

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

CIVIL DIVISION

CASE NO. 11-04262CI-21

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JANINE BARNES and JULIE FOURNIER,)
)
Plaintiffs,)
)
v.)
)
BAYSIDE ORTHOPAEDICS, INC.,)
)
Defendant.)
-----)

**ANSWER TO COMPLAINT, SEPARATE DEFENSES,
AND JURY DEMAND OF
DEFENDANT BAYSIDE ORTHOPAEDICS, INC.**

Defendant Bayside Orthopaedics, Inc (“Defendant” or “Bayside”) responds to Plaintiffs Janine Barnes and Julie Fournier’s Complaint as follows. The repetition of some of the Complaint’s subheadings is done solely for organizational purposes and is not an admission as to their truth.

1. Defendant admits that Plaintiffs have brought an action for damages against Bayside but expressly denies that Plaintiffs are entitled to damages. Defendant further admits that Bayside is an independent contractor distributor of DePuy Orthopaedics, Inc. (“DePuy”) medical devices in the State of Florida. Defendant further admits that DePuy is the responsible United States entity for the design, manufacture, labeling, distribution, marketing, and sale of the ASR™ XL System and ASR™ Surface Replacement femoral head component and that DePuy issued a voluntary global recall of the ASR™ XL System and ASR™ Hip Resurfacing System

on August 24, 2010. Defendant denies the remaining allegations contained in Paragraph 1 and expressly denies that it is a seller of hip replacement components.

PARTIES AND JURISDICTION

2. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 2 and therefore denies them.

3. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 3 and therefore denies them.

4. Defendant admits that Bayside is a Florida corporation with its principal place of business located at 14450 46th Street North, Suite 112, Clearwater, Florida 33762 in Pinellas County. Defendant denies the remaining allegations contained in Paragraph 4.

5. Defendant admits that Bayside is a Florida corporation with its principal place of business located in Florida. Defendant further admits that Bayside is an independent contractor distributor of DePuy medical devices in the State of Florida. Defendant denies the remaining allegations contained in Paragraph 5.

6. Defendant admits that Bayside is an independent contractor distributor of DePuy medical devices in the State of Florida, including Pinellas and Lee County, but denies that it is a seller of hip replacement components. Defendant denies the remaining allegations contained in Paragraph 6 as phrased and expressly denies that the recalled hip replacement components are defective.

7. Defendant denies the allegations contained in Paragraph 7 as phrased and incompletely and inaccurately presented and expressly denies that it is a seller of hip replacement components.

8. Defendant lacks knowledge or information sufficient to form a belief as to what

Plaintiffs or their “surgeons, nurses, and hospital staff” relied on at any given time and therefore denies these allegations. Defendant denies the remaining allegations contained in Paragraph 8 and expressly denies that Bayside is a seller of hip replacement components.

VENUE

9. Defendant admits that its principal place of business is located in Pinellas County, Florida. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 9 and therefore denies them.

10. Defendant denies the allegations contained in Paragraph 10.

11. Defendant denies the allegations contained in Paragraph 11 as phrased and incompletely and inaccurately presented.

12. Defendant states that DePuy’s “literature” speaks for itself. Defendant denies the remaining allegations contained in Paragraph 12 as phrased and incompletely presented.

13. Defendant states that DePuy’s “literature” speaks for itself. Defendant denies the remaining allegations contained in Paragraph 13 as phrased and incompletely presented.

14. Defendant denies the allegations contained in Paragraph 14 as interpreted, phrased and incompletely and inaccurately presented and expressly denies that it is a seller of hip replacement components.

15. Defendant denies the allegations contained in Paragraph 15 as interpreted, phrased and incompletely and inaccurately presented.

16. Defendant denies the allegations contained in Paragraph 16 as interpreted, phrased and incompletely and inaccurately presented.

17. Defendant denies the allegations contained in Paragraph 17 as interpreted, phrased and incompletely and inaccurately presented.

18. Defendant denies the allegations contained in Paragraph 18 as interpreted, phrased and incompletely and inaccurately presented.

19. Defendant denies the allegations contained in Paragraph 19 as phrased and incompletely and inaccurately presented.

20. Defendant denies the allegations contained in Paragraph 20.

21. Defendant denies the allegations contained in Paragraph 21 and expressly denies that the hip replacement components “failed”.

