IN THE CIRCUIT COURT OF THE
17TH JUDICIAL CIRCUIT IN AND FOR
BROWARD COUNTY, FLORIDA

JEANNINE MALLARD,

Plaintiff,

CIRCUIT CIVIL DIVISION

CASE NO.:

v.

U.S. STEM CELL, INC., f/k/a Biohart, Inc.,
US STEM CELL CLINIC LLC,
REGENESTEM, LLC,
REGENESTEM NETWORK, LLC,
and KRISTIN C. COMELLA,

Defendants.
_____/

COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL

The Plaintiff Jeannine Mallard sues the Defendants U.S. Stem Cell, Inc, f/k/a Biohart, Inc., US Stem Cell Clinic LLC, Regenestem, LLC, Regenestem Network, LLC, and Kristin C. Comella, and alleges as follows:

1. This case arises out of negligent preoperative clearance of the Plaintiff by the Defendants and the subsequent provision of "stem cell" therapy to Plaintiff. As alleged in detail below, Defendants negligently allowed the Plaintiff participate in and be subjected to a so-called clinical trial wherein a "stem cell" medical product was injected directly into Plaintiff's eyes, causing her to suffer permanent blindness.

JURISDICTIONAL STATEMENT AND IDENTIFICATION OF THE PARTIES

2. This is an action for damages in excess of this Court's minimum jurisdictional limits, exclusive of interest and costs.

3. Venue is proper in Broward County, Florida, where one or more of the Defendants reside and the events giving rise to this lawsuit occurred.

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4. Plaintiff Jeannine Mallard resides in France.

5. Defendant U.S. Stem Cell, Inc. f/k/a Bioheart, Inc. is a Florida for-profit corporation with a principal place of business in Sunrise, Florida.

6. Defendant US Stem Cell Clinic LLC is a Florida company with a principal place of business in Sunrise, Florida.

7. Defendant Regenestem, LLC is a Florida company with its principal place of business in Plantation, Florida.

8. Defendant Regenestem Network, LLC is a Florida company with its principal place of business in Plantation, Florida. Regenestem Network, LLC, together with Defendants U.S. Stem Cell, Inc., US Stem Cell Clinic LLC, and Regenestem, LLC owned and operated a stem cell therapy business in Sunrise, Florida, described in further detail below.

9. Defendant Kristin C. Comella is the director of U.S. Stem Cell, Inc. and manages, oversees, and engaged in the sale of stem therapies on behalf of the Defendants U.S. Stem Cell, Inc., US Stem Cell Clinic LLC, Regenestem, LLC, and Regenestem Network, LLC. She lives in Weston, Florida.

FACTS GIVING RISE TO THE ACTIONS

A. U.S. Stem Cell Claims to Provide Effective Stem Cell Therapy.

10. The Defendants U.S. Stem Cell, Inc., US Stem Cell Clinic LLC, Regenestem, LLC, Regenestem Network, LLC, and Kristin Comella jointly operate a "stem cell" therapy business, formerly known as "Bioheart," which it advertises including research and clinical trials.

11. Defendants administer their stem cell services and operate their business out of a clinic called "U.S. Stem Cell Clinic," located at the Sawgrass Mall in Sunrise, Florida (the "Clinic").

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12. Defendant Kristin C. Comella, an aerobics instructor at the YMCA in Weston, Florida, serves as U.S. Stem Cell's chief scientific officer at the Clinic. Ms. Comella is not a physician, and, at all times relevant to this lawsuit, she did not have any degree in medicine or cell biology. Nonetheless, Ms. Comella touted herself as an expert in adipose stem cell research and actively participated in Defendants' stem cell procedures at the Clinic.

13. Defendants claim to harvest stem cells by using liposuction to collect adipose tissue from patients and by processing that tissue to isolate stem cells. Defendants, through their agents, officers and employees, including Kristin Comella, inject or arrange for stem cells to be injected via needle into various parts of patients' bodies.

14. Defendants claim that this stem cell therapy offered at the Clinic is cutting edge therapy and can be used to treat a myriad of ailments and diseases, including macular degeneration.

15. Despite these representations of fact, no scientific evidence or peer-reviewed literature shows that Defendants' stem cell therapies provide any medical benefit for macular degeneration.

B. Defendants Design, Formulate and Produce Stem Cell Therapy.

16. The Defendants were in privity with Ms. Mallard.

17. The Defendants developed, designed, tested, manufactured, inspected, distributed, marketed, promoted, sold, supplied, and otherwise released into the stream of commerce the product at issue in this case, a product created using liposuction to collect adipose tissue from the Plaintiff and processing this tissue.

18. The Defendants claim they processed this tissue to isolate stem cells.

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19. The Defendants intended this product be delivered via needle injection either directly or behind Ms. Mallard's eyes.

20. The Defendants claimed the product, when used through injection into or behind the eyes, would stop the progression of macular degeneration, and created, designed, manufactured, distributed, sold, and supplied the product for that purpose.

21. The product breached the Defendants' express warranties, breached the Defendants' implied warranties of merchantability and fitness for a particular purpose, was defective in design, manufacture, and in its failure to warn Ms. Mallard, and was manufactured, designed, and marketed in a negligent manner by the Defendants.

C. Defendants Convince Ms. Mallard to Participate in the AMD Clinical Trial.

22. Age-related macular degeneration ("AMD") is a common eye condition causing vision loss over time. It is caused by the deterioration of the central portion of the retina, known as the macula, which is responsible for focusing central vision in the eye and controlling the ability to see objects in fine detail.

23. Defendants listed their stem cell therapy as a "clinical trial" for AMD on the U.S. Health and clinical trials website, effectively advertising to people with the disorder looking for an effective treatment.

24. Ms. Mallard had been diagnosed with "dry" AMD, the most common form and had experienced some progression of the disorder. But, as of the fall of 2014, Ms. Mallard could see well enough to live independently, travel and enjoy her daily life without assistance.

25. Plaintiff Ms. Mallard discovered U.S. Stem Cell, Inc.'s AMD clinical

trial one day while browsing the U.S. Health clinical trials website.

26. Ms. Mallard phoned U.S. Stem Cell and spoke directly with Defendant Comella and/or other US Stem Cell representatives and then with a doctor, Shereen Greenbaum, who Defendant Comella introduced as having experience with the procedure.

27. Based on Ms. Mallard's conversations with Defendants and their representatives, Ms. Mallard agreed to pay Defendants a total of $7000 ($5,000, for stem cell therapy treatment for both of her eyes plus $2000 for the storage of the harvested stem cells). She then made arrangements to travel to Florida to undergo the procedure.

28. On February 8, 2015, Ms. Mallard traveled alone to the United States to have the stem cell procedure.

29. On February 10, 2015, she saw Dr. Greenbaum, who conducted a pre-procedure exam of Ms. Mallard, and told her she was eligible to have the procedure performed on both eyes, clearing her to participate in the AMD "clinical trial."

30. Dr. Greenbaum assured Ms. Mallard that she was a candidate for the procedure and that it was safe for her to proceed.

31. The following day, on February 11, 2015, Ms. Mallard arrived at Dr. Greenbaum's office where, Dr. Greenbaum, assisted by Defendant Comella performed the "stem cell" treatment, which entailed a mini liposuction procedure to extract adipose tissue or fat from Ms. Mallard's abdomen, and then another procedure to inject adipose derived "stem cells" directly into Ms. Mallard's eyes.

32. Despite having no medical training, Ms. Comella was present for and participated in the liposuction operation performed on Ms. Mallard.

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33. Once the adipose tissue or fat was removed from Ms. Mallard, Defendant Comella performed or oversaw the "stem cell" extraction and isolation process. She then returned to the operating room to show Ms. Mallard the vials of "stem cells." Next, Dr. Greenbaum injected the "stem cells" directly into Ms. Mallard's eyes – she injected her right eye intravitreally and her left eye behind the eye (retrobulbar).

