

STATE OF MINNESOTA

DISTRICT COURT

COUNTY OF CARVER

FIRST JUDICIAL DISTRICT

Linda Anderson, James Feser and
Judith Peskar,

Court File No. 10-CV-11-706
CASE TYPE: Product Liability
Hon. Janet L. Cain

Plaintiffs,

v.

**FIRST AMENDED COMPLAINT FOR
DAMAGES AND DEMAND FOR JURY TRIAL**

Simpson and Associates, Inc.,

Defendant.

Plaintiffs Linda Anderson, James Feser and Judith Peskar, by and through their undersigned counsel, and bring this First Amended Complaint for Damages and Demand for Jury Trial against Defendants Simpson and Associates, Inc.; DePuy Orthopaedics, Inc.; DePuy, Inc.; DePuy International, LTD; Johnson & Johnson International; Johnson & Johnson; Tim Hughes; Company ABC; and Does 1-50 in the above-captioned cause of action, and allege as follows:

DESCRIPTION OF THE PARTIES

1. This is an action for damages resulting from Defendants' developing, texting, manufacturing, designing, constructing, promoting, marketing, distributing, supplying, selling, and servicing defective hip replacement components that were subsequently recalled by the United States Food and Drug Administration.

2. Plaintiff Linda Anderson ("Anderson") is a citizen and resident of Hibbing, Minnesota.

3. Plaintiff James Feser ("Feser") is a citizen and resident of Bismarck, North Dakota.

4. Plaintiff Judith Peskar (“Peskar”) is a citizen and resident of River Falls, Wisconsin.

5. Defendant Simpson and Associates, Inc. (“Simpson”) is a Minnesota corporation with its principal place of business in Chanhassen, Minnesota, County of Carver and as such is a citizen of the State of Minnesota.

6. At all times relevant to this action, Simpson promoted, marketed, distributed, supplied, sold, and serviced the recalled defective hip replacement components in the states of Minnesota, South Dakota, and North Dakota.

7. Defendant Simpson promoted, marketed, distributed, supplied, sold, and serviced the ASR Hip replacement components implanted in each of the Plaintiffs to this action.

8. The directors, managers, and sales representatives of Simpson received training and education from DePuy including orthopedic and surgical training, product design rationale for the DePuy ASR Hip, surgical technique tips for demonstrating and implanting the DePuy ASR Hip, training in the use of the tools used to implant the DePuy ASR Hip, training in selecting the hip replacement components to mate with the DePuy ASR Hip cup, and training on how to sell to orthopedic surgeons including training on the advantages of the DePuy ASR Hip over its major competitors.

9. Defendant Simpson provided information to Plaintiffs’ orthopedic surgeons including but not limited to: the advantages of the DePuy ASR Hip compared to its competitors, information regarding the design rationale for the DePuy ASR Hip, surgical techniques on how to implant the DePuy ASR Hip and demonstrations on how to implant the DePuy ASR Hip, and the components that could best be mated with the DePuy ASR Hip cup, including providing a variety of scenarios involving the various instrumentation used in implanting a DePuy ASR Hip.

10. Defendant Simpson 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.

11. The above information was provided by Simpson to Plaintiffs' orthopedic surgeons and was intended for the purpose of convincing and inducing Plaintiffs' orthopedic surgeons to use the DePuy ASR Hip instead of one of the competing hip replacements.

12. Plaintiffs and their surgeons, nurses, and hospital staff relied on information from Defendant in selecting, purchasing, implanting, and servicing the hip replacement components.

13. Plaintiffs' orthopedic surgeons, nurses and hospital staff relied on information and/or assistance from Simpson during Plaintiffs' surgical procedures in implanting the DePuy ASR Hip.

14. Defendant DePuy Orthopaedics, Inc. ("DePuy Orthopaedics"), is an Indiana corporation doing business in the State of Minnesota.

15. Upon information and belief, DePuy Orthopaedics, Inc. is a wholly owned subsidiary of DePuy Inc., which in turn is a subsidiary of Johnson & Johnson International ("J&J International"), which is in turn a subsidiary of Johnson & Johnson ("J&J"). Upon information

and belief, DePuy Orthopaedics. was involved in the business of designing, licensing, manufacturing, distributing, selling, marketing and introducing into interstate commerce, either directly or indirectly, through third parties or related entities, numerous orthopedic products, including the components of the ASR, as well as monitoring and reporting adverse events, and having a role in the decision process and response of the Defendants, if any, related to these adverse events.

16. Upon information and belief, Defendant DePuy Inc. is a Delaware corporation doing business in the State of Minnesota.

17. As DePuy Orthopaedics's parent company, DePuy Inc. was involved in the business of designing, licensing, manufacturing, distributing, selling, marketing and introducing into interstate commerce, either directly or indirectly, through third parties or related entities, numerous orthopedic products, including the components of the DePuy ASR Hip, as well as monitoring and reporting adverse events, and having a role in the decision process and response of the Defendants, if any, related to these adverse events.

18. Defendant DePuy International, Ltd. (hereinafter "DePuy International") is a foreign corporation with its principal place of business located at St. Anthony's Road, Leeds, LS11 8DT, England, and doing business in the State of Minnesota.

19. At all times relevant, DePuy International was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing and introducing into interstate commerce, either directly or indirectly, through third parties or related entities, numerous orthopedic products, including the components of the DePuy ASR Hip, as well as monitoring and reporting adverse events throughout the world, and having a role in the decision-making process and response of the Defendants, if any, related to these adverse events.

20. DePuy International is a subsidiary of Johnson & Johnson.

21. Upon information and belief, Defendant J&J International is a New Jersey corporation doing business in the State of Minnesota.

