Case Number: CACE-15-021101 Division: 04

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

ELIZABETH NOBLE,

Plaintiff,

CIRCUIT CIVIL DIVISION

CASE NO.:

V.

U.S. STEM CELL, INC. f/k/a BIOHEART, INC.; US STEM CELL CLINIC, LLC; ALEJANDRO PEREZ, ARNP; SHAREEN GREENBAUM, M.D.

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COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL

The Plaintiff Elizabeth Noble sues the Defendants U.S. Stem Cell, Inc.;
US Stem Cell Clinic, LLC; Alejandro Perez, ARNP; and Shareen Greenbaum,
M.D., and alleges as follows:

JURISDICTIONAL STATEMENT AND IDENTIFICATION OF THE PARTIES

- This is an action for damages in excess of this Court's minimum jurisdictional limits, exclusive of interest and costs.
 - Plaintiff Elizabeth Noble resides in Kansas City, Missouri.
- Defendant U.S. Stem Cell, Inc. f/k/a Bioheart, Inc. is a Florida for-profit corporation with a principal place of address of 13794 NW 4th St 212 Sunrise, FL 33325.
- Defendant US Stem Cell Clinic, LLC is a Florida Limited Liability Company with a principal place of address of 12651 W. Sunrise Blvd. Suite 104 Sunrise, FL 33323.

Law Offices Grossman Roth, PC4
2525 Ponce de tren Boulevind, Suiter 1430, Coral Gables, Flories 33134 1, 305, 442,8668 1, 305, 283, 1668

- Defendant Alejandro Perez, ARNP is an advanced nurse practitioner who resides in Miami FL.
- Defendant Shareen Greenbaum, M.D. is a medical doctor who practices medicine in Hollywood, Florida and Sunrise Florida, and resides in Florida.

FACTS GIVING RISE TO THE ACTIONS

- The Defendants were in privity with Elizabeth Noble.
- 8. 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.
- The Defendants claim they processed this tissue to isolate stem cells.
- The Defendants intended this product be delivered via needle injection into Elizabeth Noble's eyes.
- 11. The Defendants claimed the product, when used through injection into the eyes, would stop the progression of macular degeneration, and created, designed, manufactured, distributed, sold, and supplied the product for that purpose.
- 12. 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 Elizabeth Noble, and was manufactured, designed, and marketed in a negligent manner by the Defendants.

- The product was injected into Elizabeth Noble's eyes as directed on or about June 16, 2015 in Florida.
- As a direct and proximate cause of the product, Elizabeth Noble suffered permanent damage, as alleged in more detail below.

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

- 15. The Plaintiff adopts and realleges paragraphs 1 through 14 and further alleges:
- 16. 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 Elizabeth Noble relied in the use of the product.
- 17. Defendant U.S. Stem Cell, Inc. represented the fact that the product was capable of treating and stopping the progression of macular degeneration.
- Despite this representation of fact, no scientific evidence shows that the product provides any benefit for macular degeneration.
- No peer-reviewed literature shows the product provides any benefit for macular degeneration.

- 20. The prevailing opinion in the scientific community is that the product cannot provide a benefit for macular degeneration.
- 21. 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.
- 22. Defendant U.S. Stem Cell, Inc. 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.
- The Defendant received notice of the breach of warranty when it discovered the condition of Elizabeth Noble's eyes after receiving the product.
- 24. As a direct and proximate cause of the breach of express warranty alleged, Elizabeth Noble sustained serious permanent damages as alleged in detail below.

COUNT II EXPRESS WARRANTY CLAIM AGAINST DEFENDANT US STEM CELL CLINIC, LLC

- 25. The Plaintiff adopts and realleges paragraphs 1 through 14 and further alleges:
- 26. 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 Elizabeth Noble relied in the use of the product.

- 27. Defendant US Stem Cell Clinic, LLC represented the fact that the product was capable of treating and stopping the progression of macular degeneration.
- Despite this representation of fact, no scientific evidence shows that the product provides any benefit for macular degeneration.
- No peer-reviewed literature shows the product provides any benefit for macular degeneration.
- 30. The prevailing opinion in the scientific community is that the product cannot provide a benefit for macular degeneration.
- 31. 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 US Stem Cell Clinic, LLC.
- 32. 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.
- 33. The Defendant received notice of the breach of warranty when it discovered the condition of Elizabeth Noble's eyes after receiving the product.
 - 34. As a direct and proximate cause of the breach of express warranty

alleged, Elizabeth Noble sustained serious permanent damages as alleged in detail below.

