UNITED STATES DISTRICT COURT

DISTRICT OF NEW HAMPSHIRE

James D. Brown and Kimberly Brown Plaintiffs, VS. Atrium Medical Corporation and DOES 1-20 Defendants	))))))))))	Civil Action No.:

COMPLAINT AND JURY DEMAND

PARTIES

1. Plaintiff, James D. Brown, is a resident of Nashua, New Hampshire and is now and has been at all relevant times a citizen of New Hampshire.

2. Plaintiff, Kimberly Brown, is a resident of Nashua, New Hampshire and is now and has been at all relevant times a citizen of New Hampshire. At all times material to the within Complaint, Kimberly Brown was the spouse of James D. Brown.

3. Defendant Atrium Medical Corporation ("Atrium") is a corporation organized under the laws of Delaware with its corporate headquarters and principal place of business located in Merrimack, New Hampshire.

4. At all relevant times, Defendant Atrium was involved in the research, design, development, testing, manufacturing, licensing, production, marketing, distribution, and/or sale of medical devices used for hernia repair, including C-Qur Mesh. Through such actions Atrium has placed in the stream of commerce the Hernia Mesh Products, including certain Hernia Mesh Products at issue in this lawsuit.

5. The true names and capacities, whether individual, corporate, associate or otherwise, of Defendants Does one (1) through twenty (20), are unknown to Plaintiffs who therefore sues these Defendants by such fictitious names. Plaintiffs will amend this Complaint when the true names and capacities of these fictitiously named Defendants are ascertained. Plaintiffs are informed and believe, and thereon alleges, that each fictitiously named Defendant, whether as a supplier, manufacturer, distributor, researcher, analyst, manager, supervisor, marketer, seller, parent company, or subsidiary, is responsible, strictly, negligently, or otherwise, for the occurrences alleged in this Complaint, and caused the injuries and damages sustained by Plaintiffs as herein alleged.

6. At all relevant times, each of the Defendants designed, developed, tested, manufactured, licensed, produced, marketed, distributed, and/or sold medical devices used for hernia repair, including C-Qur Mesh.

7. At all times mentioned herein, Defendants acted, by and through their agents, representatives and employees who acted within the scope and course of their agency and employment.

8. At all relevant times, Defendant Atrium, was and still is a corporation authorized to do business in the State of New Hampshire.

9. At all times hereinafter mentioned, upon information and belief, each

of the Defendants, was and still is a business entity actually doing business in the State of New Hampshire.

10. At all times hereinafter mentioned, the Defendants were and are currently engaged in the business of designing, manufacturing, advertising, marketing, and selling Hernia Mesh Products including the Atrium C-Qur Mesh, and in pursuance of this business, transacts business within the State of New Hampshire and contracts to provide goods and services in the State of New Hampshire.

11. At all times hereinafter mentioned, upon information and belief, Defendants committed a tortious act inside the State of New Hampshire, which caused injury to Plaintiffs.

VENUE AND JURISDICTION

12. Damages sought in this matter are in excess of Seventy-Five Thousand Dollars ($75,000.00). This Court has subject matter jurisdiction pursuant to 28 U.S.C. §331(a)(e)(k), 351(f)(j), 360 (j) and 21 C.F.R. §806.10(a)(1)

13. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this Court has *in personam* jurisdiction over Defendants, because Defendants are present in the State of New Hampshire.

14. Venue is proper in this District pursuant to 28 U.S.C § 139l(b), (c) and (d) because Defendant Atrium resides in this District, a substantial part of the events or omissions giving rise to the claim occurred in this District, and Defendants' products are sold to and consumed by individuals in the State of New Hampshire, thereby subjecting Defendants to personal jurisdiction in this action.

DEFENDANTS' HERNIA MESH PRODUCTS

15. In 1993, Defendants began to market and sell surgical mesh for the treatment of multiple medical conditions, primarily hernia repair.

16. Specifically, Atrium sought and secured 520(k) clearance on the following medical devices indicated and/or sold for hernia repair; ProLite Mesh (K930669) on December 16, 1993, ProLite Ultra Mesh (K002093) on July 24, 2000, C-Qur Mesh (K050311) on March 31, 2006, ProLite Ultra S Mesh (K070192) on March 8, 2007, C-Qur Lite V-Patch (K080688) on April 16, 2008, C-Qur Edge V-Patch (K080691) on April 16, 2008, ProLite S Mesh (K082748) on January 14, 2009, C-Qur V-Patch (K090909) on June 4, 2009, C-Qur Ovt (K100076) on January 26, 2010, Centrilfx (Kll0110) on February 15, 2011, C-Qur Rpm (K121070) on April 26, 2012, ProLite, Prolite Ultra, Proloo (K151437) on August 27, 2015 and C-Qur, C-Qur Fx, C- Qur Tachshield, C-Qur V-Patch, C-Qur CentriFX, and C-Qur Mosaic(K 151386) on October 22, 2015.

17. Defendants' Hernia Mesh Products were designed, patented, manufactured, labeled, marketed, sold and distributed by the Defendants,

18. Defendants' products contain polypropylene mesh. Despite claims that this material is inert, a substantial body of scientific evidence shows that this mesh material is biologically incompatible with human tissue and promotes an immune response in a large subset of the population receiving Defendants' products. This immune response promotes degradation of the polypropylene mesh, as well as the surrounding tissue, and can contribute to the formation of severe adverse reactions to the mesh.