22. As one of DePuy Orthopaedics's parent companies, J&J International was involved in the business of designing, licensing, manufacturing, distributing, selling, marketing and introducing into interstate commerce, either directly or indirectly, through third parties or related entities, numerous orthopedic products, including the components of the DePuy ASR Hip, as well as monitoring and reporting adverse events, and having a role in the decision process and response of the defendants, if any, related to these adverse events.

23. Upon information and belief, Defendant J&J is a New Jersey corporation doing business in the State of Minnesota.

24. As DePuy Orthopaedics's most senior parent company, J&J was involved in the business of designing, licensing, manufacturing, distributing, selling, marketing and introducing into interstate commerce, either directly or indirectly, through third parties or related entities, numerous orthopedic products, including the components of the DePuy ASR Hip, as well as monitoring and reporting adverse events, and having a role in the decision process and response of the defendants, if any, related to these adverse events.

25. Defendants DePuy Orthopaedics, DePuy Inc., DePuy International, J&J International, and J&J are collectively referred to herein as "DePuy" or the "DePuy Defendants."

26. At all times relevant to this action, the DePuy Defendants, either directly or through their agents, developed, designed, manufactured, promoted, marketed, tested, labeled, distributed, sold and/or profited from the sale of the defective and recalled DePuy ASR Hip devised, through interstate commerce and in the State of Minnesota.

27. Upon information and belief, each of the DePuy Defendants was the agent or employee of the other and was acting at all times within the course and scope of such agency and employment and contributed to and caused the breaches and other liabilities alleged in this Complaint and is legally responsible for the damages alleged herein. In all instances where it is alleged that any of the DePuy Defendants had knowledge of certain facts or events, they obtained such knowledge either directly or through each other or their agents, including by and through their officers, directors, and managing agents. At all times herein mentioned, the DePuy Defendants, and each of them, were acting as agents and employees of each of the other, and at all times herein mentioned, were acting within the scope, purpose, and authority of that agency and employment and with the full knowledge, permission, and consent of each of the other DePuy Defendants.

28. Defendant Tim Hughes ("Hughes") is a resident of the state of Minnesota.

29. Upon information and belief, Hughes is a sales representative for DePuy orthopedic devices and Hughes promoted, marketed, distributed, supplied, sold and serviced the recalled DePuy ASR Hip replacement component in the state of Minnesota and particularly in the area of Duluth, Minnesota.

30. Upon information and belief, Hughes specifically promoted, marketed, distributed, supplied, sold and serviced the ASR Hip installed in Plaintiff Anderson.

31. Defendant Hughes was responsible for educating Plaintiff Anderson's orthopedic surgeon regarding the supposed advantages of the ASR Hip replacement components, answer any questions asked by Plaintiff Anderson's orthopedic surgeon regarding the ASR Hip replacement components, providing Plaintiff Anderson's orthopedic surgeon with information regarding the proper surgical technique to employ when implanting the ASR Hip replacement

components, providing Plaintiff Anderson's orthopedic surgeon with information concerning the ASR Hip replacement components appropriate for her, providing Plaintiff Anderson's orthopedic surgeon with the tools to be used to implant the ASR Hip replacement components, assisting Plaintiff Anderson's orthopedic surgeon during surgery regarding the ASR Hip replacement components and selling to Plaintiff Anderson's orthopedic surgeon.

32. Plaintiff Anderson, her orthopedic surgeon, nurses and hospital staff relied on information from Hughes when selecting, purchasing, implanting and servicing the ASR Hip replacement components.

33. Upon information and belief, Defendant Company ABC ("Company ABC") is a corporation, partnership, limited partnership or other business entity doing business in the state of Minnesota.

34. Upon information and belief, Hughes was the agent and/or employee of Company ABC and at all such times was acting within the scope and course of his agency and/or employment, thus making Company ABC liable for the actions of Hughes.

35. The true name and legal capacity, whether individual, corporate, associate, limited partnership or otherwise, of Company ABC is unknown to Plaintiffs, who therefore sue Company ABC by a fictitious name until such time as Plaintiffs become aware of Company ABC's true identity through discovery in this action.

36. The true names and capacities, whether individual, corporate, associate, or otherwise, of defendants named herein as Does 1-50, are unknown to Plaintiffs, who therefore sues said defendants by fictitious names until such time as Plaintiffs become aware of such persons' true identities through discovery in this action.

37. Plaintiffs are informed and believe and based thereupon allege that each of the Defendants designated herein as Does 1-50 took part in and participated with the named Defendants in all matters referred to herein and were in some manner responsible for the injuries and losses suffered by Plaintiffs.

38. At all times alleged herein, use of the collective term "Defendant(s)" refers to all named Defendants as well as Defendants Does 1-50, inclusive.

39. At all times alleged herein, each of the Defendants were the agent and employee of every other Defendant in doing the acts herein alleged, and was, at all time, acting within the purpose and scope of said agency and employment and all said acts and conduct were ratified and approved by said Defendants.

JURISDICTION AND VENUE

40. Venue in this action properly lies in Carver County as Simpson maintains its headquarters in this county.

HIP REPLACEMENT COMPONENTS

41. In 2005, Defendants began promoting and selling in Minnesota, South Dakota, and North Dakota, hip replacement components with the model identification of "ASR" manufactured by DePuy International, LTD of the United Kingdom.