COUNT III EXPRESS WARRANTY CLAIM AGAINST DEFENDANT ALEJANDRO PEREZ, ARNP

- 35. The Plaintiff adopts and realleges paragraphs 1 through 14 and further alleges:
- 36. The product developed, designed, tested, manufactured, inspected, distributed, marketed, promoted, sold, supplied, and otherwise released into the stream of commerce by Defendant Alejandro Perez, ARNP was defective because it did not conform to representations of fact made by Defendant Alejandro Perez, ARNP, orally and in writing, in connection with the transaction on which Elizabeth Noble relied in the use of the product.
- 37. Defendant Alejandro Perez, ARNP represented the fact that the product was capable of treating and stopping the progression of macular degeneration.
- Despite this representation of fact, no scientific evidence shows that the product provides any benefit for macular degeneration.
- No peer-reviewed literature shows the product provides any benefit for macular degeneration.
- 40. The prevailing opinion in the scientific community is that the product cannot provide a benefit for macular degeneration.
- 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 Alejandro Perez, ARNP, and expertise not possessed by Defendant Alejandro Perez, ARNP.

- 42. The product was not capable of treating or stopping the progression of macular degeneration.
- 43. The Defendant received notice of the breach of warranty when it discovered the condition of Elizabeth Noble's eyes after receiving the product.
- 44. As a direct and proximate cause of the breach of express warranty alleged, Elizabeth Noble sustained serious permanent damages as alleged in detail below.

COUNT IV EXPRESS WARRANTY CLAIM AGAINST DEFENDANT SHAREEN GREENBAUM, M.D.

- 45. The Plaintiff adopts and realleges paragraphs 1 through 14 and further alleges:
- 46. The product developed, designed, tested, manufactured, inspected, distributed, marketed, promoted, sold, supplied, and otherwise released into the stream of commerce by Defendant Shareen Greenbaum, M.D. was defective because it did not conform to representations of fact made by Shareen Greenbaum, M.D., orally and in writing, in connection with the transaction on which Elizabeth Noble relied in the use of the product.
- 47. Defendant Shareen Greenbaum, M.D. represented the fact that the product was capable of treating and stopping the progression of macular degeneration.

- 48. Despite this representation of fact, no scientific evidence shows that the product provides any benefit for macular degeneration.
- No peer-reviewed literature shows the product provides any benefit for macular degeneration.
- 50. The prevailing opinion in the scientific community is that the product cannot provide a benefit for macular degeneration.
- 51. 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 Shareen Greenbaum, M.D., and an expertise not possessed by Shareen Greenbaum, M.D.
- 52. The product was not capable of treating or stopping the progression of macular degeneration.
- 53. The Defendant received notice of the breach of warranty when it discovered the condition of Elizabeth Noble's eyes after receiving the product.
- 54. As a direct and proximate cause of the breach of express warranty alleged, Elizabeth Noble sustained serious permanent damages as alleged in detail below.

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

- 55. The Plaintiff adopts and realleges paragraphs 1 through 14 and further alleges:
 - 56. 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.

- The product is not fit for use as a product for any purpose.
- 58. 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.
- 59. The product was defective for its intended and reasonably foreseeable uses.
- 60. Privity of contract exists between Plaintiff Elizabeth Noble and Defendant U.S. Stem Cell, Inc.
- 61. Elizabeth Noble 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.
- 62. The Defendant received notice of the breach of warranty when it discovered the condition of Elizabeth Noble's eyes after receiving the product.
- 63. As a direct and proximate cause of the breach of implied warranty of merchantability alleged, Elizabeth Noble sustained serious permanent damages as alleged in detail below.

COUNT VI IMPLIED WARRANTY OF MERCHANTABILITY CLAIM AGAINST US STEM CELL CLINIC, LLC

- 64. The Plaintiff adopts and realleges paragraphs 1 through 14 and further alleges:
 - 65. 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.

- 66. The product is not fit for use as a product for any purpose.
- 67. 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.
- 68. The product was defective for its intended and reasonably foreseeable uses.
- Privity of contract exists between Plaintiff Elizabeth Noble and Defendant US Stem Cell Clinic, LLC.
- 70. Elizabeth Noble 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.
- 71. The Defendant received notice of the breach of warranty when it discovered the condition of Elizabeth Noble's eyes after receiving the product.
- 72. As a direct and proximate cause of the breach of implied warranty of merchantability alleged, Elizabeth Noble sustained serious permanent damages as alleged in detail below.