19. Defendants' statements made to the FDA regarding these Medical

Devices inadequately relied on predicate devices and not clinical testing or other design verification or testing. These statements induced the Plaintiff James D. Brown into relying upon the Defendants' judgment.

20. Upon information and belief, Defendants' numerous suppliers of various forms of polypropylene warn on their United States Material Safety Data Sheet ("MSDS") that it prohibited to permanently implant polypropylene in the human body.

21. Defendants' polypropylene based Hernia Mesh Products are designed, intended, and utilized for permanent implantation into the human body.

22. Defendants failed to warn or notify doctors, regulatory agencies, and consumers of the known severe and life-threatening risk associated with polypropylene.

23. Upon information and belief, Defendants' adulterated polypropylene in their Hernia Mesh Products.

24. Defendants' failed to warn or notify doctors, regulatory agencies, and consumers of the Defendants' use of adulterated polypropylene in the Hernia Mesh Products.

25. Defendants' C-Qur Mesh utilizes a blend of Omega 3 Fatty Acid Fish Oil ("03FA") to form a barrier coating on its C-Qur Mesh.

26. 03FA is derived from fish. Fish are considered to be commonly allergenic. If various remnants of the fish, such as proteins, remain in the 03FA coating, allergic reactions can occur, ranging from increased sensitivity and rashes to death.

27. Proteins are not very soluble in oils; however, non-soluble proteins are still able to be present in the oil as particulate matter.

28. Upon information and belief, Defendants failed to adequately test, inspect, and/or verify that each supplied batch of 03FA was free from proteins.

29. Upon information and belief, Defendants' utilized adulterated 03FA.

30. Prior to the C-Qur Mesh entering the stream of commerce, the United States Food and Drug Administration ("FDA") and other governmental regulatory agencies worldwide expressed their concerns to Defendants regarding severe, life-threatening allergic reactions to the 03FA coating when implanted in humans.

31. Upon receiving reports from surgeons and physicians of apparent allergic reactions to the C-Qur Mesh, Defendants not only failed to notify the FDA, but misled physicians about the ability and tendency of 03FA to cause allergic reactions in patients implanted with C-Qur Mesh and attempted to convince the physicians of alternate causes. Defendants intentionally, or at the very least, recklessly disregarded human life by lying to physicians about the possible causes of the allergic reactions, resulting in significantly more severe injuries in those already implanted with C-Qur Mesh, and more patients nationwide being implanted with the C-Qur Mesh.

32. Upon information and belief, Defendants changed the way in which they handled and/or applied the 03FA coating to the C-Qur Mesh. This change in the manufacturing process was a deviation from the initial design and was carried out without first conducting tests to determine the effect of the change on patient safety. The FDA was not notified of the deviation.

33. Upon information and belief, Defendants utilized non-conforming goods in the production of the C-Qur Mesh, including accepting goods without the required documentation to verify the source, quality, authenticity, or chain of custody of

the goods.

34. Upon information and belief, the 03FA component of Defendants' C-Qur Mesh is cytotoxic and not biocompatible, resulting in complications such as delayed wound healing, inflammation, foreign body response, rejection and death.

35. Upon information and belief, Defendants had actual knowledge of the cytotoxic properties of the 03FA component of the C-Qur Mesh prior to introducing it into the stream of commerce.

36. Defendants failed to adequately test the effects of the known cytotoxicity of the C-Qur Mesh in animals and humans, both before and after the product entered the stream of commerce.

37. Defendants' failed to warn or notify doctors, regulatory agencies, and consumers of the cytotoxicity of the C-Qur Mesh.

38. Defendants utilize Ethylene oxide ("ETO") in an attempt to sterilize the C-Qur Mesh. ETO is an effective disinfectant; however, dry spores are highly resistant to ETO. Moisture must be present to eliminate spores using ETO. Presoaking the product to be sterilized is most desirable, but high levels of humidity during the ETO process can also be effective in eliminating spores. C-Qur Mesh implanted with spores will result in an infection. The spores can remain dormant for extended periods of time, resulting in infections months or years after implantation with the C-Qur Mesh.

39. Moisture and high humidity levels are contraindicated for the C-Qur Mesh, as it will result in the 03FA coating peeling off the polypropylene and/or sticking to the packaging.

40. Defendants use of ETO on the C-Qur Mesh results in either:

a. High infection rates due to inadequate moisture during the ETO cycle; or

b. 03FA coating peeling off the polypropylene due to moisture.

41. Defendant failed to warn or instruct distributors and facilities of critical environmental guidelines, such as relative humidity or temperature during transportation and/or storage of the C-Qur Mesh and are not necessary for other similar or competing hernia mesh products. Excess temperature and/or humidity result in the C-Qur Mesh degrading and transforming into an even more dangerous product.

42. Defendants failed to conduct adequate testing to determine the proper environmental guidelines for storage and transportation of the C-Qur Mesh prior to introducing it into the stream of commerce.

43. ETO is ineffective at sterilizing the C-Qur Mesh due the 03FA coating, multiple layers of the mesh, and mated surfaces of the C-Qur Mesh.

44. Defendants changed the process of their ETO sterilization cycle without performing adequate testing or verification of sterility, or other effects the changes might have had on the product. This change in the manufacturing process was a deviation from the initial design and was carried out without first conducting tests to determine the effect of the change on patient safety. The FDA was not notified of the deviation.

45. Upon information and belief, Defendants utilized a package that allowed humidity levels to fluctuate to unacceptably high levels within the package.