34. Thus, Dr. Greenbaum and Ms. Comella both had direct patient contact and communication during the "clinical trial" procedures.

35. Ms. Mallard was released after these procedures and she returned to the hotel where she was staying.

36. The following day, Ms. Mallard was in significant pain and called Defendants for help. Dr. Greenbaum advised Ms. Mallard that the pain was normal and caused by inflammation.

37. By the following day, February 13, however, Ms. Mallard's condition had not improved and the pain persisted. She went to see Dr. Greenbaum, who again told her that her pain was due to inflammation and gave her anti-inflammatory medication.

38. With Defendants permission, Ms. Mallard returned to France, but she continued to experience pain in her eyes over the next two weeks. Her condition progressed and worsened and by March 2015, she was diagnosed with retinal detachment in her right eye. By June 2015, Ms. Mallard was permanently blind in that eye.

39. Ms. Mallard has undergone several surgeries to attempt to correct her vision and repair her right eye, but these efforts have been unsuccessful.

40. Ms. Mallard's vision in her left eye has worsened drastically.

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41. As a direct and proximate cause of the Defendants' negligence, Ms. Mallard suffered permanent vision loss and the damages set forth below.

COUNT I

EXPRESS WARRANTY CLAIM AGAINST DEFENDANT U.S. STEM CELL, INC.

42. The Plaintiff adopts and realleges paragraphs 1 through 41 and further alleges:

43. The product developed, designed, tested, manufactured, inspected, distributed, marketed, promoted, sold, supplied, and otherwise released into the stream of commerce by Defendant U.S. Stem Cell, Inc. was defective because it did not conform to representations of fact made by Defendant U.S. Stem Cell, Inc., orally and in writing, through its employees and agents, in connection with the transaction on which Plaintiff Mallard relied in the use of the product.

44. Defendant U.S. Stem Cell, Inc. represented the fact that the product was capable of treating and stopping the progression of macular degeneration.

45. Despite this representation of fact, no scientific evidence shows that the product provides any benefit for macular degeneration.

46. No peer-reviewed literature shows the product provides any benefit for macular degeneration.

47. The prevailing opinion in the scientific community is that the product cannot provide a benefit for macular degeneration.

48. Creating, designing, manufacturing, distributing, selling, and supplying a product with such an express promise to stop the progression of macular degeneration requires safeguards not taken by Defendant U.S. Stem Cell, Inc., and expertise not possessed by Defendant U.S. Stem Cell, Inc.

49. Defendant U.S. Stem Cell, Inc. knew the product was not capable of

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treating or stopping the progression of macular degeneration at this stage in product development, but promoted the treatment as such without any evidence to support such promotion.

50. The Defendant received notice of the breach of warranty when it discovered the condition of Plaintiff Mallard's eyes after receiving the product.

51. As a direct and proximate cause of the breach of express warranty alleged, Plaintiff Mallard sustained serious permanent damages as alleged in detail below.

COUNT II

EXPRESS WARRANTY CLAIM AGAINST DEFENDANT US STEM CELL CLINIC LLC

52. The Plaintiff adopts and realleges paragraphs 1 through 41 and further alleges:

53. The product developed, designed, tested, manufactured, inspected, distributed, marketed, promoted, sold, supplied, and otherwise released into the stream of commerce by Defendant US Stem Cell Clinic LLC was defective because it did not conform to representations of fact made by Defendant US Stem Cell Clinic LLC, orally and in writing, through its employees and agents, in connection with the transaction on which Plaintiff Mallard relied in the use of the product.

54. Defendant US Stem Cell Clinic LLC represented the fact that the product was capable of treating and stopping the progression of macular degeneration.

55. Despite this representation of fact, no scientific evidence shows that the product provides any benefit for macular degeneration.

56. No peer-reviewed literature shows the product provides any benefit for macular degeneration.

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57. The prevailing opinion in the scientific community is that the product cannot provide a benefit for macular degeneration.

58. Creating, designing, manufacturing, distributing, selling, and supplying a product with such an express promise to stop the progression of macular degeneration requires safeguards not taken by Defendant US Stem Cell Clinic LLC, and expertise not possessed by Defendant US Stem Cell Clinic LLC.

59. Defendant US Stem Cell Clinic LLC knew the product was not capable of treating or stopping the progression of macular degeneration at this stage in product development, but promoted the treatment as such without any evidence to support such promotion.

60. The Defendant received notice of the breach of warranty when it discovered the condition of Plaintiff Mallard's eyes after receiving the product.

61. As a direct and proximate cause of the breach of express warranty alleged, Plaintiff Mallard sustained serious permanent damages as alleged in detail below.

COUNT III

EXPRESS WARRANTY CLAIM AGAINST DEFENDANT REGENESTEM, LLC

62. The Plaintiff adopts and realleges paragraphs 1 through 41 and further alleges:

63. The product developed, designed, tested, manufactured, inspected, distributed, marketed, promoted, sold, supplied, and otherwise released into the stream of commerce by Defendant Regenestem, LLC was defective because it did not conform to representations of fact made by Defendant Regenestem, LLC, orally and in writing, through its employees and agents, in connection with the transaction on which Plaintiff Mallard relied in the use of the product.

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64. Defendant Regenestem, LLC represented the fact that the product was capable of treating and stopping the progression of macular degeneration.

65. Despite this representation of fact, no scientific evidence shows that the product provides any benefit for macular degeneration.

66. No peer-reviewed literature shows the product provides any benefit for macular degeneration.

67. The prevailing opinion in the scientific community is that the product cannot provide a benefit for macular degeneration.

68. Creating, designing, manufacturing, distributing, selling, and supplying a product with such an express promise to stop the progression of macular degeneration requires safeguards not taken by Defendant Regenestem LLC, and expertise not possessed by Defendant Regenestem, LLC.

69. Defendant Regenestem, LLC knew the product was not capable of treating or stopping the progression of macular degeneration at this stage in product development, but promoted the treatment as such without any evidence to support such promotion.

70. The Defendant received notice of the breach of warranty when it discovered the condition of Plaintiff Mallard's eyes after receiving the product.

71. As a direct and proximate cause of the breach of express warranty alleged, Plaintiff Mallard sustained serious permanent damages as alleged in detail below.

COUNT IV

EXPRESS WARRANTY CLAIM AGAINST DEFENDANT REGENESTEM NETWORK, LLC

72. The Plaintiff adopts and realleges paragraphs 1 through 41 and further alleges:

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73. The product developed, designed, tested, manufactured, inspected, distributed, marketed, promoted, sold, supplied, and otherwise released into the stream of commerce by Defendant Regenestem Network, LLC was defective because it did not conform to representations of fact made by Defendant Regenestem Network, LLC, orally and in writing, through its employees and agents, in connection with the transaction on which Plaintiff Mallard relied in the use of the product.

74. Defendant Regenestem Network, LLC represented the fact that the product was capable of treating and stopping the progression of macular degeneration.

75. Despite this representation of fact, no scientific evidence shows that the product provides any benefit for macular degeneration.

76. No peer-reviewed literature shows the product provides any benefit for macular degeneration.

77. The prevailing opinion in the scientific community is that the product cannot provide a benefit for macular degeneration.

78. Creating, designing, manufacturing, distributing, selling, and supplying a product with such an express promise to stop the progression of macular degeneration requires safeguards not taken by Defendant Regenestem Network, LLC, and expertise not possessed by Defendant Regenestem, Network, LLC.

79. Defendant Regenestem Network, LLC knew the product was not capable of treating or stopping the progression of macular degeneration at this stage in product development, but promoted the treatment as such without any evidence to support such promotion.