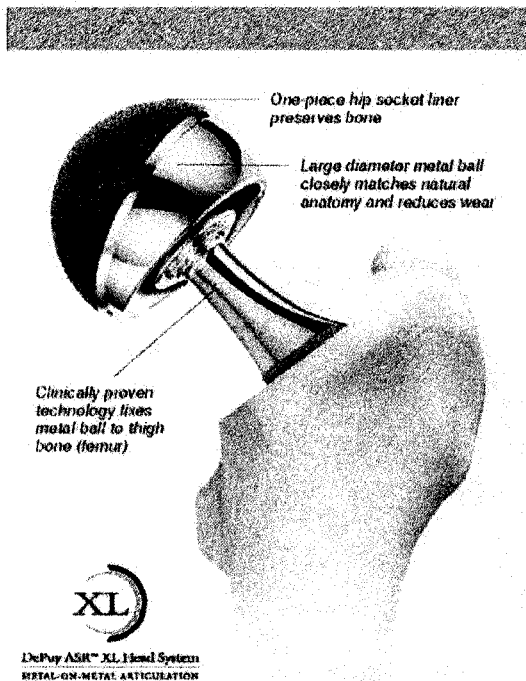
42. In addition to other means, Defendants used brochures and other printed literature to promote the ASR Hip replacement components.

43. Defendants disseminated literature to the orthopedic community in Minnesota, South Dakota, and North Dakota 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.”

44. Defendants also claimed in information provided to the Minnesota, South Dakota, and North Dakota orthopedic communities that the ASR Hip replacement components were “based on a strong clinical history” and “reduces wear compared to traditional hip replacement.”

45. In a 2006 patient brochure, titled *DePuy ASR™ XL Head System: Metal on Metal Articulation: High Performance Hip Replacement*, Defendants touted the advantages of the ASR Hip, including reduced wear:



46. The 2006 patient brochure contains the following chart stating that the DePuy ASR Hip is “based on a strong clinical history” and “reduces wear compared to traditional hip replacement”:

Benefits¹	Hip Resurfacing	The ASR™ XL System
Preserves Bone in the Hip Socket	YES	YES
Provides Excellent Range of Motion	YES	YES
Reduces Wear Compared to Traditional Hip Replacement	YES	YES
Provides Ball Diameters that Closely Match Natural Anatomy	YES	YES
Allows Surgeon to Adjust Leg Length and Offset	NO	YES
Involves a Relatively Small Surgical Incision	NO	YES
Based on Strong Clinical History	NO	YES

47. The 2006 patient brochure contains photographs of the following three individuals engaged in demanding athletic activities with the DePuy ASR Hip logo superimposed over one of each of their hips, implying that each has a DePuy ASR Hip implanted in that hip. They include a man with the DePuy ASR logo superimposed over his right hip taking a very aggressive golf swing:



a man with a DePuy ASR logo superimposed over his right hip playing Frisbee with a dog on a loose sand beach:



and a young woman with the DePuy ASR logo superimposed over her left hip jogging on a loose sand beach:



48. Defendant Simpson's efforts were so successful that in 2008 it won a national sales award for selling increasing sales of the ASR Hip replacement components in its territory by 362%, generating millions of dollars in additional sales.

49. As a result in large part of aggressive sales of ASR Hip replacement components, in 2010 Simpson had sales of more than \$60,000,000.00.

50. As a result of Simpson's intense promotion of the ASR hip components in Minnesota, South Dakota, and North Dakota, sales of ASR Hip replacement components were substantially higher in this region than in comparable regions.

WARNINGS FROM INDEPENDENT ORTHOPEDIC EXPERTS

51. The same year Defendants 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.

52. Orthopedic experts warned that some of the ASR hip cup was too thin and thus prone to deformation.

53. 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.

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

55. 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.

DEFENDANTS' RESPONSE TO WARNINGS

56. DePuy countered these warnings concerning the defective nature of the DePuy ASR Hip with a host of arguments and continued to heavily promote its ASR Hip for the next four years by and through Simpson and Hughes.

57. Defendant DePuy disseminated its arguments responding to the warnings about the ASR Hip through their distributors, including Simpson and Hughes.

58. The employees and agents of Simpson and Hughes were aware of the problems with the design of the ASR Hip, and also aware of excessive failures necessitating revision of the DePuy ASR Hip, but failed to convey this information to the Plaintiffs' orthopedic surgeons and instead continued to strongly promote the DePuy ASR Hip.

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

60. Defendants, through their employees and agents, were also aware of the problems with the design of the ASR Hip replacement components based upon complaints of orthopedic surgeons.

61. Defendants were additionally aware of excessive failures necessitating revision of ASR Hip replacement components due to revision surgeries in which Defendants' sales representatives participated, but failed to convey this information to the Plaintiffs' orthopedic surgeons.

SUSPENSION AND RECALL

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

63. 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.

64. In late 2009, DePuy, citing decreased sales, stated that it was phasing out sales of the DePuy ASR Hip.

65. In early 2010, DePuy sent letters to orthopedic surgeon warning of high failure rates with the DePuy ASR Hip.

66. Finally, on August 24, 2010, DePuy announced that it was recalling the DePuy ASR Hip, noting in the Recall Notice that reasons for high failure rates included “component loosening, component malalignment, infection, fracture of the bone, dislocation, metal sensitivity and pain.”

67. On March 24, 2011, the United States Food and Drug Administration issued a recall of all ASR Hip replacement components.

68. Unfortunately, the recall came far too late for the Plaintiffs to this action.

LINDA ANDERSON

69. Plaintiff Anderson, a homemaker and a mother of three, is a resident of the State of Minnesota.

70. In March of 2007, Linda Anderson's orthopedic surgeon, Brad Edgerton, M.D., advised Ms. Anderson to undergo a total hip replacement surgery for pain in her right hip.

71. Dr. Edgerton explained to Linda Anderson information about the ASR Hip replacement components based on the information previously conveyed to him by Defendant's sales representatives.

