UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

RALPH MILLER, Plaintiff, v. JOHNSON & JOHNSON and ETHICON, INC., And DAVOL INC. and C. R. BARD INC., Defendants.	)	MDL Docket No. 2846 Case No. JURY TRIAL DEMANDED

COMPLAINT

Plaintiff Ralph Miller, by and through his counsel, hereby brings this civil action as a related action against DAVOL, INC ("Davol") and C.R. BARD, INC ("Bard") (collectively, "the Bard Defendants"), and JOHNSON & JOHNSON ("J&J"), a New Jersey corporation and ETHICON, INC. ("Ethicon") (collectively, "the Ethicon Defendants"), a New Jersey corporation, arising out of the failure of the Defendants' hernia mesh products. As a result of being implanted with Defendants' hernia mesh product, Plaintiff suffered permanent injuries and significant pain and suffering, emotional distress, monetary losses, and diminished quality of life. Plaintiff respectfully seeks all damages to which he may be legally entitled.

PARTIES

1. Plaintiff is a citizen and resident of the County of Walker, Georgia and the United States.

2. Defendant Davol, Inc. ("Davol") is a corporation that is incorporated under the laws

of the State of Rhode Island. Davol has its principal place of business in the State of Rhode Island. It manufactures the Ventralight ST mesh (hereinafter also referred to as "ST Bard Mesh" or "product") and is located at 100 Crossings Boulevard, Warwick, Rhode Island. Davol is a medical device company involved in the research, development, testing, manufacture, production, marketing, promotion and/or sale of medical devices including the ST Bard Mesh.

3. Defendant C. R. Bard, Inc. ("Bard") is a corporation that is incorporated under the laws of the State of New Jersey. Bard's principal place of business is located at 730 Central Avenue, Murray Hill, New Jersey, 07974. Bard is a multinational marketer, promoter, seller, producer, manufacturer, and developer of medical devices. Bard controls the largest market share of the hernia mesh market. It is the corporate parent/stockholder of Davol and participates in the manufacture and distribution of the ST Bard Mesh. Bard also manufactures and supplies Davol with material that forms part of the ST Bard Mesh.

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

5. Defendant Johnson & Johnson ("J&J") is a corporation incorporated under the laws of New Jersey with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. All acts and omissions of J&J as described herein were done by its agents, servants, employees, and/or owners, acting in the course and scope of their respective agencies,

services, employments, and/or ownership. J&J is a manufacturer of medical devices, diagnostics and consumer products related to healthcare, health, beauty products, and medical devices. J&J's misfeasance and malfeasance caused Plaintiff to suffer injury and damages.

6. Defendant J&J organizes its subsidiary businesses into individual Business Units, which coordinate the development, manufacture, testing, marketing, promoting, training, distribution, and sale of J&J products, including its hernia repair mesh devices such as the Ethicon Multi-Layered Hernia Mesh at issue here. The corporate structure of J&J contains three sectors: (1) medical devices and diagnostics; (2) pharmaceutical; and (3) consumer.

7. Within the medical devices and diagnostic sector are "Business Units" as well, including the "Ethicon Franchise". J&J charged the Ethicon Franchise with the design, development, promotion, marketing, testing, training, distribution and sale of the Proceed Mesh and Physiomesh Flexible Composite (hereinafter, collectively "Ethicon Multi-Layered Hernia Mesh"), the hernia repair devices that were implanted in Plaintiff.

8. Gary Pruden, the Company Group Chairman and Worldwide Franchise Chairman for the Ethicon Franchise, is a J&J employee. The companies comprising the Ethicon Franchise are thus controlled by Defendant J&J, and include Defendant Ethicon, Inc.

9. Defendant Ethicon, Inc. ("Ethicon") is a corporation incorporated under the laws of New Jersey with its principal place of business in Sommerville, New Jersey. It is a wholly owned subsidiary of Defendant J&J. All acts and omissions of Ethicon as described herein were done by its agents, servants, employees, and/or owners, acting in the course and scope of their respective agencies, services, employments, and/or ownership. Ethicon is a is a medical device company involved in the research, development, testing, manufacture, production, marketing, promotion and/or sale of medical devices, including the Ethicon Multi-Layered Hernia Mesh.

Ethicon's secondary corporate headquarters is located in Cincinnati, Ohio. Ethicon's misfeasance and malfeasance caused Plaintiff to suffer injury and damages.

10. "C.R. Bard" and "Davol" are collectively hereinafter referred to as the "Bard Defendants."

11. "J&J" and "Ethicon" are collectively hereinafter referred to as the "Ethicon Defendants."

12. C.R. Bard, Davol, J&J, and Ethicon are hereinafter collectively referred to as "Defendants," unless under a heading that designates Ethicon or Bard allegations and facts.

13. Defendants are individually, jointly and severally liable to Plaintiff for damages suffered by Plaintiff arising from the Defendants' design, manufacture, marketing, labeling, distribution, sale and placement of its defective Mesh Products at issue in the instant suit, effectuated directly and indirectly through their respective agents, servants, employees and/or owners, all acting within the course and scope of their representative agencies, services, employments and/or ownership.

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

JURISDICTION & VENUE

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

16. This Court has personal jurisdiction over each of the Bard Defendants as Davol has its principal place of business in Rhode Island and Bard was responsible for Davol's actions. This

Court has personal jurisdiction over all Defendants as they transact business within the State of Rhode Island, contracted to sell and supply their Mesh Products in the State of Rhode Island, and committed tortious acts and omissions in Rhode Island. Defendants' tortious acts and omissions caused injury to Plaintiff Ralph Miller. Defendants employ sales representatives in the State of Rhode Island to sell their Mesh Products throughout the State, including the Mesh Products implanted in Plaintiff Ralph Miller. Defendants have purposefully engaged in the business of developing, manufacturing, publishing information, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties, as successor in interest, or other related entities, medical devices including Mesh Products in Rhode Island, for which they derived significant and regular income. The Defendants intended and reasonably expected that that their defective Mesh Products would be sold and implanted in Rhode Island and could cause injury in Rhode Island.