COUNT VII IMPLIED WARRANTY OF MERCHANTABILITY CLAIM AGAINST ALEJANDRO PEREZ, ARNP

- 73. The Plaintiff adopts and realleges paragraphs 1 through 14 and further alleges:
 - 74. The product was defective because it was not reasonably fit for

both the uses intended and the uses reasonably foreseeable by Defendant Alejandro Perez, ARNP.

- The product is not fit for use as a product for any purpose.
- 76. The product is not fit for the use intended by Defendant Alejandro Perez, ARNP, namely to give a therapeutic benefit and stop the progression of macular degeneration.
- The product was defective for its intended and reasonably foreseeable uses.
- Privity of contract exists between Plaintiff Elizabeth Noble and Defendant Alejandro Perez, ARNP.
- 79. Elizabeth Noble justifiably relied on the Defendant Alejandro Perez, ARNP representations about the product when agreeing to use the product to stop the progression of her macular degeneration.
- 80. The Defendant received notice of the breach of warranty when it discovered the condition of Elizabeth Noble's eyes after receiving the product.
- 81. As a direct and proximate cause of the breach of implied warranty of merchantability alleged, Elizabeth Noble sustained serious permanent damages as alleged in detail below.

COUNT VIII IMPLIED WARRANTY OF MERCHANTABILITY CLAIM AGAINST DEFENDANT SHAREEN GREENBAUM, M.D.

- 82. The Plaintiff adopts and realleges paragraphs 1 through 14 and further alleges:
 - 83. The product was defective because it was not reasonably fit for

both the uses intended and the uses reasonably foreseeable by Defendant Shareen Greenbaum, M.D.

- 84. The product is not fit for use as a product for any purpose.
- 85. The product is not fit for the use intended by Defendant Shareen Greenbaum, M.D., namely to give a therapeutic benefit and stop the progression of macular degeneration.
- 86. The product was defective for its intended and reasonably foreseeable uses.
- 87. Privity of contract exists between Plaintiff Elizabeth Noble and Defendant Shareen Greenbaum, M.D.
- 88. Elizabeth Noble justifiably relied on the Defendant Shareen Greenbaum, M.D. representations about the product when agreeing to use the product to stop the progression of her macular degeneration.
- 89. The Defendant received notice of the breach of warranty when it discovered the condition of Elizabeth Noble's eyes after receiving the product.
- 90. As a direct and proximate cause of the breach of implied warranty
 of merchantability alleged, Elizabeth Noble sustained serious permanent
 damages as alleged in detail below.

COUNT XIX

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

- 91. The Plaintiff adopts and realleges paragraphs 1 through 14 and further alleges:
 - 92. 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 Elizabeth Noble bought the product.

- 93. The Defendant knowingly manufactured and sold the product for the specific purpose of treating and stopping the progression macular degeneration.
- Privity of contract exists between Plaintiff Elizabeth Noble and Defendant U.S. Stem Cell, Inc.
- 95. The product did not treat or stop the progression of macular degeneration, nor was it approved for any such use.
- 96. The Defendant received notice of the breach of warranty when it discovered the condition of Elizabeth Noble's eyes after receiving the product.
- 97. As a direct and proximate cause of the breach of implied warranty of fitness for a particular purpose alleged, Elizabeth Noble sustained serious permanent damages as alleged in detail below.

COUNT X IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE CLAIM AGAINST US STEM CELL CLINIC, LLC

- 98. The Plaintiff adopts and realleges paragraphs 1 through 14 and further alleges:
- 99. The product was defective because it was not reasonably fit for the specific purpose for which Defendant US Stem Cells Clinic, LLC knowingly sold the product and for which, in reliance on the judgment of Defendant US Stem Cells Clinic, LLC the Plaintiff Elizabeth Noble bought the product.

- 100. The Defendant knowingly manufactured and sold the product for the specific purpose of treating and stopping the progression macular degeneration.
- 101. Privity of contract exists between Plaintiff Elizabeth Noble and Defendant US Stem Cells Clinic, LLC.
- 102. The product did not treat or stop the progression of macular degeneration, nor was it approved for any such use.
- 103. The Defendant received notice of the breach of warranty when it discovered the condition of Elizabeth Noble's eyes after receiving the product.
- 104. As a direct and proximate cause of the breach of implied warranty of fitness for a particular purpose alleged, Elizabeth Noble sustained serious permanent damages as alleged in detail below.