46. Upon information and belief, Defendants utilized a packaging material that promoted the 03FA coating to adhere to the packaging of the C-Qur Mesh.

47. Upon information and belief, Defendants manufactured the C-Qur Mesh

in a way that promoted that 03FA coating to adhere to the packaging of the C-Qur Mesh.

48. Defendants failed to properly warn physicians, regulatory agencies, and consumers of the risk associated with the 03FA coating adhering to the package. Defendants assured physicians and regulatory agencies that the C-Qur Mesh was still fit for human implantation, even if some or all of the 03FA coating had been pulled away.

49. Once the 03FA coating has started or shown propensity to detach from the polypropylene, it is much more likely that the 03FA coating wi11 detach from the polypropylene once implanted. The 03FA coating detaches once implanted, it can float in the body or ball up, causing an even more ·intense foreign body reaction, resulting in rejection and other complications the C-Qur Mesh. Detachment of the 03FA coating also greatly increases the risk of the C-Qur Mesh adhering to the patients underlying organs, resulting in significantly more difficult and complex surgeries to remove the mesh. Due to the C-Qur Mesh adhering to the underlying organs, patients experience significant, life-changing injuries, prolonged hospital stays, and even death.

50. Defendants were and are currently aware of the life-threatening complications associated with the 03FA coating peeling off inside of patients.

51. Defendants encouraged physicians to implant C-Qur Mesh in which the 03FA coating had peeled away from the polypropylene and was stuck to the packaging.

52. Defendants' encouragement of physicians to implant C-Qur Mesh in which the 03FA coating had adhered to the packaging and was no longer present on the

polypropylene was an intentional, or at very least, a reckless disregard of human life.

53. Defendants changed the way in which the C-Qur Mesh is packaged. This change in the manufacturing process was a deviation from the initial design and was carried out without first conducting tests to determine the effect of the change on patient safety. The FDA was not notified of the deviation.

54. Upon information and belief, at relevant times, Defendants modified the processing temperature and processing speed of one or more steps in the manufacturing process. This change in the manufacturing process was a deviation from the initial design and was carried out without first conducting tests to determine the effect of the change on patient safety. The FDA was not notified of the deviation.

55. Upon information and belief, Defendants adjusted the threshold for reporting and recalling the C-Qur Mesh due to nonconformities and adverse event reports when the threshold was met, resulting in a large number of injurious events that were deemed by the Defendants to be "acceptable" and went unreported as a result and unrecalled.

56. Upon information and belief, Defendants manipulated, altered, skewed, slanted, misrepresented, and/or falsified pre-clinical and/or clinical studies to bolster the perceived performance of the C-Qur Mesh.

57. Upon information and belief, Defendants paid researchers, doctors, clinicians, study designers, authors, and/or scientist to study the effectiveness of the C-Qur Mesh, but did not disclose these relationships in the study itself or to any regulatory body.

58. Upon information and belief, Defendants paid doctors, surgeons, physicians, and/or clinicians to promote the C-Qur Mesh, but did not readi1y disclose this

information.

59. Defendants failed to properly investigate and disclose adverse event reports to the FDA and other regulatory agencies worldwide.

60. Defendants failed to implement adequate procedures and systems to report, track and evaluate complaints and adverse events.

61. Defendants failed to employ an adequate number of staff to receive, process, investigate, document, and report adverse events.

62. Defendants "stealth recalled" multiple types of C-Qur Mesh that were experiencing high levels of adverse events, by simply halting production of multiple types of C- Qur Mesh without notifying physicians, regulatory agencies, or consumers of the recall or high levels of adverse events.

63. Defendants failed to implement adequate procedures and policies to detect the presence of foreign materials in or on the C-Qur Mesh.

64. Defendants failed to implement adequate procedures and policies to prevent C- Qur Mesh with known foreign materials from entering the stream of commerce.

65. Defendants failed to design a method or process that ensures conformity in the amount of 03FA applied to each type of C-Qur Mesh.

66. Defendants failed to warn or instruct physicians on the proper and/or contraindicated methods of securing and/or implanting the C-Qur Mesh. Defendants blamed physicians' methods of implantation and securing the C-Qur Mesh when complications known by the Defendants to be caused by a defect in the C-Qur Mesh were reported by physicians. This resulted in fewer adverse event reports to the FDA and more C-Qur Mesh implants nationwide.

67. Defendants marketed the C-Qur Mesh to the medical community and to patients as safe, effective, reliable medical devices for the treatment of hernia repair, and as safer and more effective as compared to the traditional products and procedures for treatment, and other competing mesh products. Defendants' did not undergo pre-market approval for the C-Qur Mesh and are therefore prohibited by the FDA from asserting superiority claims. Defendants have made claims that the C-Qur Mesh is superior in a variety of ways, but have never conducted a single clinical study on the C-Qur Mesh implanted in humans. Defendants' deception through false advertising resulted in more physicians utilizing the C-Qur Mesh.

68. Defendants signed a national contract with Premier Inc. ("Premier"), a group purchasing organization, on August 10, 2010. Premier supplies medical devices in bulk to member hospitals at a reduced cost. Defendants' contract with Premier greatly increased the nationwide demand for the C-Qur Mesh. Defendants changed numerous aspects of the manufacturing process of the C-Qur Mesh, before and after the contract with Premier, in order to increase production and decrease cost.