17. Bard Defendants are registered to transact business in Rhode Island.

18. Venue is proper in this Court pursuant to 28 U.S.C. § 1332(a)-(c) by virtue of the fact that (a) a substantial part of the events or omissions giving rise to the claims occurred in this District; (b) Defendants' products are sold to and consumed by individuals in the State of Rhode Island; and (c) Davol has its principle place of business in Rhode Island and Bard was responsible for Davol's actions; thereby, subjecting Defendants to personal jurisdiction in this action and making them all "residents" of this judicial District.

19. Defendants have and continue to conduct substantial business in the State of Rhode Island and in this District, distribute the Mesh Products in this District, receive substantial compensation and profits from sales of Mesh Products in this District, and made material omissions and misrepresentations and breaches of warranties in this District, so as to subject all

Defendants to in personam jurisdiction in this District.

PROCEED HISTORY

20. Defendants were the designers, manufacturers, marketers, distributors and suppliers of the Ethicon Proceed Surgical Mesh at all material times.

21. Defendants warranted the Ethicon Proceed Hernia Mesh and placed the device into the United States stream of commerce.

22. Defendants knew that the oxidized regenerated cellulose layer of the Ethicon Proceed Hernia Mesh 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.

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

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

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

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

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

28. Before placing the Ethicon Proceed 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.

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

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

31. The Ethicon Proceed Hernia Mesh is 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)

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

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

34. Defendants sterilize the Ethicon Proceed Hernia Mesh with gamma irradiation.

35. Gamma irradiation degrades, weakens, and embrittles the polypropylene base of the Ethicon Proceed Hernia Mesh.

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

[1] U.S. Patent No. 3,943,933 (Issued Mar. 16, 1976).

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

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

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

40. 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.

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

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

PHYSIOMESH HISTORY

43. Defendants were the designers, manufacturers, distributors and suppliers of the Physiomesh at all material times.

44. Defendants warranted the Physiomesh and placed the device into the United States stream of commerce.

[2] Proceed Surgical Mesh Instructions for Use, Status 04/2010.
[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).

45. Physiomesh has a unique multi-layer design incorporating five (5) distinct layers: two layers of poliglecaprone-25 ("Monocryl") film covering two underlying layers of polydioxanone film ("PDS"), which in turn coat a polypropylene mesh. 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 adhesion and inflammation and to facilitate incorporation of the mesh into the body, but it did not. Instead, the multi-layer coating prevented adequate incorporation of the mesh into the body and caused or contributed to an intense inflammatory and chronic foreign body response resulting in an adverse tissue reaction including migration and damage to surrounding tissue in the form of sclerotic, granulomatous and/or fibrotic tissue and improper healing.

46. When implanted intraperitoneally, which involves the abdomen being inflated and then deflated, and the product being implanted in contact with the intestines and/or other internal organs, the Physiomesh design unnecessarily increases the risk of mesh deformation, adhesion, erosion, fistula formation, and other injuries. When implanted using an open procedure, the Physiomesh design provides no benefit, and instead increases the risks associated with the product.

47. The multi-layer coating of the Defendants' Physiomesh is not biocompatible, which causes or contributes to complications such as delayed wound healing, inflammation, foreign body response, rejection, infection, and other complications.

48. When affixed to the body's tissue, the impermeable multi-layer coating of the Physiomesh prevents fluid escape, which leads to seroma formation, and which in turn can cause infection, abscess formation and other complications.

49. The multi-layer coating provides a breeding ground for bacteria in which the bacteria cannon be eliminated by the body's immune response, which allows infection to

proliferate.

50. Defendants knew or should have known of the lack of biocompatibility of the multi-layer coating of the Physiomesh prior to introducing it into the stream of commerce.

51. The polypropylene material used in the Physiomesh 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.

52. The polypropylene mesh portion of the Physiomesh lacked sufficient strength to withstand normal abdominal forces, which results in recurrent hernia formation and/or rupture and deformation of the mesh itself.

53. One of the purported benefits of the Physiomesh design was implantation using laparoscopy, which involves minimally invasive surgery. However, treatment of complications associated with Physiomesh often requires open surgery, thus obviating any purported benefit from the intended laparoscopic implantation technique.

54. In May 2016, Defendants issued an "Urgent: Field Safety Notice" relating to the Physiomesh, the same product implanted in Plaintiff, and sent such notification to hospitals and medical providers in various countries worldwide. In this Urgent Field Safety Notice, Defendants advise these providers of "a voluntary product recall," citing two international device registries which reported data reflecting recurrence/reoperation rates being higher than that observed form a data set relating to patient outcomes after being implanted with other mesh. Ethicon's "Urgent: Field Safety Notice" stated Ethicon believed the higher rates to be a multifactorial issue, including possible product characteristics. However, in the United States, Defendants failed to issue a nationwide recall, opting instead to simply remove the product from the market and cease further sale within the United States. Ethicon also knew or had reason to know that those implanted with

the Physiomesh were still at risk for adverse events since Ethicon stated in the Field Safety Notice that those implanted with Physiomesh should continue to be followed. Despite its knowledge, Ethicon did not issue any warning, caution or instruction to hospitals, physicians or patients regarding the importance of monitoring for potential complications.

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

55. 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.

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

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

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

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

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

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

62. 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.

63. 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.

64. When the multi-layer coating of Ethicon Multi-Layered Hernia Mesh 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.

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

66. 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.

67. 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 organs to the Ethicon Multi-Layered Hernia Mesh, resulting in bowel complications, mesh contracture, hernia recurrence, increased foreign body reaction, chronic severe pain, and more.

68. 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.

69. 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.

70. The Proceed and Physiomesh IFU has a section for contraindications, both list "None known."

71. The Proceed and Physiomesh 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.

72. Defendants failed to warn that Ethicon Multi-Layered Hernia Mesh creates a solid barrier preventing the body from adequately clearing or transporting fluid, which results in seroma formation, potentiating infections and fistula formation.

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

74. Defendants did not fully and/or adequately test the configuration of these new, multi-layered barrier hernia meshes, that were implanted into Plaintiff.

75. 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.

76. Reassurances of device safety were made through direct promotional contact by Defendants' sales representatives and distributors, through word-of-mouth from Defendants' physician/technical consultants, and/or through industry targeted promotional materials.

77. 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, and additional complications.

78. Defendants were aware that the ORC and Monocryl 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 its Ethicon Multi-Layered Hernia Mesh in a reckless disregard for the safety of patients, including Plaintiff.

79. 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 the Proceed as being safe and effective for hernia repair.

80. 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.

