

IN THE NINTH JUDICIAL CIRCUIT OF THE STATE OF FLORIDA
IN AND FOR OSCEOLA COUNTY, FLORIDA

WYNNE GARRON,

Plaintiff,

v.

CASE NO. 11 CD 3010 PL

MARK DEBIASE, INC. d/b/a JOINT VENTURE, INC.

Defendant.

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COMPLAINT

COMES NOW, the Plaintiff, WYNNE GARRON, by and through her undersigned attorneys and hereby sues Defendant, MARK DEBIASE, INC. d/b/a JOINT VENTURE, INC., ("MARK DEBIASE, INC.") and alleges as follows:

1. This is an action for damages in excess of \$75,000.00, exclusive of attorney's fees and costs, resulting from Defendant's promoting, marketing, distributing, supplying, selling, and servicing defective hip replacement components that were subsequently recalled by the United States Food and Drug Administration.

PARTIES AND JURISDICTION

2. At all times material to this Complaint, WYNNE GARRON, was and continues to be a resident of the State of Florida.

3. Defendant, MARK DEBIASE, INC., is a Florida corporation with its principal place of business at 1525-A The Greens Way, Jacksonville Beach, FL 32250, in Duval County, Florida, and as such is a citizen of the State of Florida.

4. At all times material to this Complaint, Defendant was a corporation organized and existing pursuant to the laws of the State of Florida and operating within the State of Florida.

5. At all times material to this Complaint, Defendant was registered to do business under the fictitious name of “Joint Venture, Inc.”.

6. At all times relevant to this action, Defendant promoted, marketed, distributed, supplied, sold, and serviced the recalled defective hip replacement components in the State of Florida, including Osceola County.

7. Defendant utilized and employed sales representatives that were responsible for educating Plaintiff’s orthopedic surgeons regarding the supposed advantages of the hip replacement components, answering any questions Plaintiff’s orthopedic surgeons had regarding the hip replacement components, providing the Plaintiff’s orthopedic surgeons with information regarding the proper surgical technique to employ in implanting the hip replacement components, providing the Plaintiff’s orthopedic surgeons with information concerning the hip replacement components appropriate for the patient, providing the Plaintiff’s orthopedic surgeons with the tools to be used to implant the hip replacement components, assisting Plaintiff’s orthopedic surgeons at surgery regarding the hip replacement components, and selling the hip replacement components to Plaintiff’s orthopedic surgeons.

8. Plaintiff and her surgeons, nurses, and hospital staff relied on information from Defendant in selecting, purchasing, implanting, and servicing the hip replacement components.

VENUE

9. Venue is proper in Osceola County in that at present and at all times relevant to this action, the primary residence of Plaintiff was in Osceola County, Florida.

HIP REPLACEMENT COMPONENTS

10. In 2005, Defendant began promoting and selling in Florida hip replacement components with the model identification of “ASR” manufactured by DePuy International, LTD of the United Kingdom.

11. In addition to other means, Defendant used brochures and other printed literature to promote the ASR hip replacement components.

12. Defendant disseminated literature to the orthopedic community in Florida stating that the DePuy ASR hip replacement components were “large diameter, high performance metal-on-metal bearings [are] designed and manufactured within fine tolerances to facilitate a state of fluid film lubrication” and “designed to reduce wear and provide high function for all patients.”

13. Defendant also claimed in information provided to the Florida orthopedic community that the DePuy ASR hip replacement components were “based on a strong clinical history” and “reduces wear compared to traditional hip replacement.”

WARNINGS FROM INDEPENDENT ORTHOPEDIC EXPERTS

14. The same year Defendant began selling the ASR hip replacement components, independent experts from around the world were warning that the design of the ASR hip replacement components was defective.

15. Orthopedic experts warned that some of the ASR hip replacement components were too thin and thus prone to deformation.

16. Orthopedic experts warned that the clearance between the ASR hip replacement component cup and heads was too small and in some patients could lead to jamming of components.

17. Orthopedic experts warned that the treatment of the metal used for the ASR hip replacement components rendered them prone to increased wear.

18. By 2005, ASR hip replacement components were shown to have a 4-fold higher rate of revision than similar components in the Australian Joint Registry.

DEFENDANT'S RESPONSE TO WARNINGS

19. When questioned by members of the orthopedic community about independent expert warnings that the ASR hip replacement components were defective, Defendant's sales representatives were instructed how to argue that the independent experts were mistaken and to continue to heavily promote the ASR hip replacement components.

20. Defendant, through its employees and agents, was also aware of the problems with the design of the ASR hip replacement components based upon complaints of orthopedic surgeons.

21. Defendant was additionally aware of excessive failures necessitating revision of ASR hip replacement components due to revision surgeries in which Defendant's sales representatives participated, but failed to convey this information to the Plaintiff's orthopedic surgeons.