69. Defendants marketed and sold the C-QUR Mesh Products to the medical community at large and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, aggressive marketing to health care providers at medical conferences, hospitals, and private offices, and include the provision of valuable benefits to health care providers. Also utilized were documents, patient brochures, and websites.

70. For years the Defendants have been notified and were warned about the widespread catastrophic complications associated with the C-Qur Mesh by leading hernia repair specialists, surgeons, hospitals, patients, regulatory agencies, internal

consultants, and employees. Defendants have misrepresented the efficacy and safety of the C-Qur Mesh, through various means and media, actively and intentionally misleading the FDA, the medical community, patients, and the public at large.

71. Defendants have known and continue to know that their disclosures to the FDA were and are incomplete and misleading; and that the Defendants' C-Qur Meshes were and are causing numerous patients severe injuries and complications. The Defendants suppressed this information and failed to accurately and completely disseminate or share this and other critical information with the FDA, health care providers, or the patients. As a results, the Defendants actively and intentionally misled and continue to mislead the public, including the medical community, health care providers and patients, into believing that the Defendants' C-Qur Meshes were and are safe and effective, leading to the prescription for and implantation of the C-Qur Mesh into the Plaintiff James D. Brown.

72. Defendants failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Defendants' C-Qur Mesh.

73. Defendants failed to design and establish a safe, effective procedure for removal of the Defendants' C-Qur Mesh; therefore, in the event of a failure, injury, or complications it is impossible to easily and safely remove the Defendants' C-Qur Mesh;

74. Feasible and suitable alternative procedures and instruments, as well as suitable alternative designs for implantation and treatment of hernias and soft tissue repair have existed at all times relevant as compared to the Defendants' C-Qur Mesh.

75. The Defendants' C-Qur Meshes were at all times utilized and implanted in a manner foreseeable to the Defendants.

76. The Defendants have at all times provided incomplete, insufficient and misleading training and information to physicians, in order to increase the number of physicians utilizing the Defendants' C-Qur Mesh, and thus increase the sales of the C-Qur Mesh and also leading to the dissemination of inadequate and misleading information to patients, including Plaintiffs.

77. The C-Qur Mesh implanted into the Plaintiff James D. Brown was in the same or substantially similar condition as when it left the possession of the Defendant, and in the condition directed by and expected by the Defendants.

FACTUAL BACKGROUND

78. Plaintiff James D. Brown is a fifty-six (56) year old male who was diagnosed with an umbilical hernia in December 2013.

79. On December 11, 2013, Plaintiff James D. Brown underwent umbilical hernia repair with Atrium C-QUR Mesh.

80. Defendants manufactured, sold, and/or distributed the C-QUR Mesh Products to Plaintiff James D. Brown through his doctors, to be used for treatment of hernia repair.

81. Several months following the December 11, 2013 implant of the C-QUR Mesh Plaintiff James D. Brown continued to experience abdominal pain.

82. In December 2015, Plaintiff James D. Brown learned that the cause of his continued abdominal pain was the C-QUR Mesh.

83. On January 12, 2016, the Plaintiff James D. Brown underwent surgical removal of the C-QUR Mesh.

84. The pathology report from the January 12, 2016 surgery noted synthetic mesh and soft tissue excision, fibrous tissue with imbedded mesh, **foreign**

body giant cell reaction, hemosiderin and fibrosis.

85. Despite removal of the C-QUR Mesh, Plaintiff James D. Brown continues to suffer severe abdominal pain warranting further medical treatment.

86. The C-QUR Mesh Products were at all times utilized and implanted in a manner foreseeable to Defendants, as Defendants generated the instructions for use and created procedures for implanting the mesh.

87. Other than any degradation caused by faulty design or faulty packaging, the C- QUR Mesh implanted into the Plaintiff James C. Brown was in the same or substantially similar condition as when it left the possession of Defendant, and in the condition directed by and expected by Defendant.

88. Plaintiff James D. Brown and his physicians foreseeably used and implanted the C-QUR Mesh Products, and **did** not misuse, or alter the Products in an unforeseeable manner.

89. Defendant Atrium advertised, promoted, marketed, sold, and distributed the C-QUR Mesh Products as a safe medical device when Defendant knew or should have known the C- QUR Mesh Products were not safe for their intended purposes and that the mesh products could cause serious medical problems.

90. Defendant Atrium provided incomplete, insufficient, and misleading information to physicians in order to increase the number of physicians utilizing the C-QUR Mesh Products, and thus increase the sales of the products, and also leading to the dissemination of inadequate and misleading information to patients, including Plaintiffs.

91. Defendant Atrium made representations with the intent of inducing the

medical community to recommend, prescribe, dispense, and purchase C-QUR for use as a means of treatment for hernia repairs which evinced an indifference to the health, safety, and welfare of Plaintiff James D. Brown.

92. Defendant Atrium had sole access to material facts concerning the defective nature of the products and their propensity to cause serious and dangerous side effects.

93. At all relevant times herein, Defendant Atrium continued to promote C-QUR Mesh Products as safe and effective even when no valid c1inica1 trials had been done supporting long or short term efficacy.

94. In reliance on Defendant's representations, Plaintiff's doctor was induced to, and did use the C-QUR Mesh Products, thereby resulting in severe and permanent personal injuries and damages.

COUNT I - NEGLIGENCE

95. Plaintiffs incorporate by reference the forgoing paragraphs as if fully set forth herein.

96. At all relevant times, Defendants had a duty to use reasonable care in designing, manufacturing, marketing, labeling, packaging, and/or selling the mesh products.