FACTS COMMON TO THE ETHICON DEFENDANTS

81. A defectively designed, manufactured and marketed Proceed left the hands of Defendants in its defective condition, delivered into the stream of commerce. Dr. William Cockerham, MD implanted the Proceed Surgical Mesh in Ralph Miller's abdomen to repair a ventral hernia on or about January 29, 2010 at Parkridge Medical Center in Chattanooga, Tennessee. Ralph Miller was implanted with a PCDH1.

82. A defectively designed, manufactured and marketed Physiomesh left the hands of Defendants in its defective condition, delivered into the stream of commerce. Dr. Cockerham implanted the Physiomesh in Ralph Miller's abdomen to repair a ventral hernia on or about December 6, 2010 at Parkridge Medical Center in Chattanooga, Tennessee. Ralph Miller was implanted with a PHY2025V.

83. 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 December 6, 2010, Ralph Miller underwent revision of the Ethicon Proceed at Parkridge Medical Center in Chattanooga, Tennessee, by William Cockerham, MD. Upon visualizing the Ethicon Proceed, Dr. Cockerham notes: Incision was made directly over his previous incision. The abdomen was entered below the level of the previously placed mesh. Very dense adhesions to the previously placed mesh in the abdominal wall were encountered and were carefully dissected off. Some of the bowel could not be dissected off the mesh and so the mesh was incised, cut and left to stay on top of the abdominal wall. The remainder of the mesh that had been placed intraperitoneally was then dissected off, removed, and excised. Adhesiolysis was extremely difficult due to the dense adhesions. The hernia was in the right upper quadrant away from the previous dissection. The transverse right upper quadrant defect was closed using interrupted #1 PDS sutures. A 20 cm x 25 cm Physiomesh was then placed in the abdominal cavity which was sutured circumferentially to the abdominal wall with a large amount of overlap using #1 Nurulon sutures. A second row of sutures was then placed along the right side to help reinforce the mesh placement. Once it was circumferentially sutured, the sutures were overall tied. Approximately 200 ml of blood loss occurred during surgery.

b. On or about November 16, 2012, Ralph Miller underwent removal of the Ethicon Physiomesh at Parkridge Medical Center in Chattanooga, Tennessee. Upon visualizing the Ethicon Physiomesh, the surgeon noted: There were a large amount of adhesions and in several places bowel was plastered to the abdominal wall. Extensive adhesiolysis was done, taking approximately two hours. After the adhesions were taken down, the procedure was converted to an open procedure by making an elliptical incision to excise the patient's old scar. Excess skin was then removed and the surgeon was able to dissect down to the level of the hernia. Two very large hernias were noted; one approximately 10-12 cm in greatest diameter just to the right of the midline and the other in the midline smaller, but still approximately 8-10 cm. "We were able to suture the fascia closed and in the midline by using interrupted #1 Prolene using a Smead-Jones Technique. We also had an area off to the right side that we sutured horizontally right up to the vertical

incision and so the entire fascia was closed without problem and minimal tension." A 20 x 16 cm Strattice BIOMESH was trimmed and used to cover the defects after being sutured. The mesh was placed in a horizontal position in a diamond shape to cover the hernia defect. It was also noted that the patient's appendix was in a precarious position, stuck to the abdominal wall, and re-entry back into this patient for possible appendicitis would be potentially problematic, so decision was made for an appendectomy. Three pieces of mesh, two pieces of 10 x 15 cm ovals and one 10 cm circle, was used to cover and buttressed the suture repair of the appendectomy. Part of previous mesh was explanted during this procedure and sent to pathology.

c. Ralph Miller experienced and/or continues to experience severe pain, neuropathic pain, nausea, diarrhea, chills, inflammation, loss of appetite, and disability which have impaired Plaintiff's activities of daily living.
d. Ralph Miller continues to suffer complications as a result of Plaintiff's implantation with Ethicon Multi-Layered Hernia Mesh.
e. Ralph Miller is at a higher risk of severe complications during an abdominal surgery, to the extent that future abdominal operations might not be feasible.

84. 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.

85. 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.

86. 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

87. 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.

88. No clinical testing is required under this process.

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

90. 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.

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

92. 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.**

93. 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."

94. Defendants cleared the Proceed, 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.

95. 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.**

96. 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-barrier 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.

97. 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.

98. The Physiomesh did not undergo premarket approval, but instead received 510(k) clearance on or about April 9, 2010. The Proceed was listed as a predicate device on the Physiomesh 510(k) application. Defendants did not claim that the Physiomesh was a resorbable adhesions barrier in their 510(k) application. However, after 510(k) clearance, Defendants marketed the Physiomesh as a resorbable adhesion barrier.

FACTS COMMON TO THE BARD DEFENDANTS

99. On or about November 16, 2012, Plaintiff underwent repair of a recurrent abdominal incisional hernia at Parkridge Medical Center in Chattanooga, Tennessee. Three Ventralight ST mesh products were implanted in Plaintiff, including (1) Reference No. 5954450, Lot No. HJWz052L; (2) Reference No. 5954460, Lot No. HJWH1076; and (3) Reference No. 5954460, Lot No. HJWZ1165.

100. Defendants, manufactured, sold, and/or distributed the ST Bard Mesh to Plaintiff, through his doctors, to be used for treatment of hernia repair.

101. On or about June 4, 2019, Plaintiff received a Primary Diagnosis of chronic abdominal wall and groin pain with a Secondary Diagnosis of neuropathic pain related to hernia mesh. Plaintiff is currently on Short Term Disability due to the failure of all of the Ethicon Defendants and Bard Defendants mesh products he has been implanted with.

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

103. Defendants were responsible for the research, design, development, testing, manufacture, production, marketing, promotion, distribution and sale of ST Bard Mesh, including providing the warnings and instructions concerning the product.

104. Among the intended purposes for which Defendants designed, manufactured and sold ST Bard Mesh was the use by surgeons for hernia repair surgeries, the purpose for which the ST Bard Mesh was implanted in Plaintiff.

105. Defendants represented to Plaintiff and his physicians that ST Bard Mesh was a safe and effective product for hernia repair.

FACTS COMMON TO ALL DEFENDANTS

106. The Mesh Products were designed, manufactured and distributed by Defendants who own the patent on their respective devices that were inserted into Plaintiff's body.

