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CHERYL LECZA, Plaintiff, v. JOHNSON & JOHNSON and ETHICON, INC., Defendants.	SUPERIOR COURT OF NEW JERSEY LAW DIVISION BERGEN COUNTY Docket No.: **CIVIL ACTION** **COMPLAINT** **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiff Cheryl Lecza by and through her counsel, hereby sues JOHNSON & JOHNSON ("J&J"), a New Jersey corporation; and ETHICON, INC. ("Ethicon"), a New Jersey corporation (collectively "Defendants").

NATURE OF THE ACTION

1. This is an action for strict products liability, failure to warn, defective design, brought by Plaintiff Cheryl Lecza for injuries arising out of the Proceed Surgical Mesh ("Proceed") and the Prolene Hernia System ("PHS").

2. Defendants J&J and Ethicon designed, manufactured and supplied to doctors multi-layered hernia mesh, including the Proceed and PHS, collectively "Ethicon Multi-Layered Hernia Mesh".

3. Ethicon Multi-Layered Hernia Mesh created an unreasonable risk of harm to Cheryl Lecza.

4. The unreasonable risk of pain, dense adhesion formation, bowel complications, mesh shrinkage, hernia recurrence, seroma and fistula formation, and infection, whether from a prolonged and pronounced inflammatory response caused by the multiple layers, degradation of polymers due to exposure to gamma irradiation, non-conforming subcomponents, or some other mechanism, renders Ethicon Multi-Layered Hernia Mesh a defective product.

5. The selection and implantation of the Ethicon Multi-Layered Hernia Mesh by Cheryl Lecza's surgeons was a result of the misinformation, marketing, sales, promotion and direction by Defendants.

JURISDICTION & VENUE

6. This is a lawsuit over defective hernia mesh designed, marketed, manufactured, promoted and sold within New Jersey and the United States by Defendant Ethicon and its parent company J&J.

7. Cheryl Lecza currently resides in Daytona Beach, Florida and is a citizen and resident of Florida.

8. Plaintiff underwent hernia repair surgery on or about May 7, 2009 at Union Hospital in Elkton, Maryland. At that time, the Proceed that Defendants manufactured, designed, distributed, and warranted by Defendants was implanted into Plaintiff. Plaintiff's surgeon, medical staff, and other healthcare providers met or exceeded the standard of care applicable to the hernia

surgery.

9. Plaintiff underwent recurrent hernia repair surgery on or about March 5, 2010 at Union Hospital in Elkton, Maryland. At that time, the PHS that Defendants manufactured, designed, distributed, and warranted by Defendants was implanted into Plaintiff. Cheryl Lecza's surgeon, medical staff, and other healthcare providers met or exceeded the standard of care applicable to the hernia surgery.

10. Defendant J&J is a corporation incorporated in New Jersey, and according to its website, the world's largest and most diverse medical device and diagnostics company, with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey.

11. Defendant J&J organizes its subsidiary businesses into individual Business Units to coordinate the development, manufacture, testing, marketing promotion, training, distribution and sale of its products, including but not limited to its hernia repair mesh products. Within J&J there are three sectors: medical devices and diagnostics, pharmaceutical, and consumer. Within the medical devices and diagnostic sector are "Business Units" including the "Ethicon Franchise." J&J charged the Ethicon Franchise with the design, development, promotion, marketing, testing, training, distribution and sale of the Proceed and PHS, the hernia repair products at issue in this case. The Company Group Chairman and Worldwide Franchise Chairman for the Ethicon Franchise, Gary Pruden, is employed by J&J. The companies which comprise the Ethicon Franchise are thus controlled by Defendant J&J and include Ethicon, Inc.

12. Defendant Ethicon is a wholly owned subsidiary of Defendant J&J. Defendant Ethicon is a corporation incorporated in the State of New Jersey with its principal place of business in Somerville, New Jersey. Defendants conduct business in every county in New Jersey.

13. Defendant Ethicon is a medical device company involved in the research,

development, testing, manufacture, production, marketing, promotion and/or sale of medical devices including Ethicon Multi-Layered Hernia Mesh.

14. J&J, directly and/or through the actions of Ethicon, has at all pertinent times been responsible for the research, development, testing, manufacture, production, marketing, promotion, distribution and/or sale of Ethicon Multi-Layered Hernia Mesh.

15. At all relevant times, Defendants either directly, or through their agents, apparent agents, servants or employees sold, distributed and marketed the defective Ethicon Multi-Layered Hernia Mesh in the State of New Jersey. Defendants derive substantial revenue from hernia mesh products used or implanted in the State of New Jersey. As such, Defendants expected or should have expected that their business activities could or would subject them to legal action in the State of New Jersey.

16. All Defendants were also involved in the business of monitoring and reporting adverse events concerning the Ethicon Multi-Layered Hernia Mesh, and having a role in the decision process and response of Defendants, if any, related to these adverse events.

17. The Ethicon Multi-Layered Hernia Mesh Defendants are subject to jurisdiction within the State of New Jersey and this Court because:

a. Defendants are engaged in substantial and not isolated business activity within the State of New Jersey, Bergen County.

b. Defendants' hernia mesh products, including the subject Proceed and PHS, were designed, manufactured, and placed into the stream of commerce in State of New Jersey by the Defendants.

c. Defendants maintain an office or agency within the State of New Jersey.

d. Upon information and belief, at all relevant times, Defendants committed tortious acts within the State of New Jersey out of which these causes of action arise.

18. At all times relevant hereto, the Defendants developed, manufactured, advertised, promoted, marketed, sold and/or distributed defective Ethicon Multi-Layered Hernia Mesh throughout the United States, including within the State of New Jersey and specifically to Cheryl Lecza's implanting physicians or their practice groups, or to the hospitals where the Ethicon Multi-Layered Hernia Mesh was implanted.

19. Plaintiff Cheryl Lecza has reviewed potential legal claims and causes of action against Defendants and has chosen to only pursue state-law claims. Any reference to any federal agency, regulation or rule is stated solely as background information and does not raise a federal question. Defendants J&J and Ethicon are both New Jersey corporations and both maintained their principal place of business in New Jersey. Accordingly, this Court may rightfully exercise jurisdiction, and venue is proper.

20. Defendants designed, manufactured, fabricated, marketed, packaged, advertised, and sold Ethicon Multi-Layered Hernia Mesh throughout the world, including in Bergen County, State of New Jersey.

21. Ethicon knowingly markets to, and derives income from, patients in the State of New Jersey from the sale of Ethicon Multi-Layered Hernia Mesh.

22. This is an action for damages in excess of Fifteen Thousand Dollars ($15,000.00), exclusive of interest and cost.

PROCEED HISTORY

23. Defendants were the designers, manufacturers, marketers, distributors and suppliers of the Proceed at all material times.

24. Defendants warranted the Proceed and placed the device into the United States stream of commerce.

25. The Proceed is multi-layered mesh made of the following, starting with the component which would be placed closest to the bowel of the patient-consumer:

- Oxidized Regenerated Cellulose (ORC) barrier layer
- Polydioxanone (PDS) film layer
- Large pore polypropylene (Prolene soft mesh)

26. Polypropylene hernia meshes are traditionally sterilized with ethylene oxide.

27. The ORC layer of the Ethicon Proceed will react and degrade in the presence of ethylene oxide.

28. Defendants sterilize the Ethicon Proceed with gamma irradiation, despite long-standing knowledge that polypropylene will degrade and embrittle if exposed to any amount of gamma irradiation.

29. Decades prior to the release of the Ethicon Proceed, Defendants were aware that polypropylene degrades, weakens, and embrittles when exposed gamma irradiation.[1]

30. The embrittled polypropylene of the Ethicon Proceed increases the propensity of the polypropylene to tear away from the securing devices, such as sutures or tacks.

31. The polypropylene base is the only permanent, non-resorbable portion or the Ethicon Proceed.

32. Defendants designed, manufactured, promoted, sold and/or marketed the Ethicon Proceed to be utilized in anyone with a soft tissue defect, including, but not limited to: "infants, children, pregnant women, or women planning pregnancies…"[2]

33. For decades, there were concerns in the medical community about severe complications if polypropylene was placed too close to the bowel or other underlying organs, due to the formation of dense adhesions to the polypropylene.

