UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

HOLLY A. BURRITT,
THERESA D. CLAYBAUGH,
THOMAS E. CLAYBAUGH,
MICHAEL F. COOPER,
GLENDA L. MAZZA,
MICHAEL A. MAZZA,
ANN MCCRACKEN,
RONALD J. NIGRO,
JOANNE HUME-NIGRO,
JEANNE TREMBETH,

Plaintiffs,

vs.

DEPUY ORTHOPAEDICS, INC. and
JOHNSON & JOHNSON,

Defendants.

COMPLAINT and
DEMAND FOR JURY TRIAL

Civil Action No.

Plaintiffs by and through their attorneys, Faraci Lange, LLP, complaining of the defendants herein, respectfully allege to this Court upon and belief the following:

PARTIES

1. Plaintiff, Holly A. Burritt, is a resident of the State of New York, residing in Rochester, Monroe County, New York.

2. Plaintiff, Holly A. Burritt, was born on December 19, 1958.

3. Plaintiff, Holly A. Burritt, was implanted with defendants' ASR™ XL Acetabular Hip Replacement System and ASR™ Hip Resurfacing System ("ASR Hip") on or around January 30, 2007 and as a result plaintiff suffered, and continues to suffer, serious bodily injury, and was forced to undergo revision surgery on or around July 29, 2010.

4. Plaintiff, Theresa D. Claybaugh, is a resident of the State of New York, residing in Rochester, Monroe County, New York.

5. Plaintiff, Theresa D. Claybaugh, was born on October 10, 1962.

6. Plaintiff, Theresa D. Claybaugh, was implanted with defendants' ASR Hip on or around January 11, 2010, and as a result plaintiff suffered, and continues to suffer, serious bodily injury, and was forced to undergo revision surgery on or around November 1, 2010.

7. Plaintiff, Michael F. Cooper, is a resident of the State of New York, residing in East Rochester, Monroe County, New York.

8. Plaintiff, Michael F. Cooper, was born on October 15, 1985.

9. Plaintiff, Michael F. Cooper, was implanted with defendants' ASR Hip on or around December 1, 2008, and as a result plaintiff suffered, and continues to suffer, serious bodily injury, and was forced to undergo revision surgery on or around April 21, 2010.

10. Plaintiff, Glenda L. Mazza, is a resident of the State of New York, residing in Spencerport, Monroe County, New York.

11. Plaintiff, Glenda L. Mazza, was born on November 10, 1937.

12. Plaintiff, Glenda L. Mazza, was implanted with defendants' ASR Hip on or around March 11, 2008, and as a result plaintiff suffered, and continues to suffer, serious bodily injury, and was forced to undergo revision surgery on or around November 1, 2010.

13. Plaintiff, Ann McCracken, is a resident of the State of New York, residing in Rochester, Monroe County, New York.

14. Plaintiff, Ann McCracken, was born on August 18, 1955.

15. Plaintiff, Ann McCracken, was implanted with defendants' ASR Hip on or around August 24, 2009, and as a result plaintiff suffered, and continues to suffer, serious bodily injury, and was forced to undergo revision surgery on or around January 17, 2011.

16. Plaintiff, Ronald J. Nigro, is a resident of the State of New York, residing in Victor, Ontario County, New York.

17. Plaintiff, Ronald J. Nigro, was born on October 15, 1944.

18. Plaintiff, Ronald J. Nigro, was implanted with defendants' ASR Hip on or around February 9, 2009, and as a result plaintiff suffered, and continues to suffer, serious bodily injury, and was forced to undergo revision surgery on or around October 28, 2010.

19. Plaintiff, Jeanne Trembeth, is a resident of the State of New York, residing in Rochester, Monroe County, New York.

20. Plaintiff, Jeanne Trembeth, was born on July 24, 1961.

21. Plaintiff, Jeanne Trembeth, was implanted with defendants' ASR Hip on or around April 13, 2009, and as a result plaintiff suffered, and continues to suffer, serious bodily injury, and was forced to undergo revision surgery on or around October 13, 2010.

