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UNITED STATES DISTRICT COURT

DISTRICT OF HAWAI'I

JAMES K. KEAULANA; EILEEN KEAULANA, Plaintiff, vs. C.R. BARD, INC.; BARD DAVOL, INC.; JOHN DOES 1-10, JANE DOES 1-10, DOE PARTNERSHIPS 1-10, DOE CORPORATIONS 1-10, DOE ENTITIES 1-10, and DOE GOVERNMENTAL UNITIS 1-10, Defendants.	Case No.: 1:19-cv-619 COMPLAINT; DEMAND FOR JURY TRIAL; SUMMONS

COMPLAINT

COMES NOW Plaintiffs, JAMES K. KEAULANA ("Plaintiff" or "James") and EILEEN KEAULANA ("Eileen," and collectively with James, "Plaintiffs"), by and through their attorneys Miyoshi & Hironaka LLLC, brings this Complaint for damages against Defendants, and alleges as follows:

INTRODUCTION

This is a device tort action brought on behalf of the above-named Plaintiffs arising out of the failure of Defendants' hernia mesh product, the Ventralex Hernia Patch ("Mesh Patch"). As a result, Plaintiff James K. Keaulana has suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Eileen has suffered loss of consortium. Plaintiffs respectfully seeks all damages to which they may be legally entitled.

PARTIES

1. Plaintiff James K. Keaulana is and was at all relevant times herein a resident of the State of Hawaii and the United States.

2. Plaintiff Eileen Keaulana is and was at all relevant times herein a resident of the State of Hawaii and the United States.

3. Defendant, C.R. Bard, Inc. ("Bard") is incorporated and based in New Jersey. Bard is a multinational marketer, promoter, seller, producer,

manufacturer, and developer of medical devices. Bard controls the largest share of the hernia mesh market. It is the corporate parent/shareholder of Davol and participates in the manufacture and distribution of the Mesh Patch. Bard also manufactures and supplies Davol with material that forms part of the Mesh Patch.

4. Defendant Davol, Inc. ("Davol") is incorporated in Delaware and has its principal place of business in Rhode Island. Davol is a medical device company involved in the research, development, testing, manufacture, production, marketing, promotion and/or sale of medical devices, including the Mesh Patch composed of polypropylene.

5. Bard was at all times relevant responsible for the actions of Davol, and exercised control over Davol's functions specific to the oversight of and compliance with applicable safety standards relating to and including the Mesh Patch sold in the United States. In such capacity, Bard committed or allowed to be committed tortious and wrongful acts, including the violation of numerous safety standards relating to device manufacturing, quality assurance/control, and conformance with design and manufacturing specifications. Bard's misfeasance and malfeasance caused Plaintiffs to suffer injury and damages.

6. Defendants are individually, jointly and severally liable to Plaintiffs for damages suffered by Plaintiffs arising from their design, manufacture, marketing, labeling, distribution, sale and placement of the defective Mesh Patch at

issue in this suit. All acts were effectuated directly and indirectly through Defendants' respective agents, servants, employees and/or owners, acting within the course and scope of their representative agencies, services, employments and/or ownership.

7. Defendants are vicariously liable for the acts and/or omissions of their employees and/or agents, who were at all times relevant acting on Defendants' behalf and within the scope of their employment or agency with Defendants.

VENUE AND JURISDICTION

8. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a), based on complete diversity of citizenship between Plaintiffs and all Defendants. The amount in controversy exceeds $75,000.00.

9. Venue is proper in this Court pursuant to 28 U.S.C. § 1332(a)-(c) by virtue of the facts that (a) substantial part of the acts or omissions giving rise to Plaintiff's claims occurred in this District; and (b) Defendants' products are sold to and consumed by individuals in the State of Hawaii. Defendants are thus subject to personal jurisdiction in this action and made 'residents" of this judicial District.

10. Defendants have conducted, and continue to conduct, substantial business in the State of Hawaii and in this District; distribute Mesh

Patch in this District; receive substantial compensation and profits from sales of the Mesh Patch in this District; and make material omissions and misrepresentations and breaches of warranties in this District, so as to subject them to personal jurisdiction in this District.