[1] U.S. Patent No. 3,943,933 (Issued Mar. 16, 1976).
[2] Proceed Surgical Mesh Instructions for Use, Status 04/2010.

34. Defendants were aware that the ORC layer utilized in the Proceed was ineffective at preventing adhesion formation to polypropylene over a decade before Defendants brought the Proceed to market.[3]

35. Despite significant evidence to contrary, Defendants marketed the Proceed and its ORC layer as a tissue separating barrier that would prevent adhesion formation from the underlying polypropylene to any nearby organs.

PHS HISTORY

36. Defendants were the designers, manufacturers, distributors and suppliers of the PHS at all material times.

37. Defendants warranted the PHS and placed the device into the United States stream of commerce.

38. PHS has a unique multi-layer design incorporating two distinct layers of polypropylene connected by a central polypropylene tube. This design is not used in any other hernia repair product sold in the United States. The multi-layer coating was represented and promoted by the Defendants to prevent or minimize recurrence, pain and inflammation, but it did not. Instead, the multi-layer design caused or contributed to an intense inflammatory and chronic foreign body response, resulting in an adverse tissue reaction and damage to surrounding tissue in the form of sclerotic, granulomatous and/or fibrotic tissue and improper healing. The severe inflammatory response caused by the multi-layer design also results in the PHS contracting and contorting, increasing the risk of chronic pain and recurrence. Additionally, the multi-layers of the PHS occupy multiple inguinal compartments, necessitating additional revision surgeries with increased complexity and morbidity.

[3] Robert J. Fitzgibbons, Jr., M.D. et al., *A Laparoscopic Intraperitoneal Onlay Mesh Technique for the Repair of an Indirect Inguinal Hernia*, 219-2 ANNALS OF SURGERY 114 (1994).

39. Defendants knew or should have known of the lack of biocompatibility of the multiple layers of polypropylene of the PHS prior to introducing it into the stream of commerce.

40. The polypropylene material used in the PHS is unreasonably susceptible to in vivo oxidative degradation, which causes or exacerbates excessive inflammation and adverse foreign body reaction, leading to shrinkage, scarification, pain and mesh deformation.

41. In 2018, the HerniaSurge Group published *International Guidelines for Groin Hernia Management*. The Guidelines were endorsed by the European Hernia Society, Americas Hernia Society, Asia Pacific Hernia Society, Afro Middle East Hernia Society, Australasian Hernia Society, International Endo Hernia Society, and European Associated for Endoscopic Surgery and Other Interventional Techniques. The HerniaSurge Group's Guidelines note the following: "three dimensional implants (plug-and-patch and bilayer) are not recommended because of the excessive use of foreign material, the need to enter both the anterior and posterior planes and the additional cost."

FAILURE TO WARN PHYSICIANS OF THE DANGERS ASSOCIATED WITH ETHICON MULTI-LAYERED HERNIA MESH

42. Defendants knew that the oxidized regenerated cellulose layer of the Proceed was ineffective at preventing adhesion formation to the underlying polypropylene of the Proceed before the Defendants set out to design the Proceed Surgical Mesh in 2003.

43. Before 2003, Defendants were aware that the Oxidized Regenerated Cellulose utilized in the Proceed had pores which were too large to prevent adhesion formation.

44. Before 2003, Defendants were aware that increased adhesion formation would result in increased mesh shrinkage.

45. Before 2003, Defendants were aware that Oxidized Regenerated Cellulose would result in dense adhesions in the presence of blood or other fibrinous exudate.

46. Before 2003, Defendants were aware that polypropylene elicits a chronic, life-long inflammatory response that is accompanied by exudation of fibrinogen.

47. Defendants failed to warn that Ethicon Multi-Layered Hernia Mesh would elicit a fibrinous exudate.

48. Before 2003, Defendants were aware that any exposure to gamma irradiation would weaken and embrittle the polypropylene of the Proceed.

49. Before placing Ethicon Multi-Layered Hernia Mesh on the market, Defendants were required to mitigate risks of the product, including any element of design or sterilization which could render the device ineffective, weaken the structural integrity of the device, or increase or prolong inflammation once the device is implanted, which would result in an increase in adhesion formation, mesh shrinkage, pain, bowel complications, hernia recurrence, and/or the need for early surgical revision in patients-consumers.

50. Defendants designed, manufactured, and marketed the Ethicon Multi-Layered Hernia Mesh, despite long-standing knowledge that the materials utilized in Ethicon Multi-Layered Hernia Mesh would cause dense adhesions, chronic pain, mesh shrinkage, bowel obstructions, and early hernia recurrence.

51. When the multi-layer coating of Proceed is disrupted and/or degrades, the "naked" polypropylene mesh is exposed to the adjoining tissue and viscera, and can become adhered to organs, and cause damage to organs, and potentiate fistula formation.

52. Defendants marketed Ethicon Multi-Layered Hernia Mesh to general surgeons, hospitals, and group purchasing organizations (GPOs), rather than end-user patients.

53. Defendants had the ability to inform surgeons, hospitals, or GPOs of developing problems or defects related to Ethicon Multi-Layered Hernia Mesh in its devices through e-mail,

letter, recalls, warnings in product inserts, and/or through its product representatives, who work directly with the surgeon.

54. The multiple layers of Ethicon Multi-Layered Hernia Mesh increase the intensity and duration of the inflammatory response. That response in turn increases dense adhesion formation from underlying structures to the Ethicon Multi-Layered Hernia Mesh, resulting in bowel complications, mesh contracture, hernia recurrence, increased foreign body reaction, chronic severe pain, and more.

55. Defendants state in the Ethicon Proceed IFU that "The PROLENE Soft Mesh component is constructed of knitted filaments of extruded polypropylene identical in composition to that used in PROLENE Polypropylene Suture, Nonabsorbable Surgical Suture, U.S.P." This statement is false, or at very least misleading, as the Proceed undergoes gamma irradiation that changes the composition of the polypropylene.

56. Defendants also state in the Proceed IFU that the polypropylene material "when used as a suture, has been reported to be nonreactive and to retain its strength indefinitely in clinical use. The PROLENE Soft Mesh affords excellent strength, durability and surgical adaptability, with a porous structure to enable mesh incorporation into surrounding tissues." This statement is false, or at very least misleading, as Defendants are aware that the Proceed is reactive and does not retain its strength. Furthermore, Defendants are aware of reports that the small polypropylene sutures do elicit a small reaction, and increasing amounts of polypropylene greatly increase such reaction. The very reason the Defendants added the ORC layer to the Prolene Soft Mesh was to protect organs from reacting with the polypropylene of the Prolene Soft Mesh.

57. The Proceed IFU has a section for contraindications, which list "None known." The PHS IFU does not have a contraindication section.

58. The Proceed and PHS IFU has a section for adverse reactions, both list "Potential adverse reactions are those typically associated with surgically implantable materials…" The polypropylene base of Ethicon Multi-Layered Hernia Mesh carries many potential adverse reactions, such as a life-long inflammatory response that other surgically implantable materials do not present. Additionally, the multiple layers of Ethicon Multi-Layered Hernia Mesh further increase the inflammatory response and rate of infection, adhesion formation, chronic pain, seroma formation, fistula formation, hematomas, mesh contracture, hernia recurrence, mesh migration, bowel complications, foreign body response, extrusion, and other additional injuries.

59. Defendants never performed any clinical trials and/or studies prior to marketing Ethicon Multi-Layered Hernia Mesh.

60. Defendants did not fully and/or adequately test the configuration of these new, multi-layered Hernia Meshes, that were implanted into Plaintiff.

61. Defendants continue to market the Proceed without warning of the massive mesh shrinkage or the necessary overlap to prevent early hernia recurrence due to mesh shrinkage.

62. Reassurances of Multi-Layered hernia mesh safety were made through direct promotional contact by Defendants' sales representatives and distributors, through word-of-mouth from Defendant's physician/technical consultants, and/or through industry targeted promotional materials.

63. Despite these reassurances, the defective design and manufacture of Ethicon Multi-Layered Hernia Mesh continued to elicit severe and chronic inflammatory responses, resulting in adhesion formation, bowel injuries, mesh contracture, pain, hernia recurrence, infections, seromas, fistulas, erosion, extrusion, revision surgeries, and additional complications.

