IN THE UNITES STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO

JANICE NOWELL,
Plaintiff

Case No.

v.

COVIDIEN, LP,
Defendant

COMPLAINT FOR DAMAGES FOR PERSONAL INJURY RESULTING FROM NEGLIGENCE, STRICT LIABILITY AND BREACH OF WARRANTIES

1. Plaintiff, Janice Nowell ("Plaintiff"), by and through her attorney, Jason S. Montclare, Esq., brings this complaint for damages for personal injury caused by Covidien, LP. who sold a surgical mesh product Parietex Mesh™ Composite (the Product) which was inserted into the body of Plaintiff to treat medical conditions, including but not limited to an abdominal hernia. The Product caused and continues to cause significant injury to the Plaintiff, as described below, while she resided and resides in the state of New Mexico.

2. The Plaintiff is a citizen of New Mexico.

3. Covidien, LP ("Covidien") is a Delaware Limited Partnership, headquartered at 15 Hampshire Street, Mansfield, Massachusetts 02048.

4. Defendant Covidien derives substantial revenue from sales directed at and occurring within the State of New Mexico, including Parietex Mesh™, the subject of the present action.

5. At all relevant times, Covidien designed, manufactured, tested, analyzed, distributed, recommended, merchandised, advertised, promoted, supplied and sold to distributors, physicians, hospitals and medical practitioners, certain hernia surgical repair products to

be surgically implanted in patients throughout the United States, including the State of New Mexico.

6. Covidien sold the product, which was designed to fix such hernias as the medical condition suffered by Plaintiff.

7. All acts and omissions of the Defendant as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

8. Federal subject matter jurisdiction in this action is based upon 28 U.S.C. § 1332(a), in that in this action there is complete diversity among the Plaintiff and Defendant and the amount in controversy exceeds $75,000 as to each cause of action alleged in this complaint.

9. Defendant has significant contacts with the federal judicial district of New Mexico such that it is subject to the personal jurisdiction of the court in said district. Such contacts include but are not limited to selling the Product to patients that would not only forseeably live within the state of New Mexico, but would also potentially suffer injury caused by the Product within the state of New Mexico.

10. A substantial part of the events and omissions giving rise to Plaintiff's causes of action occurred in the federal judicial district of New Mexico. Such events and omissions include but are not limited to the significant injuries caused by the Product and sustained by Plaintiff while she resided within the state of New Mexico. Pursuant to 28 U.S.C. § 1391(a), venue is proper in the federal judicial district of New Mexico.

11. The Product sold and distributed by the Defendant may be properly identified as Parietex Mesh™.

12. Defendant designed, manufactured, packaged, labeled, marketed, sold, and distributed the Product, including that which was implanted in the Plaintiff.

FACTUAL BACKGROUND

HERNIAS, HERNIA MESH PRODUCTS AND KNOWN ALTERNATIVES

13. A hernia is a medical condition caused by the penetration of fatty tissue, intestine, or organs through a weakened or compromised location in the muscle of connective tissue.

14. The most common types of hernias are: inguinal, hiatal, umbilical, ventral, incisional, and femoral hernias, most occurring near the abdominal wall.

15. Hernias sometimes manifest as visibly observable protrusions or bulges, and can cause the patient pain, discomfort, and decreased mobility.

16. Hernias can be treated surgically, either by laparoscopic or open repair surgical procedures.

17. Hernia repairs are common surgeries, and are performed more than one-million times per year in the U.S. Of all hernia repair surgeries, inguinal hernias account for approximately 80% of all hernia surgeries (an excess of 800,000 performed annually.)

18. The surgical mesh used to execute hernia repairs to damaged tissue can be constructed from synthetic or biologic materials and tissue. Synthetic surgical mesh is made of knitted or non-knitted sheets that can be absorbable, non-porous, or a combination of absorbable and nonabsorbent in composition.

19. Hernias have a high propensity for recurrence. Because of the propensity to require additional surgeries or revisions, surgical mesh can be introduced to the hernia site to strengthen the repair, in hopes of reducing the likelihood of recurrence.

20. Hernia mesh made from animal byproduct is usually derived from animal tissue sourced from skin or intestine, and is designed to be absorbed into the human body upon use.

21. Non-absorbable mesh, made from synthetic materials, is intended to remain within the body permanently.

22. The most common injuries caused by hernia surgeries using hernia mesh are: pain, infection, recurrence of hernia, adhesion of scar tissue sticking together, blockages that obstruct intestines, internal bleeding, fistula between organs (abnormal organ connection or fusion), serenoma or fluid build-up at site, and perforation of other organs.

23. The hernia mesh introduced to the body can cause serious injuries, including migration of the mesh and mesh shrinkage or contraction as well as the aforementioned conditions.

