SUPERIOR COURT FOR THE STATE OF
NEW JERSEY COUNTY OF MIDDLESEX

----------X Index No.:

JO ANN LAX,

Plaintiff,

COMPLAINT AND JURY DEMAND

-against-

JOHNSON & JOHNSON, ETHICON INC., and COVIDIEN, LP.

Defendants.

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Plaintiff, Jo Ann Lax, by her attorney, MARC J. BERN & PARTNERS LLP, complaining of the Defendants, upon information and belief, respectfully alleges upon information and belief:

PARTIES

1. Plaintiff, Jo Ann Lax, is an individual and resident of the state of Arkansas.

2. Plaintiff resides at I.C.R. 411, Lafe, AR 72436.

3. Defendant, Johnson & Johnson, is a corporation, and according to its website, the world's largest and most diverse medical devices, and diagnostics company, with its worldwide headquarters located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

4. Defendant, Ethicon, Inc., is a wholly owned subsidiary of Defendant Johnson & Johnson located in Somerville, New Jersey 08876.

5. Defendants Johnson & Johnson and Ethicon, Inc. will be referred to collectively herein as "The Ethicon Defendants."

6. The Ethicon Defendants derives substantial revenue from sales directed at and occurring within the State of Arkansas, including Physiomesh™, a subject of the present action.

7. Defendant, Covidien LP, ("Covidien"), is a Delaware Limited Partnership, headquartered at 15 Hampshire Street, Mansfield, Massachusetts 02048, with an additional place of business located at 480 Washington Blvd, Jersey City, NJ 07310.

8. Defendant Covidien derives substantial revenue from sales directed at and occurring within the State of New Jersey, including Symbotex Mesh, a subject of the present action.

9. Defendants are and have been at all times pertinent to this proceeding, engaged in the design and manufacturing of medical technologies used by surgeons to treat a variety of conditions, including, but not limited to, hernia repairs. The Defendant Corporations designed, manufactured, packaged, labeled, marketed, sold, and distributed one or more of the Hernia Mesh products at issue in this lawsuit.

10. Defendant Ethicon and Defendant Covidien will be collectively referred to as "Defendants."

JURIDSICTION AND VENUE

11. This Court has personal jurisdiction over Defendant Ethicon and Covidien pursuant to N.J. R. 4: 4-3(a)(6), as resident corporations of the State of New Jersey, conducting business in the State of New Jersey.

12. Venue is proper in this Court pursuant to N.J.R. 4: 3-2, because venue is deemed proper in the Superior Court in the county in which cause of action arose, or where any party to the action resides.

13. Pursuant to N.J.R. 4: 3-2(b) a corporation is deemed to reside in any county in which its registered office is located or in any county in which is it actually doing business.

14. Further, venue is proper in this Court pursuant to N.J. R. 4: 4-3(a)(6) by virtue of the fact that Defendants' products are produced in, sold to, and implanted in individuals in the State of New Jersey, thereby subjecting Defendants to personal jurisdiction in this action.

15. Plaintiff's claim arises from Defendant's presence and transactions in New Jersey.

16. Defendants' activity with New Jersey were purposeful and are substantially related to Plaintiff's injuries.

17. Defendants at all relevant times regularly conducted and solicited, and continue to conduct and solicit, business in the State of New Jersey through its agents, servants and employees, and because Defendants were engaged, and continue to engage, in marketing, distributing, promoting, and/or selling, either directly or indirectly, and/or through third parties or related entities, products, including but not limited to hernia mesh products, in New Jersey.

18. Defendants, at all relevant times, engage and continue to engage, in a persistent course of conduct in the State of New Jersey and derive substantial revenue from interstate and/or international commerce.

19. Requiring Defendants to litigate these claims in New Jersey does not offend traditional notions of fair play and substantial justice and is permitted by the United States Constitution.

20. Defendants Ethicon and Covidien actively sell, market and promote their Hernia Mesh Products (Physiomesh™ and Symbotex mesh™) to physicians and consumers in this state on a regular and consistent basis.

