit, and proper for its intended use in order to induce its purchase or use, thereby making an express warranty that the Conserve Cup would conform to the representations.

65. Plaintiff was in privity with Defendants through his surgeon, acting as agent, and relied on the Defendants express representations to choose and purchase the Wright Conserve cup hip replacement.

66. The Defendants advertised on their website and product brochures distributed to Physicians and Patients as early as March of 2006 that their metal-on-metal hip replacements were designed to be an improvement over the metal-on-polyethylene implants because the metal-on-metal design would reduce the amount of wear particles. Defendants stated "Despite improvements in the manufacturing, processing, and sterilization of polyethylene, wear related problems still exist in modern Total Hip Arthroplasty.[9] To address this problem, the CONSERVE® Total Hip System has eliminated polyethylene from the design altogether. The result is a one-piece, highly superfinished metal-metal hip design, which provides significantly less wear particles than a conventional total hip replacement."[1] Defendants also provided the following graphic intended to make Physicians and patients believe that there will be only a minute amount of wear debris generated from the Wright Conserve Cup.

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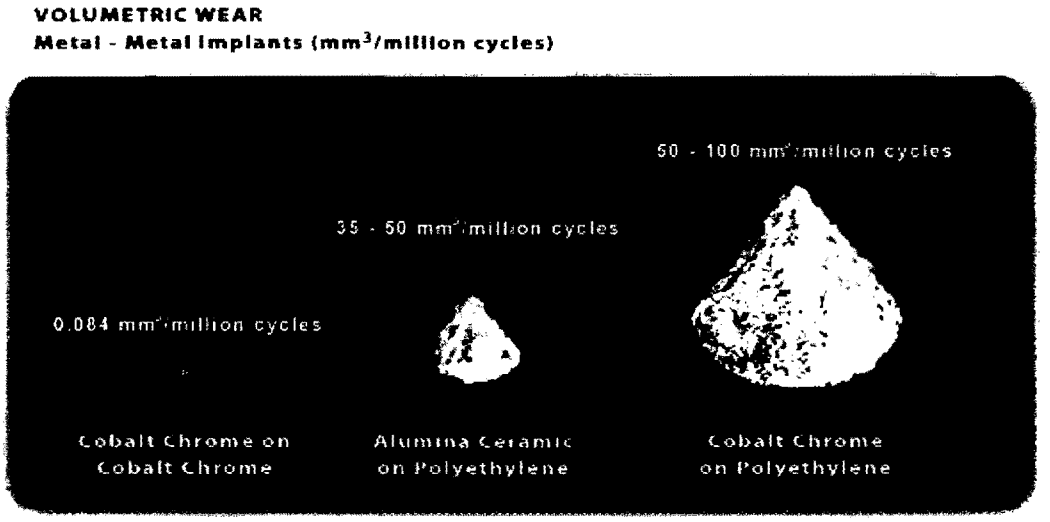
[1] http://web.archive.org/web/20060311160643/http://www.wmt.com/bigfemoralhead/physicians/yweardata.asp



67. In a press release issued August 25, 2005 on Wright Medical's website, Defendants stated, "Wright Medical Group, Inc. (NASDAQ:WMGI), a global orthopaedic medical device company, today announced the launch of its wear-reducing A-CLASS(TM) Advanced Metal for use with the Company's BFH(R) hip technology featuring large femoral heads for increased range of motion and a lowered potential for dislocation. The new A-CLASS(TM) Advanced Metal is the result of a patent-pending process developed to reduce the creation of material debris in metal-on-metal total hip arthroplasty, significantly enhancing the cutting-edge design features of Wright's total hip systems that feature BFH(R) Technology. Metal-on-metal articulation in hip systems is recognized for its high level of durability through reduced wear. A-CLASS(TM) Advanced Metal focuses on further minimizing wear debris, thereby potentially reducing the creation of metal ions. Wright's A-CLASS(TM) Advanced Metal minimizes wear through optimized durability, reducing the surface run-in wear to one-tenth the rate experienced by conventional total hip systems with BFH(R) Technology, while reducing cumulative lifetime wear by more than two-thirds."

68. Plaintiffs' physicians communicated the Defendants representations to the Plaintiff. These representations about the extended durability of the Conserve Cup gave Plaintiff and Plaintiffs' physicians the understanding that the Conserve Cup would last longer than the 15-20 years that a conventional hip replacement would last.

69. Unfortunately for the Plaintiff, contrary to the Defendants' express representations, the Defendants' metal-on-metal design actually increases severe complications from wear debris causing extensive soft-tissue damage and pseudotumors as in the case of Plaintiff.

70. Defendants' representations, mentioned above, 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.

71. Defendants' Conserve Cup did not conform to their representations that the Conserve Cup was safe, effective, fit, and proper for its intended use, nor that it reduced complications from wear debris over conventional hip replacements.