COUNT XI IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE CLAIM AGAINST ALEJANDRO PEREZ, ARNP

- 105. The Plaintiff adopts and realleges paragraphs 1 through 14 and further alleges:
- 106. The product was defective because it was not reasonably fit for the specific purpose for which Defendant Alejandro Perez, ARNP knowingly sold the product and for which, in reliance on the judgment of Defendant Alejandro Perez, ARNP the Plaintiff Elizabeth Noble bought the product.
- 107. The Defendant knowingly manufactured and sold the product for the specific purpose of treating and stopping the progression macular degeneration.

- 108. Privity of contract exists between Plaintiff Elizabeth Noble and Defendant Alejandro Perez, ARNP.
- 109. The product did not treat or stop the progression of macular degeneration, nor was it approved for any such use.
- 110. The Defendant received notice of the breach of warranty when it discovered the condition of Elizabeth Noble's eyes after receiving the product.
- 111. As a direct and proximate cause of the breach of implied warranty of fitness for a particular purpose alleged, Elizabeth Noble sustained serious permanent damages as alleged in detail below.

COUNT XII

IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE CLAIM AGAINST DEFENDANT SHAREEN GREENBAUM, M.D.

- 112. The Plaintiff adopts and realleges paragraphs 1 through 14 and further alleges:
- 113. The product was defective because it was not reasonably fit for the specific purpose for which Defendant Shareen Greenbaum, M.D. knowingly sold the product and for which, in reliance on the judgment of Defendant Shareen Greenbaum, M.D. Plaintiff Elizabeth Noble bought the product.
- 114. The Defendant knowingly manufactured and sold the product for the specific purpose of treating and stopping the progression macular degeneration.
- 115. Privity of contract exists between Plaintiff Elizabeth Noble and Defendant Shareen Greenbaum, M.D.
 - 116. The product did not treat or stop the progression of macular

degeneration, nor was it approved for any such use.

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

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

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

119. The Plaintiff adopts and realleges paragraphs 1 through 14 and further alleges:

120. 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 Elizabeth Noble, and therefore had a duty to create a product that was not defective.

- 121. The product created, designed, manufactured, distributed, sold, and/or supplied by Defendant U.S. Stem Cell, Inc. was defective because of a manufacturing defect.
- 122. The product reached Elizabeth Noble in a condition unreasonably dangerous to Elizabeth Noble.
- 123. The product reached Elizabeth Noble without substantial change affecting its condition.
 - 124. 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.

125. The Defendant's defective product directly and proximately caused Elizabeth Noble serious permanent damage, as alleged in detail below.

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

- 126. The Plaintiff adopts and realleges paragraphs 1 through 14 and further alleges:
- 127. 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 Elizabeth Noble, and therefore had a duty to create a product that was not defective.
- 128. The product created, designed, manufactured, distributed, sold, and/or supplied by Defendant US Stem Cell Clinic, LLC was defective because of a manufacturing defect.
- 129. The product reached Elizabeth Noble in a condition unreasonably dangerous to Elizabeth Noble.
 - 130. The product reached Elizabeth Noble without substantial change

affecting its condition.

131. 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.

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

Elizabeth Noble serious permanent damage, as alleged in detail below.

COUNT XV
STRICT LIABILITY- MANUFACTURING DEFECT
AGAINST DEFENDANT ALEJANDRO PEREZ, ARNP

133. The Plaintiff adopts and realleges paragraphs 1 through 14 and

further alleges:

134. Defendant Alejandro Perez, ARNP 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 Elizabeth Noble, and therefore

had a duty to create a product that was not defective.

The product created, designed, manufactured, distributed, sold,

and/or supplied by Defendant Alejandro Perez, ARNP, was defective because of

a manufacturing defect.

136. The product reached Elizabeth Noble in a condition unreasonably

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dangerous to Elizabeth Noble.

137. The product reached Elizabeth Noble without substantial change

affecting its condition.

138. 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.

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

Elizabeth Noble serious permanent damage, as alleged in detail below.

COUNT XVI STRICT LIABILITY- MANUFACTURING DEFECT

AGAINST DEFENDANT SHAREEN GREENBAUM, M.D.