22. On information and belief, defendant, DePuy Orthopaedics, Inc. ("DePuy"), is a corporation organized and existing under the laws of Indiana with its principal place of business in Warsaw, Indiana. DePuy designed, manufactured and sold the ASR Hip that is the subject of this lawsuit.

23. On information and belief, defendant, Johnson & Johnson ("J&J"), is a corporation organized and existing under the laws of New Jersey with its principal place of business in New Brunswick, New Jersey. As DePuy's parent company, J&J was involved in the design, manufacture and sale of the ASR Hip that is the subject of this lawsuit.

24. At all times mentioned herein, each of the defendants was the representative, agent, employee, or alter ego of the other defendant and in doing the things alleged in this Complaint was acting within the scope its authority.

25. DePuy and J&J are collectively referred to as "defendants."

DEMAND FOR JURY TRIAL

26. Plaintiffs hereby demand trial by jury as to all issues.

JURISDICTION AND VENUE

27. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the amount in controversy as to each plaintiff exceeds $75,000.00, exclusive of interest and costs, and because complete diversity exists between the parties, as plaintiffs are citizens of New York, which is different from the states where the defendants are incorporated and have their principal places of business.

28. Venue is proper within this District pursuant to 28 U.S.C. § 1391 because it is a judicial district where a substantial part of the events and omissions giving rise to the claims occurred.

GENERAL FACTUAL ALLEGATIONS

29. Defendants' ASR Hip was designed with the metal femoral ball in direct contact with the metal acetabular cup. There is no polyethylene liner in the acetabular shell.

30. The design of the ASR Hip was never approved by the United States Food and Drug Administration ("FDA") as safe or effective for its intended purpose.

31. The ASR Hip is defined as a Class III medical device by the FDA. The 1976 Medical Device Amendments to the Food, Drug and Cosmetics Act of 1938 ("MDA") require Class III medical devices to undergo premarket approval by the FDA, except that a medical

device on the market prior to the effective date of MDA – otherwise known as a "grandfathered" device – is not required to undergo premarket approval.

32. 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.

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

34. Instead of assuring the safety of the ASR Hip through appropriate clinical trials, DePuy sought to market its ASR Hip by obtaining FDA approval under section 510(k). In 2005, defendants submitted a section 510(k) premarket notification of intent to market the ASR Hip.

35. DePuy avoided the rigorous safety review required for premarket approval, including clinical trials, by telling the FDA that the ASR Hip was "substantially equivalent" to other hip products on the market.

36. In August 2005, the FDA approved the ASR Hip for sale by the 510(k) process and as result did not require the ASR Hip to undergo clinical trials.

37. The 510(k) notification of the ASR Hip includes only defendant DePuy's representation that it "believes the DePuy ASR™ Modular Acetabular Cup System to be substantially equivalent . . . based upon the similarities in design, material composition, and

intended use/indications for use" to devices that themselves had never been reviewed for safety and effectiveness.

38. 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.

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

40. On August 25, 2005 the FDA sent a letter to DePuy, indicating that the ASR Hip was "substantially equivalent to devices introduced into interstate commerce prior to May 28, 1976". However, the letter also stated that the agency's determination of substantial equivalence "does not mean that FDA has made a determination that [DePuy's] device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies."

41. To market the ASR Hip for use in ASR surgery, the FDA would have required DePuy to undergo premarket approval, which would have required DePuy to conduct clinical trials, prove that the product is safe and effective and monitor long-term safety and performance of the product once it was placed on the market.

42. DePuy told the FDA that the components on the ASR Hip would be indicated for use in "total hip replacement procedures" and in patients with congenital hip dysplasia, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock was inadequate for other reconstruction techniques," *not* for ASR surgeries.