64. Defendants were aware that the ORC layer was ineffective at preventing adhesions

to the polypropylene; gamma irradiation would weaken the polypropylene; the polypropylene utilized was already too weak; and the multi-layered mesh would contract massively over time. Nonetheless, Defendants employed the design in the Proceed in a reckless disregard for the safety of patients, including Plaintiff.

65. Defendants were aware that the multi-layers of the PHS would increase patient pain and mobility, and make revision surgeries more likely

66. Moreover, despite direct knowledge of significant adverse events reported by patients and physicians, as well as awareness of failures that have been reported in literature and published clinical trials, Defendants have continued to market Ethicon Multi-Layered Hernia Mesh as being safe and effective for hernia repair.

67. From the time that Defendants first began selling Ethicon Multi-Layered Hernia Mesh in the United States through today, product labeling and product information failed to contain adequate information, instructions, and warnings concerning the following: implantation of the mesh, specifically its propensity to massively shrink, the increased duration and intensity of inflammation, and the elevated rate of adhesions, bowel complications, chronic pain, hernia recurrence, seroma formation, hematoma formation, fistula formation, erosion, extrusion, infection, and other injuries that occur at a higher rate than other surgically implanted devices.

USE OF THE PRODUCTS

68. A defectively designed, manufactured and marketed Proceed left the hands of Defendants in its defective condition, delivered into the stream of commerce. Dr. Hien Q. Nguyen laparoscopically implanted the Proceed in Cheryl Lecza's abdomen to repair a hernia on or about May 7, 2009 at Union Hospital in Elkton, Maryland. Cheryl Lecza was implanted with a 4" x 6" Proceed, Cat #: PCDN1, Lot#, AEG292.

69. A defectively designed, manufactured and marketed PHS left the hands of Defendants in its defective condition, delivered into the stream of commerce. Dr. Hien Q. Nguygen implanted the PHS in Cheryl Lecza's groin to repair a right inguinal hernia on or about March 5, 2010 at Union Hospital in Elkton, Maryland. Cheryl Lecza was implanted with a Large Prolene Hernia System, Cat# PHSL, Lot# 21080-11.

70. As a direct and proximate result of Defendants defective design, manufacture, marketing, distribution, and/or sale of Ethicon Multi-Layered Hernia Mesh and placing the defective products into the stream of commerce, Plaintiff has been injured and damaged as follows:

a. On or about May 11, 2010, Cheryl Lecza underwent revision of the Ethicon Proceed due to pain at Union Hospital, Elkton, Maryland, by Dr. Zahid Aslam. Upon entering the Plaintiff's abdomen, Dr. Aslam noted "left sided omental adhesions, extensive amount of bowel adhesions on right side to the mesh" Dr. Aslam was "unable to do the complete lysis on the right side due to adherence to the mesh. Pictures were taken."
b. On or about July 31, 2015, Cheryl Lecza underwent removal of the failed Ethicon PHS and Proceed at Halifax Health in Port Orange, FL by Dr. Bruce Ramshaw. After lysing adhesions from the patient's small bowel, Dr. Ramshaw noted "there were two pieces of mesh, one for a right lower quadrant Spigelian hernia and one over the right groin. These were overlapped and all excised together, although these meshes were cut at one point to allow easier mesh removal. As the mesh excision got down toward the right groin there was noted to be two nerves, presumably a femoral branch and lateral femoral cutaneous that were imbedded in the fibrosis of the mesh were carefully lysed and freed up. Then there was right inferior epigastric vessels which had grown into the mesh and so these were clipped and divided and the mesh in the area of dissection was evaluated and placed to the side."
c. Cheryl Lecza experienced and/or continues to experience severe pain, nausea, diarrhea, chills, inflammation, loss of appetite, and extreme weight loss which have impaired Plaintiff's activities of daily living.

d. Cheryl Lecza continues to suffer complications as a result of Plaintiff's implantation with Ethicon Multi-Layered Hernia Mesh.
e. Cheryl Lecza is at a higher risk of severe complications during an abdominal surgery, to the extent that future abdominal operations might not be feasible.

71. The mechanism of failure in Plaintiff's device was a mechanism of failure that Defendants had marketed and warranted would not occur because of Ethicon Multi-Layered Hernia Mesh design and composition. The Proceed failure was also the same failure mechanism that the medical and scientific community had been studying and documenting since the 1990s, *i.e.,* ORC was ineffective at preventing adhesions to polypropylene, and polypropylene contracts when dense adhesions form to it.

72. Moreover, the symptoms and findings associated with Ethicon Multi-Layered Hernia Mesh product failures that have been reported in the literature are identical to those Plaintiff suffered.

73. As a direct and proximate result of Defendants' defective design, manufacturing, marketing, distribution, sale and warnings of the defective Ethicon Multi-Layered Hernia Mesh, Plaintiff has suffered and continues to suffer both injuries and damages, including, but not limited to: past, present and future physical and mental pain and suffering; physical disability, and past, present, and future medical, hospital, rehabilitative, and pharmaceutical expenses, and other related damages.

THE FDA'S 510(k) CLEARANCE PROCESS

74. The 510(k) clearance process refers to Section 510(k) of the Medical Device Amendments of 1976 MDA of the Federal Food, Drug and Cosmetic Act. Under this process, device manufacturers are only required to notify the FDA at least 90 days before they market a

device claimed to be "substantially equivalent" to a device the FDA approved for sale prior to 1976, when the MDA was enacted.

75. No clinical testing is required under this process.

76. Subsequent amendments to the MDA allowed for 510(k) clearance of products deemed "substantially equivalent" to post-MDA, 510(k) cleared devices.

77. Through this domino effect, devices deemed "substantially equivalent" to devices previously deemed "substantially equivalent" to devices approved for sale by the FDA prior to 1976 could be sold to patients in a matter of 90 days without any clinical testing.

78. Clearance for sale under the 510(k) process does not equate to FDA approval of the cleared device.

79. In 2012, at the request of the FDA, the National Institute of Health (NIH) conducted a thorough review of the 510(k) process, coming to the following major conclusion:

> **The 510(k) clearance process is not intended to evaluate the safety and effectiveness of medical devices with some exceptions. The 510(k) process cannot be transformed into a pre-market evaluation of safety and effectiveness so long as the standard for clearance is substantial equivalence to any previously cleared device.**

80. The NIH explained, "The assessment of substantial equivalence does not require an independent demonstration that the new device provides a 'reasonable assurance of safety and effectiveness.'" Further, the NIH even pointed out that the classification of predicate devices approved for sale prior to the 1976 MDA "did not include any evaluation of the safety and effectiveness of individual medical devices . . . Thus is common for devices to be cleared through the 510(k) program by being found substantially equivalent to devices that were never individually evaluated for safety and effectiveness, either through the original device classification program or through the 510(k) process."

81. Defendants cleared the all Ethicon Multi-Layered Hernia Mesh, and its related components, under the 510(k) Premarket Notification. Under Section 510(k) of the Federal Food, Drug and Cosmetic Act, a medical device does not have to go through the rigors of a clinical study to gain approval by the FDA. Instead, the device was supposed to demonstrate substantial equivalence to a predicate medical device.

82. On June 18, 2002, the Food and Drug Administration issued a document titled "Guidance for Resorbable Adhesion Barrier Devices for Use in abdominal and/or Pelvic Surgery; Guidance for Industry." The 26 page document starts by explaining:

> **FDA has determined that the resorbable adhesion barrier is a significant risk device as defined in 21 CFR 812.3(m)(4). The resorbable adhesion barrier is a class III device which is subject to premarket approval in accordance with section 515 of the Federal Food, Drug, and Cosmetics (FD&C) Act.**

83. The Proceed Surgical Mesh did not undergo premarket approval, but instead received 510(k) clearance on or about September 17, 2003. The only predicate device listed on the 510(k) application is the Prolene Soft Polypropylene Mesh, a non-Multi-Layered Hernia Mesh. Defendants did not claim that the Proceed Surgical Mesh was a resorbable adhesions barrier in their 510(k) application. However, after 510(k) clearance, Defendants marketed the Proceed Surgical Mesh as a resorbable adhesion barrier.