21. Defendants systematically availed themselves of the State of New Jersey by conducting regular and sustained business and engaging in substantial commerce and business activity in New Jersey, including without limitation researching, developing, designing, setting specifications for, licensing, manufacturing, preparing, compounding, assembling, processing,

marketing, promoting, distributing, selling, and/or introducing into interstate commerce in the State of New Jersey either directly or indirectly, its products, including hernia mesh products. Defendants should expect that their acts would have consequences within the United States, specifically, in the State of New Jersey.

22. Plaintiff's claims arise from and relate to Defendants' purposeful availment of the State of New Jersey because Defendants' wrongful conduct in researching, developing, designing, setting specifications for, licensing, manufacturing, preparing, compounding, assembling, processing, marketing, promoting, distributing, selling, hernia mesh products, took place, in whole or in part, in the State of New Jersey. Therefore, the claims of this Plaintiff relate to and arise from Defendants' explicit contacts and purposeful availment of the State of New Jersey.

FACTUAL BACKGROUND

I. HERNIAS, HERNIA MESH PRODUCTS AND KNOWN ALTERNATIVES

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

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

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

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

27. 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.)

28. 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 non-absorbent in composition.

29. 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.

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

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

32. 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.

33. 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.

34. 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.

35. 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."

36. Safer and more effective alternatives to hernia mesh exist and have existed since the introduction of hernia mesh products into the market.

37. These safer more effective alternatives include the Shouldice Repair, McVay Repair, Bassini Repair, and Desarda Repair.

II. DEFENDANT ETHICON: PHYSIOMESH

38. Ethicon Defendants' Physiomesh™ was designed, patented, manufactured, labeled, packaged, marketed, sold, and distributed by Defendants at all relevant times herein. Ethicon Defendants were responsible for the research, design, development, testing, manufacture, production, marketing, packaging, promotion, distribution, and sale of Physiomesh™, as well as providing the warnings and instructions concerning the product.

39. Among the intended purposes for which Defendants designed, manufactured, marketed, and sold, Physiomesh™ was for the use by surgeons for hernia repair surgeries- the purpose for which the Prolene Mesh was implanted in the Plaintiff, Jo Ann Lax.

40. Ethicon Defendants' Hernia Mesh Products are designed, intended, and utilized for permanent implantation in the human body.

41. The Physiomesh™ product is a sterile, low profile, flexible, composite, large pore partially absorbable, polypropylene mesh that was designed to match the compliance of the abdominal wall.

42. The mesh product is composed of a non-absorbable, macroporous polypropylene mesh laminated between two polyglecaprone-25 films.

43. An undyed polydioxanone film provides the bond between the polyglecaprone-25 film and polypropylene mesh.

44. The polypropylene component is constructed of knitted filaments of extruded polypropylene.

45. An additional dyed (D&C Violet No. 2) polydioxanone film marker has been added for orientation purposes.

46. Ethicon Defendants represented to Plaintiff and Plaintiff's physicians that the Physiomesh™ was safe and effective products for hernia repair and for permanent implantation in humans.

47. Ethicon Defendants applied for U.S. Food and Drug Administration ("FDA") clearance to market their Physiomesh™ under Section 510(k) of the Medical Device Amendment.

48. 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.

49. Ethicon Defendants obtained clearance by a 510(k) application, submitted on March 18, 2010, and approved by the FDA on April 9, 2010 as 510(k) No: K093932.

50. In promotional and information materials about Physiomesh™ on the Ethicon Defendants' website, the Physiomesh™ is described as "Designed to promote strong and comfortable healing, and Exceptional intraoperative handling," and designed to match the compliance of the abdominal wall.

51. The FDA maintains an active compulsory database ("MAUDE DATABASE") of adverse incidents reported by medical providers regarding pharmaceutical implants and devices.

52. 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.

53. MAUDE reports have been published documenting serious malfunctions of Ethicon's Physiomesh™.

54. Among the MAUDE reports are documented instances of the mesh pulling away from the abdominal wall, embedding into the abdominal wall resulting in subsequent surgeries, removal of mesh, recurrent hernia, and intestinal fistulas.