72. Based upon the information originally provided by Defendant, in March of 2007, Ms. Anderson agreed to undergo a right total hip replacement utilizing ASR Hip replacement components performed by Dr. Edgerton at St. Mary's Hospital in Duluth, Minnesota.

73. Following the surgery, Linda Anderson went through a long and painful recovery period.

74. Despite the pain, Ms. Anderson forced herself to undergo extensive physical therapy to regain her strength.

75. Unfortunately, Linda Anderson continued to have pain in her hip and groin, for which she saw Dr. Edgerton monthly.

76. Dr. Edgerton took x-rays at each visit but was unable to determine the cause of the pain.

77. Finally, in late 2007, Dr. Edgerton found fractures on the x-rays in Linda Anderson's pelvis around the ASR Hip replacement components.

78. Linda Anderson was required to avoid using her hip, which effectively put her on bed rest for several weeks.

79. Following her recovery from the pelvic fractures, Linda Anderson returned to Dr. Edgerton's office with continued severe hip and groin pain.

80. Dr. Edgerton referred her for a second opinion to Robert T. Trousdale, M.D. in Rochester, Minnesota.

81. Dr. Trousdale reviewed x-rays of Linda Anderson's hip and could find nothing visibly wrong.

82. However, Dr. Trousdale recommended that Ms. Anderson undergo a revision surgery to examine the possibility that her pain might stem from a problem with her tendons.

83. On March 5, 2010, Ms. Anderson underwent a revision surgery of her right hip performed by Dr. Trousdale at Rochester Methodist Hospital in Rochester, Minnesota.

84. During that surgery, Dr. Trousdale found Linda Anderson's ASR Hip replacement component cup to be grossly loose and replaced both the cup and the femoral head.

85. Since that surgery, Linda Anderson has had a difficult recovery and continues to experience significant pain in her right hip.

JAMES FESER

86. Plaintiff James Feser, the general manager of a grocery wholesaler, is a resident of the State of North Dakota.

87. On March 10, 2008, James Feser saw orthopedic surgeon Timothy Bopp, M.D. to discuss a possible hip resurfacing, at which time they discussed at length the difference between resurfacing and total hip replacement and the many different models of both total hip and resurfacing products.

88. Despite the fact that ASR Hip replacement components were not approved for use in resurfacing procedures in the United States, Defendant's employees had aggressively marketed this device for just that use to Dr. Bopp.

89. In promoting the ASR Hip replacement components for use in resurfacing procedures, Defendant's employee failed to inform Dr. Bopp that the components were not approved for that use in the United States.

90. On April 3, 2008, James Feser underwent a resurfacing of his right hip performed by orthopedic surgeon Timothy Bopp, MD and utilizing ASR Hip replacement components at the St. Alexius Medical Center in Bismarck, North Dakota.

91. Thereafter, James Feser initially recovered well from the procedure and seemed to do well for approximately two years.

92. However, by late 2010, Mr. Feser was experiencing pain in his right hip.

93. At a visit on October 6, 2010, Dr. Bopp ordered laboratory tests to measure James Feser's cobalt and chromium levels and kidney function, and follow up tests to be conducted three months later.

94. The test results showed from the first tests showed that Mr. Feser's cobalt level was 124, 124 times the acceptable range.

95. James Feser underwent additional testing in January of 2011 that showed his cobalt level had increased to 146, 146 times the acceptable range.

96. James Feser returned to Dr. Bopp's office on January 31, 2011 for a consultation regarding his laboratory results, at which time Dr. Bopp explained the results of the metal debris testing.

97. Dr. Bopp immediately prescribed an MRI scan to look for possible fluid collection to be followed by a revision surgery to remove ASR Hip replacement components.

98. On March 9, 2011, Plaintiff underwent a revision surgery of his right hip performed by Dr. Bopp at St. Alexius Medical Center in Bismarck, North Dakota.

99. In his operative report on March 9, 2011, Dr. Bopp noted the following:

We then opened up the hip joint, which had a fair amount of fluid in the hip and metallosis was encountered immediately; that is, the fluid was dark metal-stained type fluid that we do see when metallosis present and this was consistent with metallosis. There was no foul smell and no indication of infection... The entire undersurface of the abductors was stained with metal debris and you could see where this actually dissected down along the vastus lateralis, so we incised the vastus lateral is to take out some of that metal debris. Then we completed our exposure by opening up the capsule and thoroughly excising the capsule because it was all stained with metallosis.... At this point, we continued on by placing our acetabular retractors and then we used the Explant Acetabular System to remove the well-fixed acetabulum... We then did a further thorough search for any additional metallosis. Any found was removed. We thoroughly irrigated with copious amounts of bacitracin and saline to try and get all the foreign debris out of the hip as much as possible.

100. Following the surgery to remove the ASR Hip replacement components, James Feser has begun a long and painful rehabilitation process.

JUDITH PESKAR

101. Plaintiff Judith Peskar is a retired resident of the State of Wisconsin.

102. On May 21, 2009, Judith Peskar underwent a total hip arthroplasty of her right hip performed by orthopedic surgeon Andrea Saterbak, MD at Lakeview Hospital in Stillwater, Minnesota.

103. During the surgery, Dr. Saterbak implanted ASR Hip replacement components into the body of Judith Peskar.

104. Plaintiff Peskar initially seemed to recover well from the procedure and Dr. Saterbak was pleased with her recovery and the position of the device in immediate follow-up visits.

105. Unfortunately, despite the appearance of initial success, the hip rapidly became painful.

106. On February 8, 2010, Judith Peskar returned to Dr. Saterbak's office complaining of pain and a grinding sensation.

107. Dr. Saterbak took x-rays which demonstrated no visible loosening or misalignment and recommended that she wait for the symptoms to resolve.