43. Defendants were permitted to put the ASR Hip on the market in the United States ostensibly for use in an application for which is was not designed—total hip replacement. To

date, despite being implanted in the bodies of thousands of Americans who believed that the device was safe, DePuy's ASR Hip has *never* been approved by the FDA as being safe or effective for ASR procedures, and DePuy never even conducted a typical safety review of the ASR Hip.

44. Unlike most hip replacements which use a polyethylene plastic acetabular cup, DePuy's ASR Hip uses a metal acetabular cup. By using a metal acetabular cup with a metal femoral ball, the ASR Hip forces metal to rub against metal with the full weight and pressure of the human body. Because of the failure of the ASR Hip, hundreds of patients, including plaintiffs, have been forced to undergo surgeries, known as revision surgeries, to replace the failed hip implants.

45. Shortly after DePuy launched the ASR Hip, DePuy began receiving reports of failures of its product. Since then, DePuy has received hundreds of similar complaints reporting that the ASR Hip had failed due to premature loosening of the acetabular cup and that the failure forced patients to undergo painful and risky surgeries to remove and replace the failed hip component. By 2007, DePuy had received more than 100 reports and by the end of 2008, well over 300 reports similar reports.

46. Consequently, by 2008, DePuy was fully aware that the ASR Hip was defective and that hundreds of patients had already been injured by its product. In or about 2007 doctors in Britain began taking blood samples from patients and the results showed that patients with the ASR Hip had elevated levels of two metals, cobalt and chromium, in their blood.

47. These increased cobalt and chromium blood levels were believed to occur because the interior surface of the ASR cup was so shallow that it was particularly vulnerable to

edge-loading and shedding metallic debris that later absorbed into the bloodstreams of these patients.

48. In February 2009, two British physicians, Dr. Antoni Nargol and Dr. David Langston, met with DePuy officials to express their concern regarding the safety of the ASR Hip due to the defective cup design.

49. DePuy officials failed to take any action in response to Dr. Nargol and Dr. Langston's concerns.

50. Despite its knowledge that the ASR Hip had a defect and that it failed hundreds of times, causing hundreds of patients to undergo the agony of another surgery, DePuy continued selling the defective hip implant concealing the known defect from doctors and patients, including plaintiffs and their doctors, and misrepresenting that the ASR Hip was safe and effective.

51. In 2009 alone, DePuy had more than $5.4 billion in sales. Hip implant sales are critically important to DePuy's parent company, J&J, and DePuy is one of J&J's most profitable business groups.

52. In March 2010, DePuy finally began to disclose some of the alarming information about the ASR Hip. It sent a letter to doctors warning them of the increased failure rate associated with the ASR Hip. DePuy admitted that the ASR Hip suffered from a "higher than expected revision rate," and that data compiled by the Australian National Joint Registry showed that 5.4 percent of the ASR Hips implanted had been surgically removed after only three years and that the expected failure could be as high as 10 percent. The letter also stated that DePuy was planning to stop selling the ASR Hip, allegedly because of "declining demand."

53. On July 17, 2010, the FDA announced a nationwide recall of the DePuy ASR Hip. The FDA classified this recall as a Class 2 Recall, which means the product may cause medically reversible adverse health consequences.

54. On August 25, 2010, DePuy confirmed that in the first five years after implantation, approximately 12 percent of patients (1 in 8) who received the ASR resurfacing device and 13 percent (1 in 8) who received the ASR total hip replacement required revision surgery due to failure of the product.

55. DePuy also confirmed that at least 90,000 people have had ASR Hips implanted in their bodies, meaning that over time, at least 11,700 people will have an ASR Hip failure and will be forced to undergo painful surgery to remove and replace the ASR Hip.

56. On August 26, 2010, following the nationwide recall, DePuy issued a worldwide recall of its ASR Hip and all components for these devices due to the high percentage of patients who needed to undergo a complex, risky and painful revision surgery.