24. Additional defects and known side effects of hernia mesh, as used for reinforcement and strengthening of hernia repairs, include:

a. Mesh materials, as used, react to human tissues, organs and other body contents adversely.

b. Mesh materials can harbor or cultivate infections, which can affect surrounding areas, tissues, and organs.

c. Mesh material abrades bodily tissue, and can cause erosion of tissue and organs surrounding the placement of the mesh implant.

d. Mesh components routinely fail, malfunction or lose efficacy, resulting in serious adverse health implications, often requiring subsequent revision or removal surgery.

e. Mesh material causes significant injury, extending to perforation of surrounding tissue and/or organs, adhesion to other tissue and/or organs, and nerve damage.

f. Mesh material is intended to be rounded and reinforced to be safely cut, but when mesh is defective, it can become frayed, sharp, and protruding.

g. Unreasonable risk of malfunction, injury and health consequences, such as: severe chronic pain, infection, recurrence of hernia, adhesion, intestinal blockages, migration of mesh, contraction/shrinkage of mesh, and requirement of repeat surgical intervention.

25. In April of 2016, the FDA wrote and published an article on hernia mesh implants; "Many complications related to hernia repair with surgical mesh that have been reported to the FDA have been associated with recalled mesh products that are no longer on the market. Pain, infection, recurrence, adhesion, obstruction, and perforation are the most common complications associated with recalled mesh."

26. Safer and more effective alternatives to hernia mesh exist and have existed since the introduction of hernia mesh products into the market. These include the Shouldice Repair, McVay Repair, Bassini Repair, and Desarda Repair.

DEFENDANT COVIDIEN: PERIETEX MESH®

27. Parietex Mesh™ is designed, researched, tested, developed, manufactured, marketed, advertised, promoted, distributed and/or sold by Covidien.

28. The Parietex Mesh™ product is a surgical mesh material that is composed of a microporous monofilament textile and is partially absorbable. Parietex Mesh™ is a bicomponent mesh constructed of hydrophilic monofilament polyester (PET) knit with resorbable polylactic acid (PLA) micro-grips.

29. Polyester is a hydrophilic material as opposed to hydrophobic material such as polypropylene or polytetrafluoroethylene and thus encourages early biologic fixation and collagen ingrowth into surrounding tissue.

30. Parietex Mesh™ is intended for permanent use to reinforce soft-tissue.

31. Parietex Mesh™ is advertised to support "tissue integration while minimizing visceral attachment with collagen film."

32. Parietex Mesh™ was promoted based on its strength and surgical adaptability.

33. Defendant Covidien, applied for U.S. Food and Drug Administration ("FDA") clearance to market Parietex Mesh™ under Section 510(k) of the Medical Device Amendment.

34. Section 510(k) allows for the marketing of medical devices, so long as the medical device or material is deemed substantially equivalent to other legally marketed predicate devices or materials without predicate devices without formal review for the safety of efficacy of the device. Parietex Mesh™ was deemed approved based upon being substantially equivalent to legally marketed predicate devices marketed in interstate commerce.

35. The FDA maintains an active compulsory database ("MAUDE DATABASE") of adverse incidents reported by medical providers regarding pharmaceutical implants and devices. Every year, the FDA received hundreds of medical device reports ("MDRs") of suspected device-associated deaths, serious injuries, and malfunctions to contribute to the medical community's risk-benefit analysis of the use of certain devices.

36. MAUDE reports have been published documenting serious malfunctions of Defendant Covidien's Parietex Mesh™.

37. Parietex Mesh™ malfunctions include serious pain in the groin, belly button and testicles, an electric jolt sensation between the testicles and legs, lower abdominal pain and spasms, and permanent disability.

38. On or about October 20, 2014, Dr. William Pollard removed an infected and disintegrated Parietex Mesh™ from Ms. Nowell's abdomen in Alamogordo, New Mexico. Dr. Powell initially attempted a laparoscopic repair using a 20-cm circular Parietex mesh in October, 2010. Thereafter, a CT scan of the abdomen and pelvis revealed a large fluid collection associated with the majority of the mesh. There was a sinus tracking from this to an area that had reopened in the left lower aspect of her incision. Based on these findings, the Plaintiff was taken electively to surgery on October 20, 2017 and as noted above, an infected and disintegrated ventral hernia mesh was removed.

39. The Parietex Mesh™ caused Plaintiff serious injuries to her person including but not limited to abdominal pain, infection, tenderness at the site where the Product was inserted, trauma to the Plaintiff's abdomen and thereafter severe emotional distress.

40. These symptoms of injury were caused by the Parietex Mesh™'s defects, including but not limited to the effect of the disintegration and misshape of the Parietex Mesh™ on Plaintiff's person. The physical structure of the disintegrated mesh caused trauma to the Plaintiff's abdomen as it repeatedly came in contact with it. Furthermore, the composition of the mesh itself caused and exacerbated infection since the materials used to construct the mesh were not chemically compatible to the Defendant's tissue.

41. The disintegration and misshapening and infection of the Parietex Mesh™ occurred because the product was unsafe and defective.

42. The materials used to manufacture the Parietex Mesh™ were not strong and resilient enough to prevent this disintegration and misshapening.