55. Ethicon Defendant's Physiomesh™ was recalled on May 25, 2016 after a review of unpublished data from European registries and the Physiomesh's™ high revision rates.

III. DEFENDANT COVIDIEN: SYMBOTEX MESH

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

57. The Symbotex Mesh™ product is a surgical mesh material that is constructed of a three-dimensional monofilament polyester textile, which is covered with an absorbable, continuous and hydrophilic film on one of its sides.

58. 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. Polyester has also been used as an implanted material in humans for decades in the form of vascular grafts with good safety record.

59. Symbotex Mesh™ is best used for laparoscopic and open ventral repair.

60. Symbotex Mesh™ is intended for permanent use to reinforce soft-tissue.

61. Symbotex Mesh™ is advertised as having excellent tissue integration and minimized visceral attachments; "Composite mesh is designed to match the surgeon's demands for ease of handling, operative efficiency, and versatility."

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

63. 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.

64. Symbotex Mesh™ was deemed approved based upon being substantially equivalent to legally marketed predicate devices marketed in interstate commerce.

65. The complications associated with the use of Symbotex™ Composite Mesh are seroma, hematoma, recurrence, fistula formation, adhesions, infection, inflammation, chronic pain, and/or allergic reactions to the components of the product.

IV. PLAINTIFF SPECIFIC FACTS

66. At all times relevant to this action Plaintiff, Jo Ann Lax, was and is a resident of the state of Arkansas, residing at I.C.R. 411, Lafe, AK 72436.

67. On October 27, 2014, Plaintiff underwent a laparoscopic ventral umbilical hernia repair procedure performed by Robert Warner Jr. M.D. to introduce Ethicon Defendant's Physiomesh™ to Plaintiffs ventral hernia to reinforce tissue affected by the hernia.

68. A Physiomesh™ manufactured and sold by Defendant Ethicon, was used for Plaintiffs surgery.

69. Specifically, a Physiomesh 15x15 CM LOT: HM8GCGBO, positively identified on surgical and operative reports prepared by Warner, was implanted into Plaintiff.

70. On or about May 28, 2015, Plaintiff underwent a subsequent a removal surgery of the Physiomesh™ to remedy the failure of the implant. Specifically, the mesh had disconnected and torn, leaving fragmentation of the mesh into surrounding tissue.

71. On the May 28, 2015 surgery, Plaintiff subsequently was implanted with another mesh to fix the umbilical hernia.

72. To this day, Defendant Covidien's Symbotex Mesh ™ remains implanted in Plaintiff, Jo Ann Lax.

73. Plaintiff has experienced and continuous to experience pain in lower part of her stomach, sores on her stomach, blisters, stinging sensation around the area of surgery, and removal of her naval.

74. Plaintiff'sinjuries were not present before the implantation of the mesh products.

75. As a direct and proximate result of the implanted mesh products into her body, Plaintiff suffered, is suffering, and/or will continue to suffer the abovementioned injuries, including the risk of malfunction, decreased efficacy, recurrent hernia, perforation of tissue and/or organs, adherence to tissue/organs, infection, nerve damage, subsequent surgeries, and other complications.

76. As a direct and proximate result of the wrongful acts and omissions of Defendants, Plaintiff has suffered economic damages, severe and possibly permanent injuries, and emotional distress.

77. Plaintiff has also endured and continues to suffer the mental anguish and psychological trauma of living with this defective product implanted in her body.

COUNT I

(Strict Liability- Defective Design and Manufacture)

78. Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set forth herein.

79. Defendants placed their hernia mesh products, defined herein, into the stream of commerce with the actual or constructive knowledge that it would be used without inspection for defects.

80. Defendants' hernia mesh products were defective in their manufacture.

81. Defendants' hernia mesh products were defective by design.

82. Because of defects in the Defendants' hernia mesh products, it is, and at all relevant times material hereto were, unreasonably dangerous.