108. Unfortunately, rather than resolving, Judith Peskar's symptoms worsened, she became concerned that the grinding sensation was causing metal debris, and she saw a second orthopedic surgeon, Robert V. Knowlan, M.D., for an aspiration and injection of her hip.

109. On April 20, 2010, Judith Peskar underwent the hip aspiration, performed by Dr. Knowlan, who found that the fluid in her hip was a grayish color as the result of metallosis.

110. Subsequently, on August 21, 2010, Judith Peskar underwent a revision surgery of her right hip performed by Daniel P. Hoeffel, M.D. at Woodwinds Health Campus in Woodbury, Minnesota.

111. Following the surgery to remove the ASR Hip replacement components, Judith Peskar has begun a long and painful rehabilitation process.

EFFECT ON PLAINTIFFS

112. Each of the Plaintiffs to this action had ASR Hip replacement components that were promoted, marketed, distributed, supplied, sold, and serviced by Defendant.

113. Each of 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.

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

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

116. 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.

117. 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.

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

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

120. Plaintiffs' orthopedic surgeons relied on the misinformation provided by Defendants and used, continued to use, and failed to suspect the premature failure of the ASR Hip replacement components.

COUNT ONE – NEGLIGENCE – SIMPSON

121. Plaintiffs re-allege and incorporate by reference all paragraphs above as if fully stated herein.

122. Defendant Simpson, as the promoter, marketer, seller, distributor, and servicer of the ASR Hip replacement components, owed a duty to Plaintiffs to provide accurate information to Plaintiffs, their orthopedic surgeons, and the orthopedic community.

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

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

125. 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 normal lives; 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 – SIMPSON

126. Plaintiffs re-allege and incorporate by reference all paragraphs above as if fully stated herein.

127. At the time that Simpson 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.

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

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

130. 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.

131. 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 normal lives; 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 – SIMPSON

132. Plaintiffs re-allege and incorporate by reference all paragraphs above as if fully stated herein.

133. Defendant Simpson promoted, marketed, distributed, supplied, sold, and serviced the ASR Hip replacement components at issue in this case.

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

135. Plaintiffs were foreseeable users of the ASR Hip replacement components.

136. Plaintiffs purchased the ASR Hip replacement components from Defendant.

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

138. 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 normal lives; 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 - INTENTIONAL MISREPRESENTATION AGAINST SIMPSON

139. Plaintiffs re-allege and incorporate by reference all paragraphs above as if fully stated herein.

140. As stated above, defendant made false misrepresentations of material facts.

141. Defendant Simpson did so knowing that the misrepresentations were false or was ignorant of the truth of the assertion.

142. Defendant Simpson did so with the intention of inducing the Plaintiffs and their agents to purchase and continue to purchase the ASR Hip replacement components.

143. Plaintiffs and their agents were induced to act in reliance on Simpson's misrepresentations.

144. The damages incurred by Plaintiffs were proximately caused by Simpson's misrepresentations.

COUNT FIVE - NEGLIGENCE – DEPUY DEFENDANTS

145. Plaintiffs re-allege and incorporate by reference all paragraphs above as if fully set forth herein.

146. Defendant DePuy, as the manufacturer of the DePuy ASR Hip owed a duty to Plaintiffs to exercise reasonable care in the design, manufacture, testing, researching, assembling, labeling, producing, selling and distribution of the device to insure it was fit for its intended use.

147. Defendant DePuy, as the manufacturer of the DePuy ASR Hip, owed a duty to Plaintiffs to inform their orthopedic surgeon in a timely manner of the significant problems being experienced with the product and to warn of any risks and dangers of the product.

148. Defendant DePuy, in breach of the duties described above, negligently and carelessly designed, manufactured, tested, researched, assembled, produced, labeled, sold and distributed the DePuy ASR Hip implanted in Plaintiffs and failed to adequately test and warn of the risks and dangers of the DePuy ASR Hip.

149. As a direct and proximate result of the conduct of DePuy, the DePuy ASR Hip was unfit for its intended use and Plaintiffs needlessly suffered pain and weakness.

150. As a direct and proximate cause of the negligence and carelessness of DePuy, Plaintiffs have suffered severe physical pain, distress and injury; emotional distress and injury; incurred medical and other expenses; suffered shame, humiliation and the inability to lead a normal life; and has suffered loss of enjoyment of life.

151. The injuries and losses of Plaintiffs are permanent in nature and Plaintiffs will continue to suffer such losses in the future.

**COUNT SIX – STRICT LIABILITY – DESIGN DEFECT –
DEPUY DEFENDANTS**

152. Plaintiffs re-allege and incorporate by reference all paragraphs above as if fully set forth herein.

153. At the time DePuy manufactured, developed, researched, produced, tested, assembled, labeled, distributed, marketed and sold the DePuy ASR Hip, it contained a defect that made it unreasonably dangerous and unfit for its intended use.

154. The DePuy ASR Hip manufactured by DePuy was defective in design or formulation in that, when it left the hands of DePuy, the foreseeable risk of harm grossly exceeded the benefits associated with the design or formulation of the DePuy ASR Hip.

155. The DePuy ASR Hips were expected to and did reach Plaintiffs without substantial change in their condition as manufactured, created, designed, tested, labeled, packaged, supplied, marketed, sold, advertised, warned and otherwise distributed.

156. Plaintiffs used the DePuy ASR Hip in a manner for which it was intended or in a reasonably foreseeable manner.

157. The DePuy ASR Hip caused increased risk of serious personal injury and harm upon use, and therefore constitutes a product unreasonably dangerous for normal use due to its defective design, defective manufacture and DePuy's misrepresentations and inadequate facts disclosed to Plaintiff.