140. The Plaintiff adopts and realleges paragraphs 1 through 14 and

further alleges:

141. Defendant Shareen Greenbaum, M.D. 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 Elizabeth Noble,

and therefore had a duty to create a product that was not defective.

142. The product created, designed, manufactured, distributed, sold,

and/or supplied by Defendant Shareen Greenbaum, M.D., was defective

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because of a manufacturing defect.

143. The product reached Elizabeth Noble in a condition unreasonably dangerous to Elizabeth Noble.

144. The product reached Elizabeth Noble without substantial change affecting its condition.

manufacturing defect if it was different from its intended design and failed to

145. The product was unreasonably dangerous because of a

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.

The Defendant's defective product directly and proximately caused

Elizabeth Noble serious permanent damage, as alleged in detail below.

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

147. The Plaintiff adopts and realleges paragraphs 1 through 14 and

further alleges:

148. 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 Elizabeth Noble, and therefore

had a duty to create a product that was not defective.

- 149. The product is defective because it was in a condition unreasonably dangerous to Elizabeth Noble when created, designed, manufactured, distributed, sold, and/or supplied by Defendant U.S. Stem Cell, Inc.
- 150. The product reached Elizabeth Noble without substantial change affecting that condition after creation, design, manufacture, distribution, sale, and/or supply by Defendant U.S. Stem Cell, Inc.
- 151. 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 Elizabeth Noble.
- 152. The product's risk of danger in the design outweighs the nonexistent benefits of a therapy with no evidence of therapeutic value to a reasonable degree of scientific certainty.
- 153. Defendant U.S. Stem Cell, Inc., through its defective product, directly and proximately caused Elizabeth Noble serious permanent damage, as alleged in detail below.

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

- 154. The Plaintiff adopts and realleges paragraphs 1 through 14 and further alleges:
- 155. 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 Elizabeth Noble, and therefore had a duty to create a product that was not defective.

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

- 157. The product reached Elizabeth Noble without substantial change affecting that condition after creation, design, manufacture, distribution, sale, and/or supply by Defendant US Stem Cell Clinic, LLC.
- 158. The product failed to perform as safely as an ordinary consumer would expect when used as intended, causing damage to Elizabeth Noble.
- 159. The product's risk of danger in the design outweighs the nonexistent benefits of a therapy with no evidence of therapeutic value to a reasonable degree of scientific certainty.
- 160. Defendant US Stem Cell Clinic, LLC, through its defective product, directly and proximately caused Elizabeth Noble serious permanent damage, as alleged in detail below.

COUNT XIX STRICT LIABILITY- DESIGN DEFECT AGAINST DEFENDANT ALEJANDRO PEREZ, ARNP

- 161. The Plaintiff adopts and realleges paragraphs 1 through 14 and further alleges:
- 162. Defendant Alejandro Perez, ARNP 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 Elizabeth Noble, and therefore had a duty to create a product that was not defective.

- 163. The product is defective because it was in a condition unreasonably dangerous to Elizabeth Noble when created, designed, manufactured, distributed, sold, and/or supplied by Defendant Alejandro Perez, ARNP.
- 164. The product reached Elizabeth Noble without substantial change affecting that condition after creation, design, manufacture, distribution, sale, and/or supply by Defendant Alejandro Perez, ARNP.
- 165. The product failed to perform as safely as an ordinary consumer would expect when used as intended, causing damage to Elizabeth Noble.
- 166. The product's risk of danger in the design outweighs the nonexistent benefits of a therapy with no evidence of therapeutic value to a reasonable degree of scientific certainty.
- 167. The Defendant's defective product directly and proximately caused Elizabeth Noble serious permanent damage, as alleged in detail below.

COUNT XX STRICT LIABILITY- DESIGN DEFECT AGAINST DEFENDANT SHAREEN GREENBAUM, M.D.

- 168. The Plaintiff adopts and realleges paragraphs 1 through 14 and further alleges:
- 169. Defendant Shareen Greenbaum, M.D. 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 Elizabeth Noble, and therefore had a duty to create a product that was not defective.

170. The product is defective because it was in a condition unreasonably dangerous to Elizabeth Noble when created, designed, manufactured, distributed, sold, and/or supplied by Defendant Shareen Greenbaum, M.D.