PLAINTIFFS' SPECIFIC FACTUAL ALLEGATIONS

57. On or about January 30, 2007, plaintiff, Holly A. Burritt, underwent a surgical procedure to implant an ASR Hip.

58. Neither plaintiff, Holly A. Burritt, nor her physician were made aware by DePuy of the failures reported to have occurred by that date in patients who had ASR Hips implanted.

59. As a result of her defective ASR hip, plaintiff, Holly A. Burritt, began experiencing symptoms, including, but not limited to, pain and loss of mobility, and suffering from loss of enjoyment of life.

60. Plaintiff, Holly A. Burritt's, orthopedic surgeon, Dr. Michael J. Klotz, investigated her symptoms concluded that plaintiff, Holly A. Burritt, was going to have to undergo revision surgery.

61. On or around July 29, 2010, plaintiff, Holly A. Burritt, underwent painful and risky revision surgery years sooner than anticipated had the ASR Hip functioned as intended.

62. On or about January 11, 2010, plaintiff, Theresa D. Claybaugh, underwent a surgical procedure to implant an ASR Hip.

63. Neither plaintiff nor her physician were made aware by DePuy of the failures reported to have occurred by that date in patients who had ASR Hips implanted.

64. As a result of her defective ASR hip, plaintiff, Theresa D. Claybaugh, began experiencing symptoms, including, but not limited to, pain and loss of mobility, and suffering from loss of enjoyment of life.

65. Plaintiff, Theresa D. Claybaugh's, orthopedic surgeon, Dr. Raymond J. Stefanich, investigated her symptoms concluded that plaintiff Theresa Claybaugh was going to have to undergo revision surgery.

66. On or around, November 1, 2010, plaintiff, Theresa D. Claybaugh, underwent painful and risky revision surgery years sooner than anticipated had the ASR Hip functioned as intended.

67. On or about December 1, 2008, plaintiff, Michael F. Cooper, underwent a surgical procedure to implant an ASR Hip.

68. Neither plaintiff, Michael F. Cooper, nor his physician were made aware by DePuy of the failures reported to have occurred by that date in patients who had ASR Hips implanted.

69. As a result of his defective ASR Hip, plaintiff, Michael F. Cooper, began experiencing symptoms, including, but not limited to, pain and loss of mobility, and suffering from loss of enjoyment of life.

70. Plaintiff, Michael F. Cooper's, orthopedic surgeon, Dr. Stephen L. Kates, investigated his symptoms concluded that plaintiff, Michael F. Cooper, was going to have to undergo revision surgery.

71. On or around April 21, 2010, plaintiff, Michael F. Cooper, underwent painful and risky revision surgery years sooner than anticipated had the ASR Hip functioned as intended.

72. On or about March 11, 2008, plaintiff, Glenda L. Mazza, underwent a surgical procedure to implant an ASR Hip.

73. Neither plaintiff, Glenda L. Mazza, nor her physician were made aware by DePuy of the failures reported to have occurred by that date in patients who had ASR Hips implanted.

74. As a result of her defective ASR Hip, plaintiff, Glenda L. Mazza, began experiencing symptoms, including, but not limited to, pain and loss of mobility, and suffering from loss of enjoyment of life.

75. Plaintiff, Glenda L. Mazza's, orthopedic surgeon, Dr. Raymond J. Stefanich, investigated her symptoms concluded that plaintiff, Glenda L. Mazza, was going to have to undergo revision surgery.

76. On or around November 1, 2010, plaintiff, Glenda L. Mazza, underwent painful and risky revision surgery years sooner than anticipated had the ASR Hip functioned as intended.

77. On or about August 24, 2009, plaintiff, Ann McCracken, underwent a surgical procedure to implant an ASR Hip.

78. Neither plaintiff, Ann McCracken, nor her physician were made aware by DePuy of the failures reported to have occurred by that date in patients who had ASR Hips implanted.

79. As a result of her defective ASR Hip, plaintiff, Ann McCracken, began experiencing symptoms, including, but not limited to, pain and loss of mobility, and suffering from loss of enjoyment of life.