158. The DePuy ASR Hip manufactured and/or supplied by DePuy was defective due to:

- a. defective design or formulation in that when it left the hands of DePuy and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation;
- b. defective marketing in that DePuy made inappropriate, misleading, inaccurate and incomplete representations about the DePuy ASR Hip in advertisements, brochures, pamphlets and direct information provided to

Plaintiffs' orthopedic surgeons. These deceptive marketing representations were made in order to induce sales and increase profits;

- c. defective design or formulation in that when the DePuy ASR Hip left the hands of the manufacturer or suppliers, it was unreasonably dangerous, it was more dangerous than an ordinary consumer would expect and more dangerous than other competitive hip replacements;
- d. inadequate warnings or instructions because DePuy knew or should have known that the ASR Hip created a risk of dangerous side effects and other related conditions and diseases;
- e. inadequate pre-marketing testing which, if conducted properly, would have revealed the serious problems with the DePuy ASR Hip, prior to its first sale; and/or
- f. inadequate post-marketing warning or instruction because, after DePuy knew or should have known of the risks of dangerous side effects or other related conditions and diseases, DePuy failed to provide adequate warnings to users or consumers of the product and continued to promote the DePuy ASR Hip.

159. Defendant DePuy, therefore, is strictly liable to Plaintiffs.

160. The product reached Plaintiffs without substantial change in the condition in which it was sold.

161. As a direct and proximate cause of the defective conditions of the DePuy ASR Hip, Plaintiffs have suffered severe physical pain, distress and injury; emotional distress and

injury; incurred medical and other expenses; suffered shame, humiliation and the inability to lead a normal life; and has suffered loss of enjoyment of life.

162. The injuries and losses of Plaintiffs are permanent in nature and Plaintiffs will continue to suffer such losses in the future.

COUNT SEVEN - STRICT LIABILITY—FAILURE TO WARN—
DEPUY DEFENDANTS

163. Plaintiffs re-allege and incorporate by reference all paragraphs above as if fully set forth herein.

164. The DePuy ASR Hip was defective at the time of its manufacture, development, production, testing, inspection, endorsement, prescription, sale and distribution, in that, and not by way of limitation, said product and its warnings, instructions and directions failed to warn of the dangerous propensities of said product, which risks were known or reasonably scientifically knowable to DePuy.

165. Defendant DePuy, knew or should have known of the defective condition, characteristics and risks associated with the DePuy ASR Hip, as previously set forth herein.

166. At all times herein mentioned, the DePuy ASR Hip was defective, and DePuy knew that the product was to be used by the user without inspection for defects therein.

167. Moreover, Plaintiffs neither knew, nor had reason to know at the time of the use of the DePuy ASR Hip, of the existence of the aforementioned defects.

168. As a result of DePuy's failure to warn of the defective condition of the DePuy ASR Hip, Plaintiffs suffered injuries and damages as alleged herein.

COUNT EIGHT - BREACH OF IMPLIED WARRANTY—
DEPUY DEFENDANTS

169. Plaintiffs re-allege and incorporate by reference all paragraphs above as if fully set forth herein.

170. Defendant DePuy designed, manufactured, labeled, distributed and sold the DePuy ASR Hip at issue in this case.

171. Defendant DePuy impliedly warranted to Plaintiffs and Plaintiffs' orthopedic surgeons that the DePuy ASR Hip was reasonably fit and safe for its intended use as a hip joint replacement system and was of marketable quality throughout.

172. Plaintiffs were foreseeable users of the DePuy ASR Hip.

173. Plaintiffs were and are unskilled in the research, design and manufacture of the DePuy ASR Hip and reasonably relied entirely on the skill, judgment and implied warranty of DePuy in using the DePuy ASR Hip.

174. Plaintiffs purchased the DePuy ASR Hip from Simpson as distributor for DePuy.

175. The DePuy ASR Hip was neither safe for its intended use nor of merchantable quality, as warranted by DePuy, in that it had dangerous propensities when put to its intended use and would cause severe injuries to the user.

176. The DePuy ASR Hip failed while being used for its intended purpose, causing injury to Plaintiffs.

177. As a direct and proximate cause of this breach of warranty, Plaintiffs have suffered severe physical pain, distress and injury; emotional distress and injury; incurred medical and other expenses; suffered shame, humiliation and the inability to lead a normal life; and have suffered loss of enjoyment of life.

178. The injuries and losses of Plaintiffs are permanent in nature and Plaintiffs will continue to suffer such losses in the future.

COUNT NINE - BREACH OF EXPRESS WARRANTY—DEPUY DEFENDANTS

179. Plaintiffs re-allege and incorporate by reference all paragraphs above as if fully set forth herein.

180. Defendant DePuy designed, manufactured, labeled, and distributed the DePuy ASR Hip at issue in this case.

181. Defendant DePuy expressly warranted by affirmation, promise, description, and sample that the DePuy ASR Hip was reasonably fit for extended, safe use as a hip joint replacement system.

182. The above representations made by DePuy were meant to directly or indirectly induce persons such as Plaintiffs and the orthopedic surgeon of Plaintiffs to purchase the DePuy ASR Hip.

183. Plaintiffs were foreseeable users of the DePuy ASR Hip.

184. Plaintiffs relied on the skill, judgment, representations and foregoing express warranties of DePuy.

185. Plaintiffs purchased the DePuy ASR Hip from DePuy as distributor for DePuy.

186. The warranties and representations made by DePuy were false in that the DePuy ASR Hip was not safe and was unfit for the uses for which it was intended.