84. Defendants applied for 510(k) clearance for the Proceed Surgical Mesh again in May of 2006. The only predicate device listed on the 510(k) application is the prior Proceed Surgical Mesh. In this 510(k) application, Defendants did not claim the intended use of the Proceed was a resorbable adhesion barrier; however, in the device description Defendants note that the "ORC side provides a bioresorbable layer that physically separates the polypropylene mesh from underlying tissue and organ surfaces during the wound-healing period to minimize tissue

attachment to the mesh." Defendants continued to market the Proceed Surgical Mesh as a resorbable adhesion barrier.

85. The PHS did not undergo premarket approval, but instead received 510(k) clearance on or about September 20, 1997. The PHS was initially approved for the intended use of repairing "indirect and direct inguinal hernia defects." However, in the Instructions for Use for the PHS, Defendants market the PHS as "indicated for the repair of inguinal (direct & indirect) and abdominal wall hernia defects."

CAUSES OF ACTION PURSUANT TO NEW JERSEY LAW

COUNT I: PRODUCTS LIABILITY ACT – STRICT PRODUCTS LIABILITY – DEFECTIVE DESIGN (N.J.S.A. 2A:58C-1, et seq.)

86. Plaintiff incorporates herein by reference the allegations in all prior paragraphs and further alleges as follows:

87. Defendants had a duty to design and manufacture, distribute, market, promote and sell, Ethicon Multi-Layered Hernia Mesh so that it was neither defective nor unreasonably dangerous when put to the use for which it was designed, manufactured, distributed, marketed and sold.

88. In and before 2003, Defendants were engaged in the business of designing, manufacturing, marketing, distributing and selling hernia mesh implants and did design, manufacture, distribute, market and sell the Proceed.

89. In and before 1997, Defendants were engaged in the business of designing, manufacturing, marketing, distributing and selling hernia mesh implants, and did design, manufacture, distribute, market and sell the PHS.

90. Defendants expected the Ethicon Multi-Layered Hernia Mesh they were manufacturing, selling, distributing, supplying, and/or promoting to reach, and they did in fact

reach, implanting physicians and consumers in the State of New Jersey and the United States, including Plaintiff and Plaintiff's implanting physician, without substantial change in their condition.

91. At the time the Ethicon Multi-Layered Hernia Mesh left Defendants' possession and the time the Ethicon Multi-Layered Hernia Mesh entered the stream of commerce in the State of New Jersey, it was in an unreasonably dangerous or defective condition. These defects include, but are not limited to the following:

- Ethicon Multi-Layered Hernia Mesh was not reasonably safe as intended to be used;
- Ethicon Multi-Layered Hernia Mesh had an inadequate design for the purpose of hernia repair;
- Ethicon Multi-Layered Hernia Mesh contained unreasonably dangerous design defects, utilizing multiple layers, which increases and prolongs the inflammatory response;
- Ethicon Multi-Layered Hernia Mesh was not appropriately or adequately tested before distribution; and
- Ethicon Multi-Layered Hernia Mesh had an unreasonably high propensity for adhesion formation, mesh contracture, hernia recurrence, chronic pain, bowel complications, seroma formation, fistula formation, hematoma formation, infection, erosion, and extrusion.
- the Proceed contained unreasonably dangerous design defects, including a large pore ORC layer that is ineffective at preventing adhesion formation to the underlying polypropylene;
- the Proceed is unreasonably dangerous, due to the degraded state of the polypropylene utilized, which has been exposed to gamma irradiation;
- the PHS contained unreasonably dangerous design defects, including multiple layers of polypropylene intended to be implanted in different anatomical compartments, increasing inflammation, pain, mesh contracture, recurrence, revision surgeries, among other complications.
- the PHS is unreasonably dangerous, due to the heavyweight polypropylene, which is incites a pronounced, severe, life-long inflammation response, and is prone to becoming stiff and/or fibrotic.

92. At the time the Defendants' initial design, manufacture, marketing, and sale of Ethicon Multi-Layered Hernia Mesh, a feasible, alternative safer design was known and available, including, but not limited to, a flat, non-coated, single-layer mesh placed away from the bowel.

93. At the time subsequent to Defendants' initial design and manufacture and marketing and sale of Ethicon Multi-Layered Hernia Mesh, including before Plaintiff's hernia surgery, Defendants had the ability to eliminate the unsafe character of the Ethicon Multi-Layered Hernia Mesh without impairing its usefulness.

94. Had the Defendants properly and adequately tested Ethicon Multi-Layered Hernia Mesh, they would have discovered that an ORC layer was ineffective at preventing adhesion formation to the polypropylene of the Proceed; occupying multiple anatomical planes would result in increased rates of debilitating pain with the PHS; multiple layers increase and prolong the inflammatory response; the mesh experiences significant contraction over time; recurrence rates are unacceptably high; and that these defects result in bowel obstructions, seromas, fistulas, infections, erosion, extrusion, pain, recurrence, a pronounced foreign body response, among other complications.

95. Ethicon Multi-Layered Hernia Mesh, manufactured, supplied, distributed, marketed, promoted and sold by Defendants, were therefore defective in design for formulation in that, when it left Defendants, the foreseeable risk of harm from the product exceeded or outweighed the benefit or utility of the consumer would expect, and/or it failed to comply with federal requirements for these medical devices.

96. As a direct and proximate result of Defendants' wrongful conduct, including the defective and dangerous design and inadequate warnings of Ethicon Multi-Layered Hernia Mesh, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, economic loss,

and other damages including, but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

97. Defendants are strictly liable in tort to Plaintiff for their wrongful conduct pursuant to the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1 et seq.

COUNT II: PRODUCTS LIABILITY ACT – STRICT PRODUCTS LIABILITY – FAILURE TO WARN (N.J.S.A. 2A:58C-1, et seq.)

98. Plaintiff incorporates the allegations in all prior paragraphs, and further alleges as follows:

99. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce Ethicon Multi-Layered Hernia Mesh; and directly advertised or marketed the product to the FDA, health care professionals, GPOs, and consumers, including Plaintiff. Therefore, Defendants had a duty to warn of the risks associated with the use of Ethicon Multi-Layered Hernia Mesh.

100. Defendants distributed and sold Ethicon Multi-Layered Hernia Mesh in their original form of manufacture, which included the defects described herein.

101. Ethicon Multi-Layered Hernia Mesh was expected to and did reach Plaintiff and Plaintiff's implanting physician, without substantial change or adjustment in its condition as manufactured and sold by Defendants.

102. Each Ethicon Multi-Layered Hernia Mesh designed, developed, tested, manufactured, distributed, promoted, marketed, and/or sold or otherwise placed into the stream of commerce by Defendants, was in a dangerous and defective condition and posed a threat to any user or consumer.

103. At all material times, Plaintiff was the person the Defendants should have considered to be subject to the harm caused by the defective nature of Ethicon Multi-Layered Hernia Mesh.

104. Ethicon Multi-Layered Hernia Mesh was implanted in Plaintiff and used in a manner for which it was intended.

105. This use has resulted in severe physical, financial, emotional and other injuries to Plaintiff.

106. Defendants failed to adequately warn health care professionals and the public, including Plaintiff and Plaintiff's implanting physician, of the true risks of Ethicon Multi-Layered Hernia Mesh, which was ineffective at protecting underlying organs from adhesion formation and would contract significantly upon implantation, resulting in significant pain, bowel and other organ complications, hernia recurrence, reoperation, infections, fistulas, seromas, hematomas, erosion, extrusion, subsequent operations, and more.

107. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of Ethicon Multi-Layered Hernia Mesh. Had they done so, proper warnings would have been heeded and no health care professional, including Plaintiff's physician, would have used Ethicon Multi-Layered Hernia Mesh, or no consumer, including Plaintiff, would have purchased and/or consented to the use of Ethicon Multi-Layered Hernia Mesh.

108. Defendants failed to timely and reasonably provide adequate instructions and training concerning safe and effective use of Ethicon Multi-Layered Hernia Mesh.

109. Ethicon Multi-Layered Hernia Mesh, which Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce, was defective due to inadequate post-marketing

warnings and/or instruction because Defendants knew or should have known that there was reasonable evidence of an association between Ethicon Multi-Layered Hernia Mesh and dense adhesion formation, mesh contracture, and hernia recurrence, causing serious injury and pain. Nonetheless, Defendants failed to provide adequate warnings to health care professionals and the consuming public, including Plaintiff, and continued to aggressively promote Ethicon Multi-Layered Hernia Mesh.