SUSPENSION

22. From 2005 to 2009, numerous complaints of premature failure of ASR hip replacement components were made by orthopedic surgeons and hospitals to Defendant and the United States Food and Drug Administration.

23. Independent studies showed numerous problems with ASR hip replacement components, including failure of ASR hip replacement cups to achieve proper fixation due to the lack of bony ingrowth into the back of the cup, fracture resulting from loose ASR hip replacement components, significant metal debris in patients with ASR hip replacement components, and the formation of pseudotumors in patients with ASR hip replacement components.

24. In the fall of 2009, DePuy International, LTD. announced that the company would be phasing out sales of the ASR hip replacement components worldwide, citing slowing sales as the only reason for the change.

25. Unfortunately, this action came far too late for the Plaintiff to this action.

BACKGROUND OF PLAINTIFF WYNNE GARRON

26. Plaintiff, WYNNE GARRON, is a resident of the State of Florida.

27. Plaintiff was implanted with an ASR hip replacement component on April 8, 2008 in her right hip by her orthopedic surgeon, Michael A. Karr, M.D. at Osceola Regional Medical Center in Kissimmee, Florida.

28. Plaintiff was then implanted with another ASR Hip on July 16, 2008 under the care of Dr. Karr, again at Osceola Regional Medical Center.

29. Though Plaintiff recovered well from her initial surgeries, she struggled with pain throughout the healing process, which required significant pain medications. This pain persisted for over two years without a diagnosis. On June 11, 2010, Dr. Karr became concerned with the metal-on-metal articulation.

30. On August 30, 2010, Plaintiff presented to George Haidukewych, M.D. at Orlando Health for a second opinion regarding her hip. Dr. Haidukewych determined that Plaintiff was in need of revision surgeries, starting with the left hip.

31. Plaintiff underwent revision surgery of her left hip on September 29, 2010 under the care of Dr. Haidukewych at Orlando Health in Orlando, Florida. In this surgery, the doctor discovered that the cup was loose and had failed to achieve bony ingrowth. He stated in the operative report that:

The acetabulum was then circumferentially exposed and noted to be loose. With a simple tap of an impactor on the rim, the cup essentially fell out of the pelvis. There was no evidence of any bony ingrowth on the cup

32. Plaintiff then underwent revision surgery of her right hip on November 22, 2010 under the care of Dr. Haidukewych at Orlando Health. In this surgery, the doctor found evidence of a reaction to the metal:

Tissue was sent which showed no significant acute inflammation, but did show significant perivascular lymphocytes consistent with an adverse reaction to the metal device. The situation was discussed with the pathologist and we both agreed that the situation appeared more like a metal reaction than a metal reaction and an infection. [...] The acetabular component was circumferentially exposed and was found to be loose.

33. Plaintiff is now in the slow process of recovering from these traumatic surgeries.

EFFECT ON PLAINTIFF

34. The Plaintiff to this action had ASR hip replacement components that were promoted, marketed, distributed, supplied, sold, and serviced by Defendant.

35. The Plaintiff to this action had ASR hip replacement components that were defective when implanted in her body and were subsequently recalled by the United States Food and Drug Administration.

36. In the instance of the Plaintiff to this action, the ASR hip replacement cups failed to achieve proper bone ingrowth into the cups and thus failed to achieve proper fixation.

37. In the instance of the Plaintiff to this action, the ASR hip replacement components generated excessive metal debris.

38. In the instance of the Plaintiff to this action, the recognition that ASR hip replacement components had failed was delayed by the failure of Defendant to convey to Plaintiff's orthopedic surgeons the warnings regarding the product made by independent orthopedic experts, the information regarding other failures of ASR hip replacement components throughout the United States and worldwide, the complaints of other orthopedic surgeons to Defendant regarding the ASR hip replacement components and the knowledge of other failures requiring revision surgeries, which Defendant's representatives attended.

39. As a result of this significant delay in the recognition that the ASR hip replacement components had failed, Plaintiff needlessly suffered pain and damage to the bones and tissues of her hips.

40. The defective ASR hip replacement components implanted and allowed to remain in the body of the Plaintiff caused extreme pain and suffering to Plaintiff.

41. Despite Defendant's knowledge of extensive problems with and defects in the ASR hip replacement components, Defendant continued to heavily promote the components.

42. Plaintiff's orthopedic surgeon relied on the misinformation provided by Defendant and used, continued to use, and failed to suspect the premature failure of the ASR hip replacement components

COUNT ONE – NEGLIGENCE

43. Plaintiff re-alleges and incorporates by reference paragraphs 1-42 above as if fully stated herein.

44. Defendant, as the promoter, marketer, seller, distributor, and servicer of the ASR hip replacement components, owed a duty to Plaintiff to provide accurate information to Plaintiff, her orthopedic surgeon, and the orthopedic community.