11. Davol is registered to transact business in New Jersey.

FACTUAL SUMMARY

12. On or about October 21, 2010, Plaintiff James K. Keaulana underwent an epigastric hernia repair by Dr. Brandt Lapschies at The Queen's Medical Center, in Honolulu, Hawaii. A Davol Mesh Patch Ventralex, Medium Circle, with Serial No. 0010302 was implanted in Plaintiff during this repair.

13. Defendants manufactured, sold, and/or distributed the Mesh Patch to Plaintiff, through Plaintiff's doctors, to be used for treatment of hernia repair.

14. On or about November 1, 2018, Plaintiff James K. Keaulana underwent removal of the defective Mesh Patch by Dr. Mihae Yu at The Queen's Medical Center in Honolulu, Hawaii.

15. Plaintiff continues to suffer pain and permanent disfigurement and chronic pain.

16. The Mesh Patch is a bilayer construction of a self-expanding patch containing two layers of polypropylene mesh stitched with

polytetrafluorethylene (PTFE) monofilament to an expanded polytetrafluoroethylene (ePTFE) sheet. The mesh component is described as containing a "fully absorbable" recoil ring using SorbaFlex Memory Technology, an absorbable polydioxanone (PDO) monofilament.

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

18. Upon information and belief, Defendants' numerous suppliers of various forms of polypropylene cautioned all users in their United States Material Safety Data Sheet that the polypropylene was not to be used for medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues.

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

20. Defendants were responsible for the research, design, development, testing, manufacture, production, marketing, promotion, distribution

and sale of the Mesh Patch, including providing the warnings and instructions concerning the product.

21. Among the intended purposes for which Defendants designed, manufactured and sold the Mesh Patch is used by surgeons for hernia repair surgeries. That is the purpose for which the Mesh Patch was implanted in Plaintiff.

22. Defendants represented to Plaintiff and Plaintiff's physicians that the Mesh Patch was safe and an effective product for hernia repair.

COUNT I (STRICT LIABILITY – MANUFACTURING DEFECT)

23. Plaintiffs incorporate by reference and realleges as if fully set forth herein the allegations contained in paragraphs 1-22.

24. Defendants expected and intended the Mesh Patch to reach users such as Plaintiff in the condition in which the product was sold.

25. The implantation of Mesh Patch in Plaintiff's body was medically reasonable and was a type of use that Defendants intended and foresaw when they designed, manufactured and sold the product.

26. The Mesh Patch was defectively manufactured when it was implanted in Plaintiff's body.

27. Defendants' poor quality control and general non-compliance resulted in the nonconformance of the Mesh Patch implanted in Plaintiff. The

implanted Mesh Patch did not conform to Defendants' intended manufacturing and design specifications.

28. Upon information and belief, Defendants utilized substandard and adulterated polypropylene in the Mesh Patch, which deviated from Defendants' material and supply specifications.

29. As a direct and proximate result of Defendants' defective manufacture of the Mesh Patch, Plaintiffs suffered injuries and damages as summarized in this Complaint.

COUNT II (STRICT LIABILITY – DESIGN DEFECT)

30. Plaintiffs incorporate by reference and realleges as if fully set forth herein the allegations contained in paragraphs 1-29.

31. Defendants' Mesh Patch was defectively designed and/or manufactured and was not reasonably safe for its intended use in hernia repair. The risks of the design outweighed any potential benefits associated with the design. As a result of the defective design and/or manufacture of the Mesh Patch, there was an unreasonable risk of severe adverse reactions to the mesh or mesh components including: chronic pain; recurrence of hernia; foreign body response; rejection; infection; scarification; improper wound healing; excessive and chronic inflammation; allergic reaction; adhesions to internal organs; erosion; abscess; fistula formation; granulomatous response; seroma formation; nerve damage;

tissue damage and/or death; and other complications.

32. These manufacturing and design defects associated with the Mesh Patch were directly and proximately related to the injuries Plaintiff suffered.

33. Neither Plaintiff nor Plaintiff's implanting physician was adequately warned or informed by Defendants of the defective and dangerous nature of the Mesh Patch. Moreover, neither Plaintiff nor his implanting physician was adequately warned or informed by Defendants of the risks associated with the Mesh Patch.

