UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF MICHIGAN

CLAUDIA D. ORR,

Plaintiff,

vs. Case No.
Hon.

SMITH & NEPHEW, INC.,

Defendant.
_____/

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_____/

COMPLAINT AND JURY DEMAND

Jurisdiction

Claudia D. Orr, by counsel, John A. Zick, states the following complaint against the defendant:

1. Claudia D. Orr is a citizen of the state of Michigan, residing in Wayne County, Michigan.

2. Smith & Nephew, Inc. is a corporation organized under the laws of the state of Delaware, with its principal place of business in the state of Massachusetts.

3. The amount in controversy exceeds the sum of $75,000, exclusive of interest and costs.

4. This Court has original diversity jurisdiction of this action pursuant to Title 28 U.S.C. sec. 1332(a).

Common Allegations

5. Hip implants were developed for the purpose of reconstructing diseased human hip joints from conditions such as osteoarthritis, rheumatoid arthritis, avascular necrosis, fracture and other degenerative conditions. The hip joint connects the thigh bone (femur) 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 rotates within the curved surface of the acetabulum. The hip implant is made up of four components: the metal femoral stem is inserted inside the femur, the metal femoral head (or ball) connects to the top of the stem and then makes contact with a liner that is attached to the interior portion of the metal acetabular cup (socket). The acetabular cup is comprised of metal. A polyethylene liner is then placed on the inside of the acetabular cup. The metal femoral head rotates within the polyethylene liner.

6. At all relevant times, the defendant designed, manufactured and sold various hip implant components, including the Reflection Microstable Acetabular Cup Liner.

7. On December 14, 2004, Ms. Orr underwent right total hip replacement surgery at Henry Ford Wyandotte Hospital in Wyandotte, Michigan. The procedure was performed by Kevin J. Sprague, M.D.

8. The prosthesis received by Ms. Orr was expected to last approximately 15-20 years before requiring revision.

9. The acetabular cup liner received by Ms. Orr is described as a Reflection Microstable Acetabular Liner, reference number 71743250, lot number 03CM10410.

10. In March 2011 - less than 6.5 years post-implant - Ms. Orr returned to Dr. Sprague with reports of right hip pain. Dr. Sprague identified premature wearing of the acetabular cup liner, causing osteolysis and loosening of the acetabular cup.

11. Given the extent of premature liner wear, and the associated osteolysis and acetabular cup loosening, revision surgery was required in order to prevent further damage to Ms. Orr's right hip.

12. On November 7, 2011, Ms. Orr underwent revision surgery by Dr. Sprague at Oakwood Southshore Medical Center in Wyandotte, Michigan. It was necessary to revise the acetabular cup and liner, as well as the femoral head.

13. Thereafter, Ms. Orr underwent a lengthy period of recovery, including months of physical therapy and multiple office visits with Dr. Sprague. Ambulation required the assistance of a walker for three months, and a cane for an additional 1-2 months.

14. As a result of the premature wearing of the acetabular cup liner, and the revision surgery which this necessitated, Ms. Orr experienced pain and suffering, emotional distress, inconvenience and the limitation of her activities for an extended period of time. She was unable to perform the duties of her profession, the practice of law. She has been left with a limp, and her mobility is permanently impaired.

15. As a further result of the premature wearing of the acetabular cup liner, and the revision surgery which this necessitated, Ms. Orr sustained special damages including the cost of hospitalization, physical therapy and other medical care; lost income due to her inability to practice her profession; and other incidental amounts.

Highly Cross-Linked v. Conventional Polyethylene

16. The acetabular cup liner received by Ms. Orr was constructed of a material known as Ultra High Molecular Weight Polyethylene ("UHMWPE").

17. The UHMWPE of Ms. Orr's cup liner is described as conventional polyethylene, as distinguished from highly cross-linked polyethylene.

18. When the defendant introduced the Reflection acetabular cup and liner in the 1990's, the manufacturing state of the art was to use conventional UHMWPE to construct such liners.

19. The use of conventional polyethylene for acetabular cup liners was problematic, as the polyethylene tended to wear and deteriorate due to the movement of the femoral head. This liner wear and deterioration shortened the useful life of the prosthesis, and further, acted to generate polyethylene debris which is deleterious to the human body.

20. During the 1990's, the major prosthetic implant manufacturers, including the defendant, developed and began to use processes which created highly cross-linked UHMWPE. The use of this material in acetabular cup liners represented a significant improvement over conventional UHMWPE, as it was much less susceptible to wear from the femoral head, and it significantly extended the useful life of hip implants, resulting in fewer revision surgeries.

21. In 1999, the defendant received the requisite approval from the United States Food & Drug Administration to begin selling acetabular cup liners constructed of highly cross-linked UHMWPE.