187. The DePuy ASR Hip failed while being used for its intended purpose, causing injury to Plaintiff.

188. As a direct and proximate cause of this breach of warranty, Plaintiffs have suffered severe physical pain, distress and injury; emotional distress and injury; incurred medical

and other expenses; suffered shame, humiliation and the inability to lead a normal life; and have suffered loss of enjoyment of life.

189. The injuries and losses of Plaintiffs are permanent in nature and Plaintiffs will continue to suffer such losses in the future.

**COUNT TEN – INTENTIONAL MISREPRESENTATION –
DEPUY DEFENDANTS**

190. Plaintiffs re-allege and incorporate by reference all paragraphs above as if fully set forth herein.

191. Defendant DePuy, from the time that the DePuy ASR Hip was first tested, studied, researched, evaluated, endorsed, manufactured, marketed, distributed and sold, and up to the present, willfully deceived Plaintiffs by concealing from Plaintiffs, Plaintiffs' orthopedic surgeons and the general public, the true material facts as previously identified herein concerning the DePuy ASR Hip, which the DePuy had a duty to disclose.

192. Defendant DePuy conducted a sales and marketing campaign to promote the sale of the DePuy ASR Hip and willfully deceived Plaintiffs, Plaintiffs' orthopedic surgeons and the general public as to the health risks and consequences of the use of the DePuy ASR Hip.

193. Defendant DePuy was aware of the foregoing, and that the DePuy ASR Hip was not safe, fit, or effective for human use, was hazardous to health, and had a substantial propensity to cause serious injuries to users, including but not limited to the injuries suffered by Plaintiffs as delineated herein.

194. Defendant DePuy intentionally concealed and suppressed the true facts concerning the DePuy ASR Hip with the intent to defraud Plaintiffs, in that DePuy knew that Plaintiffs' orthopedic surgeons would not recommend and prescribe the DePuy ASR Hip, and

Plaintiffs would not have used the DePuy ASR Hip, if they were aware of the true facts concerning the dangers of the DePuy ASR Hip.

195. At all times herein mentioned, Plaintiffs nor their physicians were aware of the facts set forth, and had they been aware of said facts, they would not have acted as they did, that is, reasonably would not have relied upon said misrepresentations of safety and efficacy and utilized the DePuy ASR Hip.

196. As a direct and proximate cause of the DePuy Defendants' concealment of material facts as set forth above, Plaintiffs have suffered severe physical pain, distress and injury; emotional distress and injury; incurred medical and other expenses; suffered shame, humiliation and the inability to lead a normal life; and have suffered loss of enjoyment of life.

197. The injuries and losses of Plaintiffs are permanent in nature and Plaintiffs will continue to suffer such losses in the future.

COUNT ELEVEN - NEGLIGENT MISREPRESENTATION—
DEPUY DEFENDANTS

198. Plaintiffs re-allege and incorporate by reference all paragraphs above as if fully set forth herein.

199. Defendant DePuy, from the time that the DePuy ASR Hip was first tested, studied, researched, evaluated, endorsed, manufactured, marketed, sold and distributed, and up to the present, made represented and marketed the DePuy ASR Hip as being safe and effective.

200. After DePuy became aware of the numerous risks associated with the DePuy ASR Hip, however, DePuy failed to communicate to Plaintiffs, Plaintiffs' medical providers, or the general public that the DePuy ASR Hip was not safe, fit, or effective for human use, was hazardous to health, and had a substantial propensity to cause serious injuries to users, including but not limited to the injuries suffered by Plaintiffs as delineated herein.

201. Defendant DePuy conducted a sales and marketing campaign to promote the sale of the DePuy ASR Hip and willfully deceived Plaintiffs, Plaintiffs' orthopedic surgeons and the general public as to the health risks and consequences of the use of the DePuy ASR Hip.

202. Defendant DePuy made the foregoing and below representations without any reasonable grounds for believing them to be true, when it knew or reasonably should have known of the falsity of such misrepresentations, including but not limited to:

- a. The DePuy ASR Hip is designed to reduce wear and provide higher function for all patients;
- b. The DePuy ASR Hip is clinically proven to reduce wear;
- c. The DePuy ASR Hip is based on a strong clinical history and reduces wear compared to the traditional hip replacement; and
- d. The DePuy ASR Hip is designed to be installed in younger and more active patients and will last longer.

203. Defendant DePuy failed to disclose information concerning the DePuy ASR Hip which was known at the time of the purchase by Plaintiffs and was used to induce Plaintiffs' orthopedic surgeons and Plaintiffs into purchasing the DePuy ASR Hip, including but not limited to:

- a. Failing to disclose that independent experts from around the world were warning that the design of the DePuy ASR Hip was flawed;
- b. Failing to disclose that orthopedic experts were warning that the DePuy ASR Hip cup was too thin and prone to deformation;

- c. Failing to disclose that the clearance between the DePuy ASR Hip cup and head was too small and patients could experience jamming of the components;
- d. Failing to disclose that the treatment of the metal used for the DePuy ASR Hip cup was prone to increased wear and caused excessive metal debris;
- e. Failing to disclose that the DePuy ASR Hip cup failed to obtain bony ingrowth and became loose;
- f. Failing to disclose that by 2005, the DePuy ASR Hip cup was shown, in Australia, to have a 4-fold higher rate of revision than similar cups of competitors; and
- g. Failing to disclose the DePuy ASR Hip was not approved by the FDA for a resurfacing procedure.

204. These representations and omissions were made directly by DePuy, by sales representatives and other authorized agents of DePuy, and in publications and other written materials directed to physicians, medical patients and the public, with the intention of inducing reliance and the prescription, purchase and use of the DePuy ASR Hip, even though DePuy knew or reasonably should have known that such representations and omissions were false and misleading.