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80. The Defendant received notice of the breach of warranty when it discovered the condition of Plaintiff Mallard's eyes after receiving the product.

81. As a direct and proximate cause of the breach of express warranty alleged, Plaintiff Mallard sustained serious permanent damages as alleged in detail below.

COUNT V

EXPRESS WARRANTY CLAIM AGAINST DEFENDANT KRISTIN C. COMELLA

82. The Plaintiff adopts and realleges paragraphs 1 through 41 and further alleges:

83. The product developed, designed, tested, manufactured, inspected, distributed, marketed, promoted, sold, supplied, and otherwise released into the stream of commerce by Defendant Kristin C. Comella was defective because it did not conform to representations of fact made by Defendant Kristin C. Comella, orally and in writing, through its employees and agents, in connection with the transaction on which Plaintiff Mallard relied in the use of the product.

84. Defendant Kristin C. Comella, represented the fact that the product was capable of treating and stopping the progression of macular degeneration.

85. Despite this representation of fact, no scientific evidence shows that the product provides any benefit for macular degeneration.

86. No peer-reviewed literature shows the product provides any benefit for macular degeneration.

87. The prevailing opinion in the scientific community is that the product cannot provide a benefit for macular degeneration.

88. Creating, designing, manufacturing, distributing, selling, and supplying a product with such an express promise to stop the progression of

macular degeneration requires safeguards not taken by Defendant Kristin C. Comella, and expertise not possessed by Defendant Kristin C. Comella.

89. Defendant Kristin C. Comella knew the product was not capable of treating or stopping the progression of macular degeneration at this stage in product development, but promoted the treatment as such without any evidence to support such promotion.

90. The Defendant received notice of the breach of warranty when it discovered the condition of Plaintiff Mallard's eyes after receiving the product.

91. As a direct and proximate cause of the breach of express warranty alleged, Plaintiff Mallard sustained serious permanent damages as alleged in detail below.

COUNT VI

IMPLIED WARRANTY OF MERCHANTABILITY CLAIM AGAINST DEFENDANT U.S. STEM CELL, INC.

92. The Plaintiff adopts and realleges paragraphs 1 through 41 and further alleges:

93. The product was defective because it was not reasonably fit for both the uses intended and the uses reasonably foreseeable by Defendant U.S. Stem Cell, Inc.

94. The product is not fit for use as a product for any purpose.

95. The product is not fit for the use intended by the Defendant U.S. Stem Cell, Inc., namely to give a therapeutic benefit and stop the progression of macular degeneration.

96. The product was defective for its intended and reasonably foreseeable uses.

97. Privity of contract exists between Plaintiff Mallard and Defendant U.S. Stem Cell, Inc.

98. Plaintiff Mallard justifiably relied on the Defendant U.S. Stem Cell, Inc.'s representations about the product when agreeing to use the product to stop the progression of her macular degeneration.

99. The Defendant received notice of the breach of warranty when it discovered the condition of Plaintiff Mallard's eyes after receiving the product.

COUNT VII

IMPLIED WARRANTY OF MERCHANTABILITY CLAIM AGAINST DEFENDANT US STEM CELL CLINIC LLC

100. As a direct and proximate cause of the breach of implied warranty of merchantability alleged, Plaintiff Mallard sustained serious permanent damages as alleged in detail below.

101. The Plaintiff adopts and realleges paragraphs 1 through 41 and further alleges:

102. The product was defective because it was not reasonably fit for both the uses intended and the uses reasonably foreseeable by Defendant US Stem Cell Clinic LLC, Inc.

103. The product is not fit for use as a product for any purpose.

104. The product is not fit for the use intended by the Defendant US Stem Cell Clinic LLC, namely to give a therapeutic benefit and stop the progression of macular degeneration.

105. The product was defective for its intended and reasonably foreseeable uses.

106. Privity of contract exists between Plaintiff Mallard and Defendant US Stem Cell Clinic LLC.

107. Plaintiff Mallard justifiably relied on the Defendant US Stem Cell Clinic LLC's representations about the product when agreeing to use the product to stop the progression of her macular degeneration.

108. The Defendant received notice of the breach of warranty when it discovered the condition of Plaintiff Mallard's eyes after receiving the product.

109. As a direct and proximate cause of the breach of implied warranty of merchantability alleged, Plaintiff Mallard sustained serious permanent damages as alleged in detail below.

COUNT VIII

IMPLIED WARRANTY OF MERCHANTABILITY CLAIM AGAINST DEFENDANT REGENESTEM, LLC

110. The Plaintiff adopts and realleges paragraphs 1 through 41 and further alleges:

111. The product was defective because it was not reasonably fit for both the uses intended and the uses reasonably foreseeable by Defendant Regenestem, LLC.

112. The product is not fit for use as a product for any purpose.

113. The product is not fit for the use intended by the Defendant Regenestem, LLC, namely to give a therapeutic benefit and stop the progression of macular degeneration.

114. The product was defective for its intended and reasonably foreseeable uses.

115. Privity of contract exists between Plaintiff Mallard and Defendant Regenestem, LLC.

116. Plaintiff Mallard justifiably relied on the Defendant Regenestem,

LLC's representations about the product when agreeing to use the product to stop the progression of her macular degeneration.

117. The Defendant received notice of the breach of warranty when it discovered the condition of Plaintiff Mallard's eyes after receiving the product.

118. As a direct and proximate cause of the breach of implied warranty of merchantability alleged, Plaintiff Mallard sustained serious permanent damages as alleged in detail below.

COUNT IX

IMPLIED WARRANTY OF MERCHANTABILITY CLAIM AGAINST DEFENDANT REGENESTEM NETWORK, LLC

119. The Plaintiff adopts and realleges paragraphs 1 through 41 and further alleges:

120. The product was defective because it was not reasonably fit for both the uses intended and the uses reasonably foreseeable by Defendant Regenestem Network, LLC, Inc.

121. The product is not fit for use as a product for any purpose.

122. The product is not fit for the use intended by the Defendant Regenestem Network, LLC, Inc., namely to give a therapeutic benefit and stop the progression of macular degeneration.

123. The product was defective for its intended and reasonably foreseeable uses.

124. Privity of contract exists between Plaintiff Mallard and Defendant U.S. Stem Cell, Inc.

125. Plaintiff Mallard justifiably relied on the Defendant Regenestem Network, LLC's representations about the product when agreeing to use the product to stop the progression of her macular degeneration.

126. The Defendant received notice of the breach of warranty when it discovered the condition of Plaintiff Mallard's eyes after receiving the product.

127. As a direct and proximate cause of the breach of implied warranty of merchantability alleged, Plaintiff Mallard sustained serious permanent damages as alleged in detail below.

COUNT X

IMPLIED WARRANTY OF MERCHANTABILITY CLAIM AGAINST DEFENDANT KRISTIN C. COMELLA

128. The Plaintiff adopts and realleges paragraphs 1 through 41 and further alleges:

129. The product was defective because it was not reasonably fit for both the uses intended and the uses reasonably foreseeable by Defendant Kristin C. Comella.

130. The product is not fit for use as a product for any purpose.

131. The product is not fit for the use intended by the Defendant Kristin C. Comella, namely to give a therapeutic benefit and stop the progression of macular degeneration.

132. The product was defective for its intended and reasonably foreseeable uses.

133. Privity of contract exists between Plaintiff Mallard and Defendant Kristin C. Comella.

134. Plaintiff Mallard justifiably relied on the Defendant Kristin C. Comella's representations about the product when agreeing to use the product to stop the progression of her macular degeneration.

135. The Defendant received notice of the breach of warranty when it discovered the condition of Plaintiff Mallard's eyes after receiving the product.