110. Ethicon Multi-Layered Hernia Mesh, which Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce, was defective due to inadequate post-marketing warnings and/or instruction regarding the increased risk of failure of Ethicon Multi-Layered Hernia Mesh resulting in revision surgery, although Defendants knew of a safer alternative design including, but not limited to, a flat, non-coated, single-layer mesh placed away from the bowel.

111. Defendants failed to perform or otherwise facilitate adequate testing on Ethicon Multi-Layered Hernia Mesh; failed to reveal and/or concealed such testing and research data; and selectively and misleadingly revealed and/or analyzed such testing and research data.

112. Plaintiff and Plaintiff's physicians used Ethicon Multi-Layered Hernia Mesh for its intended purpose, *i.e.*, hernia repair.

113. Plaintiff could not have discovered any defect in Ethicon Multi-Layered Hernia Mesh through the exercise of due care.

114. Defendants, as designers, manufacturers, distributors, promoters, marketers and/or sellers of medical devices are held to the level of knowledge of experts in their field.

115. Neither Plaintiff nor Plaintiff's implanting physician had substantially the same knowledge about Ethicon Multi-Layered Hernia Mesh as Defendants.

116. Defendants reasonably should have known Ethicon Multi-Layered Hernia Mesh was unsuited to repair a hernia in Plaintiff.

117. As a direct and proximate result of Defendants' failure to adequately communicate a warning and/or failure to provide an adequate warning and other wrongful conduct, Plaintiff has sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages, as set forth in this Complaint.

118. Defendants are strictly liable in tort to Plaintiff for their wrongful conduct pursuant to the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1 et seq.

COUNT III: PRODUCTS LIABILITY ACT – STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT (N.J.S.A. 2A:58C-1, et seq.)

119. Plaintiff incorporates the allegations in all prior paragraphs, and further alleges as follows:

120. Defendants designed, developed, manufactured, tested, packaged, advertised, promoted, marketed, distributed, labeled and/or sold Ethicon Multi-Layered Hernia Mesh, in a condition which rendered it unreasonably dangerous due to it propensity to result in early failure of the device. Ethicon Multi-Layered Hernia Mesh was unreasonably dangerous in construction or composition.

121. Ethicon Multi-Layered Hernia Mesh manufactured by Defendants was defective in construction or composition in that, when it left the hands of Defendants, it deviated in a material way from their manufacturing performance standards and/or it differed from otherwise identical products manufactured to the same design formula. Defendants knew or should have known that Ethicon Multi-Layered Hernia Mesh could fail early in patients, thereby giving rise to pain and suffering, debilitation and the need for revision surgery to replace the device with the attendant

risk of complications and death from such further surgery, Defendants continued to market the Proceed and PHS as safe and effective Multi-Layered Hernia Meshes.

122. As a direct and proximate result of the use of the subject product as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered harm, damages and economic loss as previously described and will continue to suffer such harm, damages and economic loss in the future.

123. Defendants are strictly liable in tort to Plaintiff for their wrongful conduct pursuant to the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1 et seq.

ASSERTION OF CLAIMS PURSUANT TO THE LAWS OF MARYLAND AND FLORIDA

124. Plaintiff incorporates the allegations in all prior paragraphs, and further alleges as follows:

125. Plaintiff was injured outside the state of New Jersey as a result of being implanted with Ethicon Multi-Layered Hernia Mesh. To the extent the court chooses to apply the law of a state other than New Jersey, Plaintiff hereby places Defendants on notice of Plaintiff's intention to plead and assert all claims available under the state's law applied by this Court.

**COUNT IV: NEGLIGENCE-
PURSUANT TO COMMON LAW**

126. Plaintiff incorporates the allegations in all prior paragraphs, and further alleges as follows:

127. Although Defendants had a duty to use reasonable care in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, training, and preparing written instructions and warnings for Ethicon Multi-Layered Hernia Mesh, they failed to do so.

128. Defendants knew, or in the exercise of reasonable care should have known, that Ethicon Multi-Layered Hernia Mesh was defectively and unreasonably designed and/or

manufactured, and was unreasonably dangerous and likely to injure patients like Plaintiff in whom Ethicon Multi-Layered Hernia Mesh was implanted. They also knew or should have known that Plaintiff and Plaintiff's physicians were unaware of the dangers and defects inherent in Ethicon Multi-Layered Hernia Mesh.

129. As a direct and proximate result of Defendants' negligence in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, training and preparing written instructions and warnings for Ethicon Multi-Layered Hernia Mesh, Plaintiff suffered injuries and damages as summarized in this Complaint.

COUNT V: STRICT LIABILITY – DESIGN DEFECT-PURSUANT TO COMMON LAW

130. Plaintiff incorporates the allegations in all prior paragraphs, and further alleges as follows:

131. At the time Ethicon Multi-Layered Hernia Mesh was implanted in Plaintiff, the mesh product was defectively designed. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended. Further, Defendants failed to design against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

132. Defendants expected and intended Ethicon Multi-Layered Hernia Mesh to reach users such as Plaintiff in the condition in which the product was sold.

133. The implantation of Ethicon Multi-Layered Hernia Mesh in Plaintiff was medically reasonable, and was a type of use that Defendants intended and foresaw when they designed, manufactured and sold the product.

134. The risks of Ethicon Multi-Layered Hernia Mesh significantly outweigh any benefits that Defendants contend could be associated with the design.

135. At the time Ethicon Multi-Layered Hernia Mesh was implanted in Plaintiff, it contained unreasonably dangerous design defects. Specifically, the ORC is ineffective at preventing adhesion formation to the polypropylene of the Proceed; occupying multiple anatomical planes would result in increased rates of debilitating pain with the PHS; the multiple layers increase and prolong the inflammatory response; the mesh experiences significant contraction over time; recurrence rates are unacceptably high; the polypropylene is too weak. These defects result in bowel obstructions, seromas, fistulas, infections, erosion, extrusion, mesh contraction, and a pronounced foreign body response, among other complications.

136. At the time subsequent to Defendants' initial design and manufacture and marketing and sale of Ethicon Multi-Layered Hernia Mesh, including before Plaintiff's hernia surgery, Defendants had the ability to eliminate the unsafe character of Ethicon Multi-Layered Hernia Mesh without impairing its usefulness.

137. At the time Ethicon Multi-Layered Hernia Mesh was implanted in Plaintiff, the warnings and instructions provided by Defendants for the Ethicon Multi-Layered Hernia Mesh were inadequate and defective. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended, and Defendants failed to design and/or manufacture against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

138. At the time Ethicon Multi-Layered Hernia Mesh was implanted in Plaintiff, there were safer feasible alternative designs for hernia mesh products that would have prevented the injuries she suffered.

139. The Ethicon Multi-Layered Hernia Meshes implanted in Plaintiff failed to reasonably perform as intended and had to be surgically removed, necessitating further invasive

surgery to repair the very issue that the product was intended to repair. Thus, it provided no benefit to her.

140. As a direct and proximate result of the defective and unreasonably dangerous condition of Ethicon Multi-Layered Hernia Mesh, Plaintiff suffered injuries and damages as summarized in this Complaint.

COUNT VI: STRICT LIABILITY- FAILURE TO WARN- PURSUANT TO COMMON LAW

141. Plaintiff incorporates the allegations in all prior paragraphs, and further alleges as follows:

142. At the time Ethicon Multi-Layered Hernia Mesh was implanted in Plaintiff, the warnings and instructions Defendants provided for the Ethicon Multi-Layered Hernia Mesh were inadequate and defective. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended. Defendants failed to design and/or manufacture against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

143. Defendants expected and intended Ethicon Multi-Layered Hernia Mesh to reach users such as Plaintiff in the condition in which the product was sold.

144. Plaintiff and Plaintiff's physicians were unaware of the defects and dangers of the Ethicon Multi-Layered Hernia Mesh, and were unaware of the frequency, severity, and duration of the defects and risks associated with Ethicon Multi-Layered Hernia Mesh.