107. Defendants designed, manufactured and distributed the Mesh Products that were inserted into Plaintiff's body.

108. Defendants, through its agents, servants, and employees, participated in the manufacture and delivery of the Mesh Products that were inserted into Plaintiff's body.

109. At all relevant times, Defendants held themselves out to the public as being knowledgeable, skilled and experienced in the design, manufacture, production, assembly, distribution and sale of medical devices used for hernia repair, including the polypropylene Mesh Products at issue.

110. Defendants had the requisite knowledge, skill and expertise to know that implanted devices, such as polypropylene mesh, must be chemically inert, non-carcinogenic, and able to withstand mechanical stress. Implanted devices, such as polypropylene mesh, must also not be physically modified by tissue fluids, not allow tissue infiltration, not incite an inflammatory or foreign body cell reaction, and not produce allergic reactions.

111. Polypropylene is not biologically inert in the human body, as it is known to expand as well as shrink, and can cause serious injury to patients, significantly impacting their quality of life.

112. Moreover, it is well known within the scientific and medical community that the polypropylene used for surgical treatment begins to degrade after implantation in the human body, which can lead to infection and irritation, and result in serious pain as the body tries to rid itself of the foreign material.

113. Scientific literature regarding the safety and effectiveness of these devices suggests that polypropylene mesh repair does not improve symptomatic results or quality of life over traditional non-mesh repair.

114. Defendants were fully aware of the dangers defective products they were placing into the stream of commerce posed to their customers, specifically the Mesh Products polypropylene mesh, which has been shown to pose an unreasonable risk of human body inflammation, granuloma formation, foreign body reaction, excessive scar tissue formation and long-term complications.

115. Despite the abundance of scientific and medical information available relating to the dangerous properties and serious risks of the Mesh Products, Defendants deliberately ignored these dangers and aggressively promoted the Mesh Products polypropylene mesh to healthcare providers and/or directly to consumers.

116. Defendants expressly warranted that the Mesh Products polypropylene mesh were safe and fit for use by consumers, that they were of merchantable quality, and they were adequately tested and fit for its intended use, even though they were not safe and had numerous side effects, many of which Defendants did not accurately warn about.

117. The Mesh Products, with its unusual design, were nothing more than a marketing ploy to capture the revenue stream from the lucrative hernia mesh market.

118. Defendants designed, developed, manufactured, assembled, distributed, tested, marketed, promoted and/or sold to the public, including Plaintiff, for profit, the at issue Mesh Products polypropylene mesh in a defective condition such that the Mesh Products polypropylene mesh failed and had to be surgically removed after numerous complications arose.

119. The Mesh Products that were implanted in Plaintiff were designed, manufactured, sold and distributed by Defendants to be used by surgeons for hernia repair surgeries and were further represented by Defendants to be an appropriate, cost-effective and suitable products for such purpose.

120. The polypropylene mesh used in the manufacture of the Mesh Products, which were implanted into Plaintiff is unreasonably dangerous, defective, and negligently designed in the following ways:

(a) The weave of the mesh produces very small interstices which allow bacteria to enter and hide from the host defenses designed to eliminate them. The bacteria can secrete an encasing slime (biofilm) which further serves to protect them from destruction by white blood cells and macrophages

(b) Polypropylene is impure: there is no such thing as pure polypropylene (PP). PP contains about 15 additional compounds which are leached from the PP and are toxic to tissue which enhances the inflammatory reaction and the intensity of fibrosis.

(c) Mesh was shown to be not inert in 2003 with flaking and fissuring demonstrated by scanning electron microscopy which leads to degradation and release of toxic compounds. This enhances the inflammatory and fibrotic reactions.

(d) With loss of PP due to degradation, the surface area is greatly increased, thus providing greater areas for bacterial adherence and more elution of toxic compounds from the PP, and also the freed toxic PP itself, all of which increases the inflammatory reaction and intensity of fibrosis.

(e) By 1998 polypropylene mesh was known to shrink 30-50%.

(f) Heat begins the process of degradation.

(g) Predominate infection/inflammation was noted at least in 2007 in explanted samples.

(h) Allergic reactions occur with polypropylene after implantation.

(i) Polypropylene is subject to oxidation by acids produced during the inflammatory reaction which caused degradation and loss of compliance.

(j) Mesh porosity is important for tissue ingrowth, with low porosity decreasing tissue incorporation. Porosity also affects the inflammatory and fibrotic reaction. With mechanical stress the porosity of the pores is decreased.

(k) Observation of mesh under the scanning electron microscope reveals that very small interstices exist between the mesh fibrils, which are too small for a macrophage to enter to destroy incubating bacteria. Some bacteria are capable of degrading polypropylene.

(l) Polypropylene is known to depolymerize, cross-link, undergo oxidative degradation by free radicals, and stress crack after implantation in the human body.

(m) Polypropylene migrates to lymph nodes when there is a foreign body giant cell reaction.

(n) The large surface area promotes wicking of fluids and bacteria and is a "bacterial super highway" which provides a safe haven for bacteria.

(o) Common complications associated with PP include restriction of abdominal wall mobility and local wound disturbances. Often failures of PP include persistent and active inflammatory processes, irregular or low formation of scar tissue and unsatisfying integration of the mesh in the regenerative tissue area.

(p) Klosterhalfen published a series of 623 explanted mesh samples removed for pain, infection and recurrence. There are also reports of mesh migration and erosion into the sigmoid colon. Reduced mobility of the abdominal wall has also been found. Moreover, the rate of chronic pain after mesh hernia repair ranges from 4-40%. Thus, Defendants should have been aware of these issues with polypropylene.

121. A malfunction of this device can lead to bowel perforations and/or chronic intestinal fistulae (abdominal connections or passageways between the intestines and other organs), as well as other chronic and debilitating conditions

122. Upon information and belief Defendants failed to comply with the FDA application and reporting requirements.

123. Upon information and belief Defendants were aware of the high degree of complication and failure rate associated with the Mesh Products.

124. Upon information and belief Defendants were aware of the defects in the manufacture and design of the Mesh Products.

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

126. Upon information and belief, Defendants paid doctors, surgeons, physicians, and/or clinicians to promote the Mesh Products but did not readily disclose this information.