22. After 1999, and continuing until the time of Ms. Orr's hip replacement surgery in 2004, the defendant manufactured and sold acetabular cup liners constructed of both highly cross-linked UHMWPE and conventional UHMWPE.

23. Prior to 2004, the defendant performed and supported many research studies, comparing the performance of acetabular cup liners constructed of highly cross-linked UHMWPE, with the performance of liners constructed of conventional UHMWPE.

24. These studies uniformly showed highly cross-linked UHMWPE to be superior to conventional UHMWPE as a material for acetabular cup liners, as the liners made of highly cross-linked UHMWPE demonstrated significantly greater durability. As a consequence, there was a significant reduction in revision surgeries necessitated by premature liner wear.

25. The defendant did not fully and fairly communicate the results of these studies to the medical community, including surgeons such as Dr. Sprague.

26. As a result, many surgeons, including Dr. Sprague, continued to specify and use acetabular cup liners constructed of conventional UHMWPE.

27. By 2004, the manufacturing state of the art called for the use of highly cross-linked UHMWPE in the construction of acetabular cup liners. Still, the defendant continued to manufacture and sell liners made of conventional polyethylene.

Count I - Failure to Warn

28. The plaintiff repeats the Common Allegations, the same as if set forth verbatim.

29. At all relevant times, the defendant had a duty of reasonable care in the design, manufacture and sale of the acetabular cup liner at issue, including the issuance of complete and accurate product information, warnings and instructions.

30. The defendant breached this duty by failing to disseminate to the medical community, including Dr. Sprague, its research showing highly cross-linked UHMWPE to be far superior to conventional UHMWPE for the production of acetabular cup liners in hip implants.

31. As a direct and proximate result of the defendant's failure to disclose its research findings regarding conventional UHMWPE v. highly cross-linked UHMWPE, Dr. Sprague selected and implanted in Ms. Orr's right hip an acetabular cup liner constructed of conventional UHMWPE.

32. As a result of her receipt of an acetabular cup liner made of conventional UHMWPE, Ms. Orr experienced the premature wearing of the acetabular cup liner in her prosthesis, and she was compelled to undergo the revision surgery which this necessitated, sustaining the damages previously set forth.

WHEREFORE, Claudia D. Orr demands judgment against the defendant for that sum in excess of $75,000 which is justified by the evidence brought forth at trial, together with costs, interest and attorney fees.

Count II - Negligent Misrepresentation

33. The plaintiff repeats the Common Allegations and the allegations of Count I, the same as if set forth verbatim.

34. At all relevant times, the defendant had a duty of reasonable care in the design, manufacture and sale of the acetabular cup liner at issue, including the

issuance of appropriate information regarding the product's performance, and the availability of an alternative material - highly cross-linked UHMWPE - which would provide superior performance, with no disadvantages in cost, surgical technique or complications experienced by the patient.

35. The defendant breached this duty by failing to disseminate to the medical community, including Dr. Sprague, its research showing highly cross-linked UHMWPE to be far superior to conventional UHMWPE for the production of acetabular cup liners in hip implants.

36. As a direct and proximate result of the defendant's failure to disclose its research findings regarding conventional UHMWPE v. highly cross-linked UHMWPE, Dr. Sprague selected and implanted in Ms. Orr's right hip an acetabular cup liner constructed of conventional UHMWPE.

37. As a result of her receipt of an acetabular cup liner made of conventional UHMWPE, Ms. Orr experienced the premature wearing of the acetabular cup liner in her prosthesis, and she was compelled to undergo the revision surgery which this necessitated, sustaining the damages previously set forth.

WHEREFORE, Claudia D. Orr demands judgment against the defendant for that sum in excess of $75,000 which is justified by the evidence brought forth at trial, together with costs, interest and attorney fees.

Count III - Silent Fraud

38. The plaintiff repeats the Common Allegations and the allegations of Counts I and II, the same as if set forth verbatim.

39. Given its possession of information demonstrating the superiority of highly cross-linked UHMWPE as a material for use in acetabular cup liners, the defendant had a duty to disclose these facts to the medical community and in particular, to surgeons such as Dr. Sprague.

40. Rather than disclosing its findings showing highly cross-linked polyethylene to be a superior material for the construction of acetabular cup liners, the defendant provided product information which continued to hold out conventional polyethylene as an acceptable alternative.

41. The defendant intended that members of the medical community, including Dr. Sprague, would rely on the product information which it distributed.

42. The defendant's nondisclosure had the effect of misleading members of the medical community, including Dr. Sprague.

43. The defendant knew or should have known that the incomplete and inaccurate product information which it provided would be misleading to medical professionals.

44. In selecting a liner made of conventional UHMWPE for Ms. Orr's implant, Dr. Sprague acted in reliance on the misimpression created by the defendant.