145. Defendants failed to adequately warn health care professionals and the public, including Plaintiff and Plaintiff's implanting physician, of the true risks of Ethicon Multi-Layered Hernia Mesh, which was ineffective at protecting underlying organs from adhesion formation and would contract significantly upon implantation, resulting in significant pain, bowel and other organ

complications, hernia recurrence, reoperation, infections, fistulas, seromas, hematomas, erosion, extrusion, subsequent operations, and more.

146. Defendants failed to timely and reasonably provide adequate instructions and training concerning safe and effective use of Ethicon Multi-Layered Hernia Mesh.

147. Defendants failed to perform or otherwise facilitate adequate testing of Ethicon Multi-Layered Hernia Mesh; failed to reveal and/or concealed such testing and research data; and selectively and misleadingly revealed and/or analyzed such testing and research data.

148. Ethicon Multi-Layered Hernia Mesh, which Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce, was defective due to inadequate post-marketing warnings and/or instruction because Defendants knew or should have known that there was reasonable evidence of an association between Ethicon Multi-Layered Hernia Mesh and dense adhesion formation, mesh contracture, and hernia recurrence, causing serious injury and pain. Nonetheless, Defendants failed to provide adequate warnings to health care professionals and the consuming public, including Plaintiff, and continued to aggressively promote Ethicon Multi-Layered Hernia Mesh.

149. With respect to the complications listed in their warnings, Defendants provided no information or warning regarding the frequency, severity and duration of those complications, although the complications associated with Ethicon Multi-Layered Hernia Mesh were more frequent and severe, and lasted longer than those with safer feasible alternative hernia repair treatments.

150. If Plaintiff or Plaintiff's physician had been properly warned of the defects and dangers of Ethicon Multi-Layered Hernia Mesh, and of the frequency, severity and duration of the

risks associated with Ethicon Multi-Layered Hernia Mesh, she would not have consented to allow Ethicon Multi-Layered Hernia Mesh to be implanted in Plaintiff's body, and Plaintiff's physician would not have implanted it in her.

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

COUNT VII: STRICT LIABILITY- MANUFACTURING DEFECT- PURSUANT TO COMMON LAW

152. Plaintiff incorporates the allegations in all prior paragraphs, and further alleges as follows:

153. Ethicon Multi-Layered Hernia Mesh contained a manufacturing defect when it left the possession of Defendants. Ethicon Multi-Layered Hernia Mesh differs from their intended result and/or from other ostensibly identical units of the same product line.

154. The manufacturing defects in Ethicon Multi-Layered Hernia Mesh were a producing cause of Plaintiff's injuries and damages as specified in this Complaint.

COUNT VIII: BREACH OF IMPLIED WARRANTY

155. Plaintiff incorporates the allegations in all prior paragraphs, and further alleges as follows:

156. At the time Defendants designed, manufactured, produced, tested, studied, inspected, labeled, marketed, advertised, sold, promoted and distributed Ethicon Multi-Layered Hernia Mesh for use by Plaintiff, they knew of the intended use of Ethicon Multi-Layered Hernia Mesh, and impliedly warranted their product to be of merchantable quality, and safe and fit for its intended use.

157. When Ethicon Multi-Layered Hernia Mesh was implanted in Plaintiff to treat a hernia, the Ethicon Multi-Layered Hernia Mesh was being used for the ordinary purposes for which it was intended.

158. Plaintiff, individually and/or by and through Plaintiff's physicians, relied upon Defendants' implied warranties of merchantability in consenting to have the Ethicon Multi-Layered Hernia Mesh implanted.

159. Contrary to such implied warranties, the Ethicon Multi-Layered Hernia Mesh was not of merchantable quality, and was not safe and/or was not fit for its intended use. The Ethicon Multi-Layered Hernia Mesh was unreasonably dangerous and unfit for the ordinary purposes for which it was used. Defendants failed to warn of known or reasonably scientifically knowable defects in Ethicon Multi-Layered Hernia Mesh.

160. As a direct and proximate result of the conduct of Defendants, Plaintiff suffered the injuries and damages described in this Complaint.

COUNT IX: BREACH OF EXPRESS WARRANTY

161. Plaintiff incorporates the allegations in all prior paragraphs, and further alleges as follows:

162. At all relevant times, Defendant manufactured, distributed, advertised, promoted, and sold Ethicon Multi-Layered Hernia Mesh.

163. At all relevant times, Defendant intended Ethicon Multi-Layered Hernia Mesh be used in the manner that Plaintiff in fact used it and Defendants expressly warranted in its brochures and advertising that each product was safe and fit for use by consumers, that it was of merchantable quality, that its side effects were minimal and comparable to other mesh products, and that it was adequately tested and fit for its intended use.

164. At all relevant times, Defendants were aware that consumers, including Plaintiff, would use Ethicon Multi-Layered Hernia Mesh. Therefore, Plaintiff was a foreseeable user of Defendants' Ethicon Multi-Layered Hernia Mesh.

165. Plaintiff and/or Plaintiff's implanting physician were at all relevant times in privity with Defendants.

166. Defendants' Ethicon Multi-Layered Hernia Mesh was expected to reach and did in fact reach consumers, including Plaintiff and Plaintiff's implanting physician, without substantial change in the condition in which it was manufactured and sold by Defendants.

167. Defendants breached various express warranties with respect to the Ethicon Multi-Layered Hernia Mesh, including the following particulars:

- Defendants represented to Plaintiff and Plaintiff's physicians and healthcare providers through their labeling, advertising marketing materials, detail persons, seminar presentations publications, notice letters, and regulatory submissions that Ethicon Multi-Layered Hernia Mesh was safe and fraudulently withheld and concealed information about substantial risks or serious injury and/or death associated with using Ethicon Multi-Layered Hernia Mesh;

- Defendants represented to Plaintiff and Plaintiff's physicians and healthcare providers that their Ethicon Multi-Layered Hernia Mesh was as safe, and/or safer than other alternative procedures and devices and fraudulently concealed information, which demonstrated that Ethicon Multi-Layered Hernia Mesh was not safer than alternatives available on the market; and

- Defendants represented to Plaintiff and Plaintiff's physicians and healthcare providers that Ethicon Multi-Layered Hernia Mesh was more efficacious than other alternatives and fraudulently concealed information regarding the true efficacy of Ethicon Multi-Layered Hernia Mesh.

168. In reliance upon Defendants' express warranty, Plaintiff was implanted with Defendants' Ethicon Multi-Layered Hernia Mesh as prescribed and directed, and therefore, in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

169. At the time of making such express warranties, Defendants knew or should have known that Ethicon Multi-Layered Hernia Mesh does not conform to these express representations because Ethicon Multi-Layered Hernia Mesh was not safe and had numerous serious side effects, many of which Defendants did not accurately warn about, thus making Ethicon Multi-Layered Hernia Mesh unreasonably unsafe for its intended purpose.

170. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiff and the public, relied upon the representations and warranties of Defendants in connection with the use recommendation, description, and/or dispensing of Ethicon Multi-Layered Hernia Mesh.

171. Defendants breached their express warranties to Plaintiff in that the Ethicon Multi-Layered Hernia Mesh was not of merchantable quality, safe, and fit for its intended purpose, nor was it adequately tested.

172. As a direct and proximate result of Defendants' conduct, Plaintiff has sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses, and other damages.

COUNT X: PUNITIVE DAMAGES

173. Plaintiff incorporates the allegations in all prior paragraphs, and further alleges as follows:

174. Plaintiff is entitled to punitive damages because Defendants' wrongful acts and/or omissions were wanton or in conscious disregard of the rights of others. Defendants misled both

the medical community and the public at large, including Plaintiff, by making false representations about the safety and efficacy of Ethicon Multi-Layered Hernia Mesh and by failing to provide adequate instructions and training concerning its use. Defendants downplayed, understated, and/or disregarded their knowledge of the serious and permanent side effects and risks associated with the use of Ethicon Multi-Layered Hernia Mesh, despite available information demonstrating that Ethicon Multi-Layered Hernia Mesh lacked adequate testing, was ineffective at preventing adhesion formation of polypropylene, would significantly contract upon implantation, would fail early, and would cause an increased and prolonged inflammatory and foreign body response, high rates of bowel complications, seromas, infections, fistulas, pain, and other harm to patients. Such risk and adverse effects could easily have been avoided had Defendants not concealed knowledge of the serious and permanent side effects and risks associated with the use of Ethicon Multi-Layered Hernia Mesh or provided proper training and instruction to physicians regarding use of Ethicon Multi-Layered Hernia Mesh. Defendants' misrepresentations included knowingly withholding material information from the FDA, the medical community and the public, including Plaintiff, concerning the safety of Ethicon Multi-Layered Hernia Mesh.