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

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

129. Defendants marketed the Mesh Products to the medical community and to patients as safe, effective, reliable, medical devices for the treatment of hernia repair, and as safer and more effective as compared to the traditional products and procedures for treatment, and other competing mesh products. Defendants did not undergo pre-market approval for the Mesh Products and are, therefore, prohibited by the FDA from asserting superiority claims.

130. Defendants failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Mesh Products.

131. Defendants failed to design and establish a safe, effective procedure for removal of the Mesh Products; therefore, in the event of a failure, injury, or complications it is difficult to safely remove the Mesh Products.

132. Defendants provided incomplete, insufficient, and misleading information to physicians in order to increase the number of physicians using the Mesh Products for the purpose of increasing their sales. By so doing, Defendants caused the dissemination of inadequate and misleading information to patients, including Plaintiff.

133. The Mesh Products were utilized and implanted in a manner foreseeable to Defendants.

134. The Mesh Products were implanted into Plaintiff were in the same or substantially similar condition as when they left the possession of the Defendants, and in the condition directed by the Defendants.

135. Plaintiff has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

136. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective hernia patch that was implanted.

ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS

137. Defendants are estopped from relying on any statutes of limitations or repose by virtue of their acts of fraudulent concealment, which include intentional concealment from Plaintiff and/or the general public that the Mesh Products are defective, while continually marketing the products with the effects described in this Complaint.

138. Given Defendants' affirmative actions of concealment by failing to disclose this known but non-public information about the defects—information over which Defendants had exclusive control—and because Plaintiff could not reasonably have known the Mesh Products was defective, Defendants are estopped from relying on any statutes of limitations that might otherwise be applicable to the claims asserted in this Complaint.

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

140. Furthermore, in the existence of due diligence, Plaintiff could not have reasonably discovered the Defendants' wrongful conduct, including, but not limited to, the defective design and/or manufacturing of the products until a date within the statute of limitations. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the statutory limitations period.

CAUSES OF ACTION

COUNT I: STRICT LIABILITY – MANUFACTURING DEFECT

141. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

142. Defendants expected and intended the Mesh Products to reach users such as Plaintiff in the condition in which the products were sold.

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

144. When the Mesh Products was implanted in Plaintiff's body it was defectively manufactured.

145. Defendants' poor quality control and general non-compliance resulted in the non-conformance of the Mesh Products implanted in Plaintiff. The implanted product did not conform to Defendants' intended manufacturing and design specifications.

146. Upon information and belief, Defendants utilized substandard and adulterated polypropylene and raw materials used to make the Mesh Products, which deviated from Defendants' material and supply specifications.

147. As a direct and proximate result of the defective manufacture of the Mesh Products, Plaintiff suffered injuries and damages as summarized in this Complaint.

148. Plaintiff has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

149. Plaintiff has also incurred substantial medical bills and has suffered loss of other

monies due to the Mesh Products that were implanted.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

150. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

151. The Mesh Products were defectively designed and/or manufactured and were not reasonably safe for their intended use in hernia repair; and the risks of the design outweighed any potential benefits associated with them. As a result of the defective design and/or manufacture of the Mesh Products, there was an unreasonable risk of severe adverse reactions to the meshes or their components including: chronic infections; chronic pain; recurrence of hernia; foreign body response; rejection; infection; scarification; improper wound healing; excessive and chronic inflammation; allergic reaction; adhesions to internal organs; erosion; abscess; fistula formation; granulomatous response; seroma formation; nerve damage; tumor formation, cancer, tissue damage and/or death; and other complications

152. When affixed to the body's tissue, the impermeable Mesh Products prevent fluid escape, which leads to seroma formation, and which in turn can cause infection or abscess formation and other complications.

153. The Mesh Products are defective in its design in part due to a material mismatch. This material mismatch results in the Mesh Products curling after implantation.

154. The multi-layer design of the Mesh Products results in ineffective sterilization more often than single layer mesh.

155. The Mesh Products are cytotoxic, immunogenic, and not biocompatible, which causes or contributes to complications such as delayed wound healing, inflammation, foreign body

response, rejection, infection, and other complications.

156. These manufacturing and design defects associated with the product were directly and proximately related to the injuries Plaintiff suffered.

157. Neither Plaintiff nor Plaintiff's implanting physician were adequately warned or informed by Defendants of the defective and dangerous nature of the products. Moreover, neither Plaintiff nor Plaintiff's implanting physician were adequately warned or informed by Defendants of the risks associated with the Mesh Products.

158. The products implanted in Plaintiff failed to reasonably perform as intended. They caused serious injury and had to be removed via invasive surgery and necessitated additional invasive surgeries to repair the hernia that the products were initially implanted to treat.

159. When the Mesh Products were implanted in Plaintiff's body, they were defectively designed. As described above, there was an unreasonable risk that the products would not perform safely and effectively for the purposes for which they were intended. Defendants failed to design against such dangers and failed to provide adequate warnings and instructions concerning the products' risks.

160. Defendants expected and intended the products to reach users such as Plaintiff in the condition in which the products were sold.

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

162. The risks of the products significantly outweigh any benefits that Defendants contend could be associated with it. Mesh Products incite an intense inflammatory response, leading to encapsulation, deformation, scarification and contraction, migration, erosion and

rejection.

163. The polypropylene mesh was in itself dangerous and defective, particularly when used in the manner intended by Defendants. The polypropylene material used in the Mesh Products was substandard, adulterated and non-medical grade, and was unreasonably subject to oxidative degradation within the body, further exacerbating the adverse reactions caused by the product. The Mesh Products polypropylene mesh is unreasonably susceptible to adhesion, perforation or erosion, fistula formation and bowel strangulation or hernia incarceration, and other injuries.

164. The appropriate treatment for complications associated with the Mesh Products involves additional invasive surgery in an attempt to remove the mesh from the body, thus eliminating any purported benefit that the products were intended to provide to the patient.

165. When the Mesh Products were implanted in Plaintiff, there were safer feasible alternative designs for hernia mesh products available.

166. The Mesh Products provides no benefit to consumers over other mesh types and increased the risks to patients implanted with these devices.

167. The Mesh Products implanted in Plaintiff failed to reasonably perform as intended and had to be surgically removed. Thus, further invasive surgery was necessary to repair the very problem that the products were intended to repair, providing only harm and no benefit to him.

168. As a direct and proximate result of the defective and unreasonably dangerous condition of the Mesh Products, Plaintiff suffered injuries and damages.