136. As a direct and proximate cause of the breach of implied warranty of merchantability alleged, Plaintiff Mallard sustained serious permanent damages as alleged in detail below.

COUNT XI

IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE CLAIM AGAINST DEFENDANT U.S. STEM CELL, INC.

137. The Plaintiff adopts and realleges paragraphs 1 through 41 and further alleges:

138. The product was defective because it was not reasonably fit for the specific purpose for which Defendant U.S. Stem Cell, Inc. knowingly sold the product and for which, in reliance on the judgment of Defendant U.S. Stem Cell, Inc. the Plaintiff Jeannine Mallard bought the product.

139. The Defendant knowingly manufactured and sold the product for the specific purpose of treating and stopping the progression macular degeneration.

140. Privity of contract exists between Plaintiff Jeannine Mallard and Defendant U.S. Stem Cell, Inc.

141. The product did not treat or stop the progression of macular degeneration, nor was it approved for any such use.

142. The Defendant received notice of the breach of warranty when it discovered the condition of Jeannine Mallard's eyes after receiving the product.

143. As a direct and proximate cause of the breach of implied warranty of fitness for a particular purpose alleged, Jeannine Mallard sustained serious permanent damages as alleged in detail below.

COUNT XII

IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE CLAIM AGAINST DEFENDANT US STEM CELL CLINIC LLC

144. The Plaintiff adopts and realleges paragraphs 1 through 41 and further alleges:

145. The product was defective because it was not reasonably fit for the specific purpose for which Defendant US Stem Cell Clinic LLC knowingly sold the product and for which, in reliance on the judgment of Defendant US Stem Cell Clinic LLC the Plaintiff Jeannine Mallard bought the product.

146. The Defendant knowingly manufactured and sold the product for the specific purpose of treating and stopping the progression macular degeneration.

147. Privity of contract exists between Plaintiff Jeannine Mallard and Defendant US Stem Cell Clinic LLC.

148. The product did not treat or stop the progression of macular degeneration, nor was it approved for any such use.

149. The Defendant received notice of the breach of warranty when it discovered the condition of Jeannine Mallard's eyes after receiving the product.

150. As a direct and proximate cause of the breach of implied warranty of fitness for a particular purpose alleged, Jeannine Mallard sustained serious permanent damages as alleged in detail below.

COUNT XIII

IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE CLAIM AGAINST DEFENDANT REGENESTEM, LLC

151. The Plaintiff adopts and realleges paragraphs 1 through 41 and further alleges:

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152. The product was defective because it was not reasonably fit for the specific purpose for which Defendant Regenestem, LLC. knowingly sold the product and for which, in reliance on the judgment of Defendant Regenestem, LLC the Plaintiff Jeannine Mallard bought the product.

153. The Defendant knowingly manufactured and sold the product for the specific purpose of treating and stopping the progression macular degeneration.

154. Privity of contract exists between Plaintiff Jeannine Mallard and Defendant Regenestem, LLC.

155. The product did not treat or stop the progression of macular degeneration, nor was it approved for any such use.

156. The Defendant received notice of the breach of warranty when it discovered the condition of Jeannine Mallard's eyes after receiving the product.

157. As a direct and proximate cause of the breach of implied warranty of fitness for a particular purpose alleged, Jeannine Mallard sustained serious permanent damages as alleged in detail below.

COUNT XIV

IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE CLAIM AGAINST DEFENDANT REGENESTEM NETWORK, LLC

158. The Plaintiff adopts and realleges paragraphs 1 through 41 and further alleges:

159. The product was defective because it was not reasonably fit for the specific purpose for which Defendant Regenestem Network, LLC knowingly sold the product and for which, in reliance on the judgment of Defendant Regenestem Network, LLC the Plaintiff Jeannine Mallard bought the product.

160. The Defendant knowingly manufactured and sold the product for the specific purpose of treating and stopping the progression macular degeneration.

161. Privity of contract exists between Plaintiff Jeannine Mallard and Defendant Regenestem Network, LLC.

162. The product did not treat or stop the progression of macular degeneration, nor was it approved for any such use.

163. The Defendant received notice of the breach of warranty when it discovered the condition of Jeannine Mallard's eyes after receiving the product.

164. As a direct and proximate cause of the breach of implied warranty of fitness for a particular purpose alleged, Jeannine Mallard sustained serious permanent damages as alleged in detail below.

COUNT XV

IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE CLAIM AGAINST DEFENDANT KRISTIN C. COMELLA

165. The Plaintiff adopts and realleges paragraphs 1 through 41 and further alleges:

166. The product was defective because it was not reasonably fit for the specific purpose for which Defendant Kristin C. Comella knowingly sold the product and for which, in reliance on the judgment of Defendant Kristin C. Comella the Plaintiff Jeannine Mallard bought the product.

167. The Defendant knowingly manufactured and sold the product for the specific purpose of treating and stopping the progression macular degeneration.

168. Privity of contract exists between Plaintiff Jeannine Mallard and Defendant Kristin C. Comella.

169. The product did not treat or stop the progression of macular degeneration, nor was it approved for any such use.

170. The Defendant received notice of the breach of warranty when it discovered the condition of Jeannine Mallard's eyes after receiving the product.

171. As a direct and proximate cause of the breach of implied warranty of fitness for a particular purpose alleged, Jeannine Mallard sustained serious permanent damages as alleged in detail below.

COUNT XVI
STRICT LIABILITY- MANUFACTURING DEFECT
AGAINST DEFENDANT U.S. STEM CELL, INC.

172. The Plaintiff adopts and realleges paragraphs 1 through 41 and further alleges:

173. Defendant U.S. Stem Cell, Inc. researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the product, and directly advertised or marketed the product to Jeannine Mallard, and therefore had a duty to create a product that was not defective.

174. The product created, designed, manufactured, distributed, sold, and/or supplied by Defendant U.S. Stem Cell, Inc. was defective because of a manufacturing defect.

175. The product reached Jeannine Mallard in a condition unreasonably dangerous to Jeannine Mallard.

176. The product reached Jeannine Mallard without substantial change affecting its condition.

177. The product was unreasonably dangerous because of a manufacturing defect because it was different from its intended design and failed to perform as safely as the intended design would have performed, since the intended design required extreme technical competence in manufacturing stem cells suited for the purpose of injection to treat or stop the acceleration of macular degeneration, and such technical skill was not used for the product at issue.

178. The Defendant's defective product directly and proximately caused Jeannine Mallard serious permanent damage, as alleged in detail below.

COUNT XVII
STRICT LIABILITY- MANUFACTURING DEFECT
AGAINST DEFENDANT US STEM CELL CLINIC LLC

179. The Plaintiff adopts and realleges paragraphs 1 through 41 and further alleges:

180. Defendant US Stem Cell Clinic LLC researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the product, and directly advertised or marketed the product to Jeannine Mallard, and therefore had a duty to create a product that was not defective.

181. The product created, designed, manufactured, distributed, sold, and/or supplied by Defendant US Stem Cell Clinic LLC was defective because of a manufacturing defect.

182. The product reached Jeannine Mallard in a condition unreasonably dangerous to Jeannine Mallard.

183. The product reached Jeannine Mallard without substantial change affecting its condition.

184. The product was unreasonably dangerous because of a manufacturing defect because it was different from its intended design and failed to perform as safely as the intended design would have performed, since the intended design required extreme technical competence in manufacturing stem cells suited for the purpose of injection to treat or stop the acceleration of macular degeneration, and such technical skill was not used for the product at issue.

185. The Defendant's defective product directly and proximately caused

Jeannine Mallard serious permanent damage, as alleged in detail below.