45. Defendant, in breach of the duty described above, negligently and carelessly promoted, marketed, sold, distributed, and serviced the ASR hip replacement components implanted in Plaintiff.

46. As a direct and proximate result of the conduct of Defendant, Plaintiff needlessly suffered severe pain and weakness.

47. As a direct and proximate result of the breach of the duty of care set forth herein, Plaintiff has suffered severe physical distress and injury, emotional distress and injury; incurred medical and other expenses; lost wages and income; suffered shame, humiliation and the inability to lead a normal life; and has suffered loss of enjoyment of life. The injuries and losses of Plaintiff are permanent in nature and Plaintiff will continue to suffer such losses in the future.

COUNT TWO STRICT LIABILITY

48. Plaintiff re-alleges and incorporates by reference paragraphs 1-42 above as if fully stated herein.

49. At the time that Defendant promoted, marketed, distributed, supplied, sold, and serviced the ASR hip replacement components, they contained defects that made them unreasonably dangerous beyond the expectations of the ordinary consumer, and were unfit for their intended use.

50. The ASR hip replacement components reached Plaintiff without substantial change in the condition in which they were sold.

51. The ASR hip replacement components, for the reasons stated herein, were defective and unreasonably dangerous in design and manufacture.

52. At the time and on the occasions in question, the ASR hip replacement components were being properly used for the purpose for which they were intended, and such components were in fact defective, unsafe and unreasonably dangerous.

53. As a direct and proximate result of the defective, unsafe and unreasonably dangerous nature of the ASR hip replacement components, Plaintiff has suffered severe physical distress and injury, emotional distress and injury; incurred medical and other expenses; lost wages and income; suffered shame, humiliation and the inability to lead a normal life; and has suffered loss of enjoyment of life. The injuries and losses of Plaintiff are permanent in nature and Plaintiff will continue to suffer such losses in the future.

**COUNT THREE
BREACH OF IMPLIED WARRANTY**

54. Plaintiff re-alleges and incorporates by reference paragraphs 1-42 above as if fully stated herein.

55. Defendant promoted, marketed, distributed, supplied, sold, and serviced the ASR hip replacement components at issue in this case.

56. Defendant impliedly warranted that the ASR hip replacement components were reasonably fit for their intended use as hip replacement components.

57. Plaintiff was a foreseeable user of the ASR hip replacement components.

58. Plaintiff purchased the ASR hip replacement components from Defendant.

59. The ASR hip replacement components failed while being used for their intended purpose, causing serious injury to Plaintiff.

60. As a direct and proximate result of this breach, Plaintiff has suffered severe physical distress and injury; emotional distress and injury; incurred medical and other expenses; lost wages and income; suffered shame, humiliation and the inability to lead a normal life; and has suffered loss of enjoyment of life. The injuries and losses of Plaintiff are permanent in nature and Plaintiff will continue to suffer such losses in the future.

**COUNT FOUR
FLORIDA DECEPTIVE AND UNFAIR TRADE PRACTICE ACT VIOLATION**

61. Plaintiff re-alleges and incorporates by reference paragraphs 1-42 as if fully stated herein.

62. At all times relevant to this action, Plaintiff was a consumer as described in the Florida Deceptive and Unfair Trade Practices Act, Florida Statute Section 501.203(7).

63. In violation of the Florida Deceptive and Unfair Trade Practices Act, Defendant advertised and promoted its ASR hip replacement components using representations that it knew to be false.

64. This false and deceptive advertising and promotion constitutes “unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices” pursuant to Florida Statute Section 501.204.

65. Based upon the false and deceptive advertising and promotion of Defendant, Plaintiff purchased the ASR hip replacement components.

66. As a result of the ASR hip replacement components purchased by Plaintiff being other than as represented by Defendant, they were thus unfit for their intended purpose and therefore valueless.

67. As a direct and proximate result of the deceptive and unfair trade practices of Defendant, Defendant sold and Plaintiff purchased valueless hip replacement systems.

68. These violations of the Florida Deceptive and Unfair Trade Practices Act were a producing cause of Plaintiff’s damages as alleged herein below.

WHEREFORE Plaintiff demands judgment against the Defendant, for the difference in value between the ASR hip replacement components advertised and promoted by Defendant and the ASR hip replacement components actually delivered by Defendant, together with reasonable attorneys’ fees and costs of suit pursuant to Florida Statutes Section 501.211(2), and for any further relief that the Court deems just and proper.

DEMAND FOR JURY TRIAL

69. Plaintiff respectfully requests that a jury be impaneled to hear this cause of action and to award such damages as the jury finds to be fair and reasonable under the circumstances.

Dated: September 7, 2011

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