80. Plaintiff, Ann McCracken's, orthopedic surgeon, Dr. Stephen L. Kates, investigated her symptoms concluded that plaintiff Ann McCracken was going to have to undergo revision surgery.

81. On or around January 17, 2011, plaintiff, Ann McCracken, underwent painful and risky revision surgery years sooner than anticipated had the ASR Hip functioned as intended.

82. On or about February 9, 2009, plaintiff, Ronald J. Nigro, underwent a surgical procedure to implant an ASR Hip.

83. Neither plaintiff, Ronald J. Nigro, nor his physician were made aware by DePuy of the failures reported to have occurred by that date in patients who had ASR Hips implanted.

84. As a result of his defective ASR Hip, plaintiff, Ronald J. Nigro, began experiencing symptoms, including, but not limited to, pain and loss of mobility, and suffering from loss of enjoyment of life.

85. Plaintiff, Ronald J. Nigro's, orthopedic surgeon, Dr. Michael J. Klotz, investigated his symptoms concluded that plaintiff Ronald J. Nigro was going to have to undergo revision surgery.

86. On or around October 28, 2010, plaintiff, Ronald J. Nigro, underwent painful and risky revision surgery years sooner than anticipated had the ASR Hip functioned as intended.

87. On or about April 13, 2009, plaintiff, Jeanne Trembeth, underwent a surgical procedure to implant an ASR Hip.

88. Neither plaintiff, Jeanne Trembeth, nor her physician were made aware by DePuy of the failures reported to have occurred by that date in patients who had ASR Hips implanted.

89. As a result of her defective ASR Hip, plaintiff, Jeanne Trembeth, began experiencing symptoms, including, but not limited to, pain and loss of mobility, and suffering from loss of enjoyment of life.

90. Plaintiff, Jeanne Trembeth's, orthopedic surgeon, Dr. Michael J. Klotz, investigated her symptoms concluded that plaintiff, Jeanne Trembeth, was going to have to undergo revision surgery.

91. On or around October 13, 2010, plaintiff, Jeanne Trembeth, underwent painful and risky revision surgery years sooner than anticipated had the ASR Hip functioned as intended.

CLAIM I
STRICT PRODUCTS LIABILITY – DEFECTIVE DESIGN

92. Plaintiffs repeat and reallege each and every allegation previously set forth herein.

93. The ASR Hip designed, marketed, manufactured and distributed by defendants was defective and not reasonably safe due to its improper, inadequate and defective design.

94. Defendants are strictly liable in tort to plaintiffs for designing, marketing, manufacturing and distributing a product that was defective and not reasonably safe for its intended use.

95. As a direct and proximate result of the wrongful acts and omissions of defendants, plaintiffs suffered economic damages, severe and possibly permanent injuries, pain, suffering and emotional distress. Plaintiffs have also endured and continue to suffer the mental anguish

and psychological trauma of living with the knowledge that they have suffered these serious and dangerous side effects.

CLAIM II
STRICT PRODUCTS LIABILITY – FAILURE TO WARN

96. Plaintiffs repeat and reallege each and every allegation previously set forth herein.

97. Defendants developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed and/or supplied ASR Hips for sale and sold them to plaintiffs in the ordinary course of their business.

98. Defendants in developing, testing, assembling, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying and/or selling the ASR Hip distributed promotional materials, publicity and/or information to plaintiffs, including, but not limited to, the information printed on the instructions for use, labeling and/or packaging.

99. Defendants expected the ASR Hip to reach consumers in the State of New York, and it did reach consumers in New York, including plaintiffs, without substantial change in the condition.

100. Defendants failed to adequately warn the public, including plaintiffs, as well as physicians and surgeons of the risk of suffering the type and manner of injuries suffered by plaintiffs, which risks and/or danger were known or should have been known to the defendants and are liable to strictly liable to plaintiffs because their product was not reasonably safe for its intended use.