97. On the occasion in question the Defendants breached their duty by designing, manufacturing, marketing, labeling, packaging, and/or selling the unreasonably dangerous mesh products.

98. As a direct, proximate and foreseeable result of the mesh products' aforementioned defects, Plaintiff James C. Brown was caused and in the future will be

caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

99. Each act or omission of negligence was a proximate cause of the damages and injuries to Plaintiff James D. Brown.

COUNT II - STRICT LIABILITY - DESIGN DEFECT

100. Plaintiffs incorporate by reference the factual portion of this complaint as if fully set forth herein and additionally or in the alternative, if same be necessary, allege as follows:

101. At the time each implanting surgeon implanted the mesh product in patients, Defendants were engaged in the business of selling said product.

102. The mesh product was defectively designed when sold.

103. The mesh product was unreasonably dangerous, taking into consideration the utility of said product and the risks involved in their use.

104. The mesh product reached Plaintiff James D. Brown's implanting surgeon without substantial change in the condition in which it was sold.

105. The defective and unreasonably dangerous condition of the mesh product was the proximate cause of the damages and injuries to Plaintiff James D. Brown.

106. As a direct and proximate result of the mesh product's aforementioned defects, Plaintiff James D. Brown was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and

expenses, and other damages.

107. Defendant is strictly liable to Plaintiff James D. Brown.

COUNT III - STRICT LIABILITY - MANUFACTURING DEFECT

108. Plaintiffs incorporate by reference the factual portion of this complaint as if fully set forth herein and additionally or in the alternative, if same be necessary, allege as follows:

109. At the time Plaintiff James D. Brown's doctor implanted the mesh product in his body, Defendants were engaged in the business of selling said product.

110. The mesh product was defectively designed when sold.

111. The mesh product was unreasonably dangerous, taking into consideration the utility of said product and the risks involved in its use.

112. The mesh product reached implanting surgeon without substantial change in the condition in which it was sold.

113. The defective and unreasonably dangerous condition of the mesh product was a proximate cause of the damages and injuries to Plaintiff James D. Brown.

114. As a direct and proximate result of the mesh products' aforementioned defects, Plaintiff James D. Brown was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

115. Defendants are strictly liable to Plaintiff James D. Brown.

COUNT IV - STRICT LIABILITY - FAILURE TO WARN

116. Plaintiffs incorporate by reference the factual portion of this complaint as if fu11y set forth herein and additionally or in the alternative, if same be necessary,

alleges as follows:

117. The mesh product implanted in Plaintiff James D. Brown was not reasonably safe for intended use and was defective as a matter of law due to its lack of appropriate and necessary warnings.

118. As a direct and proximate result of the mesh products aforementioned defects, Plaintiff James D. Brown was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

119. Defendants are strictly liable to Plaintiff James D. Brown.

COUNT V - VIOLATION OF CONSUMER PROTECTION LAWS

120. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, a11ege as follows:

121. Plaintiff James D. Brown purchased and used the Defendants' C-Qur Mesh primarily for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

122. Had Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for the Defendants' C-Qur Mesh, and would not have incurred related medical cost and injury.

123. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiff James D. Brown for the C-Qur Mesh that would not have been paid had Defendants not engaged in unfair and

deceptive conduct.

124. Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

a.) Representing that goods or services have characteristics, ingredients, uses, benefits or qualities that they do not have.

b.) Advertising goods or services with the intent not to sell them as advertised; and,

c.) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

125. Plaintiff James D. Brown was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and se11 the Defendants' C-Qur Meshes. Each aspect of Defendants' conduct combined to artificia11y create sales of the Defendants' C-Qur Meshes.

126. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of the Defendants' C-Qur Meshes.

127. Had Defendants not engaged in the deceptive conduct described above, Plaintiff James D. Brown would not have purchased and/or paid for the C-Qur Mesh, and would not have incurred related medical cost.

128. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiffs, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes listed.

129. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state consumer protection statues, as listed below.

130. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations.

- 15 U.S.C. §§ 2301-2312
- New Hampshire Consumer Protection Act (RSA 358-A)

131. Under the statutes listed above to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

132. Defendants violated the statutes that were enacted to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Defendants' C-Qur Meshes were fit to be used for the purpose for which they were intended, when in fact they were defective and dangerous, and by other acts alleged herein. These representations were made in marketing and promotional materials.

133. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

134. Defendants had actual knowledge of the defective and dangerous

condition of the Defendants' C-Qur Mesh and failed to take any action to cure such defective and dangerous conditions.

135. Plaintiff and the medical community relied upon Defendants' misrepresentations and omissions in determining which product and/or procedure to undergo and/or perform (if any).

136. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices.

137. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiff has suffered ascertainable losses and damages.

138. As a direct and proximate result of Defendants' violations of consumer protection laws, Plaintiff has sustained economic losses and other damages and is entitled to statutory and compensatory damages in an amount to be proven at trial.

WHEREFORE, Plaintiff, James D. Brown, demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests restitution and disgorgement of profits, together with interest, and such further relief as the Court deems just and proper.

COUNT VI - UNJUST ENRICHMENT

139. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

140. Defendants are and at all times were the manufacturers, sellers, and/or suppliers of the Defendants' C-Qur Mesh.

141. Plaintiff paid for the Defendants' C-Qur Mesh for the purpose of

treatment for hernia repair.