34. The Mesh Patch implanted in Plaintiff failed to reasonably perform as intended. The Mesh Patch caused serious injury and had to be surgically removed via invasive surgery and necessitated additional invasive surgery to repair the hernia that the Mesh Patch was initially implanted to treat.

35. As described above, there was an unreasonable risk that the Mesh Patch, which was defectively designed, would not perform safely and effectively for the purposes for which it was intended. Defendants failed to design against such dangers and failed to provide adequate warnings and instructions concerning these risks.

36. Defendants expected and intended the Mesh Patch to reach users such as Plaintiff in the condition in which the Mesh Patch was sold.

37. The implantation of the Mesh Patch in Plaintiff's body was

medically reasonable and was a type of use that Defendants intended and foresaw when they designed, manufactured and sold the product.

38. The risks of the Mesh Patch significantly outweigh any benefits that Defendants contend could be associated with it.

39. The polypropylene mesh utilized to manufacture the Mesh Patch was in itself dangerous and defective, particularly when used in the manner intended by Defendants in the Mesh Patch. The particular polypropylene material used in the Mesh Patch was substandard, adulterated and non-medical grade, and was unreasonably subject to oxidative degradation within the body. When implanted as intended, adjacent internal organs, structures, nerves, arteries, and vessels, polypropylene mesh is unreasonably susceptible to adhesion formation, nerve entrapment, spermatic cord obliteration, organ perforation or erosion, fistula formation and bowel strangulation or hernia incarceration, and other injuries.

40. The appropriate treatment for complications associated with the Mesh Patch involves additional invasive surgery to remove the mesh from the body, thus eliminating any purported benefit that the mesh was intended to provide to a patient.

41. When the Mesh Patch was implanted in Plaintiff, there were safer feasible alternative designs for hernia mesh product, including but not limited to, a flat, non-coated, single layer, large pore mesh.

42. The Mesh Patch implanted in Plaintiff failed to reasonably perform as intended. It had to be surgically removed, necessitating further invasive surgery to repair the very issue that the product was intended to repair, and thus providing no benefit to Plaintiff.

43. As a direct and proximate result of the defective and unreasonably dangerous condition of the product, Plaintiffs suffered injuries and damages as summarized in this Complaint.

COUNT III (STRICT LIABILITY – FAILURE TO WARN)

44. Plaintiffs incorporate by reference and realleges as if fully set forth herein the allegations contained in paragraphs 1-43.

45. When the Mesh Patch was implanted in Plaintiff's body, the warnings and instructions Defendants provided were inadequate and defective. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended, and Defendants failed to design and/or manufacture against such dangers and failed to provide adequate warnings and instructions concerning these risks.

46. Defendants expected and intended the Mesh Patch product to reach users such as Plaintiff in the condition in which the product was sold.

47. Plaintiff and his physicians were unaware of the defects and dangers of the Mesh Patch, and were unaware of the frequency, severity and

duration of the risks associated with the product.

48. The Instructions for Use for the Mesh Patch also failed to adequately warn Plaintiff's physicians of numerous risks that Defendants knew or should have known were associated with the Mesh Patch, including: risks of the product's immunologic response, pain, encapsulation, rejection, migration, scarification, contraction, adhesion to internal structures or organs, erosion and migration through adjacent tissue and viscera, bowel obstruction, or hernia incarceration or strangulation.

49. Defendants failed as well to adequately warn Plaintiff or Plaintiff's physicians about the necessity for invasive surgical intervention in the event of complications with the Mesh Patch or train the physicians on the proper treatment of such complications when they occurred.

50. Defendants failed to adequately warn Plaintiff or his physicians that: the surgical removal of the Mesh Patch in the event of complications would leave the hernia unrepaired; the resulting hernia would be much larger than the original; and further, more complicated medical treatment to attempt to repair the same hernia would be necessary.

51. With respect to the complications listed in their warnings, Defendants provided no information or warning regarding the frequency, severity and duration of those complications, although the complications associated with

the Mesh Patch were more frequent, more severe and longer lasting than those in safer feasible alternative hernia repair treatments.