101. Defendants knew or should have known that the ASR Hips were defective and dangerous and showed reckless indifference to or conscious disregard for the plaintiffs' safety by failing to provide proper warnings to the public and the medical community.

102. As a direct and proximate result of the wrongful acts and omissions of defendants, plaintiffs suffered economic damages, severe and possibly permanent injuries, pain, suffering and emotional distress. Plaintiffs have also endured and continue to suffer the mental anguish and psychological trauma of living with the knowledge that they have suffered these serious and dangerous side effects.

CLAIM III
NEGLIGENCE

103. Plaintiffs repeat and reallege each and every allegation previously set forth herein.

104. Defendants had a duty to exercise reasonable care in designing, testing, manufacturing, marketing, promoting, selling and distributing the ASR Hip and to warn health care providers and users of the risks, dangers and adverse side effects.

105. Defendants knew or should have known the ASR Hips were unsafe when used as designed and manufactured and failed to exercise due care and were otherwise negligent in the design, manufacture and marketing of this device including the failure to adequately test the product and the failure to provide adequate warnings.

106. The conduct of defendants was intentional, wanton, willful and outrageous beyond all standards of common decency and in reckless disregard and callous indifference to the public and users of the ASR Hip.

107. The limitations of liability set forth in New York's CPLR § 1601 do not apply to this action because defendants were engaged in intentional misconduct (CPLR § 1602.5), defendants acted with reckless disregard (CPLR § 1602.7), defendants acted knowingly and intentionally and in concert to cause the acts or failures upon which liability is based (CPLR § 1602-11).

108. As a direct and proximate result of the wrongful acts and omissions of defendants, plaintiffs suffered economic damages, severe and possibly permanent injuries, pain, suffering and emotional distress. Plaintiffs have also endured and continue to suffer the mental anguish and psychological trauma of living with the knowledge that they have suffered these serious and dangerous side effects.

CLAIM IV
BREACH OF EXPRESS WARRANTY

109. Plaintiffs repeat and reallege each and every allegation previously set forth herein.

110. Defendants expressed in their literature, advertisements, promotions and through representations by their marketing team and sales agents that ASR Hips were safe, effective and fit for use in ASR surgeries for which they were designed, manufactured and marketed.

111. By making such representations, defendants expressly warranted that the ASR Hips were safe and effective, and fit for the uses for which they were designed, marketed, manufactured and distributed.

112. As explained above, in fact, the ASR Hips were not safe, effective, fit nor proper for the use for which they were designed, manufactured and marketed.

113. Plaintiffs, and their healthcare providers, and the medical profession relied on defendants' express warranties.

114. As a direct and proximate result of the wrongful acts and omissions of defendants, plaintiffs suffered economic damages, severe and possibly permanent injuries, pain, suffering and emotional distress. Plaintiffs have also endured and continue to suffer the mental anguish and psychological trauma of living with the knowledge that they have suffered these serious and dangerous side effects.

CLAIM V
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

115. Plaintiffs repeat and reallege each and every allegation previously set forth herein.

116. Upon information and belief, on or around January 30, 2007, plaintiff, Holly A. Burritt, received and began using an ASR Hip manufactured by defendants.

117. Upon information and belief, on or around January 11, 2010, plaintiff, Theresa D. Claybaugh, received and began using an ASR Hip manufactured by defendants.

118. Upon information and belief, on or around December 1, 2008, plaintiff, Michael F. Cooper, received and began using an ASR Hip manufactured by defendants.

119. Upon information and belief, on or around March 11, 2008, plaintiff, Glenda L. Mazza, received and began using an ASR Hip manufactured by defendants.

120. Upon information and belief, on or around August 24, 2009, plaintiff, Ann McCracken, received and began using an ASR Hip manufactured by defendants.

121. Upon information and belief, on or around February 9, 2009, plaintiff, Ronald J. Nigro, received and began using an ASR Hip manufactured by defendants.