72. At all relevant times, Plaintiff used the Conserve Cup for the purpose and in the manner intended by Defendants.

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

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

75. As a direct and proximate result of Defendants' actions, Plaintiff has suffered injury and Defendants are liable to Plaintiff in an amount to be determined at trial .

including the cost of the hip replacement and all economic damages stemming from the hip replacement.

COUNT III

Breach of Implied Warranty of Merchantability
(Contract Claim)
Pursuant to Ind. Code Ann. § 26-1-2-314

76. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint and further alleges:

77. Defendants were and are merchants with respect to goods, such as the Conserve Cup.

78. Plaintiff was in privity with Defendants through his surgeon, acting as agent, and relied on the Defendants express representations to choose and purchase the Wright Conserve cup hip replacement.

79. Defendants impliedly warranted to Plaintiff that the Conserve Cup was fit for its ordinary purpose.

80. Defendants breached the implied warranty of merchantability because the Conserve Cup was dangerous and could not safely be used for its ordinary purpose.

81. Defendants knew or should have known that the Conserve Cup did not meet the capabilities as represented and marketed.

82. At all relevant times, Plaintiff used the Conserve Cup for the purpose and in the manner intended by Defendants.

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

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

85. As a direct and proximate result of Defendants' actions, Plaintiff has suffered injury and Defendants are liable to Plaintiff in an amount to be determined at trial including the cost of the hip replacement and all economic damages stemming from the hip replacement.

COUNT IV

Fraud

86. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint and further alleges:

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

88. Since 2006, Defendants have had actual knowledge that the Conserve Cup Implant could fail early due to metal debris 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.

89. The fact that the Conserve Cup Implant 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.

90. 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 Conserve Cup Implant as safe and effective hip replacement systems. As explained above, Defendants advertised on its website in 2005 and 2006 that their metal-on-metal hips would reduce debris and its attendant complications. This fraudulent statement was made with the intent to induce Plaintiff and physicians to purchase the Conserve Cup Implant Devices. This fraudulent statement was specifically directed towards the Plaintiff's physician, who was acting as agent for the Plaintiff.

91. In reliance on Defendants' fraudulent concealment of a material fact, Plaintiff purchased the Conserve Cup Implant devices so that his physician could surgically implant the devices into Plaintiff. Had Plaintiff known that the Conserve Cup Implant Devices could fail early due to metal debris 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, then Plaintiff would not have purchased the Conserve Cup Implant Device.

92. As a direct and proximate result of Defendants' fraud 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. Pursuant to Ind. Code § 26-1-2-721, Plaintiff is entitled to recovery of attorney's fees.

COUNT V

Loss of Consortium

94. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint and further alleges:

95. At all times herein mentioned, Plaintiffs Coleman Jarrett and Paula Jarrett were, and are, legally married as husband and wife.

96. As a direct and proximate result of the aforementioned conduct of the Defendants, and as a result of the injuries and damages to Plaintiff Coleman Jarrett, Plaintiff Paula Jarrett has been deprived of the love, companionship, comfort, affection, society, solace or moral support, protection, loss of enjoyment of sexual relations, and loss of physical assistance in the operation and maintenance of the home, of her husband, Coleman Jarret, and has thereby sustained, and will continue to sustain damages.

COUNT VI

(Punitive Damages under Common Law)

97. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint and further alleges:

98. 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 Conserve Cup and by failing to provide adequate instructions and training concerning its use.

99. Defendants downplayed, understated, and/or disregarded their knowledge of the serious and permanent side effects and risks associated with the use of the Conserve Cup despite available information demonstrating that the Conserve Cup could loosen and

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 Conserve Cup or provided proper training and instruction to physicians regarding use of the Conserve Cup.

100. Defendants' misrepresentations included knowingly withholding material information from the FDA, the medical community and the public, including Plaintiff, concerning the safety of the Conserve Cup.

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

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

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

104. Defendants' knowing decision to place profit over the safety of consumers amounts to malice, fraud, gross negligence, and oppressiveness which was not the result of a mistake of fact or law, mere negligence, or other human failing.

105. As a direct and proximate result of Defendants' actions, Plaintiff has suffered injury and Defendants are liable to Plaintiff in an amount to be determined at trial.

WHEREFORE, Plaintiff hereby demands judgment against the Defendants as follows:

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

B. Awarding Plaintiff past and future loss of earning 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.

DEMAND FOR JURY TRIAL

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

Dated: March 7, 2012

/s/ Jeffrey A. Travers

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CERTIFICATE OF SERVICE

I hereby certify that on this day of March 7, 2012. I filed the foregoing document with the clerk of court through a process server, and have emailed and delivered via first class mail a copy of this document to defendants.

/s/ Jeffrey A. Travers
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