

IN THE SIXTH JUDICIAL CIRCUIT OF THE STATE OF FLORIDA  
IN AND FOR PINELLAS COUNTY, FLORIDA

JANINE BARNES  
and JULIE FOURNIER,

Plaintiffs,

v.

CASE NO. 11 - 04262CI-21

BAYSIDE ORTHOPAEDICS, INC.,

Defendant.

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**COMPLAINT**

COME NOW, the Plaintiffs, JANINE BARNES and JULIE FOURNIER, by and through their undersigned attorneys and hereby sue Defendant BAYSIDE ORTHOPAEDICS, INC., and allege 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, JANINE BARNES ("BARNES") was and continues to be a resident of the State of Florida.

3. At all times material to this Complaint, JULIE FOURNIER ("FOURNIER") was and continues to be a resident of the State of Florida.

4. Defendant, BAYSIDE ORTHOPAEDICS, INC., is a Florida corporation with its principal place of business at 14450 46th Street North, Suite 112, Clearwater Florida 33762, in Pinellas County, Florida, and as such is a citizen of the State of Florida.

5. 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.

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 Pinellas County and Lee County, Florida.

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

8. Plaintiffs and their 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 Pinellas County in that at present and at all times relevant to this action, the principal office of Defendant was in Pinellas 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 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 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 Plaintiffs' 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 our 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 Plaintiffs to this action.

#### **BACKGROUND OF PLAINTIFF JANINE BARNES**

26. BARNES is a resident of the state of Florida.

27. BARNES was implanted with an ASR hip replacement component on July 6, 2009 in her right hip by her orthopedic surgeon, George Markovich, M.D., at Gulf Coast Medical Center in Fort Myers, Florida.

28. Though BARNES recovered well from her initial surgery, she struggled with pain in her hip throughout the healing process. This pain persisted for over a year without diagnosis. Dr. Markovich became concerned at the possibility of the symptoms being caused by metal debris after the ASR cup was recalled. He ordered blood tests to measure serum levels of chromium and cobalt. The results were a chromium level of 9.6 and a cobalt level of 11.2, both over 10 times the highest acceptable levels of these metals.

29. BARNES underwent revision surgery on January 10, 2011 under the care of Dr. Markovich at the Gulf Coast Medical Center. In this surgery, the doctor discovered extensive amounts of inflammation and scar tissue caused by the metal debris and that the cup had failed to achieve bony ingrowth. He stated in the operative report that:

It should be noted that there was a marked effusion and yellowish milky type of fluid, characteristic of metal hypersensitivity...I carefully removed the Moreland osteotome around the implant and it was obvious that there was fibrous fixation. The 48 mm ASR 1-piece articulation was able to be removed with minimal bone loss.

30. BARNES is now in the slow process of recovering from this traumatic surgery.

### **BACKGROUND OF PLAINTIFF JULIE FOURNIER**

31. FOURNIER is a resident of the state of Florida.

32. FOURNIER was implanted with an ASR hip replacement component on December 9, 2009 in her right hip by her orthopedic surgeon, Fletcher A. Reynolds, M.D., at Lee Memorial Hospital in Fort Myers, Florida.

33. Several months after the surgery, FOURNIER returned to her doctor with complaints of knee and back pain, accompanied with paraesthesia and tingling sensations. Her doctor treated her for conditions such as radiculopathy, nerve compression, and degenerative disc disease.

34. The treatments that FOURNIER underwent for these possible diagnoses were not effective, and she continued to suffer for the following two years.

35. FOURNIER sought a second opinion from orthopedic surgeon Edward Stolarski, M.D., in late 2010.

36. Dr. Stolarski ordered various tests to determine the cause of FOURNIER'S pain, and it was determined that she was suffering from aseptic loosening of her prosthesis.