- 171. The product reached Elizabeth Noble without substantial change affecting that condition after creation, design, manufacture, distribution, sale, and/or supply by Defendant Shareen Greenbaum, M.D.
- 172. The product failed to perform as safely as an ordinary consumer would expect when used as intended, causing damage to Elizabeth Noble.
- 173. The product's risk of danger in the design outweighs the nonexistent benefits of a therapy with no evidence of therapeutic value to a reasonable degree of scientific certainty.
- 174. The Defendant's defective product directly and proximately caused Elizabeth Noble serious permanent damage, as alleged in detail below.

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

- 175. The Plaintiff adopts and realleges paragraphs 1 through 14 and further allege:
- 176. 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 Elizabeth Noble, and therefore had a duty to warn of the risks associated with the use of the product.

177. 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 Elizabeth Noble.

178. Defendant U.S. Stem Cell, Inc. downplayed the serious and dangerous side effects of the product to encourage sales of the product; consequently, the Defendant placed its profits above consumers' safety.

179. 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 Elizabeth Noble 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, it still failed to provide warnings that accurately reflected the signs, symptoms, incident, scope, or severity of the risks associated with the product.

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

- 181. 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.
- 182. Plaintiff Elizabeth Noble used the product in the manner as indicated by the Defendants.
- 183. Defendants U.S. Stem Cell, Inc., as a manufacturer of the product, is held to the level of knowledge of an expert in the field and, further, had knowledge of the dangerous risks and side effects of the product.
- 184. The Plaintiff did not have the same knowledge as Defendants and no adequate warning was communicated to her.
- 185. As a direct and proximate consequence of Defendant U.S. Stem Cell, Inc.'s actions, omissions, and misrepresentations, plaintiff Elizabeth Noble suffered permanent damage, as described in detail below.

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

- 186. The Plaintiff adopts and realleges paragraphs 1 through 14 and further allege:
- 187. 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 Elizabeth Noble, and therefore had a duty to warn of the risks associated with the use of the product.

188. 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 Elizabeth Noble.

189. Defendant US Stem Cell Clinic, LLC downplayed the serious and dangerous side effects of the product to encourage sales of the product; consequently, the Defendant placed its profits above consumers' safety.

190. 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 Elizabeth Noble 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, it still failed to provide warnings that accurately reflected the signs, symptoms, incident, scope, or severity of the risks associated with the product.

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

- 192. 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.
- 193. Plaintiff Elizabeth Noble used the product in the manner as indicated by Defendant US Stem Cell Clinic, LLC.
- 194. Defendant US Stem Cell Clinic, LLC, as a manufacturer of the product, is held to the level of knowledge of an expert in the field and, further, had knowledge of the dangerous risks and side effects of the product.
- 195. The Plaintiff did not have the same knowledge as Defendant US Stem Cell Clinic, LLC and no adequate warning was communicated to her.
- 196. As a direct and proximate consequence of Defendant US Stem Cell Clinic, LLC's actions, omissions, and misrepresentations, plaintiff Elizabeth Noble suffered permanent damage, as described in detail below.

COUNT XXIII STRICT LIABILITY- FAILURE TO WARN AGAINST DEFENDANT ALEJANDRO PEREZ, ARNP

- 197. The Plaintiff adopts and realleges paragraphs 1 through 14 and further allege:
- 198. Defendant Alejandro Perez, ARNP 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 Elizabeth Noble, and therefore had a duty to warn of the risks associated with the use of the product.

199. The product was under the control Defendant Alejandro Perez,
ARNP 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 Elizabeth Noble.

200. Defendant Alejandro Perez, ARNP downplayed the serious and dangerous side effects of the product to encourage sale of the product.

201. The product was defective and unreasonably dangerous when it left the possession of Defendant Alejandro Perez, ARNP in that it contained warnings insufficient to alert Elizabeth Noble 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, he still failed to provide warnings that accurately reflected the signs, symptoms, incident, scope, or severity of the risks associated with the product.

202. The product reached Elizabeth Noble without substantial change affecting that condition after creation, design, manufacture, distribution, sale, and/or supply by Defendant Alejandro Perez, ARNP.

203. The product was defective because the foreseeable risks of harm from the product could have been avoided by Defendant Alejandro Perez, ARNP 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.

204. Plaintiff Elizabeth Noble used the product in the manner as indicated by Defendant Alejandro Perez, ARNP.

205. Defendant Alejandro Perez, ARNP is held to the level of knowledge of an expert in the field and, further, had knowledge of the dangerous risks and side effects of the product.