83. Alternative designs for hernia mesh products and/or procedures existed that were and/or are less dangerous and equally, it not more, effective.

84. As a direct and proximate result of the defective and unreasonably dangerous hernia mesh products, Plaintiff has suffered serious bodily injuries that have resulted in pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expenses of hospitalization, medical and nursing care and treatment, aggravation of a preexisting condition, and interest on the foregoing injuries. The foregoing losses and injuries are either permanent or continuing and Plaintiff will continue to suffer those losses and injuries for the foreseeable future.

COUNT II

STRICT LIABILITY- FAILURE TO WARN

85. Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set forth herein.

86. The hernia mesh products implanted in Plaintiff were defective and unreasonably dangerous when they left the possession of the Defendants in that they contained warnings which were inadequate and insufficient to alert physicians or consumers to the dangerous risks associated with the product, including, without limitation, extreme pain, risk of malfunction, decreased efficacy, recurrent hernia, perforation of tissue and/or organs, adherence to tissue/organs, infection, nerve damage, subsequent surgeries and other complications.

87. The hernia mesh products implanted in Plaintiff were defective and unreasonably dangerous when the left the possession of the Defendants in that they failed to include proper directions for use, implantation, and/or removal.

88. Defendants' hernia mesh products implanted in Plaintiff was used for their intended purpose, i.e., repair hernias through reinforcement.

89. Plaintiff's physicians, including the surgeons who performed the implant of the Defendants' hernia mesh products, could not have discovered any defect with the product through the exercise of care.

90. Plaintiff's physicians, including the surgeons who performed the implant of Defendants' hernia mesh products, did not have substantially the same knowledge that an adequate warning from the manufacturer or a distributor would have communicated.

91. The warnings that were provided by Defendants regarding their hernia mesh products were ambiguous or were not sufficient, accurate or clear.

92. The Defendants had a continuing duty to warn Plaintiff and her doctors of the dangers associated with their hernia mesh products.

93. As a direct and legal result of the Defendants' failure to warn, Plaintiff has suffered serious bodily injuries, resulting in pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expenses of hospitalization, medical and nursing care and treatment, aggravation of a preexisting condition, and interest on the foregoing.

94. The foregoing losses and injuries are either permanent or continuing and Plaintiff will suffer the losses and injuries for the foreseeable future.

COUNT III

(NEGLIGENCE)

95. Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set forth herein.

96. Defendants owed a duty to Plaintiff, and others similarly situated as foreseeable users of their hernia mesh products, to manufacture and sell their products in a reasonably safe manner for its intended use, free from defects.

97. Defendants were negligent in designing, manufacturing, and selling the hernia mesh products by, among other things, failing to properly fabricate the hernia mesh products, failing to adequately test the hernia mesh products, and failing to conduct adequate quality control procedures for the hernia mesh products.

98. As a direct and proximate result of the Defendants' defective and unreasonably dangerous hernia mesh products, Plaintiff has suffered serious bodily injuries that have resulted in pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expenses of hospitalization, medical and nursing care and treatment, aggravation of a preexisting condition, and interest on the foregoing. The foregoing losses and injuries are either permanent or continuing and Plaintiff will suffer the losses in the future.

99. Defendants owed a duty of care to Plaintiff, to adequately warn against the risks associated with the foreseeable uses about hernia mesh products which the Defendants knew or should have known, including but not limited to: the potential for perforation into human tissue; the potential to erode or "break down"; the potential to decrease in efficacy; the potential to cause patients observable abdominal bulging and pain many months after implantation; the potential for excessive scar tissue formation due to hernia mesh implantation, requiring future excision of scar tissue and lysis of adhesions; the potential for their hernia mesh products to overlie human tissue; muscle loss, weight gain, and/or continuous stomach pain associated with and/or caused by their hernia mesh products; loss of bowel function; increased diarrhea and stool related issues; and loss in mobility.

100. Any warnings that Defendants may have provided were accurately reflect the risk, incidence, symptoms, scope or severity of such injuries to the consumer and/or the medical community.