22. Defendant denies the allegations contained in Paragraph 22 as interpreted, phrased and incompletely and inaccurately presented.

23. Defendant denies the allegations contained in Paragraph 23 as interpreted, phrased and incompletely and inaccurately presented.

24. Defendant admits that in 2009, DePuy decided to discontinue the ASR™ XL System worldwide on a market-by-market basis. Defendant denies the remaining allegations contained in Paragraph 24 as phrased and incompletely presented.

25. Defendant denies the allegations contained in Paragraph 25.

26. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 26 and therefore denies them.

27. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 27 and therefore denies them.

28. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 28 and therefore denies them.

29. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 29 and therefore denies them.

30. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 30 and therefore denies them.

31. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 31 and therefore denies them.

32. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 32 and therefore denies them.

33. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 33 and therefore denies them.

34. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 34 and therefore denies them.

35. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 35 and therefore denies them.

36. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 36 and therefore denies them.

37. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 37 and therefore denies them.

38. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 38 and therefore denies them.

39. Defendant lacks knowledge or information sufficient to form a belief as to whether Plaintiffs were implanted with ASR™ hip replacement components and therefore denies those allegations. Defendant denies the remaining allegations contained in Paragraph 39 and expressly denies that Bayside is a seller of ASR™ hip replacement components.

40. Defendant lacks knowledge or information sufficient to form a belief as to

whether Plaintiffs were implanted with ASR™ hip replacement components which were “subsequently recalled by the FDA” and therefore denies those allegations. Defendant denies the remaining allegations contained in Paragraph 40.

41. Defendant lacks knowledge or information sufficient to form a belief as to Plaintiffs’ alleged medical condition and therefore denies those allegations. Defendant denies the remaining allegations contained in Paragraph 41.

42. Defendant lacks knowledge or information sufficient to form a belief as to Plaintiffs’ alleged medical condition and therefore denies those allegations. Defendant denies the remaining allegations contained in Paragraph 42 and expressly denies that the ASR™ hip replacement components “generated excessive metal debris.”

43. Defendant denies the allegations contained in Paragraph 43 and expressly denies that the ASR™ hip replacement components “failed”.

44. Defendant denies the allegations contained in Paragraph 44 and expressly denies that the ASR™ hip replacement components “failed”.

45. Defendant denies the allegations contained in Paragraph 45 and expressly denies that the ASR™ hip replacement components are “defective”.

46. Defendant denies the allegations contained in Paragraph 46 and expressly denies that the ASR™ hip replacement components are faulty or defective.

47. Defendant lacks knowledge or information sufficient to form a belief as to what Plaintiffs’ physicians knew or relied upon at any given time and therefore denies these allegations. Defendant denies the remaining allegations contained in Paragraph 47.

COUNT ONE - NEGLIGENCE

48. Defendant realleges its answers to paragraphs 1-47 of Plaintiffs’ Complaint as if

fully set forth herein.

49. Defendant admits that Bayside is an independent contractor distributor of DePuy medical devices in the state of Florida but expressly denies that Bayside is a seller of ASR™ hip replacement components. The remaining allegations contained in Paragraph 49 constitute legal statements or conclusions to which no response is required. To the extent a response is required, Defendant denies that these allegations are an accurate and complete statement of the applicable law.

50. Defendant denies the allegations contained in Paragraph 50.

51. Defendant denies the allegations contained in Paragraph 51.

52. Defendant denies the allegations contained in Paragraph 52.

COUNT TWO
STRICT LIABILITY

53. Defendant realleges its answers to paragraphs 1-47 of Plaintiffs' Complaint as if fully set forth herein.

54. Defendant denies the allegations contained in Paragraph 54 and expressly denies that the ASR™ hip replacement components were defective, "unreasonably dangerous" or "unfit for its intended use".

55. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 55 and therefore denies them.

56. Defendant denies the allegations contained in Paragraph 56.

57. Defendant lacks knowledge or information sufficient to form a belief as to the manner in which the ASR™ hip replacement components were being used and therefore denies these allegations. Defendant denies the remaining allegations contained in Paragraph 57 and expressly denies that the ASR™ hip replacement components were "defective, unsafe and

unreasonably dangerous”.