169. Plaintiff has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

170. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective Mesh Products that were implanted.

COUNT III: STRICT LIABILITY – FAILURE TO WARN

171. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

172. When the Mesh Products were implanted in Plaintiff's body, the warnings and instructions provided by Defendants for the products were inadequate and defective. There was an unreasonable risk that the product would not perform safely and effectively for the purposes for which they were intended. Defendants failed to design and/or manufacture against such dangers and failed to provide adequate warnings and instructions concerning these risks.

173. Defendants expected and intended the products to reach users such as Plaintiff in the condition in which they were sold.

174. Plaintiff and/or Plaintiff's physicians were unaware of the defects and dangers of the Mesh Products, and were unaware of the frequency, severity and duration of the risks associated with the products.

175. Defendants' Instructions for Use provided with the products expressly understate and misstate the risks known to be associated specifically with it. Defendants provided no warning to physicians about the risks or increased risks specifically associated with the unique design of the Mesh Products.

176. Defendants' Instructions for Use failed to adequately warn Plaintiff's physicians of numerous risks, which Defendants knew or should have known were associated with the Mesh Products, including the following: immunologic response, infection, pain, dehiscence, encapsulation, rejection, migration, scarification, contraction, erosion through adjacent tissue and viscera, adhesions, bowel obstruction, and tumor or cancer formation.

177. Defendants' Instructions for Use also failed to instruct physicians how much larger than the hernia defect the products needed to be for an effective repair.

178. As well, the Instructions for Use failed to disclose the extent the Mesh Products would shrink, or that they would even shrink at all.

179. Defendants failed to adequately warn Plaintiff and/or Plaintiff's physicians about the need for invasive surgical intervention in the event of complications or inform them of the treatment for such complications when they occurred.

180. Defendants failed to adequately warn Plaintiff and/or Plaintiff's physicians that the surgical removal of the Mesh Products, in the event of complications, would leave the hernia unrepaired and the resulting hernia would be much larger than the original. Thus, more complicated medical treatment would be needed to attempt to repair the same hernia that the failed products were intended to treat.

181. Defendants failed to adequately warn Plaintiff and/or Plaintiff's physicians that in the event of complications, the products are more difficult to fully remove than other feasible hernia meshes that have been available at all material times.

182. Defendants failed to warn Plaintiff and/or Plaintiff's physicians that as a result of being implanted with the Mesh Products, he would be at a higher risk of infection for the remainder of his life.

183. With respect to the complications listed in Defendants' warnings, they provided no information or warning regarding the frequency, severity and duration of those complications, even though the complications associated with the Mesh Products were more frequent, more severe and longer lasting than those with safer feasible alternative hernia repair treatments.

184. If Plaintiff Plaintiff and/or Plaintiff's physicians had been properly warned of the

defects and dangers of the Mesh Products, and of the frequency, severity and duration of the risks associated with the products, he would not have consented to allow the products to be implanted, and his physicians would not have implanted them.

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

186. Plaintiff has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

187. Plaintiff has also incurred substantial medical bills and have suffered loss of other monies due to the defective Mesh Products that were implanted.

COUNT IV: NEGLIGENCE

188. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

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

190. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

(a) Manufacturing, producing, promoting, creating, and/or designing the Mesh Products without thoroughly testing them;

(b) Manufacturing, producing, promoting, creating, and/or designing the Mesh Products without adequately testing them;

(c) Not conducting sufficient testing programs to determine whether or not the Mesh

Products were safe for use and/or implantation; in that Defendants herein knew or should have known that the Mesh Products were unsafe and unfit for use and/or implantation by reason of the dangers to its users;

(d) Selling the Mesh Products without making proper and sufficient tests to determine the dangers to its users;

(e) Negligently failing to adequately and correctly warn the Plaintiff, the public, and/or the medical and healthcare profession, and the FDA of the dangers of the Mesh Products;

(f) Negligently advertising and recommending the use of the Mesh Products without sufficient knowledge as to their dangerous and harmful properties;

(g) Negligently representing that the Mesh Products were safe for use for their intended purpose, when, in fact, they were unsafe and harmful;

(h) Negligently representing that the Mesh Products had equivalent safety and efficacy as other types of mesh products used in similar hernia repairs;

(i) Negligently designing the Mesh Products in a manner which were dangerous to their users;

(j) Negligently manufacturing the Mesh Products in a manner which were dangerous to their users;

(k) Negligently assembling the Mesh Products in a manner which were dangerous to their users;

(l) Concealing information from Plaintiff and/or implanting surgeons in knowing that the Mesh Products were unsafe and dangerous;

(m) Improperly concealing and/or misrepresenting information from Plaintiff and/or healthcare professionals, concerning the severity of risks and dangers of the Mesh Products

compared to other hernia mesh devices used in similar hernia repairs.

191. Defendants knew, or in the exercise of reasonable care should have known, that the products were defectively and unreasonably designed and/or manufactured and were unreasonably dangerous and likely to injure patients in whom they were implanted. Defendants knew or should have known that Plaintiff and/or Plaintiff's physicians were unaware of the dangers and defects inherent in the products.

192. Defendants knew or should have known that the MSDS for the polypropylene used to manufacture the Mesh Products prohibited permanently implanting the polypropylene into the human body.

193. Defendants utilized non-medical grade polypropylene.

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

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

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

197. Defendants knew or should have known that all subsequent operations carry a greater risk of infection after the patient has been implanted with the Mesh Products.

198. As a direct and proximate result of Defendants' negligence in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for the Mesh Products, Plaintiff suffered injuries and damages as

summarized in this Complaint.

199. Plaintiff has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

200. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective Mesh Products that were implanted.

COUNT V: BREACH OF IMPLIED WARRANTY

201. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

202. At all material times, Defendants manufactured, distributed, advertised, promoted, and sold their Mesh Products.

203. At all material times, Defendants intended for their products to be implanted for the purposes and in the manner that Plaintiff and/or Plaintiff's implanting physician in fact used them; and Defendants impliedly warranted that the products and their component parts were of merchantable quality, safe and fit for such use, and adequately tested.

204. Defendants were aware that consumers, including Plaintiff and/or Plaintiff's physician, would implant their products as directed by the Instructions for Use. Therefore, Plaintiff was a foreseeable user of Defendants' Mesh Products.