101. Defendants breached their duty by failing to adequately warn Plaintiff and/or her physicians and/or the medical community of, inter alia, the aforementioned risks associated with the hernia mesh products, and that failure directly caused Plaintiffs injuries.

COUNT IV

(BREACH OF WARRANTY)

102. Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set forth herein.

103. Defendants impliedly warranted to Plaintiff and all others similarly situated that their hernia mesh products were reasonably fit for its intended use and that it was designed, manufactured, and sold in accordance with good design, engineering, and industry standards.

104. Defendants' hernia mesh products were defective in their manufacture or design and were therefore, not fit for its intended use and was not designed, manufactured, or sold in accordance with good design, engineering, and industry standards.

105. Defendants breached the above warranties in that their hernia mesh products were defective as set forth above, were not fit for its intended use and was not designed, manufactured, or sold in accordance with good design, engineering and industry standards.

106. As a direct and proximate result of Defendants' defective and unreasonably dangerous hernia mesh products, Plaintiff has suffered serious bodily injuries that have resulted in pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expenses of hospitalization, medical and nursing care and treatment, aggravation of a preexisting condition, and interest on the foregoing.

107. The foregoing losses and injuries are either permanent or continuing and Plaintiff will suffer the losses and injuries for the foreseeable future.

COUNT VI

FRADULENT MISREPRESENTATION

108. Defendants intentionally, willfully, and knowingly, fraudulently misrepresented to the medical community, the FDA, and consumers, including the Plaintiff and her health care providers, that their hernia mesh products had been adequately tested in clinical trials and were found to be safe and effective.

109. Defendants knew that its misrepresentations were false and fraudulent regarding the dangers and risks associated with use of their hernia mesh products, Defendants made fraudulent misrepresentations intentionally, willfully, wantonly, and with reckless disregarded and depraved indifference for the safety and well-being of the users of their product, including Plaintiff.

110. Defendants fraudulent misrepresentations were made with the intent of defrauding and deceiving the medical community, the public, including Plaintiff, and to induce the medical community to recommend, dispense and purchase Defendants hernia mesh products.

111. Defendants fraudulent misrepresentations intentionally concealed the following information:

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, tissue, 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.

112. Defendants were under a duty to disclose to Plaintiff's healthcare providers and physicians the defective nature, design, and formulation of their hernia mesh products, which heighten the risks of suffering the injuries and complications described in this Complaint.

113. Defendants had sole access to material facts concerning the defective nature of their hernia mesh products and its propensity to cause serious and dangerous injuries and damages to persons who used their hernia mesh products.

114. At all relevant times heretofore, Plaintiff and Plaintiff's physicians were unaware of Defendants' misrepresentations.

115. Defendants knew, and had reason to know, that their hernia mesh products could cause serious personal injury to those whom which they were implanted, and that their hernia mesh products were inherently dangerous in a manner that exceeded the inaccurate and inadequate warnings given.

116. In reliance upon Defendants' false and fraudulent misrepresentations, through her physicians and healthcare providers, the Plaintiff was induced to, and did, reasonably rely upon Defendants' misrepresentations regarding the safety and efficacy of Defendants' hernia mesh products, resulting in Plaintiff sustaining permanent personal injuries and damages.

117. The information distributed by Defendants to the public, including the Plaintiff, the medical community, and the FDA, included, but was not limited to, reports, press releases, advertising campaigns, print advertisements, commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth regarding the dangers of the use of Defendants' hernia mesh products.

118. Defendants' wrongful conduct was fraudulent, deceitful, committed and perpetrated willfully, wantonly, and purposefully.

119. As a foreseeable, direct, and proximate result of Defendants' described acts and omissions, Plaintiff suffered the serious and dangerous side effects more specifically described in this Complaint.

120. As a direct and proximate consequence of Defendants' fraudulent misrepresentations, Plaintiff sustained serious personal injuries and related losses including mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, diminished ability to work, medical and related expenses, and other losses and damages.

COUNT VII

NEGLIGENT MISREPRESENTATION

121. Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set forth herein.