206. The Plaintiff did not have the same knowledge as Defendant Alejandro Perez, ARNP and no adequate warning was communicated to her.

207. As a direct and proximate consequence of Defendant Alejandro Perez, ARNP's actions, omissions, and misrepresentations, plaintiff Elizabeth Noble suffered permanent damage, as described in detail below.

COUNT XXIV STRICT LIABILITY- FAILURE TO WARN AGAINST DEFENDANT SHAREEN GREENBAUM, M.D.

208. The Plaintiff adopts and realleges paragraphs 1 through 14 and further allege:

209. Defendant Shareen Greenbaum, M.D. 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 Elizabeth Noble,

and therefore had a duty to warn of the risks associated with the use of the product.

210. The product was under the control Defendant Shareen Greenbaum, M.D. 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 Elizabeth Noble.

211. Defendant Shareen Greenbaum, M.D. downplayed the serious and dangerous side effects of the product to encourage sale of the product.

212. The product was defective and unreasonably dangerous when it left the possession of Defendant Shareen Greenbaum, M.D. in that it contained warnings insufficient to alert Elizabeth Noble 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 Shareen Greenbaum, M.D. still failed to provide warnings that accurately reflected the signs, symptoms, incident, scope, or severity of the risks associated with the product.

213. The product reached Elizabeth Noble without substantial change affecting that condition after creation, design, manufacture, distribution, sale, and/or supply by Defendant Shareen Greenbaum, M.D.

214. The product was defective because the foreseeable risks of harm

from the product could have been avoided by Defendant Shareen Greenbaum,

M.D. 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.

- 215. Plaintiff Elizabeth Noble used the product in the manner as indicated by Defendant Shareen Greenbaum, M.D.
- 217. The Plaintiff did not have the same knowledge as Defendant Shareen Greenbaum, M.D. and no adequate warning was communicated to her.
- 218. As a direct and proximate consequence of Defendant Shareen Greenbaum, M.D.'s actions, omissions, and misrepresentations, plaintiff Elizabeth Noble suffered permanent damage, as described in detail below.

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

- 219. The Plaintiff adopts and realleges paragraphs 1 through 14 and further allege:
- 220. 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 Elizabeth Noble, and therefore had a duty of reasonable care to Elizabeth Noble, which is the care that a

reasonably careful designer, manufacturer, seller, importer, distributor, and or/ supplier would use under like circumstances.

- 221. Notwithstanding this duty of care, Defendant U.S. Stem Cell, Inc. breached its duty of care to Elizabeth Noble in the following ways:
 - Negligently failing to manufacture the product with the highly skilled personnel necessary to make therapeutic stem cells;
 - Negligently failing to design the product with the highly skilled personnel necessary to make therapeutic stem cells;
 - Negligently allowing Elizabeth Noble access to the product when she did not meet the criteria for receiving the product;
 - Negligently failing to warn Elizabeth Noble of the serious and dangerous side effects of the product to encourage sales of the product;
 - e. Negligently failing to warn Elizabeth Noble of the risk, incidence, symptoms, scope, or severity of the injuries produced by the product to Elizabeth Noble.
 - f. Negligently failing to provide reasonable instructions and warnings about the high likelihood of adverse events such as blindness, pain, and eye damage to Elizabeth Noble;
 - g. Other negligent failures as determined in discovery.
- 222. As a direct and proximate consequence of Defendant U.S. Stem Cell, Inc.'s actions, omissions, and misrepresentations, plaintiff Elizabeth Noble suffered permanent damage, as described in detail below.

COUNT XXVI NEGLIGENCE- PRODUCT LIABILITY AGAINST DEFENDANT US STEM CELL CLINIC, LLC

223. The Plaintiff adopts and realleges paragraphs 1 through 14 and further allege: 224. Defendant US Stem Cell Clinic, LLC researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the product, and directly advertised or marketed the product to Elizabeth Noble, and therefore had a duty of reasonable care to Elizabeth Noble, which is the care that a reasonably careful designer, manufacturer, seller, importer, distributor, and or/ supplier would use under like circumstances.