52. If Plaintiff and/or Plaintiff's physicians had been properly warned of the defects and dangers of the Mesh Patch, and of the frequency, severity and duration of the risks associated with the product, Plaintiff would not have consented to allow the Mesh Patch to be implanted, and Plaintiff's physicians would not have implanted the product in Plaintiff.

53. As a direct and proximate result of the inadequate and defective warnings and instructions, Plaintiffs suffered injuries and damages as summarized in this Complaint.

COUNT IV (NEGLIGENCE)

54. Plaintiffs incorporate by reference and realleges as if fully set forth herein the allegations contained in paragraphs 1-53.

55. Although Defendants had a duty to use reasonable care in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for the Mesh Patch, they failed to do so.

56. Defendants knew, or in the exercise of reasonable care should have known, that the Mesh Patch was defectively and unreasonably designed and/or manufactured, and were unreasonably dangerous and likely to injure

patients in whom the product was implanted. Defendants knew or should have known that Plaintiff and Plaintiff's physicians were unaware of the dangers and defects inherent in the Mesh Patch.

57. Defendants knew or should have known that the Material Data Safety Sheet for the polypropylene used to manufacture their Mesh Patch prohibited permanently implanting the polypropylene into the human body.

58. Defendants utilized non-medical grade polypropylene.

59. Defendants knew or should have known that polypropylene is not inert and would degrade, flake, chip, and disperse throughout the body once implanted.

60. Defendants knew or should have known that polypropylene incites a severe inflammatory response once implanted and continues to incite a severe inflammatory response indefinitely or until removed.

61. Defendants knew or should have known that every piece of polypropylene that flakes off and migrates throughout the body also incites its own chronic inflammatory response wherever it embeds.

62. Defendants knew or should have known that small pore size of the Mesh Patch would increase mesh surface area which would increase the inflammatory and foreign body response.

63. As a direct and proximate result of Defendants' negligence in

designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for Mesh Patch, Plaintiffs suffered injuries and damages as summarized in this Complaint.

COUNT V (BREACH OF EXPRESS WARRANTY)

64. Plaintiffs incorporate by reference and realleges as if fully set forth herein the allegations contained in paragraphs 1-63.

65. At all material times, Defendants manufactured, marketed, sold, distributed and otherwise placed into the stream of commerce the Mesh Patch.

66. In advertising, marketing and otherwise promoting the Mesh Patch to physicians, hospitals and other healthcare providers, Defendants expressly warranted that their product was safe for use and reasonably fit for its intended purposes. In advertising, marketing and otherwise promoting the Mesh Patch, Defendants intended that physicians, hospitals and other healthcare providers rely upon their representations regarding safety and fitness, to induce them to implant the Mesh Patch in their patients.

67. With respect to Plaintiff, Defendants intended that the Mesh Patch be implanted by his treating surgeon in a reasonable and foreseeable manner, and in accordance with the instructions for use and product specifications provided by Defendants. Plaintiff was in privity with Defendants.

68. Defendants expressly warranted the following to physicians, hospitals, other healthcare providers and the general public, including Plaintiff: the Mesh Patch was safe and fit for use by consumers; it was of merchantable quality; its risks, side effects and potential complications were minimal and comparable to other hernia mesh product; it was adequately researched and tested; and it was fit for its intended use. Plaintiff and Plaintiff's physicians and healthcare providers reasonably relied upon Defendants' representations and warranties, and consequently, Plaintiff was implanted with Defendants' product.

69. Defendants expressly warranted to physicians, hospitals, other healthcare providers and the general public, including Plaintiff, that the Mesh Patch was safe and fit for use for the repair of hernias.

70. Defendants represented that the Mesh Patch would prevent or minimize hernia recurrence and pain, and facilitate incorporation of the mesh into the body, but it did not. Instead, the Mesh Patch caused an intense systemic inflammatory and chronic foreign body response, resulting in an adverse tissue reaction including damage to surrounding tissue in the form of sclerotic, granulomatous and/or fibrotic tissue and improper or delayed healing.

71. Defendants breached these express warranties because the Mesh Patch implanted in Plaintiff were unreasonably dangerous, defective, and not as Defendants had represented.