58. Defendant denies the allegations contained in Paragraph 58.

COUNT THREE
BREACH OF IMPLIED WARRANTY

59. Defendant realleges its answers to paragraphs 1-47 of Plaintiffs’ Complaint as if fully set forth herein.

60. Defendant admits that Bayside is an independent contractor distributor of DePuy medical devices in the State of Florida. Defendant denies the remaining allegations contained in Paragraph 60 and expressly denies that it is a seller of ASR™ hip replacement components.

61. The allegations contained in Paragraph 61 constitute legal statements or conclusions to which no response is required. To the extent a response is required, these allegations are denied.

62. Defendant lacks knowledge or information sufficient to form a belief regarding the truth of the allegations contained in Paragraph 62 and therefore denies them.

63. Defendant denies the allegations contained in Paragraph 63.

64. Defendant denies the allegations contained in Paragraph 64.

65. Defendant denies the allegations contained in Paragraph 65.

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

66. Defendant realleges its answers to paragraphs 1-47 of Plaintiffs’ Complaint as if fully set forth herein.

67. The allegations contained in Paragraph 67 constitute legal statements or conclusions to which no response is required. To the extent a response is required, these allegations are denied.

68. Defendant denies the allegations contained in Paragraph 68.

69. Defendant denies the allegations contained in Paragraph 69 and expressly denies any “false and deceptive” advertising.

70. Defendant denies the allegations contained in Paragraph 70.

71. Defendant denies the allegations contained in Paragraph 71.

72. Defendant denies the allegations contained in Paragraph 72.

73. Defendant denies the allegations contained in Paragraph 73. As to the unnumbered paragraph following Paragraph 73, Defendant denies that Plaintiffs are entitled to relief of any kind.

74. Defendant denies that Plaintiffs are entitled to damages of any kind.

SEPARATE DEFENSES

FIRST DEFENSE

Plaintiffs knowingly and voluntarily assumed any and all risks associated with the use of the product at issue in this case and such assumption of the risks bars in whole or in part the damages Plaintiffs seek to recover herein.

SECOND DEFENSE

At all times mentioned herein Plaintiffs were negligent, careless and at fault, and conducted themselves so as to contribute substantially to their alleged injuries and damages. Said negligence, carelessness, and fault of Plaintiffs bar in whole or in part the damages which Plaintiffs seek to recover herein.

THIRD DEFENSE

Plaintiffs’ alleged injuries attributable to the use of the product at issue in this case, if any, were not legally caused by the product at issue, but instead were legally caused by intervening and superseding causes or circumstances.

FOURTH DEFENSE

Plaintiffs' alleged damages, if any, are barred in whole or in part by Plaintiffs' failure to mitigate such damages.

FIFTH DEFENSE

Plaintiffs' causes of action are barred by the applicable statutes of limitation, statutes of repose, and doctrine of laches.

SIXTH DEFENSE

Defendant did not make to Plaintiffs nor did it breach any implied warranties and/or breach any warranties created by law. To the extent that Plaintiffs rely on any theory of breach of warranty, such claims are barred by applicable law, and for lack of privity with Defendant and/or for failure of Plaintiffs, or Plaintiffs' representatives, to give timely notice to Defendant of any alleged breach of warranty. Defendant is not a seller as defined by section 672.103, Florida Statutes, and Plaintiffs did not rely on Defendant. Defendant further specifically pleads as to any breach of warranty claim all defenses under the Uniform Commercial Code existing and which may arise in the future.

SEVENTH DEFENSE

At the time of sale or delivery, the product conformed to the state-of-the-art for such product at that time.

EIGHTH DEFENSE

Plaintiffs' claims should be diminished in whole or in part in the amount paid to Plaintiffs by any party or non-party with whom Plaintiffs have settled or may settle.

NINTH DEFENSE

Plaintiffs' damages, if any, are barred or limited by the payments received from collateral sources.

TENTH DEFENSE

Plaintiffs' causes of action are barred by the learned intermediary doctrine.

ELEVENTH DEFENSE

Plaintiffs' claims are barred by the doctrines of informed consent, release, and waiver.