122. Upon information and belief, on or around April 13, 2009, plaintiff, Jeanne Trembeth, received and began using an ASR Hip manufactured by defendants.

123. Defendants impliedly warranted that the ASR Hips were merchantable pursuant to UCC § 2-314 and suitable for the ordinary purpose for which it was intended to be used in ASR surgeries.

124. Defendants ASR Hips were not merchantable nor reasonably suited for the ordinary purpose for which they were being used.

125. As a result, defendants breached UCC § 2-314.

126. As a direct and proximate result of the wrongful acts and omissions of defendants, plaintiffs suffered economic damages, severe and possibly permanent injuries, pain, suffering and emotional distress. Plaintiffs have also endured and continue to suffer the mental anguish and psychological trauma of living with the knowledge that they have suffered these serious and dangerous side effects.

CLAIM VI
BREACH OF IMPLIED WARRANTY OF FITNESS

127. Plaintiffs repeat and reallege each and every allegation previously set forth herein.

128. Defendants impliedly warranted, pursuant to UCC § 2-315, that the ASR Hips were fit for a particular purpose for which they were being used, ASR surgeries.

129. Defendant's ASR Hips were not fit for the particular purpose for which they were being used.

130. As a result, defendants breached UCC § 2-315.

131. As a direct and proximate result of the wrongful acts and omissions of defendants, plaintiffs suffered economic damages, severe and possibly permanent injuries, pain, suffering and emotional distress. Plaintiffs have also endured and continue to suffer the mental anguish and psychological trauma of living with the knowledge that they have suffered these serious and dangerous side effects.

CLAIM VII
VIOLATION OF NEW YORK GENERAL BUSINESS LAW § 349

132. Plaintiffs repeat and reallege each and every allegation previously set forth herein.

133. Defendants engaged in commercial conduct by selling ASR Hips and misrepresented and omitted material information regarding products by failing to disclose the known risks of their ASR Hips.

134. By failing to disclose the known dangers and risks of the ASR Hips, defendants engaged in unfair and deceptive consumer-oriented acts.

135. Reasonable consumers, including plaintiffs, were injured by defendants' unfair and deceptive acts.

136. As a direct and proximate result of the wrongful acts and omissions of defendants, plaintiffs suffered economic damages, severe and possibly permanent injuries, pain, suffering and emotional distress. Plaintiffs have also endured and continue to suffer the mental anguish and psychological trauma of living with the knowledge that they have suffered these serious and dangerous side effects.

CLAIM VIII
DERIVATIVE CLAIM ON BEHALF OF SPOUSES

137. Plaintiffs repeat and reallege each and every allegation previously set forth herein.

138. Plaintiff, Thomas E. Claybaugh, is the spouse of plaintiff, Theresa D. Claybaugh, and has lived and cohabited with the plaintiff, Theresa D. Claybaugh.

139. Plaintiff, Michael A. Mazza, is the spouse of plaintiff, Glenda L. Mazza, and has lived and cohabited with the plaintiff, Glenda L. Mazza.

140. Plaintiff, Joanne Hume-Nigro, is the spouse of plaintiff, Ronald J. Nigro, and has lived and cohabited with the plaintiff, Ronald J. Nigro.

141. By reason of the foregoing, plaintiffs, Thomas E. Claybaugh, Michael A. Mazza and Joanne Hume-Nigro, have necessarily paid and has become liable to pay for medical aid, treatment, attendance and for medications and will necessarily incur further expenses of a similar nature in the future and have been caused, presently and in the future, the loss of his/her companionship, service and society.

WHEREFORE, plaintiffs demand judgment against the defendants as follows:

A. On Claims I through VII for each injured plaintiff in a sum in excess of $75,000 each.

B. On Claim VIII for the spouse of each injured plaintiff as alleged herein in a sum in excess of $75,000 each;

C. For the court costs and disbursements;

D. For such other and further relief as is just and proper.

Dated: March 2, 2011
Rochester, New York

FARACI LANGE, LLP

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