122. Defendants had a duty to represent truthfully and accurately to the medical community, the FDA, and United States consumers accurately and truthfully, including Plaintiff, the results of Defendants' hernia mesh products testing.

123. The misrepresentations made by Defendants were false; Defendants were careless or negligent in ascertaining the truth of the representations at the time Defendants made the misrepresentations.

124. Defendants represented and marketed their hernia mesh products as being safe and effective.

125. After Defendants became aware of the risks of their hernia mesh products, Defendants failed to accurately communicate those risks associated with their products.

126. Defendants failed to exercise ordinary care in the representation concerning their products and its manufacture, sale, testing, quality assurance, quality control, and distribution. Defendants negligently and/or carelessly misrepresented and intentionally concealed the truth regarding the high risk of the product's unreasonable, dangerous, and adverse side effects associated with the administration, use, and implantation of the product.

127. Defendants breached their duty in representing to the Plaintiff, her physicians and healthcare providers, and the medical community as a whole, that their hernia mesh products did not carry the risk of serious side effects such as those suffered by Plaintiff and other similarly situated patients.

128. Plaintiff, and her healthcare providers, physicians, and surgeons justifiably relied on Defendants negligent misrepresentations.

129. As a direct and proximate consequence of Defendants negligent misrepresentations, Plaintiff sustained serious personal injuries, mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, medical and related expenses, and other losses and damages.

COUNT VIII

UNJUST ENRICHMENT

130. Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set forth herein.

131. Defendants are, and at all times were, the manufacturers, sellers, suppliers, distributors, marketers, and/or dealers of the Physiomesh™ and Symbotex Mesh™.

132. Plaintiff paid for Defendants' hernia mesh product for the purpose of hernia repair.

133. Defendants have accepted payment by Plaintiff for the purchase of their hernia mesh products.

134. Plaintiff has not received the safe and effective hernia mesh products for the hernia repair material for which she paid.

COUNT IX

CONSUMER FRAUD - VIOLATION OF

N.J.S.A. 56:8-2 and A.C.A. § 4-88-107

135. Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set forth herein.

136. The Defendants acted, used and employed unconscionable commercial practices, deception, fraud, false pretenses, false promises and misrepresentations, and knowingly concealed, suppressed and omitted material facts with the intent that consumers, including Plaintiff herein and Plaintiff's physicians and medical providers, rely upon such concealment, suppression and omission, in connection with sale, advertisement and promotion of their hernia mesh products (Physiomesh™ and Symbotex Mesh™), in violation of all applicable state consumer fraud statutes, for the purpose of influencing and inducing physicians and medical providers to implant the Defendants' hernia mesh products (Physiomesh™ and Symbotex Mesh™), to patients/consumers such as the Plaintiff herein.

137. Due to the Defendants' unconscionable, deceptive and fraudulent acts and practices, and false pretenses, false promises and misrepresentations, reasonable patients/consumers acting reasonably, such as the Plaintiff herein, were caused to suffer ascertainable loss of money and property and actual damages.

138. Defendants engaged in consumer-oriented, commercial conduct by selling and advertising the subject product.

139. Defendants misrepresented and omitted material information regarding the subject product by failing to disclose known risks.

140. Defendants' misrepresentations and concealment of material facts constitute unconscionable commercial practices, deception, fraud, false pretenses, misrepresentation, and/or the knowing concealment, suppression, or omission of materials facts with the intent that others rely on such concealment, suppression, or omission in connection with the sale and advertisement of the subject product, in violation of A.C.A. § 4-88-107 and N.J.S.A. 56:8-2.

141. Arkansas has enacted statutes to protect consumers from deceptive, fraudulent and unconscionable trade and business practices.

142. Defendants violated these statutes by knowingly and falsely representing that the subject products were fit to be used for the purpose for which it was intended, when the Defendants knew said products were defective and dangerous, and by other acts alleged herein.

143. Defendants engaged in the deceptive acts and practices alleged herein in order to sell the subject products to the public, including Plaintiff.