COUNT XVIII
STRICT LIABILITY- MANUFACTURING DEFECT
AGAINST DEFENDANT REGENESTEM, LLC

186. The Plaintiff adopts and realleges paragraphs 1 through 41 and further alleges:

187. Defendant Regenestem, LLC researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the product, and directly advertised or marketed the product to Jeannine Mallard, and therefore had a duty to create a product that was not defective.

188. The product created, designed, manufactured, distributed, sold, and/or supplied by Defendant Regenestem, LLC was defective because of a manufacturing defect.

189. The product reached Jeannine Mallard in a condition unreasonably dangerous to Jeannine Mallard.

190. The product reached Jeannine Mallard without substantial change affecting its condition.

191. The product was unreasonably dangerous because of a manufacturing defect because it was different from its intended design and failed to perform as safely as the intended design would have performed, since the intended design required extreme technical competence in manufacturing stem cells suited for the purpose of injection to treat or stop the acceleration of macular degeneration, and such technical skill was not used for the product at issue.

192. The Defendant's defective product directly and proximately caused Jeannine Mallard serious permanent damage, as alleged in detail below.

COUNT XIX
STRICT LIABILITY- MANUFACTURING DEFECT
AGAINST DEFENDANT REGENESTEM NETWORK, LLC

193. The Plaintiff adopts and realleges paragraphs 1 through 41 and further alleges:

194. Defendant Regenestem Network, LLC researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the product, and directly advertised or marketed the product to Jeannine Mallard, and therefore had a duty to create a product that was not defective.

195. The product created, designed, manufactured, distributed, sold, and/or supplied by Defendant Regenestem Network, LLC was defective because of a manufacturing defect.

196. The product reached Jeannine Mallard in a condition unreasonably dangerous to Jeannine Mallard.

197. The product reached Jeannine Mallard without substantial change affecting its condition.

198. The product was unreasonably dangerous because of a manufacturing defect because it was different from its intended design and failed to perform as safely as the intended design would have performed, since the intended design required extreme technical competence in manufacturing stem cells suited for the purpose of injection to treat or stop the acceleration of macular degeneration, and such technical skill was not used for the product at issue.

199. The Defendant's defective product directly and proximately caused Jeannine Mallard serious permanent damage, as alleged in detail below.

COUNT XX

STRICT LIABILITY- MANUFACTURING DEFECT AGAINST DEFENDANT KRISTIN C. COMELLA

200. The Plaintiff adopts and realleges paragraphs 1 through 41 and further alleges:

201. Defendant Kristin C. Comella researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the product, and directly advertised or marketed the product to Jeannine Mallard, and therefore had a duty to create a product that was not defective.

202. The product created, designed, manufactured, distributed, sold, and/or supplied by Defendant Kristin C. Comella was defective because of a manufacturing defect.

203. The product reached Jeannine Mallard in a condition unreasonably dangerous to Jeannine Mallard.

204. The product reached Jeannine Mallard without substantial change affecting its condition.

205. The product was unreasonably dangerous because of a manufacturing defect because it was different from its intended design and failed to perform as safely as the intended design would have performed, since the intended design required extreme technical competence in manufacturing stem cells suited for the purpose of injection to treat or stop the acceleration of macular degeneration, and such technical skill was not used for the product at issue.

206. The Defendant's defective product directly and proximately caused Jeannine Mallard serious permanent damage, as alleged in detail below.

COUNT XXI

STRICT LIABILITY- DESIGN DEFECT AGAINST DEFENDANT U.S. STEM CELL, INC.

207. The Plaintiff adopts and realleges paragraphs 1 through 41 and further alleges:

208. Defendant U.S. Stem Cell, Inc. researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the product, and directly advertised or marketed the product to Jeannine Mallard, and therefore had a duty to create a product that was not defective.

209. The product is defective because it was in a condition unreasonably dangerous to Jeannine Mallard when created, designed, manufactured, distributed, sold, and/or supplied by Defendant U.S. Stem Cell, Inc.

210. The product reached Jeannine Mallard without substantial change affecting that condition after creation, design, manufacture, distribution, sale, and/or supply by Defendant U.S. Stem Cell, Inc.

211. The product had a design defect because it failed to perform as safely as an ordinary consumer would expect when used as intended, causing permanent damage to Jeannine Mallard.

212. The product's risk of danger in the design outweighs the non-existent benefits of a therapy with no evidence of therapeutic value to a reasonable degree of scientific certainty.

213. Defendant US Stem Cell Clinic LLC, through its defective product, directly and proximately caused Jeannine Mallard serious permanent damage, as alleged in detail below.

COUNT XXII

STRICT LIABILITY- DESIGN DEFECT AGAINST DEFENDANT US STEM CELL CLINIC LLC

214. The Plaintiff adopts and realleges paragraphs 1 through 41 and further alleges:

215. Defendant US Stem Cell Clinic LLC researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the product, and directly advertised or marketed the product to Jeannine Mallard, and therefore had a duty to create a product that was not defective.

216. The product is defective because it was in a condition unreasonably dangerous to Jeannine Mallard when created, designed, manufactured, distributed, sold, and/or supplied by Defendant US Stem Cell Clinic LLC.

217. The product reached Jeannine Mallard without substantial change affecting that condition after creation, design, manufacture, distribution, sale, and/or supply by Defendant US Stem Cell Clinic LLC.

218. The product had a design defect because it failed to perform as safely as an ordinary consumer would expect when used as intended, causing permanent damage to Jeannine Mallard.

219. The product's risk of danger in the design outweighs the non-existent benefits of a therapy with no evidence of therapeutic value to a reasonable degree of scientific certainty.

220. Defendant US Stem Cell Clinic LLC, through its defective product, directly and proximately caused Jeannine Mallard serious permanent damage, as alleged in detail below.

COUNT XXIII

STRICT LIABILITY- DESIGN DEFECT AGAINST DEFENDANT REGENESTEM, LLC

221. The Plaintiff adopts and realleges paragraphs 1 through 41 and further alleges:

222. Defendant Regenestem, LLC researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the product, and directly advertised or marketed the product to Jeannine Mallard, and therefore had a duty to create a product that was not defective.

223. The product is defective because it was in a condition unreasonably dangerous to Jeannine Mallard when created, designed, manufactured, distributed, sold, and/or supplied by Defendant Regenestem, LLC.

224. The product reached Jeannine Mallard without substantial change affecting that condition after creation, design, manufacture, distribution, sale, and/or supply by Defendant Regenestem, LLC.

225. The product had a design defect because it failed to perform as safely as an ordinary consumer would expect when used as intended, causing permanent damage to Jeannine Mallard.

226. The product's risk of danger in the design outweighs the non-existent benefits of a therapy with no evidence of therapeutic value to a reasonable degree of scientific certainty.

227. Defendant U.S. Stem Cell, Inc., through its defective product, directly and proximately caused Jeannine Mallard serious permanent damage, as alleged in detail below.

COUNT XXIV

STRICT LIABILITY- DESIGN DEFECT AGAINST DEFENDANT REGENESTEM NETWORK, LLC

228. The Plaintiff adopts and realleges paragraphs 1 through 41 and further alleges:

229. Defendant Regenestem Network, LLC researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the product, and directly advertised or marketed the product to Jeannine Mallard, and therefore had a duty to create a product that was not defective.

230. The product is defective because it was in a condition unreasonably dangerous to Jeannine Mallard when created, designed, manufactured, distributed, sold, and/or supplied by Defendant Regenestem Network, LLC.

231. The product reached Jeannine Mallard without substantial change affecting that condition after creation, design, manufacture, distribution, sale, and/or supply by Defendant Regenestem Network, LLC.

232. The product had a design defect because it failed to perform as safely as an ordinary consumer would expect when used as intended, causing permanent damage to Jeannine Mallard.