37. FOURNIER underwent revision surgery on January 26, 2011 under the care of Dr. Stolarski at the Sarasota Memorial Hospital in Sarasota, Florida. In this surgery, the surgeon discovered that there was no bone or soft tissue ongrowth on the acetabular cup. As he stated in the operative report:

The femoral stem was well fixed, the acetabular component was removed using explant osteotomes and it was easily removed. There was no bony or soft tissue attached to the acetabular component.

38. FOURNIER is now in the process of recovering from this traumatic surgery.

### **EFFECT ON PLAINTIFFS**

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

40. The Plaintiffs to this action had ASR hip replacement components that were defective when implanted in their bodies and were subsequently recalled by the FDA.

41. In the instance of each of the Plaintiffs to this action, the ASR hip replacement cups failed to achieve proper bone ingrowth into the cup and thus failed to achieve proper fixation.

42. In the instance of each of the Plaintiffs to this action, the ASR hip replacement components generated excessive metal debris.

43. In the instance of each of the Plaintiffs to this action, the recognition that ASR hip replacement components had failed was delayed by the failure of Defendant to convey to Plaintiffs' orthopedic surgeons the warnings regarding the product made by independent orthopedic experts and information regarding other failures of ASR hip replacement components throughout the United States and worldwide.

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

45. The defective ASR hip replacement components implanted and allowed to remain in the bodies of the Plaintiffs caused extreme pain and suffering to Plaintiffs.

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

47. Plaintiffs' orthopedic surgeons 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**

48. Plaintiffs re-allege and incorporate by reference paragraphs 1-47 above as if fully stated herein.

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

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

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

52. As a direct and proximate cause of the breaches set forth herein, Plaintiffs have 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 have suffered loss of enjoyment of life. The injuries and losses of Plaintiffs are permanent in nature and Plaintiffs will continue to suffer such losses in the future.

**COUNT TWO  
STRICT LIABILITY**

53. Plaintiffs re-allege and incorporate by reference paragraphs 1-47 above as if fully stated herein.

54. 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 was unfit for its intended use.

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

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

57. 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.

58. As a direct and proximate cause of the nature of the ASR hip replacement components, Plaintiffs have 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 have suffered loss of enjoyment of life. The injuries and losses of Plaintiffs are permanent in nature and Plaintiffs will continue to suffer such losses in the future.

**COUNT THREE  
BREACH OF IMPLIED WARRANTY**

59. Plaintiffs re-allege and incorporate by reference paragraphs 1-47 above as if fully stated herein.

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

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

62. Plaintiffs were foreseeable users of the ASR hip replacement components.

63. Plaintiffs purchased the ASR hip replacement components from Defendant.

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

65. As a direct and proximate cause of this breach, Plaintiffs have 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 have suffered loss of enjoyment of life. The injuries and losses of Plaintiffs are permanent in nature and Plaintiffs will continue to suffer such losses in the future.

**COUNT FOUR**  
**FLORIDA DECEPTIVE AND UNFAIR TRADE PRACTICE ACT VIOLATION OF**  
**DEFENDANT BAYSIDE**

66. Plaintiffs re-allege and incorporate by reference paragraphs 1-47 as if fully stated herein.

67. At all times relevant to this action, Plaintiffs were consumers as described in the Florida Deceptive and Unfair Trade Practices Act, Florida Statute Section 501.203(7).

68. In violation of the Florida Deceptive and Unfair Trade Practices Act, Defendant advertised and promoted its DePuy ASR Hip Replacement System using representations that it knew to be false.

69. 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 Statutes Section 501.204.

70. Based upon the false and deceptive advertising and promotion of Defendant, Plaintiffs purchased the hip replacement systems.

71. As a result of the DePuy ASR Hip Replacement Systems purchased by Plaintiffs being other than as represented by Defendant, it was thus unfit for its intended purpose and therefore valueless.

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

73. These violations of the DTPA were a producing cause of Plaintiff’s damages as alleged herein below.

WHEREFORE Plaintiffs demand judgment against the Defendant, for the difference in value between the DePuy ASR Hip Replacement System advertised and promoted by Defendant

and the hip replacement system 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**

74. Plaintiffs respectfully request 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.

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