144. As a direct and proximate result of the Defendants' violations of A.C.A. § 4-88-107 and N.J.S.A. 56:8-2, Plaintiff suffered damages, for which Plaintiff are entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

145. As a direct and proximate result of Defendants' conduct, the Plaintiff used and/or had the hernia mesh products at issue (Physiomesh™ and Symbotex Mesh™), and the Plaintiff suffered serious physical injury, harm, and damages.

146. Defendants' action and omission as alleged in this Complaint demonstrate a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

147. Pursuant to A.C.A. § 16-64-122 and N.J.S.§ 2A:15-5.3, Defendants are liable for all of Plaintiff's damages, including but not limited to, Plaintiff's non-economic loss by reason of the fact that Defendants owed Plaintiff a non-delegable duty of care. [1]

148. Pursuant to A.C.A. § 16-64-122 and N.J.S. 2A:15-5.3, Defendants are liable for all of Plaintiff's damages, including but not limited to, Plaintiff's non-economic loss, irrespective of the provisions of A.C.A. § 16-64-122 and N.J.S.§ 2A:15-5.3, by reason of the fact that said Defendants are vicariously liable for the negligent acts and omissions of its servants, agents, affiliated physicians, surgeons and/or employees.

149. Pursuant to A.C.A. § 16-64-122 and N.J.S.§ 2A:15-5.3, Defendants are liable for all of Plaintiff's damages, including but not limited to Plaintiff's non-economic loss, irrespective of the provisions of A.C.A. § 16-64-122 and N.J.S.§ 2A:15-5.3, by reason of the fact that said Defendants acted with reckless disregard for the safety of others.

150. By reason of the foregoing, Plaintiff has been damaged in an amount that exceeds the jurisdictional limits of all lower courts, which would otherwise have jurisdiction in this matter.

[1] *See Farm Bureau Ins. Co. v. Case Corp.*, 878 S.W.2d 741 (Ark. 1994))

COUNT V

PUNITIVE DAMAGES

151. Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set forth herein.

152. Defendants sold their hernia mesh products to the healthcare providers of the Plaintiff and other healthcare providers in the state of Plaintiff's implantation (New York) and throughout the United States without doing adequate testing to ensure that these hernia mesh products were reasonably safe for implantation in the pelvic area.

153. Defendants sold the hernia mesh products to the Plaintiff's health care providers and other health care providers in the state of the implantation (New York) and throughout the United States despite their knowledge that their hernia mesh products can disintegrate and/or degrade inside the body, and cause the other problems heretofore set forth in this complaint, thereby causing severe and debilitating injuries suffered by the Plaintiff and numerous other patients.

154. Defendants ignored reports from patients and health care providers throughout the United States and elsewhere of their hernia mesh products' 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 their hernia mesh products' designs or the processes by which their hernia mesh products are manufactured as the cause of these injuries, Defendants chose instead to continue to market and sell their hernia mesh products as safe and effective. Defendants knew their hernia mesh products were unreasonably dangerous in light of their 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 their hernia mesh products, as well as other severe and personal injuries which were permanent and lasting in nature.

155. Defendants withheld material information from the medical community and the public in general, including the Plaintiff, regarding the safety and efficacy of their hernia mesh products.

156. Defendants knew and recklessly disregarded the fact that their hernia mesh products caused debilitating and potentially life altering complications with greater frequency than feasible alternative methods and/or products used to treat hernias.

157. Defendants misstated and misrepresented data and continue to misrepresent data so as to minimize the perceived risk of injuries caused by their hernia mesh products.

158. Notwithstanding the foregoing, Defendants continue to aggressively market the Products to consumers, without disclosing the true risks associated with their hernia mesh products.

159. Defendants knew of their hernia mesh products' defective and unreasonably dangerous nature, but continued to manufacture, market, distribute, and sell these hernia mesh products so as to maximize sales and profits at the expense of the health and safety of the public, including the Plaintiff.