233. The product's risk of danger in the design outweighs the non-existent benefits of a therapy with no evidence of therapeutic value to a reasonable degree of scientific certainty.

234. Defendant Regenestem Network, LLC, through its defective product, directly and proximately caused Jeannine Mallard serious permanent damage, as alleged in detail below.

COUNT XXV

STRICT LIABILITY- DESIGN DEFECT AGAINST DEFENDANT KRISTIN C. COMELLA

235. The Plaintiff adopts and realleges paragraphs 1 through 41 and further alleges:

236. Defendant Kristin C. Comella researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the product, and directly advertised or marketed the product to Jeannine Mallard, and therefore had a duty to create a product that was not defective.

237. The product is defective because it was in a condition unreasonably dangerous to Jeannine Mallard when created, designed, manufactured, distributed, sold, and/or supplied by Defendant Kristin C. Comella.

238. The product reached Jeannine Mallard without substantial change affecting that condition after creation, design, manufacture, distribution, sale, and/or supply by Defendant Kristin C. Comella.

239. The product had a design defect because it failed to perform as safely as an ordinary consumer would expect when used as intended, causing permanent damage to Jeannine Mallard.

240. The product's risk of danger in the design outweighs the non-existent benefits of a therapy with no evidence of therapeutic value to a reasonable degree of scientific certainty.

241. Defendant Kristin C. Comella, through its defective product, directly and proximately caused Jeannine Mallard serious permanent damage, as alleged in detail below.

COUNT XXVI

STRICT LIABILITY- FAILURE TO WARN AGAINST DEFENDANT U.S. STEM CELL, INC.

242. The Plaintiff adopts and realleges paragraphs 1 through 41 and further allege:

243. Defendant U.S. Stem Cell, Inc. researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the product, and directly advertised or marketed the product to Jeannine Mallard, and therefore had a duty to warn of the risks associated with the use of the product.

244. The product was under the control Defendant U.S. Stem Cell, Inc. and was unaccompanied by appropriate warnings regarding the risk of severe ocular injuries. No warnings accurately reflect the risk, incidence, symptoms, scope, or severity of such injuries to Jeannine Mallard.

245. Defendant U.S. Stem Cell, Inc. downplayed the serious and dangerous side effects of the product to encourage sale of the product.

246. The product was defective and unreasonably dangerous when it left the possession of Defendant U.S. Stem Cell, Inc. in that it contained warnings insufficient to alert Jeannine Mallard to the dangerous risks and reactions associated with it, including, but not limited to severe ocular injuries. The particular risks were known, or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution. Even though the Defendant knew or should have known of the risks and reactions associated with the product, Defendant U.S. Stem Cell, Inc. still failed to provide warnings that accurately reflected the signs, symptoms, incident, scope, or severity of the risks associated with the product.

247. The product reached Jeannine Mallard without substantial change affecting that condition after creation, design, manufacture, distribution, sale, and/or supply by Defendant U.S. Stem Cell, Inc.

248. The product was defective because the foreseeable risks of harm from the product could have been avoided by Defendant U.S. Stem Cell, Inc. by providing reasonable instructions or warnings about the high likelihood of adverse events such as blindness, pain, and damage to the eye via the compounded product and the failure to provide those instructions or warnings makes the product unreasonably dangerous.

249. Plaintiff Jeannine Mallard used the product in the manner as indicated by Defendant U.S. Stem Cell, Inc.

250. The Plaintiff did not have the same knowledge as Defendant U.S. Stem Cell, Inc. and no adequate warning was communicated to her.

251. As a direct and proximate consequence of Defendant U.S. Stem Cell, Inc.'s actions, omissions, and misrepresentations, plaintiff Jeannine Mallard suffered permanent damage, as described in detail below.

COUNT XXVII

STRICT LIABILITY- FAILURE TO WARN
AGAINST DEFENDANT US STEM CELL CLINIC LLC

252. The Plaintiff adopts and realleges paragraphs 1 through 41 and further allege:

253. Defendant US Stem Cell Clinic LLC, researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the product, and directly advertised or marketed the product to Jeannine Mallard, and therefore had a duty to warn of the risks associated with the use of the product.

254. The product was under the control Defendant US Stem Cell Clinic LLC and was unaccompanied by appropriate warnings regarding the risk of severe ocular injuries. No warnings accurately reflect the risk, incidence, symptoms, scope, or severity of such injuries to Jeannine Mallard.

255. Defendant US Stem Cell Clinic LLC downplayed the serious and dangerous side effects of the product to encourage sale of the product.

256. The product was defective and unreasonably dangerous when it left the possession of Defendant US Stem Cell Clinic LLC in that it contained warnings insufficient to alert Jeannine Mallard to the dangerous risks and reactions associated with it, including, but not limited to severe ocular injuries. The particular risks were known, or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution. Even though the Defendant knew or should have known of the risks and reactions associated with the product, Defendant US Stem Cell Clinic LLC still failed to provide warnings that accurately reflected the signs, symptoms, incident, scope, or severity of the risks associated with the product.

257. The product reached Jeannine Mallard without substantial change affecting that condition after creation, design, manufacture, distribution, sale, and/or supply by Defendant US Stem Cell Clinic LLC.

258. The product was defective because the foreseeable risks of harm from the product could have been avoided by Defendant US Stem Cell Clinic LLC by providing reasonable instructions or warnings about the high likelihood of adverse events such as blindness, pain, and damage to the eye via the compounded product and the failure to provide those instructions or warnings makes the product unreasonably dangerous.

259. Plaintiff Jeannine Mallard used the product in the manner as indicated by Defendant US Stem Cell Clinic LLC.

260. The Plaintiff did not have the same knowledge as Defendant US Stem Cell Clinic LLC and no adequate warning was communicated to her.

261. As a direct and proximate consequence of Defendant US Stem Cell Clinic LLC actions, omissions, and misrepresentations, plaintiff Jeannine Mallard suffered permanent damage, as described in detail below.

COUNT XXVIII

STRICT LIABILITY- FAILURE TO WARN AGAINST DEFENDANT REGENESTEM, LLC

262. The Plaintiff adopts and realleges paragraphs 1 through 41 and further allege:

263. Defendant Regenestem, LLC researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the product, and directly advertised or marketed the product to Jeannine Mallard, and therefore had a duty to warn of the risks associated with the use of the product.

264. The product was under the control Defendant Regenestem, LLC and was unaccompanied by appropriate warnings regarding the risk of severe ocular injuries. No warnings accurately reflect the risk, incidence, symptoms, scope, or severity of such injuries to Jeannine Mallard.

265. Defendant Regenestem, LLC downplayed the serious and dangerous side effects of the product to encourage sale of the product.

266. The product was defective and unreasonably dangerous when it left the possession of Defendant Regenestem, LLC in that it contained warnings insufficient to alert Jeannine Mallard to the dangerous risks and reactions

associated with it, including, but not limited to severe ocular injuries. The particular risks were known, or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution. Even though the Defendant knew or should have known of the risks and reactions associated with the product, Defendant Regenestem, LLC still failed to provide warnings that accurately reflected the signs, symptoms, incident, scope, or severity of the risks associated with the product.

267. The product reached Jeannine Mallard without substantial change affecting that condition after creation, design, manufacture, distribution, sale, and/or supply by Defendant Regenestem, LLC.

268. The product was defective because the foreseeable risks of harm from the product could have been avoided by Defendant Regenestem, LLC by providing reasonable instructions or warnings about the high likelihood of adverse events such as blindness, pain, and damage to the eye via the compounded product and the failure to provide those instructions or warnings makes the product unreasonably dangerous.

269. Plaintiff Jeannine Mallard used the product in the manner as indicated by Defendant Regenestem, LLC.

270. The Plaintiff did not have the same knowledge as Defendant Regenestem, LLC and no adequate warning was communicated to her.