43. Defendant did not, and have not, adequately studied the extent of the risks associated with the Parietex Mesh™ .

44. Defendant knew or should have known about the Product's risks and complications because this product caused injuries to others and similar products also caused extensive personal injuries to others.

45. Defendant knew or should have known that the Product unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks.

46. On information and belief, the material from which the Product is made is biologically incompatible with human tissue and promotes infection in people implanted with the Product, including the Plaintiff.

47. The FDA defines both "degradation" and "fragmentation" as "device problems" to which the FDA assigns a specific "device problem code." "Material Fragmentation" is defined as an "[i]ssue associated with small pieces of the device breaking off unexpectedly" and "degraded" as an "[i]ssue associated with a deleterious change in the chemical structure, physical properties, or appearance in the materials that are used in device construction." The Product was unreasonably susceptible to degradation and fragmentation inside the body. This caused the Plaintiff to sustain the injuries set forth in her complaint.

48. Defendant should have known of this serious risk and warned physicians and patients.

49. Defendant omitted and downplayed the risks, dangers, defects, and disadvantages of the Product, and advertised, promoted, marketed, sold and distributed the Product as a safe medical device when Defendant knew or should have known that the Product was

not safe for its intended purposes, and that the Product would cause, and did cause, serious medical problems, and in some patients, including the Plaintiff named in the Complaint, catastrophic injuries. Further, while some of the problems associated with the Product were made known to physicians, the magnitude and frequency of these problems were not disclosed and were hidden from physicians.

50. Contrary to Defendant's representations and marketing to the medical community and to the patients themselves, the Product and other similar products made by the Defendant have high rates of failure, injury, and complications, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including the female Plaintiff named in the Complaint, making them defective under the law.

51. Such defects caused the Plaintiff to undergo additional surgeries which otherwise would not have been necessary.

52. The specific nature of the Product's defects, each which of which caused injuries to the Plaintiff, includes, but is not limited to, the following:

1. a) On information and belief, the design of the Product to be inserted into and through an area of the body with high levels of bacteria that can adhere to the mesh causes immune reactions and subsequent tissue breakdown and adverse reactions and injuries;
2. b) Biomechanical issues with the design of the Product, including, but not limited to, the propensity of the Product to disintegrate inside the body, that in turn cause surrounding tissue to be inflamed, resulting in injury;
3. c) The propensity of the Product for degradation or fragmentation over time;

4. d) The adverse tissue reactions caused by the Product, which are causally related to infection, as the mesh is a foreign material;
5. e) The creation of a non-anatomic condition in the abdomen leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturer's instructions.

53. The Product is also defective due to Defendants' failure to adequately warn or instruct the female Plaintiff and/or her health care providers of subjects including, but not limited to, the following issues personally experienced by the Plaintiff: ;

1. a) The Product's propensities for degradation, fragmentation and/or creep;
2. b) The frequency and manner of mesh erosion or extrusion; ;
3. c) The risk of chronic infections resulting from the Product; ;
4. d) The risk of recurrent, intractable pain and other pain resulting from the Product;
5. e) The need for corrective or revision surgery to adjust or remove the Product;
6. f) The severity of complications that could arise as a result of implantation of the Product;
7. g) The hazards associated with the Product;
8. h) The Product's defects described herein;
9. i) Treatment of abdominal hernia with the Product is no more effective than feasible available alternatives;
10. j) Treatment of abdominal hernia with the Product exposes patients to greater risk than feasible available alternatives;

11. k) Treatment of abdominal hernia with the Product makes future surgical repair more difficult than feasible available alternatives;

12. l) Use of the Product puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

13. m) Removal of the product due to complications may involve multiple surgeries and may significantly impair the patient's quality of life.

54. Defendant underreported and continues to underreport information about the propensity of the Product to fail and cause injury and complications, such as those personally experienced by the Plaintiff, and have made unfounded representations regarding the efficacy and safety of the Product through various means and media.

55. Defendant failed to perform proper and adequate testing and research in order to determine and evaluate the nature, magnitude and frequency of the risks attendant to the Product.

56. Defendant failed to design and establish a safe, effective procedure for removal of the Product, or to determine if a safe, effective procedure for removal of the Product exists.

57. Feasible and suitable alternatives to the Product have existed at all times relevant that do not present the same frequency or severity of risks as do the Product.

58. The Product was at all times utilized and implanted in a manner foreseeable to Defendant, as Defendant generated the instructions for use, created the procedures for implanting the device, and trained the implanting physician.

59. Defendant knowingly provided incomplete and insufficient training and information to physicians regarding the use of the Product and the aftercare of patients implanted with the Product. The training and information were deficient because they failed to describe

the risks of the product.

60. The Product implanted in the Plaintiff was in the same or substantially similar condition as it was when it left Defendant's possession, and in the condition directed by and expected by Defendant.

61. The injuries, conditions, and complications suffered by numerous patients around the world who have been implanted with the Product and other products like it made by the Defendant include, but are not limited to, erosion, infection, inflammation, scar tissue, and pain, all of which have been experienced by the Plaintiff to a significant degree.