175. Defendants were or should have been in possession of evidence demonstrating that Ethicon Multi-Layered Hernia Mesh caused serious side effects. Nevertheless, Defendants continued to market Ethicon Multi-Layered Hernia Mesh by providing false and misleading information with regard to its safety and efficacy.

176. Defendants failed to provide warnings that would have dissuaded health care professionals from using Ethicon Multi-Layered Hernia Mesh, thus preventing health care professionals and consumers, including Plaintiff, from weighing the true risks against the benefits of using Ethicon Multi-Layered Hernia Mesh.

177. Defendants failed to provide adequate training, testing and instructions to physicians that could have prevented failure of Ethicon Multi-Layered Hernia Mesh causing serious harm and suffering to patients, including Plaintiff.

WHEREFORE, Cheryl Lecza demands judgment against Defendants for compensatory damages and punitive damages, together with interest, cost of suit and attorney's fees and such other relief as the Court deems proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Cheryl Lecza prays for judgment and an award of damages against Defendants, as follows:

a. special damages, to include past and future medical and incidental expenses, according to proof;
b. past and future loss of earnings and/or earning capacity, according to proof;
c. past and future general damages, to include pain and suffering, emotional distress and mental anguish, according to proof;
d. pre-judgment and post-judgment interest;
e. the costs of this action; and
f. treble and/or punitive damages to Plaintiff; and
g. granting any and all such other and further legal and equitable relief as the Court deems necessary, just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury to the full extent permitted by law.

NOTICE OF OTHER ACTIONS PURSUANT TO R. 4:5-1

I hereby certify that there are related civil proceedings: Cottle v. Ethicon, Inc., et al, Docket No.: BER-L-7065-17; Bassett v. Ethicon, Inc., et al, Docket No.: BER-L-7836-17; Gold v. Ethicon, Inc., et al, Docket No.: BER-L-8037-17; Noakes v. Ethicon, Inc., et al, Docket No.: BER-L-8276-17; Fowler v. Ethicon, Inc., et al, Docket No.: BER-L-8572-17; Griffin v. Ethicon, Inc., et al, Docket No.: BER-L-8827-17; Linnenbrink v. Ethicon, Inc., et al, Docket No.: BER-L-8829-

17; Campbell v. Ethicon, Inc., et al, Docket No.: BER-L-8998-17; Martin v. Ethicon, Inc., et al, Docket No.: BER-L-9127-17; Ruiz v. Ethicon, Inc., et al, Docket No.: BER-L-9130-17; Trebolo, Jr. v. Ethicon, Inc. et al, Docket No.: BER-L-9133-17; Gateley v. Ethicon, Inc., et al, Docket No.: BER-L-9151-17; Redding v. Ethicon, Inc., et al, Docket No.: BER-L-184-18; Rice v. Ethicon, Inc., et al, Docket No.: BER-L-197-18; Bean v. Ethicon, Inc., et al, Docket No.: BER-L-198-18; Alumbaugh v. Ethicon, Inc., et al, Docket No.: BER-L-207-18; Reynolds v. Ethicon, Inc., et al, Docket No.: BER-L-279-18; Smith v. Ethicon, Inc., et al, Docket No.: BER-L-652-18; Gaddis v. Ethicon, Inc., et al, Docket No.: BER-L-658-18; Clark v. Ethicon, Inc., et al, Docket No.: BER-L-691-18; Fielding v. Ethicon, Inc., et al, Docket No.: BER-L-693-18; Hollimon v. Ethicon, Inc., et al, Docket No.: BER-L-694-18; Miller v. Ethicon, Inc., et al, Docket No.: BER-L-695-18; Moore v. Ethicon, Inc., et al, Docket No.: BER-L-697-18; Rodriguez v. Ethicon, Inc., et al, Docket No.: BER-L-699-18; Sollis v. Ethicon, Inc., et al, Docket No.: BER-L-703-18; Adams v. Ethicon, Inc., et al, Docket No.: BER-L-728-18; Crossland v. Ethicon, Inc., et al, Docket No.: BER-L-729-18; Denney v. Ethicon, Inc., et al, Docket No.: BER-L-732-18; Westerbeck v. Ethicon, Inc., et al, Docket No.: BER-L-733-18; Dollanmeyer v. Ethicon, Inc., et al, Docket No.: BER-L-774-18; Jarrell v. Ethicon, Inc., et al, Docket No.: BER-L-775-18; Jennings v. Ethicon, Inc., et al, Docket No.: BER-L-777-18; Johnson v. Ethicon, Inc., et al, Docket No.: BER-L-778-18; Kennedy v. Ethicon, Inc., et al, Docket No.: BER-L-779-18; McKinney v. Ethicon, Inc., et al, Docket No.: BER-L-780-18; Morgan v. Ethicon, Inc., et al, Docket No.: BER-L-781-18; Robins v. Ethicon, Inc., et al, Docket No.: BER-L-809-18; Aaron v. Ethicon, Inc., et al, Docket No.: BER-L-870-18; Diloreto v. Ethicon, Inc., et al, Docket No.: BER-L-1018-18; Pikulsky, et al v. Ethicon, Inc., et al, Docket No.: BER-L-1052-18; Lang v. Ethicon, Inc., et al, Docket No.: BER-L-1067-18; Gibson v. Ethicon, Inc., et al, Docket No.: BER-L-1110-18; Shackelford v. Ethicon, Inc., et al, Docket

No.: BER-L-1200-18; Schriner v. Ethicon, Inc., et al, Docket No.: BER-L-1222-18; Alexander v. Ethicon, Inc., et al, Docket No.: BER-L-1241-18; Usey v. Ethicon, Inc., et al, Docket No.: BER-L-1244-18; Hart v. Ethicon, Inc., et al, Docket No.: BER-L-1349-18; Galvez v. Ethicon, Inc., et al, Docket No.: BER-L-1393-18; Lindly v. Ethicon, Inc., et al, Docket No.: BER-L-1402-18; Senkel v. Ethicon, Inc., et al, Docket No.: BER-L-1433-18; Maestas v. Ethicon, Inc., et al, Docket No.: BER-L-1456-18; Szaroleta v. Ethicon, Inc., et al, Docket No.: BER-L-1458-18; Krampen-Yerry v. Ethicon, Inc., et al, Docket No.: BER-L-1466-18; Lotridge v. Ethicon, Inc., et al, Docket No.: BER-L-1467-18; Dias v. Ethicon, Inc., et al, Docket No.: BER-L-1471-18; Alvarado, et al v. Ethicon, Inc., et al, Docket No.: BER-L-1479-18; Mountjoy, et al v. Ethicon, Inc., et al, Docket No.: BER-L-1480-18; Fontenot v. Ethicon, Inc., et al, Docket No.: BER-L-1513-18; Anawaty v. Ethicon, Inc., et al, Docket No.: BER-L-1516-18; Capshaw v. Ethicon, Inc., et al, Docket No.: BER-L-1530-18; Bradford v. Ethicon, Inc., et al, Docket No.: BER-L-1806-18; Johnson v. Ethicon, Inc., et al, Docket No.: BER-L-2003-18; Collier v. Ethicon, Inc., et al, Docket No.: BER-L-2214-18; Williams v. Ethicon, Inc., et al, Docket No.: BER-L-2337-18; Miller v. Ethicon, Inc., et al, Docket No.: BER-L-2345-18; Ward v. Ethicon, Inc., et al, Docket No.: BER-L-2353-18; Shepherd v. Ethicon, Inc., et al, Docket No.: BER-L-2354-18; Scobee v. Ethicon, Inc., et al, Docket No.: BER-L-2355-18; Wojtusiak, et al v. Ethicon, Inc., et al, Docket No.: BER-L-2456-18; Fontana v. Ethicon, Inc., et al, Docket No.: BER-L-2511-18; Hardy v. Ethicon, Inc., et al, Docket No.: BER-L-2512-18; Snyder v. Ethicon, Inc., et al, Docket No.: BER-L-2513-18; Hodge v. Ethicon, Inc., et al, Docket No.: BER-L-2577-18; Kruggel, et al v. Ethicon, Inc., et al, Docket No.: BER-L-2694-18; McCormick v. Ethicon, Inc., et al, Docket No.: BER-L-2856-18; Lloyd v. Ethicon, Inc., et al, Docket No.: BER-L-2952-18; Benton, et al v. Ethicon, Inc., et al, Docket No.: BER-L-3317-18; Muniz v. Ethicon, Inc., et al, Docket No.: BER-L-3516-18; Deffenbaugh v.