205. The foregoing representations and omissions by DePuy were in fact false, in that the DePuy ASR Hip was not safe, fit, or effective for human use, was hazardous to health, and had a substantial propensity to cause serious injuries to users, including but not limited to the injuries suffered by Plaintiffs as delineated herein.

206. The foregoing representations and omissions by DePuy were made with the intention of inducing reliance and the prescription, purchase and use of the DePuy ASR Hip.

207. In reliance on the misrepresentations and omissions by DePuy, Plaintiffs and/or Plaintiffs' orthopedic surgeons were induced to purchase and use the DePuy ASR Hip.

208. If Plaintiffs had known of the true facts and the facts concealed by DePuy, Plaintiffs and/or Plaintiffs' orthopedic surgeons would not have used the DePuy ASR Hip.

209. The reliance of Plaintiffs and/or Plaintiffs' orthopedic surgeons upon DePuy's misrepresentations and omissions was justified because such misrepresentations and omissions were made and conducted by individuals and entities that were in a position to know the true facts.

210. As a direct and proximate cause of DePuy's concealment of material facts as set forth above, Plaintiffs have suffered severe physical pain, distress and injury; emotional distress and injury; incurred medical and other expenses; suffered shame, humiliation and the inability to lead a normal life; and has suffered loss of enjoyment of life.

211. The injuries and losses of Plaintiffs are permanent in nature and Plaintiffs will continue to suffer such losses in the future.

COUNT TWELVE – NEGLIGENCE – HUGHES AND COMPANY ABC

212. Plaintiff Anderson re-alleges and incorporates by reference all paragraphs above as if fully stated herein.

213. Defendant Hughes, as the promoter, marketer, seller, distributor, and servicer of the ASR Hip replacement components, owed a duty to Plaintiff Anderson to provide accurate information to Plaintiff Anderson, her orthopedic surgeons, and the orthopedic community.

214. Defendant Hughes, in breach of the duty described above, negligently and carelessly promoted, marketed, sold, distributed, and serviced the ASR Hip replacement components implanted in Plaintiff Anderson.

215. As a direct and proximate result of the conduct of Hughes, Plaintiff Anderson needlessly suffered severe pain and weakness.

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

COUNT THIRTEEN - STRICT LIABILITY – HUGHES AND COMPANY ABC

217. Plaintiff Anderson re-alleges and incorporates by reference all paragraphs above as if fully stated herein.

218. At the time that Hughes 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.

219. The ASR Hip replacement components reached Plaintiff Anderson without substantial change in the condition in which they were sold.

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

221. 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.

222. As a direct and proximate cause of the nature of the ASR Hip replacement components, Plaintiff Anderson 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 normal lives; and have suffered loss of enjoyment of life. The injuries and losses of Plaintiff Anderson are permanent in nature and Plaintiff Anderson will continue to suffer such losses in the future.

**COUNT FOURTEEN - BREACH OF IMPLIED WARRANTY – HUGHES AND
COMPANY ABC**

223. Plaintiff Anderson re-alleges and incorporates by reference all paragraphs above as if fully stated herein.

224. Defendant Hughes promoted, marketed, distributed, supplied, sold, and serviced the ASR Hip replacement components at issue in this case.

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

226. Plaintiff Anderson was a foreseeable user of the ASR Hip replacement components.

227. Plaintiff Anderson purchased the ASR Hip replacement components from Hughes.

228. The ASR Hip replacement components failed while being used for their intended purpose, causing serious injury to Plaintiff Anderson.

229. As a direct and proximate cause of this breach, Plaintiff Anderson 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 normal lives; and have suffered loss of enjoyment of life. The injuries and losses of Plaintiff Anderson are permanent in nature and Plaintiff Anderson will continue to suffer such losses in the future.

**COUNT FIFTEEN - INTENTIONAL MISREPRESENTATION AGAINST HUGHES
AND COMPANY ABC**

230. Plaintiff Anderson re-alleges and incorporates by reference all paragraphs above as if fully stated herein.

231. As stated above, defendant made false misrepresentations of material facts.

232. Defendant Hughes did so knowing that the misrepresentations were false or was ignorant of the truth of the assertion.

233. Defendant Hughes did so with the intention of inducing the Plaintiff Anderson and her agents to purchase and continue to purchase the ASR Hip replacement components.

234. Plaintiff Anderson and her agents were induced to act in reliance on Hughes' misrepresentations.

235. The damages incurred herein by Plaintiff Anderson were proximately caused by Hughes's misrepresentations.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs prays for judgment against the Defendants for damages and for all other relief as the Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury.

Dated: Monday, November 7, 2011.

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ATTORNEYS FOR PLAINTIFFS

STATE OF MINNESOTA

DISTRICT COURT

COUNTY OF CARVER

FIRST JUDICIAL DISTRICT

Linda Anderson, James Feser and
Judith Peskar,

Court File No. 10-CV-11-706
CASE TYPE: Product Liability
Hon. Janet L. Cain

Plaintiffs,

v.

ORDER

Simpson and Associates, Inc.,

Defendant.

The above-entitled matter came on for hearing before the Honorable Janet L. Cain, Judge of District Court, on _____, 2011 at _____ a.m./p.m. seeking an Order allowing Plaintiffs to add additional parties. Appearances were made on and behalf of each party by their respective counsel.

Based upon the Memorandums of Law, files, records, proceedings, and arguments of counsel, the Court

HEREBY ORDERS:

1. Plaintiffs' Motion for Leave to Add Additional Parties is hereby granted.

BEING NO JUST CAUSE FOR DELAY, LET JUDGMENT BE ENTERED

ACCORDINGLY.

Dated: _____, 2011

The Honorable Janet L. Cain
Judge of District Court