205. Defendants' Mesh Products were expected to reach, and did in fact reach consumers, including Plaintiff and/or Plaintiff's physician, without substantial change in the condition in which they were manufactured and sold by Defendants.

206. Defendants breached various implied warranties with respect to the Mesh Products, including the following:

(a) Defendants represented to Plaintiff and/or Plaintiff's physician and healthcare providers through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that their products were safe. But at the same time, they fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the products;

(b) Defendants represented to Plaintiff and/or Plaintiff's physician and healthcare providers that their products were safe and/or safer than other alternative procedures and devices. But at the same time, they fraudulently concealed information demonstrating that the products were not safer than alternatives available on the market; and

(c) Defendants represented to Plaintiff and/or Plaintiff's physician and healthcare providers that their products were more efficacious than alternative procedures and/or devices. But at the same time, they fraudulently concealed information regarding the true efficacy of the Mesh Products.

207. In reliance upon Defendants' implied warranties, Plaintiff individually, and/or by and through his physician, used the Mesh Products as prescribed, and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

208. Defendants breached their implied warranties to Plaintiff in that their products were not of merchantable quality, nor were they safe and fit for their intended use or adequately tested.

209. As a direct and proximate result of Defendants' breaches of the aforementioned implied warranties, Plaintiff was caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including obligations for medical services

and expenses, impairment of personal relationships, and other damages.

210. Plaintiff has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

211. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective Mesh Products that were implanted.

COUNT VI: BREACH OF EXPRESS WARRANTY

212. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

213. At all relevant and material times, Defendants manufactured, marketed, sold, distributed and otherwise placed in to the stream of commerce the Mesh Products.

214. In advertising, marketing and otherwise promoting Mesh Products to physicians, hospitals and other healthcare providers, Defendants expressly warranted that their Mesh Products were safe for use and reasonably fit for their intended purposes. In advertising, marketing and otherwise promoting Mesh Products, Defendants' intended that physicians, hospitals and other healthcare providers rely upon their representations regarding safety and fitness in an effort to induce them to implant Mesh Products in their patients.

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

216. Defendants expressly warranted to physicians, hospitals, other healthcare providers and the general public including Plaintiff that Mesh Products were safe and fit for use by

consumers, that they were of merchantable quality, that its risks, side effects and potential complications were minimal and comparable to other hernia mesh products, that they was adequately researched and tested, and that they were fit for their intended use. Plaintiff and his physicians and healthcare providers reasonably relied upon Defendants' express representations and warranties, and consequently, Plaintiff was implanted with Defendants' Mesh Products.

217. The Mesh Products were manufactured from polypropylene, ePTFE, and PDO. The ePTFE was represented by the Defendants to decrease complications, but it did not. Instead, the ePTFE harbors and protects bacteria, resulting in a severe, chronic infection, which can take years to manifest.

218. Defendant breached these express warranties because the Mesh Products implanted in Plaintiff was unreasonably dangerous, defective, and not as Defendants had represented.

219. Defendants breached express representations and warranties made to the Plaintiff, as well as Plaintiff's physicians and healthcare providers, with respect to the Mesh Products, including, but not limited to, the following particulars:

A. Defendants represented to Plaintiff and his physicians and healthcare provides through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions among other ways that the Defendants' Mesh Products were safe, meanwhile Defendants fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the Mesh Products.

B. Defendants represented to Plaintiff and his physicians and healthcare providers that the Defendants' Mesh Products were as safe and/or safer than other alternative procedures and devices on the market, meanwhile Defendants

fraudulently concealed information that demonstrated that the Mesh Products were not safer than alternative therapies and products available on the market; and

C. Defendants represented to Plaintiff and his physicians and healthcare providers that the Defendants' Mesh Products were more efficacious than other alternative procedures, therapies and/or devices, meanwhile Defendants fraudulently concealed information, regarding the true efficacy of the Mesh Products.

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

221. At the time of making such express warranties, Defendants knew or should have known that Defendants' Mesh Products do not conform to the express warranties and Defendants' acts were motivated by financial gain while the adverse consequences of Defendants' conduct was outrageous, fraudulent, oppressive, done with malice or gross negligence and evidenced reckless indifference to Plaintiff's rights, health and safety so as to warrant the imposition of punitive damages.

222. As a direct and proximate result of Defendants' breaches of the aforementioned express warranties, Plaintiff suffered injuries and damages as summarized in this Complaint. Plaintiff has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective Mesh Products that were implanted.

COUNT VII: GROSS NEGLIGENCE

223. Plaintiff repeats, reiterates, and realleges each and every allegation of this

Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

224. Defendants' wrongs were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff, for which the law would allow, and for which Plaintiff will seek at the appropriate time, the imposition of exemplary damages. That is because Defendants' conduct, including the failure to comply with applicable federal standards was specifically intended to cause substantial injury to Plaintiff. Their conduct, when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others; and Defendants were actually, subjectively aware of the risk involved but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included Defendants' false material representations, with their knowledge that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that Plaintiff would act upon their representation.

225. Plaintiff relied on the representation and suffered injury as a proximate result of this reliance.

226. Plaintiff therefore will seek to assert claims for exemplary damages at the appropriate time, in an amount within the jurisdictional limits of the Court.

227. Plaintiff also alleges that Defendants' acts and omissions, whether taken singularly or in combination with others, constitute gross negligence, proximately causing their injuries. In that regard, Plaintiff will seek exemplary damages in an amount to punish Defendants for their conduct, and to deter other manufacturers from engaging in such misconduct in the future.

228. Plaintiff has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

229. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective Mesh Products that were implanted.

COUNT VIII: NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

230. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

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

232. Defendants carelessly and negligently concealed the harmful effects of the products from Plaintiff and/or Plaintiff's physician on multiple occasions and continue to do so to this day.

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

234. Plaintiff were directly impacted by Defendants' carelessness and negligence, in that he has sustained, and will continue to sustain, emotional distress, severe physical injuries, economic losses, and other damages as a direct result of the decision to purchase the Mesh Products.

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

236. Defendants continued to carelessly and negligently misrepresent the quality, safety, efficacy, dangers and contraindications of the products to Plaintiff and/or Plaintiff's physician, knowing that doing so would cause him to suffer additional and continued emotional distress,

severe physical injuries, and economic loss.

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

238. Plaintiff has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

239. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective Mesh Products that were implanted.