225. Notwithstanding this duty of care, Defendant US Stem Cell Clinic, LLC breached its duty of care to Elizabeth Noble in the following ways:

- Negligently failing to manufacture the product with the highly skilled personnel necessary to make therapeutic stem cells;
- Negligently failing to design the product with the highly skilled personnel necessary to make therapeutic stem cells;
- Negligently allowing Elizabeth Noble access to the product when she did not meet the criteria for receiving the product;
- Negligently failing to warn Elizabeth Noble of the serious and dangerous side effects of the product to encourage sales of the product;
- Negligently failing to warn Elizabeth Noble of the risk, incidence, symptoms, scope, or severity of the injuries produced by the product to Elizabeth Noble;
- f. Negligently failing to provide reasonable instructions and warnings about the high likelihood of adverse events such as blindness, pain, and eye damage to Elizabeth Noble;
- g. Other negligent failures as determined in discovery.

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

COUNT XXVII NEGLIGENCE- PRODUCT LIABILITY AGAINST DEFENDANT ALEJANDRO PEREZ, ARNP

227. The Plaintiff adopts and realleges paragraphs 1 through 14 and further allege:

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

229. Notwithstanding this duty of care, Defendant Alejandro Perez,

ARNP breached his duty of care to Elizabeth Noble in the following ways:

- Negligently manufacturing the product without the technical skill necessary to make therapeutic stem cells;
- Negligently designing the product without the technical skill necessary to make therapeutic stem cells;
- Negligently allowing Elizabeth Noble access to the product when she did not meet the criteria for receiving the product;
- Negligently failing to warn Elizabeth Noble of the serious and dangerous side effects of the product to encourage sales of the product;
- Negligently failing to warn Elizabeth Noble of the risk, incidence, symptoms, scope, or severity of the injuries produced by the product to Elizabeth Noble;

- Negligently failing to provide reasonable instructions and warnings about the high likelihood of adverse events such as blindness, pain, and eye damage to Elizabeth Noble;
- g. Other negligent failures as determined in discovery.

230. As a direct and proximate consequence of Defendant Alejandro Perez, ARNP actions, omissions, and misrepresentations, plaintiff Elizabeth Noble suffered permanent damage, as described in detail below.

COUNT XXVIII NEGLIGENCE- PRODUCT LIABILITY AGAINST DEFENDANT SHAREEN GREENBAUM, M.D.

- 231. The Plaintiff adopts and realleges paragraphs 1 through 14 and further allege:
- 232. Defendant Shareen Greenbaum, M.D. researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the product, and directly advertised or marketed the product to Elizabeth Noble, and therefore had a duty of reasonable care to Elizabeth Noble, which is the care that a reasonably careful designer, manufacturer, seller, importer, distributor, and or/ supplier would use under like circumstances.
- 233. Notwithstanding this duty of care, Defendant Shareen Greenbaum,
 M.D. breached her duty of care to Elizabeth Noble in the following ways:
 - Negligently manufacturing the product without the technical skill necessary to make therapeutic stem cells;
 - Negligently designing the product without the technical skill necessary to make therapeutic stem cells;
 - Negligently allowing Elizabeth Noble access to the product when she did not meet the criteria for receiving the product;

- Negligently failing to warn Elizabeth Noble of the serious and dangerous side effects of the product to encourage sales of the product;
- Negligently failing to warn Elizabeth Noble of the risk, incidence, symptoms, scope, or severity of the injuries produced by the product to Elizabeth Noble;
- f. Negligently failing to provide reasonable instructions and warnings about the high likelihood of adverse events such as blindness, pain, and eye damage to Elizabeth Noble;
- g. Other negligent failures as determined in discovery.
- 234. As a direct and proximate consequence of Defendant Shareen Greenbaum, M.D.'s actions, omissions, and misrepresentations, plaintiff Elizabeth Noble suffered permanent damage, as described in detail below.

CLAIMS FOR DAMAGES COMMON TO ALL COUNTS DAMAGES CLAIMED BY ELIZABETH NOBLE

- 122. The Plaintiff Elizabeth Noble, as a direct and proximate result of the breaches of warranty, strict liability, and negligence of the Defendants alleged above, has in the past and will in the future continue to suffer the following damages:
 - Bodily injury;
 - 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;

Rehabilitation expenses; and

k. Mental distress;

WHEREFORE, Plaintiff Elizabeth Noble 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

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

Dated this 30th day of November, 2015.

GROSSMAN ROTH, P.A. Attorney for Plaintiff 2525 Ponce de Leon Blvd. Suite 1150 Coral Gables, FL 33134

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By: /s/Andrew B. Yaffa

ANDREW B. YAFFA Fla. Bar No.: 897310

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