45. As a result of Dr. Sprague's selection of a liner made of conventional UHMWPE, Ms. Orr experienced the premature wearing of the acetabular cup liner in her prosthesis, and she was compelled to undergo the revision surgery which this necessitated, sustaining the damages previously set forth.

WHEREFORE, Claudia D. Orr demands judgment against the defendant for that sum in excess of $75,000 which is justified by the evidence brought forth at trial,

together with costs, interest and attorney fees.

Count III - Breach of Implied Warranties

46. The plaintiff repeats the Common Allegations and the allegations of Counts I and II, the same as if set forth verbatim.

47. The common law of the state of Michigan implies a warranty that a product, such as the acetabular cup liner received by Ms. Orr, will be reasonably fit for its intended purposes.

48. Reasonable fitness includes a requirement that the product last for a period of time which is reasonable under the circumstances.

49. The acetabular cup liner received by Ms. Orr did not last for the period of 15-20 years as was reasonably expected; rather, it developed premature wear, and failed after less than 6.5 years.

50. A Michigan statutory provision creates an implied warranty that a product will be merchantable, if the seller is a merchant with respect to goods of that kind. M.C.L.A. 440.2314.

51. M.C.L.A. 440.2314(2) provides that goods to be merchantable must be fit for the ordinary purposes for which such good are used.

52. The defendant is a merchant with respect to hip implants and hip implant components, including acetabular cup liners.

53. The premature wear and failure of the acetabular cup liner received by Ms. Orr constitutes a breach by the defendant of these implied warranties, that is, the acetabular cup liner was not fit for its ordinary purposes because it developed premature wear and failed after less than 6.5 years.

54. A Michigan statutory provision creates an implied warranty that a product will be fit for the particular purpose for which it is required, if, at the time of contracting, the seller had reason to know the particular purpose for which the product is required, and that the buyer was relying on the seller's skill or judgment to select or furnish suitable goods. M.C.L.A. 440.2315.

55. At the time of selling the acetabular cup liner at issue, the defendant knew that the liner was intended for use in a hip prosthesis, and knew that the medical community, including Dr. Sprague, and patients, including Ms. Orr, were relying on the defendant's skill and judgment to furnish a suitable liner.

56. The acetabular cup liner was not fit for the particular purpose for which it was required, because it developed premature wear and failed after less than 6.5 years, while it was reasonably expected to last 15-20 years.

57. As a result of the defendant's breach of common law and statutory implied warranties as described above, and the failure of the acetabular cup liner after less than 6.5 years, it was necessary for Ms. Orr to undergo the revision surgery described above.

58. In connection with the revision surgery necessitated by the defendant's breach of warranties, Ms. Orr sustained the damages previously set forth.

59. Further, Ms. Orr claims consequential damages for injuries to her person proximately resulting from the defendant's breach of warranties, together with costs and actual attorney fees. M.C.L.A. 440.2715.

WHEREFORE, Claudia D. Orr demands judgment against the defendant for that sum in excess of $75,000 which is justified by the evidence brought forth at trial,

together with costs, interest and attorney fees.

Count IV - Negligent Design

60. The plaintiff repeats the Common Allegations and the allegations of Counts I, II and III, the same as if set forth verbatim.

61. At all relevant times, the defendant had a duty of reasonable care in the design of the acetabular cup liners which it sold. This includes a duty to select and utilize proper materials to construct the liners.

62. The defendant breached this duty by constructing the liner at issue of conventional UHMWPE, rather than of highly cross-linked UHMWPE.

63. At a time well before 2004, the defendant was in possession of information showing highly cross-linked UHMWPE to be superior to conventional UHMWPE for use in hip implant components. That is, highly cross-linked UHMWPE had significantly greater resistance to wear, thereby extending the life of the prosthesis and reducing the need for revision surgeries. Further, there was no appreciable difference in cost, in the required surgical technique, or in complications experienced by the patients.

64. As a direct and proximate result of the defendant's negligence in constructing this acetabular cup liner of conventional UHMWPE rather than highly cross-linked UHMWPE, the liner received by Ms. Orr on December 14, 2004 was made of this inferior material.

65. Because the acetabular cup liner received by Ms. Orr was constructed of conventional UHMWPE rather than highly cross-linked UHMWPE, it developed premature wear, necessitating revision surgery after less than 6.5 years.

66. In connection with the revision surgery necessitated by the defendant's negligent design of this acetabular cup liner, Ms. Orr sustained the damages previously set forth.

WHEREFORE, Claudia D. Orr demands judgment against the defendant for that sum in excess of $75,000 which is justified by the evidence brought forth at trial, together with costs, interest and attorney fees.

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Dated: August 2, 2012

JURY DEMAND

The Plaintiff demands a trial by jury.

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Dated: August 2, 2012