62. In many cases, including the Plaintiff, patients have been forced to undergo extensive medical treatment including, but not limited to, operations to locate and remove mesh, tissue, the use of pain control and other medications, injections into various areas of the abdomen and operations.

63. The medical and scientific literature studying the effects of such mesh, like that of the Product implanted in Plaintiff, has concluded that such mesh is dangerous.

64. Removal of eroded and/or infected mesh can require multiple surgical interventions for removal of mesh and results in scarring on fragile compromised tissue and muscles. Due to the Product's defects, the Plaintiff had to undergo such multiple surgical interventions.

65. At all relevant times herein, Defendants continued to promote the Products as safe and effective.

66. In doing so, Defendant failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Product, including the magnitude and frequency of these risks.

67. At all relevant times herein, Defendants failed to provide sufficient warnings and instructions that would have put the Plaintiff and the general public on notice of the dangers and adverse effects caused by implantation of the Product.

68. The Product which is designed, manufactured, distributed, sold and/or supplied by Defendant is defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of Defendant's knowledge of lack of safety.

69. As a result of having the Product implanted in her, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

70. Defendant participated in the marketing, distribution and sale of the Product. It represented the Product as safe for its intended purpose, fully and properly tested for safety and potential risks, and free from the kinds of risks and hazards that the Product actually posed to the public.

71. After the Product was placed on the market, Defendant began receiving actual notices of failures and Product defects. Defendant actively and intentionally concealed this notice of the defective and dangerous condition associated with the Product from the Plaintiff, the Plaintiff's physicians, and the general public. The Product inserted in the Plaintiff experienced a failure due to its defective design which caused injuries to the Plaintiff.

72. After the defective and dangerous Product was already placed on the market, the Defendant was placed on notice as to its danger to the public. Whether intentionally or negligently, Defendant failed to properly conduct and monitor the safety of its product.

73. Upon information and belief, Defendant was aware of the defect in manufacture and design of the non-recalled Product and chose not to issue a recall on the Product in the face of the high degree of complication and failure rates.

74. The Product implanted in Ms. Nowell was designed, manufactured, sold and distributed by Defendant to be used by surgeons for hernia repair surgeries and was further represented by Defendant to be an appropriate, cost-effective and suitable product for such purpose.

75. Neither Ms. Nowell nor Plaintiff's physicians were aware of the defective and dangerous condition of the Product.

76. In the months that followed the surgery, Ms. Nowell's condition worsened. Ms. Nowell suffered under extreme pain and discomfort. Despite an aggressive pain control regimen, neither the pain nor discomfort were abated. Ms. Nowell was left to begin months of recovery, on-going pain maintenance, with substantial medical complications requiring expensive, painful and emotionally harmful medical intervention and care.

77. Ms. Nowell has incurred substantial medical bills and has lost earning capacity and lost quality of life as a result of the Product, and continues to suffer physical pain and mental anguish.

78. Upon information and belief, Defendant was aware of the high degree of complication and failure rate associated with the Product when it was implanted in the Plaintiff.

79. Ms. Nowell has incurred substantial medical bills and has lost earning capacity and

lost quality of life as a result of the Product, and continues to suffer physical pain and mental anguish.

80. Defendant designed, manufactured, assembled, distributed, conveyed and/or sold the Product for hernia repair surgery.

81. At all times mentioned, the Product was substantially in the same condition as when it left the possession of Defendant.

82. The Product implanted into defendant was being used in a manner reasonably anticipated at the time it was implanted in her by her surgeon.

83. Defendant knew the component parts of the Product as implemented through design and/or manufacture could cause injury to the end user.

84. Any other acts or failures to act by Defendant regarding the studying, testing, designing, developing, manufacturing, inspecting, producing, advertising, marketing, promoting, distributing, and/or sale of the Product for hernia repair surgery will be learned during discovery.

85. Defendant's conduct in continuing to market, sell and distribute the Product after obtaining knowledge they were failing and not performing as represented and intended, showed complete indifference to or a conscious disregard for the safety of others justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter Defendant and others from similar conduct in the future.

86. The Products present and constitute an unreasonable risk of danger and injury in the following respects:

1. the Product is likely to malfunction after being implanted;

2. the Product was not properly manufactured;
3. the Product was defectively designed;
4. the Product did not perform as safely as an ordinary consumer/patient would expect;
5. the Product was inadequate or insufficient to maintain its integrity during normal use after implantation in the consumer/patient; and
6. such further and additional defects as discovery and the evidence reveal.

87. At all times herein mentioned, Defendant knew, or in the exercise of reasonable care should have known, that the aforesaid products were of such a nature that they were not properly manufactured, tested, inspected, packaged, labeled, distributed, marketed, examined, sold, supplied, prepared and/or provided with proper warnings, were not suitable for the purpose they were intended and were unreasonably likely to injure the products' users.

88. Defendant's Product is defective because it possesses the potential for breakage or malfunction and, as a result, are subject to risk of resulting injury.