142. Defendants have accepted payment by Plaintiff and others on Plaintiff's behalf for the purchase of the Defendants' C-Qur Mesh.

143. Plaintiff has not received the safe and effective medical device for which Plaintiff paid.

144. It would be inequitable for Defendants to keep this money, because Plaintiff did not in fact receive a safe and effective medical device.

WHEREFORE, Plaintiff, James D. Brown, demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VII - NEGLIGENT INFLICTION

OF EMOTIONAL DISTRESS

145. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

146. Defendants carelessly and negligently manufactured, designed, developed, tested, labeled, marketed and sold the Defendants' C-Qur Mesh to Plaintiff.

147. Defendants carelessly and negligently concealed the harmful effects of the Defendants' C-Qur Mesh from Plaintiff individually and/or Plaintiff's physician on multiple occasions and continue to do so to this day.

148. Defendants carelessly and negligently misrepresented the quality, safety and efficacy of the C-Qur Mesh to Plaintiff individually and/or Plaintiff's physician on multiple occasions and continue to do so to this day.

149. Plaintiffs were directly impacted by Defendants' carelessness and negligence, in that Plaintiffs has sustained and will continue to sustain emotional distress, severe physical injuries, economic losses, and other damages as a direct result of the decision to purchase the C- Qur Mesh sold and distributed by Defendants.

150. Defendants continued to carelessly and negligently misrepresent the quality, safety, efficacy, dangers and contraindications of the C-Qur Mesh to Plaintiff individually and/or Plaintiff's physician after Plaintiff sustained emotional distress, severe physical injuries, and economic loss.

151. Defendants continued to carelessly and negligently misrepresent the quality, safety, efficacy, dangers and contraindications of the C-Qur Mesh to Plaintiff individua11y and/or Plaintiff's physician knowing that doing so would cause the Plaintiff to suffer additional and continued emotional distress, severe physical injuries, and economic loss.

152. As a proximate result of the Defendants' conduct, Plaintiff has been injured, sustained severe and permanent pain, suffering, anxiety, depression, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

WHEREFORE, Plaintiff, James D. Brown, demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, enhanced compensatory damages and such further relief as the Court deems equitable and just.

COUNT VIII - NEGLIGENT MISREPRESENATION

153. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

154. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff and the public, that the C-Qur Mesh had not been adequately tested and found to be safe and effective for the treatment of hernia or soft tissue repair. The representations made by Defendants, in fact, were false.

155. Defendants failed to exercise ordinary care in the representations concerning the C-Qur Mesh while they were involved in their manufacture, sale, testing, quality, assurance, quality control, and distribution in interstate commerce, because Defendants negligently misrepresented the C-Qur Meshes high risk of unreasonable and dangerous adverse side effects.

156. Defendants breached their duty in representing that the Defendants' C-Qur Meshes have no serious side effects different from older generations of similar products and/or procedures to Plaintiff, Plaintiff's physicians, and the medical and healthcare community.

157. Plaintiff James D. Brown and his doctors justifiably relied upon the Defendants' misrepresentations to their detriment.

158. As a foreseeable, direct and proximate result of the negligent misrepresentation of Defendants as set forth herein, Defendants knew, and had reason to know, that the C-Qur Mesh had been insufficiently tested, or had not been tested at all, and that they lacked adequate and accurate warnings, and that it created a high risk, and/or higher than acceptable risk, and/or higher than reported and represented risk, of adverse side effects, including, foreign body response, allergic reactions, rejection, infection, failure, erosion, pain and suffering, organ perforation, dense adhesions, loss of life's enjoyment, remedial surgeries to remove the product, and other severe and personal injuries, which are permanent and lasting in nature.

159. As a direct and proximate result of the Defendants' conduct, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

WHEREFORE, Plaintiff, James D. Brown, demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, enhanced compensatory damages, and such further relief as the Court deems equitable and just.

COUNT IX - NEGLIGENCE PER SE

160. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

Violation of 21 U.S.C. § 351(t)

161. Defendants' marketed, promoted, and/or sold their C-Qur Mesh to physicians, Plaintiff and the public at large as a "Barrier" mesh.

162. The term "Barrier" is a word of art used for adhesion barriers that reduce adhesions between tissues. To be a "Barrier" medical device or use the term "Barrier," the medical device must be a Class III device and must undergo Pre-Market Approval.

163. Defendants' refused to undergo the necessary safety testing and pre-clinical trials required for Pre-Market Approval.

164. Defendants' violated 21 U.S.C. § 351(f) by not obtaining Pre-Market Approval and marketing, promoting, and/or selling the Defendants' C-Qur Mesh as being a "Barrier" mesh and reducing adhesions between tissues.

165. 21 U.S.C. § 351(f) mandates safety testing and pre-clinical trials to

protect the general public who have medical device implanted.

166. Plaintiff James D. Brown is a member of the general public who had a medical device implanted, and therefore is among the class of people the regulation is meant to protect.

167. Plaintiff James D. Brown would not have been implanted with the C-Qur Mesh had the C-Qur Mesh underwent safety testing, pre-clinical trials, and Pre-Market Approval.

168. Plaintiff James D. Brown and his physician would not have selected the C-Qur Mesh had the C-Qur Mesh not been marketed and promoted as a "Barrier" mesh that was more effective at reducing adhesions between tissues.

169. As a direct and proximate result of the Defendants' violation of 21 U.S.C. 351(f), Plaintiff has been injured; sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

WHEREFORE, Plaintiff, James D. Brown, demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, enhanced compensatory damages, and such further relief as the Court deems equitable and just.