72. Defendants breached express representations and warranties to Plaintiff, as well as his physicians and healthcare providers, with respect to the Mesh Patch, by representing the following:

a. through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions, among other methods, that their product was safe; but they fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the Mesh Patch.

b. the Mesh Patch was as safe and/or safer than other alternative procedures and devices on the market; but they fraudulently concealed information demonstrating that the Mesh Patch was not safer than alternative therapies and product available on the market; and

c. the Mesh Patch was more efficacious than other alternative procedures, therapies and/or devices; but they fraudulently concealed information regarding the true efficacy of the product.

73. Defendants' breach of their express warranties resulted in the implantation of unreasonably dangerous and defective product into Plaintiff, placing his health and safety in jeopardy.

74. When Defendants made such express warranties, they knew or should have known that their Mesh Patch did not conform to their express

warranties. Defendants' acts were motivated by financial gain, while the adverse consequences of their conduct were outrageous, fraudulent, oppressive, done with malice or gross negligence and evidenced reckless indifference to Plaintiff's rights, health and safety, so as to warrant the imposition of punitive damages.

COUNT VI (VIOLATION OF FEDERAL & STATE CONSUMER PROTECTION LAWS)

75. Plaintiffs incorporate by reference and realleges as if fully set forth herein the allegations contained in paragraphs 1-74.

76. Plaintiff purchased and used the Mesh Patch primarily for personal use, and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

77. Had Defendants not engaged in the deceptive conduct described in this Complaint, Plaintiff would not have purchased and/or paid for the Mesh Patch, and would not have incurred related medical costs and injury.

78. Defendants engaged in wrongful conduct, while at the same time obtaining, under false pretenses, moneys from Plaintiff for the Mesh Patch, which would not have been paid had Defendants not engaged in unfair and deceptive conduct.

79. Unfair methods of competition or deceptive acts or practices that were proscribed by law, include 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.

80. Plaintiffs 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 sell its Mesh Patch. Each aspect of Defendants' conduct combined to artificially create sales of the product.

81. 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 Mesh Patch.

82. Had Defendants not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for the Mesh Patch, and would not have incurred related medical costs.

83. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in

violation of the federal and state consumer protection statutes listed below.

84. Defendants' actions constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of federal and state consumer protection statutes listed below.

85. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or false advertising, or have made false representations in violation of:

a. 15 U.S.C. §§ 2301-2312 (1982)

b. Haw. Rev. Stat. §§ 480-1, et. seq.

c. N.J. Stat. Ann §§ 56:8-1, et. seq.

d. R.I. Gen. Laws §§ 6-13.1, et. seq.

86. Under the statutes listed above Defendants are the suppliers, manufacturers, advertisers, and sellers subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

87. Defendants violated the statutes enacted in these states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that its Mesh Patch was 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 in this Complaint. These representations were made in marketing and

promotional materials.

88. Defendants' actions and omissions are uncured or incurable deceptive acts under the consumer protection laws.

89. Defendants had actual knowledge of the defective and dangerous condition of its Mesh Patch and failed to take any action to cure such defective and dangerous conditions.

90. 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).

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

92. By reason of the unlawful acts in which Defendants engaged, and as a direct and proximate result of those acts, Plaintiffs suffered ascertainable losses and damages.

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

COUNT VII (NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS)

94. Plaintiffs incorporate by reference and realleges as if fully set forth herein the allegations contained in paragraphs 1-93.

95. Defendants carelessly and negligently manufactured, designed, developed, tested, labeled, marketed and sold the Mesh Patch to Plaintiff.

96. Defendants carelessly and negligently concealed the harmful effects of their product from Plaintiff, individually and/or Plaintiff's physician, on multiple occasions. They continue to do so to this day.

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

98. Plaintiff was directly impacted by Defendants' carelessness and negligence, in that he 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 Mesh Patch sold and distributed by Defendants.

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

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

101. As a proximate result of the Defendants' acts or omissions, 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.

COUNT VIII (FRAUDULENT CONCEALMENT)

102. Plaintiffs incorporate by reference and realleges as if fully set forth herein the allegations contained in paragraphs 1-101.