89. Defendant did not timely apprise the public and physicians of the defect in their Product, despite Defendant's knowledge that the Product had failed due to the described defects. Plaintiff has suffered injuries and will require continual medical monitoring and care. Accordingly, Plaintiff will incur future medical costs related to the Product.

90. Defendant's concealment of a known defect from Plaintiff tolls the applicable statute of limitation.

91. Defendant's conduct, as described in the preceding paragraphs, amounts to conduct purposely committed, which Defendant must have realized was dangerous, heedless and

reckless, without regard to the consequences or the rights and safety of Plaintiff.

92. Defendant sold their Product to the healthcare providers of the Plaintiff and other healthcare providers in the state of implantation and throughout the United States without doing adequate testing to ensure that the Product was reasonably safe for implantation in the abdominal area.

93. Defendant sold the Product to Plaintiff, health care providers and other health care providers in the state of implantation and throughout the United States in spite of their knowledge that the Product can shrink, disintegrate and/or degrade inside the body.

94. This caused the other problems heretofore set forth in this complaint, thereby causing severe and debilitating injuries suffered by the Plaintiff and numerous other people.

95. Defendant ignored reports from patients and health care providers throughout the United States and elsewhere of the Product's failures to perform as intended, which lead to the severe and debilitating injuries suffered by the Plaintiff and numerous other patients. Rather than doing adequate testing to determine the cause of these injuries, or to rule out the Product's designs or the processes by which the Product is manufactured as the cause of these injuries, Defendant chose instead to continue to market and sell the Product as safe and effective.

96. Defendant knew the Product was unreasonably dangerous in light of its risks of failure, pain and suffering, loss of life's enjoyment, remedial surgeries and treatments in an effort to cure the conditions proximately related to the use of the Product, as well as other severe and personal injuries which were permanent and lasting in nature.

97. Defendant withheld material information from the medical community and the public in general, including the Plaintiff, regarding the safety and efficacy of the Product.

98. Defendant knew and recklessly disregarded the fact that the Product caused debilitating and potentially life altering complications with greater frequency than feasible alternative methods and/or products used to treat abdominal hernia.

99. Defendant misstated and misrepresented data and continue to misrepresent data so as to minimize the perceived risk of injuries caused by the Product.

100. Defendant knew of the Product's defective and unreasonably dangerous nature, but continued to mislead physicians and patients and to manufacture, market, distribute, and sell the Product so as to maximize sales and profits at the expense of the health and safety of the public, including the Plaintiff.

101. Defendant continue to conceal and/or fail to disclose to the public, including the Plaintiff, the serious complications associated with the use of the Product.

102. Defendant's conduct as described herein shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which raises the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

CAUSES OF ACTION COUNT I: NEGLIGENCE

103. All previous paragraphs of this Complaint are hereby incorporated by reference as if fully set forth herein.

104. Defendant had a duty to individuals, including the Plaintiff named in the Complaint, to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling the Product.

105. Defendant was negligent in failing to use reasonable care, and breached its duty to the Plaintiff, as described herein, in designing, manufacturing, marketing, labeling, packaging and selling the Product. But for the Defendant's breaches the Plaintiff would

not have sustained such injury. Defendant breached its aforementioned duty by, among other things:

1. a) Failing to design the Product so as to avoid an unreasonable risk of harm to patients in whom the Product was implanted, including the Plaintiff. The design did not provide for sufficient resiliency which caused the Product to disintegrate in the Plaintiff, which caused trauma to the Plaintiff;
2. b) Failing to manufacture the Product so as to avoid an unreasonable risk of harm to women in whom the Product was implanted, including the Plaintiff;
3. c) Failing to use reasonable care in the testing of the Product so as to avoid an unreasonable risk of harm to patients in whom the Product was implanted, including the Plaintiff;
4. d) Failing to use reasonable care in inspecting the Product so as to avoid an unreasonable risk of harm to patients in whom the Product was implanted, including the Plaintiff;
5. e) Failing to use reasonable care in the training and instruction to physicians for the safe use of the Product;
6. f) Failing to use reasonable care in studying the Product to evaluate its safety and to determine the nature, magnitude, and frequency of serious, life threatening complications that were known or knowable; and
7. g) Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling the Product.

106. The reasons that Defendant's negligence caused the Product to be unreasonably dangerous and defective include, but are not limited to:

1. a) The use of the material in the Product which caused adverse reactions and injuries;
2. b) The design of the Product to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;
3. c) Biomechanical issues with the design of the Product, including, but not limited to, the propensity of the Product to disintegrate inside the body, that in turn cause injuries to the surrounding;
4. d) The propensity of the Product to deform when subject to prolonged tension inside the body;
5. e) The propensity of the Product to disintegrate after implantation in the abdomen, causing pain and other adverse reactions;
6. f) The adverse tissue reactions caused by the Product, which are causally related to infection, as the materials used to construct the Product are foreign;
7. g) The creation of a non-anatomic condition in the abdomen leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

107. Defendants also negligently failed to warn or instruct the Plaintiff and/or her health care providers of subjects including, but not limited to, the following, all of which were experienced by the Plaintiff due to the Product:

1. a) The Product's propensities to deform inside the body;
2. b) The Product's propensities for degradation, fragmentation and/or creep; ;
3. c) The rate and manner of mesh erosion or extrusion;

4. d) The risk of chronic infections resulting from the Product;
5. e) The risk of recurrent, intractable abdominal pain and other pain resulting from the Product;
6. f) The need for corrective or revision surgery to adjust or remove the Product;
7. g) The severity of complications that could arise as a result of implantation of the Product;
8. h) The hazards associated with the Product;
9. i) The Product's defects described herein;
10. j) Treatment of abdominal hernia with the Product is no more effective than feasible available alternatives;
14. k) Treatment of abdominal hernia with the Product exposes patients to greater risk than feasible available alternatives;
15. l) Treatment of abdominal hernia with the Product makes future surgical repair more difficult than feasible available alternatives;
16. m) Use of the Product puts the patient at greater risk of requiring additional surgery than feasible available alternatives;
17. n) Removal of the Products due to complications may involve multiple surgeries and may significantly impair the patient’s quality of life; and

109. As a direct and proximate result of Defendant's negligence, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not

limited to, obligations for medical services and expenses, lost income, and other damages.

109. Defendants at all times mentioned had a duty to properly manufacture, test, inspect, package, label, distribute, market, examine, maintain, supply, provide proper warnings and prepare for use the Product.

110. Defendant at all times mentioned knew or in the exercise of reasonable care should have known, that the Product was of such a nature that it was not properly manufactured, tested, inspected, packaged, labeled, distributed, marketed, examined, sold supplied, prepared and/or provided with the proper warnings, and were unreasonably likely to injure the Product's users.

111. Defendant so negligently and carelessly designed, manufactured, tested, failed to test, inspected, failed to inspect, packaged, labeled, distributed, recommended, displayed, sold, examined, failed to examine and supplied the Product, that they were dangerous and unsafe for the use and purpose for which it was intended.

112. Defendant were aware of the probable consequences of the Product.

113. Defendant knew or should have known the Product would cause serious injury; they failed to disclose the known or knowable risks associated with the Product.

114. Defendant willfully and deliberately failed to avoid those consequences, and in doing so, Defendant acted in conscious disregard of the safety of Plaintiff.

115. Defendants owed a duty to Plaintiff to adequately warn her and her treating physicians, of the risks of breakage, separation, tearing and splitting associated with the Product and the resulting harm and risk it would cause patients.

116. Defendant breached their duty by failing to comply with state and

federal regulations concerning the study, testing, design, development, manufacture, inspection, production, advertisement, marketing, promotion, distribution, and/or sale of the Product.

117. As a direct and proximate result of the duties breached, the Product used in Plaintiff's hernia repair surgery failed, resulting in Plaintiff suffering pain, harm and trauma such as those described in her own words in this complaint.

118. As a direct and proximate result of Defendant's negligence, Plaintiff has suffered injuries and damages.

119. Defendant's conduct in continuing to market, sell and distribute the Product after obtaining knowledge they were failing and not performing as represented and intended, showed complete indifference to or a conscious disregard for the safety of others justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter Defendant and others from similar conduct in the future.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

120. All previous paragraphs of this Complaint are hereby incorporated by reference as if fully set forth herein.

121. The Product implanted in the Plaintiff was not reasonably safe for its intended use and was defective as described herein with respect to its design. But for the Product's design defects, the Plaintiff would not have sustained such injuries. The Product failed to perform as safely as an ordinary consumer would have expected when used in an intended or reasonably foreseeable manner. The Product's memory recoil ring was designed improperly which results in the compromising of the weld process which lead to

disintegration and misshapening. This disintegration and mishappening resulted in trauma to the Plaintiff.

As previously stated, the Product's design defects include, but are not limited to:

1. a) The material in the Product and the immune reaction that results from such material, causing adverse reactions and injuries;
2. b) The design of the Product to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;
3. c) Biomechanical issues with the design of the Product, including, but not limited to, the propensity of the Product to disintegrate inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;
4. d) The propensity of the Product for disintegration when subject to prolonged tension inside the body;
5. e) The inelasticity of the Product, causing them to be improperly mated to the delicate and sensitive areas of the abdomen where they are implanted, and causing pain upon normal daily activities that involve movement in the abdomen;
6. f) The propensity of the Product for degradation or fragmentation over time;
7. g) The propensity of the Product to disintegrate after implantation in the abdomen, causing pain and other adverse reactions;
8. h) The adverse tissue reactions caused by the Product which are causally related to infection, as the material used to construct the Product is foreign;

9. i) The creation of a non-anatomic condition in the abdomen leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

122. As a direct and proximate result of the Product's aforementioned defects as described herein, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo future medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

123. Defendants are strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective products. The Product was inherently defective because it was not sturdy enough to prevent disintegration and malformation. This resulted in the Product breaking apart while in the Plaintiff's body. This in turn caused trauma to the Plaintiff's abdominal region which resulted in internal bleeding, infection and other serious injuries. The Defendants sold the Product to the Plaintiff in this defective and unreasonably dangerous condition. The Defendants are engaged in the business of selling this Product and the Product reached the Plaintiff without substantial change in the condition in which it was sold.