Ethicon, Inc., et al, Docket No.: BER-L-3517-18; Kries v. Ethicon, Inc., et al, Docket No.: BER-L-3531-18; Kurash, et al v. Ethicon, Inc., et al, Docket No.: BER-L-3532-18; Stonaker v. Ethicon, Inc., et al, Docket No.: BER-L-3599-18; Johnson v. Ethicon, Inc., et al, Docket No.: BER-L-3720-18; Young v. Ethicon, Inc., et al, Docket No.: BER-L-3721-18; Garrett v. Ethicon, Inc., et al, Docket No.: BER-L-3726-18; Dirks v. Ethicon, Inc., et al, Docket No.: BER-L-3727-18; Hecker v. Ethicon, Inc., et al, Docket No.: BER-L-3728-18; O'Brien v. Ethicon, Inc., et al, Docket No.: BER-L-3749-18; Hendrix v. Ethicon, Inc., et al, Docket No.: BER-L-3751-18; Hinn v. Ethicon, Inc., et al, Docket No.: BER-L-3753-18; McIntosh v. Ethicon, Inc., et al, Docket No.: BER-L-3754-18; Wesch, et al v. Ethicon, Inc., et al, Docket No.: BER-L-3766-18; Morgan v. Ethicon, Inc., et al, Docket No.: BER-L-3837-18; Barker v. Ethicon, Inc., et al, Docket No.: BER-L-3853-18; Hodge v. Ethicon, Inc., et al, Docket No.: BER-L-3897-18; Wiggins v. Ethicon, Inc., et al, Docket No.: BER-L-3900-18; Jones v. Ethicon, Inc., et al, Docket No.: BER-L-3913-18; Brooks v. Ethicon, Inc., et al, Docket No.: BER-L-3916-18; Chatman v. Ethicon, Inc., et al, Docket No.: BER-L-3919-18; Mata v. Ethicon, Inc., et al, Docket No.: BER-L-4035-18; Darnell v. Ethicon, Inc., et al, Docket No.: BER-L-4038-18; Lynch v. Ethicon, Inc., et al, Docket No.: BER-L-4043-18; Parham v. Ethicon, Inc., et al, Docket No.: BER-L-4052-18; Tavian v. Ethicon, Inc., et al, Docket No.: BER-L-4056-18; Banks v. Ethicon, Inc., et al, Docket No.: BER-L-4077-18; Jones v. Ethicon, Inc., et al, Docket No.: BER-L-4082-18; Boston v. Ethicon, Inc., et al, Docket No.: BER-L-4103-18; Rivas v. Ethicon, Inc., et al, Docket No.: BER-L-4113-18; Blackistone v. Ethicon, Inc., et al, Docket No.: BER-L-4332-18; Godfrey v. Ethicon, Inc., et al, Docket No.: BER-L-4334-18; McCutcheon v. Ethicon, Inc., et al, Docket No.: BER-L-4475-18; Soares v. Ethicon, Inc., et al, Docket No.: BER-L-4476-18; Woods v. Ethicon, Inc., et al, Docket No.: BER-L-4482-18; Perez v. Ethicon, Inc., et al, Docket No.: BER-L-4486-18; Chavira v. Ethicon, Inc., et al, Docket No.:

BER-L-4489-18; Guidry v. Ethicon, Inc., et al, Docket No.: BER-L-4515-18; Newburn v. Ethicon, Inc., et al, Docket No.: BER-L-4523-18; Crawford v. Ethicon, Inc., et al, Docket No.: BER-L-4526-18; and Cordova v. Ethicon, Inc., et al, Docket No.: BER-L-4532-18. Beyond the Cottle, Bassett, Gold, Noakes, Fowler, Griffin, Linnenbrink, Campbell, Martin, Ruiz, Trebolo, Gateley, Redding, Rice, Bean, Alumbaugh, Reynolds, Smith, Gaddis, Clark, Fielding, Hollimon, Miller, Moore, Rodriguez, Sollis, Adams, Crossland, Denney, Westerbeck, Dollanmeyer, Jarrell, Jennings, Johnson, Kennedy, McKinney, Morgan, Robins, Aaron, Diloreto, Pikulsky, Lang, Gibson, Shackelford, Schriner, Alexander, Usey, Hart, Galvez, Lindly, Senkel, Maestas, Szaroleta, Krampen-Yerry, Lotridge, Dias, Alvarado, Mountjoy, Fontenot, Anawaty, Capshaw, Bradford, Johnson, Collier, Williams, Miller, Ward, Shepherd, Scobee, Wojtusiak, Fontana, Hardy, Snyder, Hodge, Kruggel, McCormick, Lloyd, Benton, Muniz, Deffenbaugh, Kries, Kurash, Stonaker, Johnson, Young, Garrett, Dirks, Hecker, O'Brien, Hendrix, Hinn, McIntosh, Wesch, Morgan, Barker, Hodge, Wiggins, Jones, Brooks, Chatman, Mata, Darnell, Lynch, Parham, Tavian, Banks, Jones, Boston, Rivas, Blackistone, Godfrey, McCutcheon, Soares, Woods, Perez, Chavira, Guidry, Newburn, Crawford, and Cordova cases, I am not aware of any other civil proceedings either pending or contemplated with respect to the matter in controversy herein, and that there are no other parties who shall be joined in this action at this time.

CERTIFICATION PURSUANT TO R. 1:38-7(c)

I hereby certify that confidential personal identifiers have been redacted from documents now submitted to the Court and will be redacted from all documents in the future in accordance with R. 1:38-8(b).

TRIAL COUNSEL DESIGNATION

Please take notice that pursuant to the provisions of R. 4:25-4, JOSHUA S. KINCANNON, ESQUIRE, is hereby designated as trial counsel on behalf of PLAINTIFF.

LOMURRO, MUNSON, COMER, BROWN & SCHOTTLAND, LLC
Attorneys for Plaintiff

/s JOSHUA S. KINCANNON
JOSHUA S. KINCANNON, ESQ.

Dated: June 20, 2018

Civil Case Information Statement

Case Details: BERGEN | Civil Part Docket# L-004559-18

Case Caption: LECZA CHERYL VS ETHICON, INC.
Case Initiation Date: 06/20/2018
Attorney Name: JOSHUA S KINCANNON
Firm Name: LOMURRO MUNSON COMER BROWN & SCHOTTLAND LLC
Address: 4 PARAGON WAY SUITE 100
FREEHOLD TWP NJ 07728
Phone:
Name of Party: PLAINTIFF : Lecza, Cheryl
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: YES
If yes, list docket numbers: 2017: 7065, 7836, 8037, 8276, 8572, 8827, 8829, 8998, 9127, 9130, 9133, 9151
2018: 184, 197, 198, 207, 279, 652, 658, 691, 693, 694, 695, 697, 699, 703, 728, 729, 732, 733, 774, 775, 777, 778, 779, 780, 781, 809, 870, 1018, 1052, 1067, 1110, 1200, 1222, 1241, 1244, 1393, 1402, 1433, 1456, 1458, 1466, 1467, 1471, 1479, 1480, 1513, 1516, 1530, 1806, 2003, 2214, 2337, 2345, 2353, 2354, 2355, 2456, 2511, 2512, 2513, 2577, 2694, 2856, 2952, 3317, 3516, 3517, 3531, 3532, 3599, 3720, 3721, 3726, 3727, 3728, 3749, 3751, 3753, 3754, 3766, 3837, 3853, 3897, 3900, 3913, 3916, 3919, 4035, 4038, 4043, 4052, 4056, 4077, 4082, 4103, 4113, 4332, 4334, 4475, 4476, 4482, 4486, 4489, 4515, 4523, 4526, 4532
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)

06/20/2018
Dated

/s/ JOSHUA S KINCANNON
Signed