103. At all material times, Defendants knew or should have known that the Mesh Patch caused large numbers of complications. Moreover, they also knew or should have known the following: the surgical technique and training of implanting physicians was not the cause of the adverse events associated with these devices; the safety and efficacy of its Mesh Patch had not been proven with respect to, among other things, the product, its components, its performance, and its method of insertion; the Mesh Patch was not safe and effective. But Defendants continued to represent that the Mesh Patch was safe and effective.

104. Despite what Defendants knew or should have known about the lack of safety and efficacy of the Mesh Patch, they failed to disclose this information to Plaintiff, to Plaintiff's physicians, and to the public at large.

105. At all material times, Defendants had the duty and obligation to disclose to Plaintiff and Plaintiff's physicians the true facts concerning the Mesh Patch: that they were dangerous and defective, lacking efficacy for their purported use and lacking safety in normal use, and the likelihood of them causing serious consequences to users, including permanent and debilitating injuries. Defendants concealed these material facts before Plaintiff was implanted with their product.

106. Defendants were under a duty to Plaintiff to disclose and warn of the defective nature of the Mesh Patch because:

a. Defendants were in a superior position to know the true quality, safety, and efficacy of the Mesh Patch;

b. Defendants knowingly made false claims in documents and marketing materials about the safety and quality of the Mesh Patch; and

c. Defendants fraudulently and affirmatively concealed the defective nature of the Mesh Patch from Plaintiff.

107. The facts concealed and/or not disclosed by Defendants to

Plaintiff and his physician were material facts that a reasonable person would have considered to be important in deciding whether to purchase and/or use the Mesh Patch.

108. At all material times, Defendants willfully, intentionally, and maliciously concealed facts as set forth above from Plaintiff and his physician, with the intent to defraud.

109. Defendants intentionally concealed and/or failed to disclose the true defective nature of the Mesh Patch so that Plaintiff would request and purchase the product, and his healthcare providers would dispense, prescribe, and recommend the Mesh Patch; and Plaintiff justifiably acted or relied upon the concealed and/or non-disclosed facts to his detriment.

110. At all material times, neither Plaintiff nor Plaintiff's physician was aware of the facts set forth above. Had they been aware of the facts, they would not have acted as they did, i.e., would not reasonably relied upon the representations of safety and efficacy and utilized the Mesh Patch in their treatment. Defendants' failure to disclose this information was a substantial factor in Plaintiff's physicians selecting Defendants' Mesh Patch. The failure to disclose also resulted in the provision of incorrect and incomplete information to Plaintiff, as a patient.

111. As a direct and proximate result of Defendants' conduct,

Plaintiff was injured.

COUNT IX (NEGLIGENT MISREPRESENTATION)

112. Plaintiffs incorporate by reference and realleges as if fully set forth herein the allegations contained in paragraphs 1-111.

113. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, and the public, that the Mesh Patch had not been adequately tested and found to be a safe and effective treatment. Defendants' representations were in fact false.

114. Defendants failed to exercise ordinary care in the representations concerning the Mesh Patch while they were involved in its manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants negligently misrepresented or concealed the Mesh Patch' high risk of unreasonable and dangerous adverse side effects.

115. Defendants breached their duty in representing to Plaintiff, Plaintiff's physicians, and the medical community, that the Mesh Patch had no serious side effects different from those of other similar product and/or procedures.

116. As a foreseeable, direct, and proximate result of Defendants' negligent misrepresentation, they knew or should have known that the Mesh Patch had been insufficiently tested, or had not been tested at all. As well, they knew or

should have known that the product lacked adequate and accurate warnings, creating a high risk—or higher than acceptable or reported and represented risk—of adverse side effects. Those included pain, graft rejection, graft migration, organ damage, complex seroma, fistula, sinus tract formation, delayed wound closure, infection, sepsis, and death.

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

COUNT X (LOSS OF CONSORTIUM)

118. Plaintiffs incorporate by reference and realleges as if fully set forth herein the allegations contained in paragraphs 1-117.