COUNT III: STRICT LIABILITY – MANUFACTURING DEFECT

124. All previous paragraphs of this Complaint are hereby incorporated by reference as if fully set forth herein.

125. The Product implanted in the Plaintiff was not reasonably safe for its intended use and was defective as described herein as a matter of law with respect to its manufacture,

in that it deviated materially from Defendants' design and manufacturing specifications in such a manner as to pose unreasonable risks of serious bodily harm to the Plaintiff.

126. As a direct and proximate result of the Product's aforementioned defects as described herein, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and/or corrective surgery and hospitalization, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

127. Defendants are strictly liable to the female Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling defective products.

COUNT IV: STRICT LIABILITY – FAILURE TO WARN

128. All previous paragraphs of this Complaint are hereby incorporated by reference as if fully set forth herein.

129. The Product implanted in the Plaintiff was not reasonably safe for its intended uses and was defective as described herein as a matter of law due to its lack of appropriate and necessary warnings. The Defendants did not adequately warn the Plaintiff of the dangers of the Product. This danger was reasonably foreseeable to the Defendants because of their knowledge of such defective products and would have been discoverable through reasonable inspection and analysis. This failure to warn caused the Plaintiff not to be aware of the defects which caused her injury. Specifically, Defendants did not provide sufficient or adequate warnings regarding, among other subjects:

1. a) The Product's propensities to disintegrate inside the body;

2. b) The Product's propensities for degradation, fragmentation, disintegration and/or creep;
3. c) The Product's inelasticity preventing proper mating with the abdominal region;
4. d) The rate and manner of mesh erosion or extrusion;
5. e) The risk of chronic inflammation resulting from the Product;
6. f) The risk of chronic infections resulting from the Product;
7. g) The risk of scarring as a result of the Product;
8. h) The risk of recurrent, intractable pain and other pain resulting from the Product;
9. i) The need for corrective or revision surgery to adjust or remove the Product;
10. j) The severity of complications that could arise as a result of implantation of the Product;
11. k) The hazards associated with the Product;
12. l) The Product's defects described herein;
13. m) Treatment of abdominal hernia with the Product is no more effective than feasible available alternatives;
14. n) Treatment of abdominal hernia with the Product exposes patients to greater risk than feasible available alternatives;
15. o) Treatment of abdominal hernia with the Product makes future surgical repair more difficult than feasible available alternatives;
16. p) Use of the Product puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

17. q) Removal of the Product due to complications may involve multiple surgeries and may significantly impair the patient's quality of life;
18. r) Complete removal of the Product may not be possible and may not result in complete resolution of the complications, including pain; and
19. s) The nature, magnitude and frequency of complications that could arise as a result of implantation of the Product.

130. As a direct and proximate result of the Product's aforementioned defects as described herein, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

131. Defendants are strictly liable to the female Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

132. At the time of the design, manufacture and sale of the Product, and more specifically at the time Plaintiff received the Product it was defective and unreasonably dangerous when put to its intended and reasonably anticipated use.

133. Further the Product was not accompanied by proper warnings regarding significant adverse consequences associated with the Product.

134. Defendant failed to provide any warnings, labels or instructions of its dangerous propensities that were known or reasonably scientifically knowable at the time of distribution.

135. The reasonably foreseeable use of the Product involved significant dangers

not readily obvious to the ordinary user of the Product. Defendant failed to warn of the known or knowable injuries associated with malfunction of the Product, including but not limited to the disintegration of the Product and infection which would require subsequent surgical procedures and could result in severe injuries.

136. The dangerous and defective conditions in the Product existed at the time it was delivered by the manufacturer to the distributor. At the time the Defendant had her hernia repair surgery the Product was in the same condition as when manufactured, distributed and sold.

127. Plaintiff did not know at the time of use of the Product, nor at any time prior thereto, of the existence of the defects in the Product.

138. Plaintiff suffered the aforementioned injuries and damages as a direct result of Defendant's failure to warn. The Plaintiff's use of the Product in a manner reasonably foreseeable to the Defendant involved a substantial danger that would not be readily recognized by the ordinary user of the Product. The Defendant knew, or should have known, of the danger given the generally recognized and prevailing scientific knowledge available at the time of the manufacture and distribution. The Defendant failed to provide an adequate warning against the danger created by the reasonably foreseeable use of the Product. The Defendant failed to adequately warn against the specific risk of harm created by the danger. The Defendant failed to provide adequate instruction to avoid the danger. The injuries sustained by the Plaintiff would not have occurred if adequate warning and instruction had been provided. The injury resulted from a use of the product that was reasonably foreseeable to the Defendant.