Violation of 21 U.S.C. §360j(f). 21 C.F.R. Part 820, 21 U.S.C. §331(a),(k)

170. A device must be manufactured, packed, stored, and installed in conformity with good manufacturing practice to ensure its safety and effectiveness. 21 U.S.C. § 360j(f). The statutory good manufacturing practice requirement is set out in the QS regulation for devices, 21 C.F.R. Part 820. A device that has been manufactured, packed, stored, or installed in violation of the QS requirement is deemed

to be adulterated. 21 U.S.C. § 351(h).

171. The introduction or delivery for introduction into interstate commerce of adulterated or misbranded device is a violation of 21 U.S.C. § 331(a).

172. Doing an act that causes the adulteration or misbranding of a device while it is held for sale after shipment of one or more of its component parts in interstate commerce is a violation of 21 U.S.C. §331(k).

173. Each of the aforementioned regulations are intended to protect the general public from being implanted with adulterated medical devices.

174. Plaintiff James D. Brown is a member of the general public and was implanted with an adulterated medical device and therefore is among the class of people the regulation is meant to protect.

175. Defendants violated 21 U.S.C. §360j(f), 21 C.F.R. Part 820, 21 U.S.C. §331(a) and (k) by adulterating the C-Qur Mesh or the components of the C-Qur Mesh and then introducing the adulterated products into the stream of commerce, and did acts that caused further adulteration or misbranding of the C-Qur Mesh once it was in the stream of commerce.

176. Plaintiff James D. Brown would not have been injured and/or his injuries would not have been as severe had the Defendants' not violated 21 U.S.C. §360j(f), 21 C.F.R. Part 820, 21 U.S.C. §33l(a) and (k) and introduced an adulterated medical device into the stream of commerce.

WHEREFORE, Plaintiff, James D. Brown, demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, enhanced compensatory damages, and such further relief as the Court deems equitable and just.

Violation of 21 U.S.C. § 331(e)

177. The failure to establish or maintain certain records, or make certain reports, with respect to medical devices, is a violation of 21 U.S.C. § 331(e), as required by 21 U.S.C. §360i.

178. 21 U.S.C. § 331(e) is intended to facilitate the detection of defective medical devices, so that such defective devices can be pulled from the market to prevent the general public from being injured due to a defective medical device.

179. Plaintiff James D. Brown is a member of the general public and was injured by a defective medical device that should have been pulled from the market.

180. Had Defendants' not violated 21 U.S.C. § 331(e), the C-Qur Mesh would have been recalled, or at very least had additional warnings.

181. Plaintiff James D. Brown would not have been implanted with the C-Qur Mesh had the C-Qur Mesh been recalled or had additional warnings.

182. As a direct and proximate result of the Defendants' violation of 21 U.S.C. § 331(e), Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

WHEREFORE, Plaintiff, James D. Brown, demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, enhanced compensatory damages, and such further relief as the Court deems equitable and just.

Violation of 21 C.F.R. § 806.01(a)(1)

183. Failure to report in writing to FDA a correction, removal, and/or

discontinuation of a device conducted to reduce a risk to health posed by the device, is in violation of 21 C.F.R. § 806.0l(a)(l).

184. 21 C.F.R. § 806.0l (a)(l) is intended to alert the FDA of a defective and dangerous medical device that is in the stream of commerce, so that the FDA can ensure that the general public and physicians are aware of and can avoid the dangerous medical device on the market.

185. Plaintiff James D. Brown is a member of the general public who was implanted with a dangerous medical device that had previously underwent correction, removal, and/or discontinuation

186. Defendants violated 21 C.F.R. § 806.0l (a)(l) by correcting, removing, and/or discontinuing multiple types of the C-Qur Mesh without reporting such actions to the FDA, physicians, or the general public.

187. The entire C-Qur Mesh family would have been pulled from the market, underwent further investigations, had additional and more prominent warnings and contraindications, and/or physicians would have been aware of additional risk had Defendants' not violated 21 C.F.R. § 806.0l (a)(l).

188. Plaintiff James D. Brown and his physician would not have utilized the C-Qur Mesh had Defendants' not violated 21 C.F.R. § 806.0l(a)(l).

189. As a direct and proximate result of the Defendants' violation of 21 C.F.R. § 806.0l (a)(l), Plaintiff James D. Brown has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

WHEREFORE, Plaintiff, James D. Brown, demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests

compensatory damages, enhanced compensatory damages, and such further relief as the Court deems equitable and just.

COUNT X - FRAUD

190. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

191. At all relevant times, Defendants' marketed, promoted, and/or sold the C-Qur Mesh as safe, efficacious, and suitable for human implantation.

192. The C-Qur mesh is not safe, efficacious, or suitable for human implantation.

193. The Defendants' marketed, promoted, and/or sold the C-Qur Mesh as safe, efficacious, and suitable for human implantation with the intent that more patients and physicians would utilize the C-Qur Mesh, increasing the Defendants' profits.

194. Plaintiff James D. Brown and his physician utilized the C-Qur Mesh because they believed the C-Qur mesh was safe, efficacious, and suitable for human implantation at the time, because the Defendant's deceptively marketed, promoted, and/or sold the C-Qur Mesh as such.