COUNT IX: FRAUDULENT CONCEALMENT

240. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

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

242. Although Defendants knew or should have known about the lack of safety and efficacy of the Mesh Products, they failed to disclose this information to Plaintiff, and/or the treating physicians, and/or the public at large.

243. At all material times, Defendants had the duty and obligation to disclose to Plaintiff

and/or Plaintiff's physicians the true facts concerning the Mesh Products, i.e., their dangerous and defective nature, their lack of efficacy for their purported use and lack of safety in normal use, and their likelihood to cause serious consequences to users, including permanent and debilitating injuries. Defendants concealed these material facts before Plaintiff was implanted with the Mesh Products.

244. Defendants were under a duty to Plaintiff to disclose and warn them of the defective nature of the products because:

(a) Defendants were in a superior position to know the products' true quality, safety, and efficacy;

(b) Defendants knowingly made false claims about the products' safety and quality in documents and marketing materials; and

(c) Defendants fraudulently and affirmatively concealed the defective nature of the products from Plaintiff.

245. The facts Defendants concealed and/or did not disclose to Plaintiff were material facts that a reasonable person would have considered important in deciding whether to purchase and/or use the Mesh Products.

246. At all material times, Defendants willfully, intentionally, and maliciously concealed facts from Plaintiff and/or Plaintiff's physician, with the intent to defraud.

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

248. At all material times, neither Plaintiff and/or Plaintiff's physician were aware of the

facts.

249. Had they been so aware, they would not have reasonably relied upon the representations of safety and efficacy and would not have utilized the Mesh Products. Defendants' failure to disclose this information was a substantial factor in Plaintiff's physician's selection of the Mesh Products. The failure to disclose also resulted in the provision of incorrect and incomplete information to Plaintiff as a patient.

250. As a direct and proximate result of this conduct, Plaintiff was injured.

251. Plaintiff has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

252. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective Mesh Products that were implanted.

COUNT X: NEGLIGENT MISREPRESENTATION

253. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

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

255. Defendants failed to exercise ordinary care in their representations concerning the Mesh Products while involved in the manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce of the products, because they negligently misrepresented the products' risk of unreasonable and dangerous adverse side effects.

256. Defendants breached their duty by representing to Plaintiff and/or Plaintiff's physician, and/or the medical community that the Mesh Products have no serious side effects different from older generations of similar products or procedures.

257. As a foreseeable, direct, and proximate result of Defendants' negligent misrepresentations, they knew, or had reason to know, that the Mesh Products had been insufficiently tested, or had not been tested at all; and that the products lacked adequate and accurate warnings, and created a high risk—and/or higher than acceptable or reported and represented risk—of adverse side effects, including pain, graft rejection, graft migration, organ damage, complex seroma, fistula, sinus tract formation, dense adhesions, delayed wound closure, infection, sepsis, and death.

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

259. Plaintiff has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

260. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective Mesh Products that were implanted.

PUNITIVE DAMAGES ALLEGATIONS

261. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

262. Defendants failed to adequately test and study the Mesh Products to determine and ensure that the products were safe and effective prior to releasing them for sale for permanent

human implantation; and Defendants continued to manufacture and sell the products after obtaining knowledge and information that they was defective and unreasonably unsafe.

263. Defendants developed, designed and sold the products, and continue to do so, because they had a significantly higher profit margin than safer hernia repair products. Defendants were aware of the probable consequences of implantation of the dangerous and defective Mesh Products, including the risk of failure and serious injury, such as that suffered by Plaintiff.

264. At all material times, Defendants knew or should have known that the Mesh Products were inherently more dangerous with respect to the risk of foreign body response, allergic reaction, rejection, infection, failure, erosion, pain and suffering, organ perforation, dense adhesions, tumor or cancer formation, loss of life's enjoyment, remedial surgeries and treatments to attempt to cure the conditions related to use of the product, as well as the other severe and personal injuries that are permanent and lasting.

265. Defendants' misrepresentations include knowingly withholding material information from the medical community and/or the public, including Plaintiff, concerning the safety and efficacy of the Mesh Products, depriving Plaintiff and/or Plaintiff's implanting physicians of vitally necessary information with which to make a fully informed decision about whether to use the products.

266. At all material times, Defendants knew and recklessly and/or intentionally disregarded the fact that the Mesh Products can cause debilitating and potentially life-threatening side effects with greater frequency than safer alternative methods, products, procedures, and/or treatment.

267. At all material times, Defendants knew and recklessly and/or intentionally disregarded the fact that the Mesh Products can cause debilitating and potentially life-threatening

side effects with greater frequency than safer alternative products and/or methods of treatment, and recklessly failed to advise the medical community and/or the general public, including Plaintiff, of those facts.

268. At all material times, Defendants intentionally misstated and misrepresented data; and continue to misrepresent data so as to minimize the perceived risk of injuries and the rate of complications caused by the Mesh Products.

269. Notwithstanding the foregoing and the growing body of knowledge and information regarding the true defective nature of the Mesh Products, and its increased risk of side effects and serious complications, Defendants continue to aggressively market the products to the medical community and/or to consumers without disclosing the true risk of such complications.

270. When Plaintiff was implanted with the Mesh Products, and since then, Defendants have known the products were defective and unreasonably dangerous. But they continued to manufacture, produce, assemble, market, distribute, and sell the products so as to maximize sales and profits at the expense of the health and safety of the public in a conscious, reckless and/or intentional disregard of the likely and foreseeable harm caused by the Mesh Products to members of the public, including Plaintiff.

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

272. Defendants' conduct, acts and omissions are of such character and nature so as to entitle Plaintiff to an award of punitive damages in accordance with applicable law. Defendants' conduct shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of

care raising the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

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

PRAYER FOR RELIEF

Plaintiff Ralph Miller demands judgment against Defendants, and each of them, individually, jointly and severally and prays for the following relief in accordance with applicable law and equity:

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

ii. restitution and disgorgement of profits;

iii. punitive damages;

iv. reasonable attorneys' fees as provided by law;

v. past and future cost of all proceedings;

vi. all ascertainable economic damages;

vii. prejudgment interest on all damages as allowed by law; and such other and further relief as this Court deems just and proper.

DEMAND FOR TRIAL BY JURY

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

Date: July 17, 2019

Respectfully submitted,

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