139. The conduct of Defendant in continuing to market, promote, sell and distribute the

Product after obtaining knowledge that the Product was failing and not performing as represented and intended, showed a complete indifference to or conscious disregard for the safety of others justifying an award in such sum which will serve to deter Defendant and others from similar conduct. But for the Defendant's failure to warn, the Plaintiff would not have sustained such injuries.

COUNT V: BREACH OF EXPRESS WARRANTY

140. All previous paragraphs of this Complaint are hereby incorporated by reference as if fully set forth herein.

141. Defendant made assurances as described herein to the general public, hospitals and health care professionals that the Product was safe and reasonably fit for its intended purposes.

142. The Plaintiff and/or her healthcare provider chose the Product based upon Defendant's warranties and representations as described herein regarding the safety and fitness of the Product.

143. The Plaintiff, individually and/or by and through her physician, reasonably relied upon Defendant's express warranties and guarantees that the Product was safe, merchantable, and reasonably fit for their intended purposes.

144. Defendant breached these express warranties because the Product implanted in the female Plaintiff was unreasonably dangerous and defective as described herein and not as Defendant had represented.

145. Defendant's breach of their express warranties resulted in the implantation of an unreasonably dangerous and defective product in the body of the Plaintiff, placing said Plaintiff's health and safety in jeopardy and causing the injuries mentioned herein.

146. As a direct and proximate result of Defendant's breach of the aforementioned express warranties, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, as described herein, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

147. In the manufacturing, design, distribution, advertising, marketing, labeling and promotion of the Product, Defendant expressly warranted them to be safe and effective for consumers like Plaintiff.

148. At the time of making these express warranties, Defendant had knowledge of the purpose for which the product was to be used and warranted same in all respects to be safe and proper for such purpose.

149. The Product did not conform to these express warranties and representations because they are not safe and pose severe and serious risks of injury.

150. The implantation and use of the Product in Plaintiffs case was proper and pursuant to the intended and foreseeable use.

Plaintiff, by use of reasonable care, would not and could not have discovered the breach and realized its danger.

COUNT VI: BREACH OF IMPLIED WARRANTY

151. All previous paragraphs of this Complaint are hereby incorporated by reference as if fully set forth herein.

152. Defendant impliedly warranted that the Product was merchantable and was fit for the ordinary purposes for which it was intended.

153. When the Product was implanted in the Plaintiff to treat her abdominal hernia, the Product was being used for the ordinary purposes for which it was intended.

154. The Plaintiff, individually and/or by and through her physician, relied upon Defendant's implied warranties of merchantability in consenting to have the Product implanted in her.

155. Defendant breached these implied warranties of merchantability because the Product implanted in the female Plaintiff was neither merchantable nor suited for its intended uses as warranted. It was not suited for its intended purpose because it disintegrated and misshappened inside the Plaintiff's body, causing injuries.

156. Defendant's breach of their implied warranties resulted in the implantation of an unreasonably dangerous and defective product in the body of the Plaintiff, placing said Plaintiff's health and safety in jeopardy.

157. As a direct and proximate result of Defendant's breach of the aforementioned implied warranties, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

158. Defendant sold the Product which was implanted in the Plaintiff.

159. Defendant impliedly warranted to the Plaintiff, her physicians and health care providers, that the Product was of merchantable quality and safe for the use for which they were intended. The Product sold to the Plaintiff would be rejected by someone with knowledge in the trade or failure to meet the contract description. The Product was not fit

for the ordinary purpose for which it was sold, namely to safely repair hernias.

160. Defendant knew or should have known that the Product at the time of sale was intended to be used for the purpose of surgically implanting them into the body for hernia repair.

161. The Plaintiff, her physicians and health care providers reasonably relied on Defendant's judgment, indications and statements that the Product was fit for such use.

162. When the Product was distributed into the stream of commerce and sold by Defendant, it was unsafe for their intended use, and not of merchantable quality, as warranted by Defendant in that they had very dangerous propensities due to problems with the memory recall ring, the weld process, and other defects, when used as intended and implanted into a patient's body where they could cause serious injury of harm or death to the end user. Plaintiff suffered such injuries and damages and death as a result of Defendant's conduct and actions related to the tolling or extension of any applicable statute of limitations, including equitable tolling, delayed discovery, discovery rule, and fraudulent concealment.

WHEREFORE, the Plaintiff demands judgment against Defendant and requests compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

- Compensatory damages to Plaintiff for past, present, and future damages, including but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiff, emotional distress, mental anguish, physical disfigurement and impairment; health and medical care costs, together with pre- and post-judgment interest and costs as provided by law;

- Restitution and disgorgement of profits;
- Reasonable attorneys' fees;
- The costs of these proceedings;
- All ascertainable economic damages;
- Punitive damages; and
- Such other and further relief as this Court deems just and proper.

PLAINTIFF DEMANDS A TRIAL BY JURY

Respectfully submitted,

THE LAW OFFICE OF
JASON S. MONTCLARE

"Electronically Filed"

/s/ Jason Montclare
JASON S. MONTCLARE

P.O. Box 2463
Alamogordo, N.M. 88311
575-921-2056
Counsel for Plaintiff