160. Defendants continue to conceal and/or fail to disclose to the public, including the Plaintiff, the serious complications associated with the use of their hernia mesh products to ensure continued and increased sales of these hernia mesh products.

161. Defendants' 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.Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set forth herein.

WHEREFORE, Plaintiff demands judgment against the Defendants herein in an amount that exceeds the jurisdictional limitations of all lower courts that would otherwise have jurisdiction over this action, together with the interest, costs and disbursements of same allowed by law.

Dated: New York, New York

August 3, 2017

MARC J. BERN & PARTNERS LLP
Attorneys for Plaintiff

By: Alexandra Colella

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60 East 42nd Street, Suite 950
New York, New York 10165
(212) 702-5000

SUPERIOR COURT OF THE STATE OF
NEW JERSEY COUNTY OF MIDDLESEX

----------X

JO ANN LAX,

Plaintiff,

-against-

JOHNSON & JOHNSON, INC., ETHICON INC. and COVIDIEN, LP.

Defendants.

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Index No.:

SUMMONS

Plaintiff designates Middlesex County as the Place of Trial

The Basis of Venue of Defendant's Place of Residence

TO THE ABOVE-NAMED DEFENDANTS:

YOU ARE HEREBY SUMMONED to answer the complaint in this action and to serve a copy of your answer, or, if the complaint is not served with this Summons, to serve a notice of appearance, on the Plaintiff's attorney within 20 days after the service of this Summons, exclusive of the day of service (or within 30 days after the service is complete if this Summons is not personally delivered to you within the State of New York); and in case of your failure to appear or answer, judgment will be taken against you by default for the relief demanded in thecomplaint.

Dated: New York, New York
August 3, 2017

MARC J. BERN & PARTNERS LLP
Attorneys for Plaintiff

By: Alexandra Colella
Alexandra Colella
One Grand Central Place
60 East 42nd Street, Suite 950
New York, New York 10165
(212) 702-5000

TO:
JOHNSON & JOHNSON, INC.
C/O C T Corporation System
One Johnson & Johnson Plaza
New Brunswick, NJ 08933

ETHICON, INC.
C/O C T Corporation System
55 U.S. Route 22 West

Somerville, NJ 08876.

COVIDIEN, LP
C/O C T Corporation System
111 8th Ave
New York, New York 10011

Civil Case Information Statement

Case Details: MIDDLESEX | Civil Part Docket# L-004616-17

Case Caption: LAX JO VS JOHNSON & JOHNSON
Case Initiation Date: 08/03/2017
Attorney Name: ALEXANDRA COLELLA
Firm Name: MARC J. BERN & PARTNERS LLC
Address: 60 EAST 42ND ST STE 950
NEW YORK NY 10165
Phone:
Name of Party: PLAINTIFF : Lax, Jo Ann
Name of Defendant's Primary Insurance Company (if known): Unknown

Case Type: PRODUCT LIABILITY
Document Type: Complaint with Jury Demand
Jury Demand: Yes - 12 JURORS
Hurricane Sandy related? NO
Is this a professional malpractice case? NO
Related cases pending: NO
If yes, list docket numbers:
Do you anticipate adding any parties (arising out of same transaction or occurrence)? NO

THE INFORMATION PROVIDED ON THIS FORM CANNOT BE INTRODUCED INTO EVIDENCE

CASE CHARACTERISTICS FOR PURPOSES OF DETERMINING IF CASE IS APPROPRIATE FOR MEDIATION

Do parties have a current, past, or recurrent relationship? NO

If yes, is that relationship:

Does the statute governing this case provide for payment of fees by the losing party? NO

Use this space to alert the court to any special case characteristics that may warrant individual management or accelerated disposition:

Do you or your client need any disability accommodations? NO
If yes, please identify the requested accommodation:

Will an interpreter be needed? NO
If yes, for what language:

I certify that confidential personal identifiers have been redacted from documents now submitted to the court, and will be redacted from all documents submitted in the future in accordance with *Rule* 1:38-7(b)

08/03/2017
Dated

/s/ ALEXANDRA COLELLA
Signed