119. As a consequence of the above-mentioned tortious conducts of Defendants, Plaintiff suffered significant injuries.

120. Prior to suffering the injuries resulting form the tortious conduct of Defendants, Plaintiff was able to and did perform all the duties of a husband and father, including but not limited to providing financial support, love, companionship, affection, society, moral support and solace to his wife, Eileen.

121. As a direct result of Defendants' tortious conduct, Eileen, as wife of Plaintiff, suffered a loss in the quality of the relationship that she had with her husband, and is therefore entitled to damages in an amount to be proven at trial.

PUNITIVE DAMAGES

122. Plaintiffs incorporate by reference and realleges as if fully set forth herein the allegations contained in paragraphs 1-121.

123. Defendants failed to adequately test and study the Mesh Patch to determine and ensure that the product was safe and effective before releasing the product for sale for permanent human implantation; and Defendants continued to manufacture and sell the product after having obtained knowledge and information that they were defective and unreasonably unsafe.

124. At all material times, Defendants knew or should have known that the Mesh Patch was inherently more dangerous with respect to the following risks: migration, foreign body response, allergic reactions, rejection, infection, failure, erosion, pain and suffering, organ perforation, dense adhesions, loss of life's enjoyment, remedial surgeries and treatments in an effort to cure the conditions proximately related to the product's use, as well as other permanent and lasting severe and personal injuries.

125. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public,

including Plaintiff, concerning the safety and efficacy of the Mesh Patch, thus depriving Plaintiff and his implanting physicians of vitally necessary information necessary to make a fully informed decision about whether to use the product.

126. At all material times, Defendants knew and recklessly and/or intentionally disregarded the fact that the Mesh Patch can cause debilitating and potentially life-threatening side effects with greater frequency than safer alternative methods, product, procedures, and/or treatment. But they recklessly failed to advise the medical community and the general public, including Plaintiff, of the risks and side effects.

127. At all material times, Defendants intentionally misstated and misrepresented data, and continue to misrepresent data, so as to minimize the perceived risk of injuries and the rate of complications associated with Mesh Patch.

128. Notwithstanding the foregoing and the growing body of knowledge and information regarding the true and defective nature of the Mesh Patch's increased risk of side effects and serious complications, Defendants continue to aggressively market the product to the medical community and to consumers without disclosing the true risk of such complications.

129. When Plaintiff was implanted with the Mesh Patch and since then, Defendants have known that the Mesh Patch was defective and

unreasonably dangerous. Nonetheless, they have continued to manufacture, produce, assemble, market, distribute, and sell the product so as to maximize sales and profits at the expense of the health and safety of the public, in a conscious reckless and/or intentional disregard of the likely and foreseeable harm caused by the Mesh Patch to the public, including Plaintiff.

130. At all material times, Defendants have concealed and/or failed to disclose to the public the serious risks and the potential complications associated with the Mesh Patch, to ensure continued and increased sales and profits, to the detriment of the public, including Plaintiff.

131. Defendants' acts and omissions are of such character and nature so as to entitle Plaintiff to an award of punitive damages in accordance with applicable statutory and common law. Defendants' conduct shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care, which raise the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants, individually, jointly, and severally; and request compensatory damages, punitive damages or enhanced compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

PRAYER FOR RELIEF

Plaintiffs demand judgment against Defendants, individually, jointly and severally, and prays for the following relief in accordance with applicable law and equity:

A. Compensatory damages to Plaintiffs for past, present, and future damages, including but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiff, permanent impairment, mental pain and suffering, loss of enjoyment of life, loss of consortium, health and medical care costs, economic damages, together with interest and costs as provided by law;

B. Restitution and disgorgement of profits;

C. Punitive or enhanced compensatory damages;

D. Reasonable attorneys' fees as provided by law;

E. Costs of these proceedings, including past and future costs of suit;

F. All ascertainable economic damages;

G. Prejudgment interest on all damages as allowed by law; and

H. Such other relief as this Court deems just and proper.

DATED: Honolulu, Hawaii, November 14, 2019.

/s/Philip W. Miyoshi
PHILIP W. MIYOSHI
Attorney for Plaintiffs
JAMES K. KEAULANA
EILEEN KEAULANA