TWELFTH DEFENSE

Defendant is entitled to, and claims the benefits of, all defenses and presumptions set forth in or arising from any rule of law or statute in the state of Florida, Plaintiffs' alleged state of citizenship and residence, including but not limited to sections 768.1256 and 768.1257, Florida Statutes, and any other state whose law is deemed to apply in this case. Defendant reserves the right to assert any additional defenses which may be disclosed during the course of additional investigation and discovery.

THIRTEENTH DEFENSE

The injuries and damages claimed by Plaintiffs, if any, were caused in whole or in part by the acts or omissions of persons over whom Defendant has no control or right of control.

FOURTEENTH DEFENSE

Plaintiffs' claims are barred by the equitable doctrine of estoppel.

FIFTEENTH DEFENSE

Upon information and belief, if the injuries referred to in the Complaint were caused by Defendant's product, which is denied, the injuries are the result of an idiosyncratic reaction to the product.

SIXTEENTH DEFENSE

Plaintiffs' alleged injuries are a result of a pre-existing and/or unrelated medical condition for which Defendant is not responsible.

SEVENTEENTH DEFENSE

To the extent Plaintiffs' claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to Buckman Co. v. Plaintiff's Legal Comm., 531 U.S. 341 (2001).

EIGHTEENTH DEFENSE

If DePuy Orthopaedics, Inc.'s product is unsafe in any way, it is unavoidably unsafe. Plaintiffs' purported action is, therefore, barred by Comment K of §402A of the Restatement (Second) of Torts and/or other applicable law.

NINETEENTH DEFENSE

Plaintiffs' injuries and damages, if any, were proximately caused by the negligence or fault of Plaintiffs, or persons or parties whose identities are unknown at this time, and such comparative negligence or fault is sufficient to proportionately reduce or bar Plaintiffs' recovery. Thus, Defendant is entitled to have its liability to the Plaintiffs, if any, reduced as a result of the negligence or fault of said persons or entities, pursuant to the provisions of section 768.81, Florida Statutes. To the extent any recovery is permitted in this case, pursuant to sections 768.31 and 768.81, Florida Statutes, judgment must be entered on the basis of Defendant's percentage of fault, taking into account the percentage of fault attributable to all other persons, whether or not a party hereto, and not on the basis of joint and several liability. The persons or entities referred to in this paragraph that are presently unknown to Defendant will be identified in a timely manner consistent with Nash v. Wells Fargo, 678 So. 2d 1262 (Fla. 1996).

TWENTIETH DEFENSE

Plaintiffs' claims are barred in whole or in part under sections 4, 6(c), and 6(d) of the Restatement (Third) of Torts: Products Liability.

TWENTY-FIRST DEFENSE

Defendant asserts all defenses available under the Florida Deceptive and Unfair Trade Practices Act, §501.201, *et seq.*

TWENTY-SECOND DEFENSE

To the extent that Plaintiffs rely on any misrepresentation-based theory, such claims are not stated with particularity as required by Rule 1.120, Florida Rules of Civil Procedure. To the extent that Plaintiffs' claims are based upon alleged representations by Defendant, those claims are barred as there was no reliance upon such representations.

TWENTY-THIRD DEFENSE

Plaintiffs fail to state a cause of action against Defendant upon which relief may be granted.

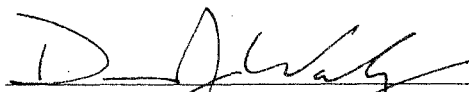
TWENTY-FOURTH DEFENSE

Defendant reserves its right to raise such further and additional defenses as may be available upon the facts to be developed in discovery and under other applicable substance of law.

JURY DEMAND

Defendant Bayside Orthopaedics, Inc. requests a trial by jury on all issues so triable.

Dated: June 13, 2011



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CERTIFICATE OF SERVICE

I CERTIFY that a copy of this notice was mailed to Altom M. Maglio, Maglio, Christopher & Toale, 1751 Mound Street, Second Floor, Sarasota, FL 34236 and Brian Franciskato, Nash & Franciskato Law Firm, 2300 Main Street, Kansas City, MO 64108, this 13th day of June, 2011.


Attorney