271. As a direct and proximate consequence of Defendant Regenestem, LLC's actions, omissions, and misrepresentations, plaintiff Jeannine Mallard suffered permanent damage, as described in detail below.

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COUNT XXIX

STRICT LIABILITY- FAILURE TO WARN AGAINST DEFENDANT REGENESTEM NETWORK, LLC

272. The Plaintiff adopts and realleges paragraphs 1 through 41 and further allege:

273. Defendant Regenestem Network, LLC researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the product, and directly advertised or marketed the product to Jeannine Mallard, and therefore had a duty to warn of the risks associated with the use of the product.

274. The product was under the control Defendant Regenestem Network, LLC and was unaccompanied by appropriate warnings regarding the risk of severe ocular injuries. No warnings accurately reflect the risk, incidence, symptoms, scope, or severity of such injuries to Jeannine Mallard.

275. Defendant Regenestem Network, LLC downplayed the serious and dangerous side effects of the product to encourage sale of the product.

276. The product was defective and unreasonably dangerous when it left the possession of Defendant Regenestem Network, LLC in that it contained warnings insufficient to alert Jeannine Mallard to the dangerous risks and reactions associated with it, including, but not limited to severe ocular injuries. The particular risks were known, or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution. Even though the Defendant knew or should have known of the risks and reactions associated with the product, Defendant Regenestem Network, LLC still failed to provide warnings that accurately reflected the signs, symptoms, incident, scope, or severity of the risks associated with the

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product.

277. The product reached Jeannine Mallard without substantial change affecting that condition after creation, design, manufacture, distribution, sale, and/or supply by Defendant Regenestem Network, LLC.

278. The product was defective because the foreseeable risks of harm from the product could have been avoided by Defendant Regenestem Network, LLC by providing reasonable instructions or warnings about the high likelihood of adverse events such as blindness, pain, and damage to the eye via the compounded product and the failure to provide those instructions or warnings makes the product unreasonably dangerous.

279. Plaintiff Jeannine Mallard used the product in the manner as indicated by Defendant Regenestem Network, LLC.

280. The Plaintiff did not have the same knowledge as Defendant Regenestem Network, LLC and no adequate warning was communicated to her.

281. As a direct and proximate consequence of Defendant Regenestem Network, LLC's actions, omissions, and misrepresentations, plaintiff Jeannine Mallard suffered permanent damage, as described in detail below.

COUNT XXX

STRICT LIABILITY- FAILURE TO WARN AGAINST DEFENDANT KRISTIN C. COMELLA

282. The Plaintiff adopts and realleges paragraphs 1 through 41 and further allege:

283. Defendant Kristin C. Comella researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the product, and directly advertised or marketed the product to Jeannine Mallard, and therefore had a duty

to warn of the risks associated with the use of the product.

284. The product was under the control Defendant Kristin C. Comella and was unaccompanied by appropriate warnings regarding the risk of severe ocular injuries. No warnings accurately reflect the risk, incidence, symptoms, scope, or severity of such injuries to Jeannine Mallard.

285. Defendant Kristin C. Comella downplayed the serious and dangerous side effects of the product to encourage sale of the product.

286. The product was defective and unreasonably dangerous when it left the possession of Defendant Kristin C. Comella in that it contained warnings insufficient to alert Jeannine Mallard to the dangerous risks and reactions associated with it, including, but not limited to severe ocular injuries. The particular risks were known, or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution. Even though the Defendant knew or should have known of the risks and reactions associated with the product, Defendant Kristin C. Comella still failed to provide warnings that accurately reflected the signs, symptoms, incident, scope, or severity of the risks associated with the product.

287. The product reached Jeannine Mallard without substantial change affecting that condition after creation, design, manufacture, distribution, sale, and/or supply by Defendant Kristin C. Comella.

288. The product was defective because the foreseeable risks of harm from the product could have been avoided by Defendant Kristin C. Comella by providing reasonable instructions or warnings about the high likelihood of adverse events such as blindness, pain, and damage to the eye via the compounded product and the failure to provide those instructions or warnings makes the product

unreasonably dangerous.

289. Plaintiff Jeannine Mallard used the product in the manner as indicated by Defendant Kristin C. Comella.

290. The Plaintiff did not have the same knowledge as Defendant Kristin C. Comella and no adequate warning was communicated to her.

291. As a direct and proximate consequence of Defendant Kristin C. Comella's actions, omissions, and misrepresentations, plaintiff Jeannine Mallard suffered permanent damage, as described in detail below.

COUNT XXXI

NEGLIGENCE- PRODUCT LIABILITY
AGAINST DEFENDANT U.S. STEM CELL, INC.

292. The Plaintiff adopts and realleges paragraphs 1 through 41 and further allege:

293. Defendant U.S. Stem Cell, Inc. researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the product, and directly advertised or marketed the product to Jeannine Mallard, and therefore had a duty of reasonable care to Jeannine Mallard, which is the care that a reasonably careful designer, manufacturer, seller, importer, distributor, and or/ supplier would use under like circumstances.

294. Notwithstanding this duty of care, Defendant U.S. Stem Cell, Inc. breached its duty of care to Jeannine Mallard in the following ways:

a. Negligently failing to manufacture the product with the highly skilled personnel necessary to make therapeutic stem cells;

b. Negligently failing to design the product with the highly skilled personnel necessary to make therapeutic stem cells;

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c. Negligently allowing Jeannine Mallard access to the product when she did not meet the criteria for receiving the product;

d. Negligently failing to warn Jeannine Mallard of the serious and dangerous side effects of the product to encourage sales of the product;

e. Negligently failing to warn Jeannine Mallard of the risk, incidence, symptoms, scope, or severity of the injuries produced by the product to Jeannine Mallard.

f. Negligently failing to provide reasonable instructions and warnings about the high likelihood of adverse events such as blindness, pain, and eye damage to Jeannine Mallard;

g. Other negligent failures as determined in discovery.

295. As a direct and proximate consequence of Defendant U.S. Stem Cell, Inc.'s actions, omissions, and misrepresentations, plaintiff Jeannine Mallard suffered permanent damage, as described in detail below.

COUNT XXXII

NEGLIGENCE- PRODUCT LIABILITY
AGAINST DEFENDANT US STEM CELL CLINIC LLC

296. The Plaintiff adopts and realleges paragraphs 1 through 41 and further allege:

297. Defendant US Stem Cell Clinic LLC researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the product, and directly advertised or marketed the product to Jeannine Mallard, and therefore had a duty of reasonable care to Jeannine Mallard, which is the care that a reasonably careful designer, manufacturer, seller, importer, distributor, and or/ supplier would use under like circumstances.

298. Notwithstanding this duty of care, Defendant US Stem Cell Clinic LLC, Inc. breached its duty of care to Jeannine Mallard in the following ways:

a. Negligently failing to manufacture the product with the highly skilled personnel necessary to make therapeutic stem cells;

b. Negligently failing to design the product with the highly skilled personnel necessary to make therapeutic stem cells;

c. Negligently allowing Jeannine Mallard access to the product when she did not meet the criteria for receiving the product;

d. Negligently failing to warn Jeannine Mallard of the serious and dangerous side effects of the product to encourage sales of the product;

e. Negligently failing to warn Jeannine Mallard of the risk, incidence, symptoms, scope, or severity of the injuries produced by the product to Jeannine Mallard.

f. Negligently failing to provide reasonable instructions and warnings about the high likelihood of adverse events such as blindness, pain, and eye damage to Jeannine Mallard;

g. Other negligent failures as determined in discovery.

299. As a direct and proximate consequence of Defendant US Stem Cell Clinic LLC's actions, omissions, and misrepresentations, plaintiff Jeannine Mallard suffered permanent damage, as described in detail below.