195. Defendants, from the time they first tested, studied, researched, evaluated, endorsed, manufactured, marketed, and distributed the C-Qur Mesh, and up to the present, knew or were consciously indifferent to the fact that their representations were false; knew and willfully deceived Plaintiff, the FDA, Plaintiff's physician, the medical community, and the general public, as to the true facts concerning the C-Qur Mesh, which the Defendants had a duty to disclose with the intention of having physician, the medical community, and the general public rely upon their representations.

196. Defendants are the sole bearer of the true, accurate, unaltered information,

tests, studies, trials, and data on the safety, efficacy, and suitable for human implantation of the C-Qur Mesh, and therefore the Plaintiff and the Plaintiff's doctor had no reason or information to believe that the Defendants claims were in fact false.

197. The Plaintiff James D. Brown and his physician intended to select a safe and efficacious mesh for hernia and/or soft tissue repair that was suitable for human implantation, justifiably relied upon the Defendants' representations and selected the Defendants' C-Qur Mesh because of the false claims that the Defendants made about the safety, efficacy and suitability of the C-Qur Mesh for hernia and/or soft tissue repair as used by the Plaintiff and the Plaintiff's physician.

198. Defendants are the sole bearer of the true, accurate, unaltered information, tests, studies, trials, and data on the safety, efficacy, and suitable for human implantation of the C-Qur Mesh, and therefore the Plaintiff and the Plaintiff's physician had no other option but to rely of the Defendants' representations.

199. As a direct and proximate result of Plaintiff James D. Brown and his physicians' reliance on the Defendants' misrepresentations, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

WHEREFORE, Plaintiff, James D. Brown demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, enhanced compensatory damages, and such further relief as the Court deems equitable and just.

COUNT XI - VICARIOUS LIABILITY

200. Whenever in this complaint it is alleged that Defendants did or omitted to do any act, it is meant that Defendant's officers, agents, servants, employees, or

representatives did or omitted to do such act and that at the time such act or omission was done, it was done with the full authorization or ratification of Defendant or was done in the normal and routine course and scope of employment of Defendants' officers, agents, servants, employees, and representatives.

COUNT XII- LOSS OF CONSORTIUM

201. Plaintiff, Kimberly Brown, incorporates by reference the factual portion of this complaint as if fully set forth herein and additionally or in the alternative, if same be necessary, allege as follows:

202. The Plaintiff, Kimberly Brown, states on account of said injuries sustained to her husband as heretofore described, she was deprived of the companionship, consortium and services of said husband and was further compelled to spend certain sums of money for medical expenses on his behalf.

WHEREFORE, the Plaintiff, Kimberly Brown demands judgment against the Defendants in an amount that is just and appropriate for the losses sustained together with interest and costs.

COUNT XIII-ENHANCED COMPENSATORY DAMAGES

203. Plaintiffs incorporate by reference the factual portion of this complaint as if fully set forth herein and additionally or in the alternative, if same be necessary, allege as follows:

204. Defendants' conduct in designing, manufacturing, marketing, labeling, packaging and selling the unreasonably safe and defective mesh products amounted to outrageous, unconscionable willful, wanton, and/or reckless conduct and/or criminal indifference to civil obligations affecting the rights of others, including Plaintiff James D. Brown.

205. The acts, conduct, and omissions of the Defendants, as alleged throughout this Complaint were willful and malicious and were done with a conscious disregard for the rights of Plaintiff and other users of Defendants' product and for the primary purpose of increasing Defendants' profits from the sale, distribution, and use of Defendants' products. Defendants' outrageous and unconscionable conduct warrants an award of enhanced compensatory damages against each Defendant in an amount appropriate to provide full and complete compensation.

206. Plaintiffs are entitled to an award of enhanced compensatory damages.

DISCOVERY RULE AND FRAUDULENT CONCEALMENT

207. Plaintiffs reallege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

208. Despite diligent investigation by Plaintiffs into the cause of their injuries, including consultations with his medical providers, the nature of his injuries and damages and their relationship to the defective C-Qur Mesh were not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statutory period for filing Plaintiffs' claims. Therefore, under appropriate application of the discovery rule, Plaintiffs' suit was filed within the applicable statutory limitations period.

209. New Hampshire provides Plaintiffs with the protection of a discovery rule that allows for the tolling of the statute of limitations "until the Plaintiffs discovers or in the exercise of reasonable diligence should have discovered not only that he has been injured but also that his injury may have been caused by the Defendant's conduct."

210. Defendants are estopped from asserting a statute of limitations defense because Defendants fraudulently concealed from Plaintiffs the nature of their injuries and the connection between the injuries and Defendants' tortious conduct.

WHEREFORE, Plaintiffs pray that Judgment enter against against Defendants and each of them, individually, jointly and severally and request compensatory damages, enhanced compensatory damages and all such other relief as the Court deems just and proper as well as:

1. For past and future general damages in an amount in excess of the minimum jurisdictional limits of this Court;
2. For general damages for personal injury, including permanent impairment, physical injury, physical and mental pain and suffering, distress, and loss of enjoyment of life;
3. For past and future medical and incidental expenses, according to proof;
4. For past and future loss of earnings and/or earning capacity, according to proof;
5. For prejudgment interest on a11 damages as is allowed by law;
6. For past and future costs of suit incurred herein;
7. For enhanced compensatory damages in an amount to be determined at trial;
8. For such other and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiffs hereby demands a trial by jury on all issues so triable.

Respectfully submitted
Plaintiffs, By Their Attorneys

Dated: January 9, 2017

/s/ Louis J. Muggeo

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