COUNT XXXIII

NEGLIGENCE- PRODUCT LIABILITY
AGAINST DEFENDANT REGENESTEM, LLC

300. The Plaintiff adopts and realleges paragraphs 1 through 41 and further allege:

301. Defendant Regenestem, LLC researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the product, and directly advertised or marketed the product to Jeannine Mallard, and therefore had a duty of reasonable care to Jeannine Mallard, which is the care that a reasonably careful designer, manufacturer, seller, importer, distributor, and or/ supplier would use

under like circumstances.

302. Notwithstanding this duty of care, Defendant Regenestem, LLC breached its duty of care to Jeannine Mallard in the following ways:

a. Negligently failing to manufacture the product with the highly skilled personnel necessary to make therapeutic stem cells;

b. Negligently failing to design the product with the highly skilled personnel necessary to make therapeutic stem cells;

c. Negligently allowing Jeannine Mallard access to the product when she did not meet the criteria for receiving the product;

d. Negligently failing to warn Jeannine Mallard of the serious and dangerous side effects of the product to encourage sales of the product;

e. Negligently failing to warn Jeannine Mallard of the risk, incidence, symptoms, scope, or severity of the injuries produced by the product to Jeannine Mallard.

f. Negligently failing to provide reasonable instructions and warnings about the high likelihood of adverse events such as blindness, pain, and eye damage to Jeannine Mallard;

g. Other negligent failures as determined in discovery.

303. As a direct and proximate consequence of Defendant Regenestem, LLC's actions, omissions, and misrepresentations, plaintiff Jeannine Mallard suffered permanent damage, as described in detail below.

COUNT XXXIV

NEGLIGENCE- PRODUCT LIABILITY
AGAINST DEFENDANT REGENESTEM NETWORK, LLC

304. The Plaintiff adopts and realleges paragraphs 1 through 41 and further allege:

305. Defendant Regenestem Network, LLC researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the

product, and directly advertised or marketed the product to Jeannine Mallard, and therefore had a duty of reasonable care to Jeannine Mallard, which is the care that a reasonably careful designer, manufacturer, seller, importer, distributor, and or/ supplier would use under like circumstances.

306. Notwithstanding this duty of care, Defendant Regenestem Network, LLC breached its duty of care to Jeannine Mallard in the following ways:

a. Negligently failing to manufacture the product with the highly skilled personnel necessary to make therapeutic stem cells;

b. Negligently failing to design the product with the highly skilled personnel necessary to make therapeutic stem cells;

c. Negligently allowing Jeannine Mallard access to the product when she did not meet the criteria for receiving the product;

d. Negligently failing to warn Jeannine Mallard of the serious and dangerous side effects of the product to encourage sales of the product;

e. Negligently failing to warn Jeannine Mallard of the risk, incidence, symptoms, scope, or severity of the injuries produced by the product to Jeannine Mallard.

f. Negligently failing to provide reasonable instructions and warnings about the high likelihood of adverse events such as blindness, pain, and eye damage to Jeannine Mallard;

g. Other negligent failures as determined in discovery.

307. As a direct and proximate consequence of Defendant Regenestem Network, LLC's actions, omissions, and misrepresentations, plaintiff Jeannine Mallard suffered permanent damage, as described in detail below.

COUNT XXXV

NEGLIGENCE- PRODUCT LIABILITY
AGAINST DEFENDANT KRISTIN C. COMELLA

308. The Plaintiff adopts and realleges paragraphs 1 through 41 and further allege:

309. Defendant Kristin C. Comella researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the product, and directly advertised or marketed the product to Jeannine Mallard, and therefore had a duty of reasonable care to Jeannine Mallard, which is the care that a reasonably careful designer, manufacturer, seller, importer, distributor, and or/ supplier would use under like circumstances.

310. Notwithstanding this duty of care, Defendant Kristin C. Comella breached its duty of care to Jeannine Mallard in the following ways:

a. Negligently failing to manufacture the product with the highly skilled personnel necessary to make therapeutic stem cells;

b. Negligently failing to design the product with the highly skilled personnel necessary to make therapeutic stem cells;

c. Negligently allowing Jeannine Mallard access to the product when she did not meet the criteria for receiving the product;

d. Negligently failing to warn Jeannine Mallard of the serious and dangerous side effects of the product to encourage sales of the product;

e. Negligently failing to warn Jeannine Mallard of the risk, incidence, symptoms, scope, or severity of the injuries produced by the product to Jeannine Mallard.

f. Negligently failing to provide reasonable instructions and warnings about the high likelihood of adverse events such as blindness, pain, and eye damage to Jeannine Mallard; and

g. Other negligent failures as determined in discovery.

311. As a direct and proximate consequence of Defendant Kristin C. Comella's actions, omissions, and misrepresentations, plaintiff Jeannine Mallard suffered permanent damage, as described in detail below.

COUNT XXXVI

NEGLIGENCE
AGAINST DEFENDANT KRISTIN C. COMELLA

312. The Plaintiff adopts and realleges paragraphs 1 through 41 and further allege:

313. Defendant Kristin C. Comella is not a medical doctor and yet actively participated in or directed a medical procedure performed on Jeannine Mallard, and therefore had a duty of reasonable care to Jeannine Mallard, which is the care that a reasonably careful person would use under like circumstances.

314. Notwithstanding this duty of care, Defendant Kristin C. Comella breached her duty of care to Jeannine Mallard by participating in and performing a procedure that she was not qualified nor trained to perform.

315. As a direct and proximate consequence of Defendant Kristin C. Comella's negligence, plaintiff Jeannine Mallard suffered permanent damage, as described in detail below.

COUNT XXXVII

NEGLIGENT MISREPRESENTATION
AGAINST DEFENDANT KRISTIN C. COMELLA

316. The Plaintiff adopts and realleges paragraphs 1 through 41 and further allege:

317. Defendant Kristin C. Comella, who is not a medical doctor, negligently represented to Jeannine Mallard that she was a candidate to undergo a "clinical trial" that would be beneficial to her medical condition.

318. At the time Defendant Comella made these statements to Ms. Mallard, Defendant Comella knew or should have known that these statements

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were misleading. The "stem cell" clinical trial was not being operated as appropriately as a "clinical trial," and the "stem cell" therapy offered would not benefit Ms. Mallard and would likely, in fact, cause her medical condition to worsen.

319. Ms. Mallard relied upon the negligent representations of Ms. Comella in agreeing to undergo stem cell therapy treatment, and did pay for and undergo that treatment.

320. As a result of Ms. Comella's negligent representations, Ms. Mallard expended monies to undergo an unhelpful and injurious procedure and suffered a permanent physical injury. Accordingly, Plaintiff Jeannine Mallard claims the damages set forth below.

DAMAGES CLAIMED BY JEANNINE MALLARD

321. The Plaintiff Jeannine Mallard, as a direct and proximate result of the Defendants alleged above, has in the past and will in the future continue to suffer the following damages:

a. Bodily injury;

b. Pain and suffering;

c. Disability;

d. Disfigurement;

e. Loss of the capacity for the enjoyment of life;

f. Aggravation of pre-existing conditions;

g. Medical and hospital care and expenses;

h. Loss of earnings;

i. Loss of earning capacity in the future;

j. Rehabilitation expenses; and

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k. Mental distress;

WHEREFORE, Plaintiff Jeannine Mallard demands judgment against Defendants for damages in an amount in excess of the jurisdictional limits of this Court exclusive of interest and costs, and all such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

322. The Plaintiff demands trial by jury of all issues triable as of right.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that the foregoing document was electronically filed with the Clerk of Court on this 12th day of December, 2017 and electronically served on all counsel on the attached Service List.

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